Dated: February 6, 1998.

Marcia E. Mulkey,

Director, 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. Section 180.1180 is amended by removing the paragraph heading for paragraph (a), revising paragraph (b), and removing paragraphs (c) and (d) to read as follows:

§ 180.1180 Kaolin; exemption from the requirement of a tolerance.

* * * * *

(b) Kaolin is exempted from the requirement of a tolerance for residues when used on or in food commodities to aid in the control of insects, fungi, and bacteria (food/feed use).

[FR Doc. 98–4652 Filed 2–24–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300603; FRL–5766–4]

RIN 2070–AB78

Bensulfuron Methyl (methyl-2[[[[[(4,6-dimethoxy-pyrimidin-2-yl) amino] carbonyl] amino] sulfonyl] methyl] Benzoate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of bensulfuron methyl in or on crayfish. In addition, this regulation raises the tolerance for residues of bensulfuron methyl on rice straw. E.I. duPont de Nemours and Company, Inc. requested this 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 February 25, 1998. Objections and requests for hearings must be received by EPA on or before April 27, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300603], 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–300603], 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–300603]. 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: Jim Tompkins, 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) 305–5697, e-mail: tompkins.jim@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 16, 1997 (62 FR 27033) (FRL-5717–7), 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 petitions (PP) 4F4367 and 5F4490. This notice included a summary of the petitions prepared by E.I. duPont de Nemours and Company, Inc., the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.445 be amended by establishing a tolerance for residues of the herbicide bensulfuron methyl, in or on rice (grain) at 0.02 parts per million (ppm), rice straw at 0.05 ppm, and crayfish at 0.05 ppm.

I. Risk Assessment and Statutory Findings

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. . . .''

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 effect level'' 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 study with 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% 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 was not regionally based.

II. 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 bensulfuron methyl-2[[[[[(4,6-dimethoxy-pyrimidin-2-yl) amino] carbonyl] amino] sulfonyl] methyl] benzoate and to make a determination on aggregate exposure, consistent with

section 408(b)(2), for tolerances for residues of bensulfuron methyl on rice straw at 0.3 ppm and crayfish 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 bensulfuron methyl-2[[[[[(4,6-dimethoxy-pyrimidin-2-yl) amino] carbonyl] amino] sulfonyl] methyl] benzoate are discussed below.

1. An acute oral study with an LD_{50} greater than 5,000 milligrams/kilogram (mg/kg) (limit test).

2. A 90-day dog feeding study with a no-observed-effect level (NOEL) of 32.1 milligrams/kilogram/day (mg/kg/day) in males and 36.3 mg/kg/day in females.

3. A 90-day mouse feeding study with a NOEL of 132 mg/kg/day in males and 133 mg/kg/day in females.

4. A 90-day rat feeding study with a NOEL of 93 mg/kg/day in males and 111 mg/kg/day in females.

5. A rat developmental study with a developmental NOEL of greater than 1,320 mg/kg/day, the highest dose tested.

6. A rabbit developmental study with a developmental NOEL of 300 mg/kg/day.

7. A two-generation rat reproduction study with a reproductive NOEL of 309 mg/kg/day in males and 405 mg/kg/day in females.

8. A *Salmonella*/Mammalian Activation Assay, negative with and without metabolic activation.

9. An *in vivo* bone marrow chromosome study in rats with no evidence of induced chromosome aberration in bone marrow.

10. An *in vitro* sister chromatid exchange assay in CHO cells with a slight increase in SCE frequency in nonactivated system at maximum concentration, but negative in the activated system at the same concentration.

11. A 1-year dog feeding study with a NOEL of 21.4 mg/kg/day in males and 19.9 mg/kg/day in females.

12. A 2-year mouse chronic feeding/carcinogenicity study with a NOEL of 226 mg/kg/day in males and 227 mg/kg/day in females for systemic effects and with no carcinogenic potential observed under conditions of the study up to 455 mg/kg/day in males and 460 mg/kg/day in females, the highest dose tested.

13. A 2-year rat chronic feeding/carcinogenicity study with a NOEL of 30 mg/kg/day in males and 40 mg/kg/day in females for systemic effects and with no carcinogenic potential observed under conditions of the study up to 309 mg/kg/day in males and 405 mg/kg/day in females, the highest dose tested.

Based on a NOEL of 19.9 mg/kg/day in the 1-year dog feeding study and a safety factor of 100, the acceptable daily intake has been set at 0.2 mg/kg/day. These tolerances have a theoretical maximum residue contribution of 0.000005 mg/kg/day and would utilize less than 1 percent of the reference dose (RfD) for the general US population. There are no population subgroups for which the percentage of the RfD utilized is greater than the general U.S. population.

