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]

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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.

II. Emergency Exemption for Fomesafen on Dry Beans and FFDCA Tolerances

Requests were received from a number of states for use of fomesafen on dry beans for control of broadleaf weeds. The Applicants state that since the loss of the herbicides dinoseb and chloramben, weed contamination in U.S. bean fields has increased and significant crop losses have occurred. The Applicants state that available alternative pesticides and control techniques have produced unreliable results, and that without this use of fomesafen, significant economic losses will occur. EPA has authorized under FIFRA section 18 the use of fomesafen on dry beans for control of broadleaf weeds in Maine, Michigan, and New York. After having reviewed the submission, EPA concurs that emergency conditions exist for these states.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of fomesafen in or on dry beans. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on October 31, 1998, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on dry beans after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions EPA has not made any decisions about whether fomesafen meets EPA's registration requirements for use on dry beans or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of fomesafen by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Maine, Michigan, and New York to use this pesticide on this crop under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for fomesafen, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effectlevel'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end

residential exposure, are aggregated. High-end exposures from all 3 sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (Non-Nursing Infants <1 Year Old) was not regionally based.

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 fomesafen and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of fomesafen on dry beans at 0.05 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies 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. The nature of the toxic effects caused by fomesafen are discussed below.

1. *Acute toxicity*. EPA has selected the developmental NOEL of 7.5 mg/kg/day from the oral rat developmental toxicity study for the acute dietary endpoint; at the developmental LOEL of 50 mg/kg/day, fetuses had delayed or partial ossification and extra ribs. Since the effect of concern is developmental, the risk assessment will evaluate acute dietary risk to the population subgroup of concern, Females 13+ Years Old.

2. *Short - and intermediate - term toxicity*. EPA has selected the NOEL of 10 mg/kg/day from the oral rabbit developmental toxicity study for calculation of short- and intermediate-term margins of exposure (MOEs). At the LOEL of 40 mg/kg/day, maternal toxicity included stomach mucosal erosion and death.

3. *Chronic toxicity*. EPA has not established the RfD for fomesafen. For the purposes of this tolerance, based upon available chronic toxicity data, the RfD of 0.0025 mg/kg/day was used. This RfD is based on the NOEL of 0.25 mg/kg/day from the rat carcinogenicity study. A 100-fold uncertainty factor was used to calculate this RfD. At the LOEL of 5.0 mg/kg/day there was liver toxicity and decreased body weight.

4. *Carcinogenicity*. Fomesafen is classified as a Group C carcinogen with a Q^* of 1.9×10^{-1} $(mg/kg/day)^{-1}$. This classification was based on: (i) Increases in both adenomas and carcinomas at several dose levels in both sexes of mice; (ii) some evidence of reduced latency for the time of tumor appearance; (iii) limited evidence of mutagenic effects; and, (iv) the structural similarity of fomesafen to other biphenyl ether herbicides which have been shown to be carcinogenic.

B. Exposures and Risks

1. *From food and feed uses*. A permanent tolerance has been established (40 CFR 180.433) for the residues of fomesafen, in or on soybeans at 0.05 ppm. A time-limited tolerance was also established on snap beans at 0.05 ppm recently, in connection with use under several emergency exemptions. Risk assessments were conducted by EPA to assess dietary exposures and risks from fomesafen as follows:

i. *Acute exposure and risk*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The acute dietary risk assessment used tolerance level residue values and assumed 100 percent of crop treated. The resulting high-end exposure estimate of 0.0002 mg/kg/day translates to a dietary MOE

of 37,500 for the population subgroup of concern, Females 13+ Years Old. This MOE is a conservative risk assessment; refinement using anticipated residue values and percent crop treated data in conjunction with Monte Carlo analysis would result in a lower acute dietary exposure estimate.

ii. *Chronic exposure and risk*. For assessing chronic exposure and risks, anticipated residue values for all commodities were used; and percent of crop treated information for soybeans only; it was assumed that 100 percent of the snap bean crop in the eastern United States (the region where exemptions were issued, equivalent to 75 percent of the domestic snap bean crop), and 100 percent of the dry bean crops were treated. Based upon this, the existing uses on soybeans, snap beans, and dry beans result in an ARC that is equivalent to the following percentages of the RfD: U.S. population, 0.3%; Nursing Infants, 0.3%; Non-nursing Infants (<1 year old), 0.8%; Children (1-6 years old), 0.7%; and Children (7-12 years old), 0.5%. Additional refinement using percent of crop treated information for all commodities would result in lower dietary exposure estimates.

iii. *Cancer risk*. A dietary (food only) cancer risk assessment using anticipated residues and percent crop treated information, as described above, was performed for the U.S. population. The calculated food cancer risk from the established tolerances (excludes this action) is 8.5×10^{-7}. This is an overestimate, as not all of the snap bean crop in the eastern United States will be treated with fomesafen. The incremental contribution to the dietary cancer risk posed by this use on dry beans, amortized over 5 years (the average duration of a section 18 exemption, including repeat uses), is 0.5×10^{-7}. Therefore, the total of the fomesafen dietary cancer risk for the U.S. population from all commodity contributions, including this new tolerance on dry beans, is 9.0×10^{-7}. It should be noted that this is an overestimation of risk, because not all of the snap bean crops in the eastern United States, nor all of the dry bean crops in the United States, will be treated with fomesafen.

2. *From drinking water.* Fomesafen was not included in EPA's National Survey of Pesticides in Drinking Water Wells. There are no entries for fomesafen in the Pesticides in Ground Water Database. The Agency has not established Maximum Contaminant Levels or Health Advisory Levels for residues of fomesafen in drinking water.

Based on available data, EPA concludes that fomesafen could leach to ground water and may reach levels of 1.0 microgram (µg)/Liter (L). The level of 1.0 µg/L was based on a small scale prospective groundwater monitoring study conducted on soybeans at a vulnerable site in North Carolina. Fomesafen residues were detected in ground water (in 4 of 9 wells) sampled between 17 and 33 months after application. Fomesafen concentrations measured 1.0 µg/L (equal to the limit of determination of the analytical method).

Exposures and risks from residues of fomesafen in drinking water were calculated, as follows:

Adult Exposure = (chemical concentration in µg/L) $\times$ (10^{-3} mg/µg) $\times$ (2 L/day consumed) divided by (70 kg body weight).

Child Exposure = (chemical concentration in µg/L) $\times$ (10^{-3} mg/µg) $\times$ (1 L/day consumed) divided by (10 kg body weight).

Adult exposure is thus calculated to be 2.9×10^{-5} mg/kg/day and exposure of children is calculated to be 1.0×10^{-4} mg/kg/day.

i. *Acute exposure and risk*. For the population subgroup of concern for acute exposure (Females 13+ Years Old), the MOE is calculated at 260,000.

ii. *Chronic exposure and risk*. Exposure to residues of fomesafen in water utilizes 1.2% of the RfD for adults and 4.0% of the RfD for children.

iii. *Cancer risk*. Based on exposure levels for drinking water, as given above, the estimate of cancer risk is 2.7×10^{-6}. This figure is an overestimate, as it was arrived at based on several very conservative assumptions. Estimates used were calculated based on data from only one small scale study conducted in NC, for use of fomesafen on soybeans at a vulnerable site. This represents a worst case scenario, so is not representative of the ''average'' conditions of use. Additionally, there is language on the product label warning of the potential of fomesafen to leach to ground water in vulnerable areas. Vulnerable areas in this case refers to areas where soils are permeable (sand and silt loams) and the water table is shallow. The majority of areas of soybean production, and potential use of fomesafen, will not likely be vulnerable sites, thus the data used from the one small scale study greatly overestimates levels which could actually occur. Further, it is assumed that this exaggerated level will occur in all drinking water throughout the US, and that each individual consumes 2 liters of drinking water per day.

3. *From non-dietary exposure.* Fomesafen is not currently registered for use on sites that would be expected to result in non-dietary (residential) exposure. A non-dietary risk assessment is thus not appropriate for existing uses of fomesafen.

4. *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.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

When considering structural similarities with other chemicals, fomesafen falls into the class of ''biphenyl ether'' chemical compounds; this means that this group of chemicals have structural similarities, including a biphenyl ether group, in common. This is used as a piece of supporting evidence for the classification of fomesafen as a Group C carcinogen, since other chemicals of this group (with similar structure) have been found to be carcinogens. However, other indications of the carcinogenicity of fomesafen (i.e., increases of adenomas and carcinomas in a mouse study, limited evidence of mutagenic effects) were also used in deciding this cancer classification. At this time, the Agency does not have sufficient understanding of the structural relationship to the mechanism of toxicity of these chemicals to conclude that they may be combined for the purposes of conducting a risk assessment. Although fomesafen contains some chemical structures in common with other chemicals that have been found to be carcinogens, EPA does not yet fully understand the implications of such a relationship, nor how, or if, these structures relate to the toxicological activity of the chemical. For the purposes of this tolerance action, therefore, EPA has not assumed that fomesafen has a common mechanism of toxicity with other substances.

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

1. *Acute risk*. For the population of concern (Females 13+ Years Old), the calculated aggregate MOE value is 23,000. The aggregate MOE is the reciprocal of the sum of the reciprocal of the MOEs for food (25,000) and water (260,000). This aggregate MOE does not exceed EPA's level of concern for acute dietary exposure.

2. *Chronic risk*. Using the ARC exposure assumptions described above, EPA has concluded that aggregate exposure to fomesafen from food will utilize 1.5% (0.3% for food and 1.2% for water) of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is Non-Nursing Infants, discussed below. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to fomesafen in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to fomesafen residues.

D. Aggregate Cancer Risk for U.S. Population

Using the conservative exposure assumptions described above, the total dietary (food only) cancer risk is estimated at 9×10^{-7}. This is an overestimate, as not all of the snap and dry bean crop in the eastern United States will be treated with fomesafen. For drinking water, the estimate of cancer risk is 2.7×10^{-6}. As stated above, this figure was based on extremely conservative assumptions, and thus is an overestimate; taking this into consideration, EPA scientists believe that the actual aggregate cancer risk will not exceed levels of concern.

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

1. *Safety factor for infants and children*. i. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of fomesafen, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

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 post-natal 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. EPA believes that reliable data support using the standard 100-fold safety factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold safety factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard safety factor.

ii. *Developmental toxicity studies*. In the rat developmental toxicity study, the maternal (systemic) NOEL was established at 100 mg/kg/day, based on stained fur at the LOEL of 200 mg/kg/day. The fetal (developmental) NOEL was 7.5 mg/kg/day, based on extra ribs and delayed ossification at the LOEL of 50 mg/kg/day.

In the rabbit developmental toxicity study, the maternal (systemic) NOEL was established at 10 mg/kg/day, based on mortality and stomach lesions at the LOEL of 40 mg/kg/day. The fetal (developmental) NOEL was established at 40 mg/kg/day (highest dose tested, no effects seen).

iii. *Reproductive toxicity study*. In the 2-generation reproductive toxicity study in rats, the parental (systemic) NOEL was 12.5 mg/kg/day, based on decreased body weight and liver necrosis at the LOEL of 50 mg/kg/day. The reproductive and developmental (pup) NOELs were 2.5 mg/kg/day, based on decreased pup body weight and reduced litter size at the LOEL of 12.5 mg/kg/day.

iv. *Pre- and post-natal sensitivity*. There were no developmental effects in rabbits at the highest dose tested, even in the presence of maternal toxicity. However, based on the developmental toxicity study in rats, developmental toxicity (alterations and delays in skeletal ossification) occurred at a dose level which was not maternally toxic, suggesting a special sensitivity to the fetus following in-utero exposure. Based on the results of the rat developmental toxicity study, an acute dietary risk assessment was conducted for Females 13+ Years Old. The MOE of 23,000 obtained for this risk assessment demonstrates that acute developmental (pre-natal) risks are low.

v. *Conclusion*. Based on the rat reproductive toxicity study discussed above, the pup LOEL (decreased body weight and reduced litter size) occurred at levels below the maternal NOEL and demonstrates post-natal pup toxicity unrelated to maternal effects. These results are suggestive of a special sensitivity for infants and children following post-natal exposure. Therefore, EPA recommends applying an extra 10-fold uncertainty (safety) factor in the chronic risk analysis. The low percentage of the RfD occupied by the most highly exposed child subgroup (4.8% of the RfD; 48% using the extra 10-fold factor) demonstrates that post-natal risks to infants and children are low.

2. *Acute risk*. The acute, aggregate dietary MOE of 33,000 which was calculated for females 13+ years old, accounts for both maternal and fetal

exposure. The large aggregate MOE calculated for females 13+ years old provides assurance that there is a reasonable certainty of no harm to infants and children.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to fomesafen from food and water utilizes from 4.3% of the RfD for nursing infants up to 4.8% of the RfD for non-nursing infants. As stated previously, the results from the developmental rat study suggest a special sensitivity to the fetus following in-utero exposure; and results from the reproductive rat study suggest a special sensitivity for infants and children following post-natal exposure. Therefore, EPA recommends applying an extra 10-fold uncertainty (safety) factor, which would bring the exposures given above to 43% and 48% of the RfD, for nursing and non-nursing infants, respectively. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The low percentage of the RfD occupied by estimates for the most highly exposed child population subgroup demonstrates that risks to infants and children are below EPA's level of concern, Use the following paragraph or delete and insert applicable text. and EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to fomesafen residues.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residues in plants and animals is adequately understood. The residue of concern is fomesafen per se. Secondary residues in meat, milk, poultry, and eggs are not expected, since dry beans are not considered a livestock feed commodity.

B. Analytical Enforcement Methodology

An adequate enforcement method (Method GAM-RM-001/86) is available to enforce fomesafen tolerances.

C. Magnitude of Residues

Residues of fomesafen are not likely to exceed 0.05 ppm in or on dry beans as a result of this use. No animal feed items are associated with this use, and therefore, no secondary residues in livestock commodities are expected to result.

D. International Residue Limits

There are no CODEX or Canadian maximum residue levels established for residues of fomesafen in or on dry beans. A Mexican tolerance of 0.01 ppm is established for fomesafen residues in or on ''beans.''

E. Rotational Crop Restrictions

The federally registered label for the fomesafen product requested under these exemptions carries the following rotational crop restrictions: 4 months for small grains; 10 months for corn, cotton, peanuts, and rice; and 18 months for all other crops, particularly sunflowers, sugar beets, and sorghum. Part of the use restrictions for these exemptions includes that all applicable restrictions on the federal label must be followed; this includes these rotational crop restrictions.

VI. Conclusion

Therefore, the tolerance is established for residues of fomesafen in dry beans at 0.05 ppm.

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 January 20, 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 Docket and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300571] (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 Room 1132 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 a time-limited tolerance under FFDCA section 408(l)(6). 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).

In addition, since these tolerances and exemptions that are established under FFDCA section 408 (l)(6), such as the tolerance in this final rule, do 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.

X. 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 has 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: October 22, 1997.

Peter Caulkins,

Acting 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.

2. In § 180.433, by alphabetically inserting the following item into the table in paragraph (b) to read as follows:

§ 180.433 Sodium salt of fomesafen; tolerance for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/Revocation Date
* * *	* * * *	
Beans, dry	0.05	10/31/98

* * * * *

[FR Doc. 97–30383 Filed 11–18–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180 and 185

[OPP–300475A; FRL–5746–5]

RIN 2070–AC78

Hydroprene Biochemical Pest Control Agent; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This rule expands the tolerance for residues of hydroprene, [(*S*)-(Ethyl (2*E*,4*E*,7*S*)-3,7,11-trimethyl-2,4-odecadienoate)], an insect growth regulator, on all food items in food-handling establishments to include perimeters and pantries, and warehouses to the list of permissible food storage sites and ultra low volume (ULV) fogging as a permissible treatment method under certain precautions and conditions. This rule also permits the use of point source device treatments providing those devices do not come into direct contact with food preparation surfaces and are kept a minimum distance of 3 feet from exposed foods. This rule also restricts the tolerance expression to residues of [(*S*)-(Ethyl(2*E*,4*E*,7*S*)-3,7,11-trimethyl 2,4-dodecadienoate)], the *S*-racemer of hydroprene since the *R*-racemer is no longer being supported in reregistration.

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–300475A], 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–300475A], 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 be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of