B. Toxicological Endpoints

1. *Acute toxicity*. No toxicological effects attributable to a single exposure (dose) were identified in any of the studies. Therefore, this risk assessment is not required.

2. *Short - and intermediate - term toxicity*. EPA has concluded that available evidence doe not indicate any evidence of significant toxicity from short and intermediate term exposure.

3. *Chronic toxicity*. EPA has established the RfD for bensulfuron methyl-2[[[[[(4,6-dimethoxy-pyrimidin-2-yl) amino] carbonyl] amino] sulfonyl] methyl] benzoate at 0.20 mg/kg/day. This RfD is based on the systemic NOEL of 19.9 mg/kg/day for females in a one year toxicity study in beagle dogs.

4. *Carcinogenicity*. Although bensulfuron methyl has not received a carcinogenicity classification, the Health Effects Division RfD Committee found no evidence of carcinogenicity in the mouse or rat.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.445) for the residues of bensulfuron methyl, in or on rice (grain) at 0.02 ppm, rice straw at 0.05 ppm. The petitioner has proposed to increase the tolerance for rice straw to 0.3 ppm. A tolerance of 0.05 ppm for bensulfuron methyl residues in crayfish is proposed. Risk assessments were conducted by EPA to assess dietary exposures and risks from bensulfuron methyl-2[[[[[(4,6-dimethoxy-pyrimidin-2-yl) amino] carbonyl] amino] sulfonyl] methyl] benzoate 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. An acute risk assessment is not required as an appropriate endpoint was not identified for bensulfuron methyl.

ii. *Chronic exposure and risk*. The Agency's Dietary Risk Evaluation System (DRES) does not contain the commodity crayfish. DRES does contain the commodity fish, shellfish which includes crayfish as well as other shellfish. For human dietary exposure calculations, The Agency has substituted the commodity fish, shellfish for crayfish. In conducting this chronic dietary risk assessment, The Agency has made very conservative assumptions: (1) 100% of all commodities having bensulfuron methyl tolerances will contain residues; (2) those residues will be at the level of the tolerance; and (3) bensulfuron methyl residues in fish, shellfish will be at the proposed tolerance level for crayfish. These assumptions will result is an overestimate of dietary exposure.

Thus, in making a safety determination for this tolerance, the Agency is taking into account this conservative exposure assessment.

The existing tolerances (published and pending, and including the proposed tolerance for crayfish) result in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to less than 1% of the RfD for the U.S. population (48 states). There are no population subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 States).

2. *From drinking water— Chronic exposure and risk*. Based on the chronic dietary (food) exposure and using default body weights and water consumption figures, chronic levels of concern (LOC) for bensulfuron methyl in drinking water were calculated. For chronic exposure, based on an adult body weight of 70 kg and 2 liters consumption of water per day, the Agency's level of concern from chronic exposure in drinking water is 7,000 parts per billion for adults. For children (10 kg and consuming 1 liter water per day) our level of concern for drinking water is 2,000 parts per billion.

Because all the Agency's estimates for the levels of bensulfuron methyl in drinking water were less than 2 parts per billion, potential residues in drinking water are not greater than the Agency's level of concern.

3. *From non-dietary exposure*. There is no non-food use of bensulfuron methyl currently registered under FIFRA, as amended. No non-dietary

exposures are expected for the general population.

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).

EPA does not have, at this time, available data to determine whether bensulfuron methyl-2[[[[[(4,6-dimethoxy-pyrimidin-2-yl) amino] carbonyl] amino] sulfonyl] methyl] benzoate has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, bensulfuron methyl-2[[[[[(4,6-dimethoxy-pyrimidin-2-yl) amino] carbonyl] amino] sulfonyl] methyl] benzoate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that methyl-2[[[[[(4,6-dimethoxy-pyrimidin-2-yl) amino] carbonyl] amino] sulfonyl] methyl] benzoate has a common mechanism of toxicity with other substances.

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

1. *Acute risk.* An acute and intermediate-term risk assessment is not required as an appropriate endpoints were not identified for bensulfuron methyl.

2. *Chronic risk.* Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to bensulfuron methyl-2[[[[[(4,6-dimethoxy-pyrimidin-2-yl) amino] carbonyl] amino] sulfonyl] methyl] benzoate from food will utilize <1% of the RfD for the U.S. population. 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 bensulfuron methyl-2[[[[[(4,6-dimethoxy-pyrimidin-2-yl) amino] carbonyl] amino] sulfonyl] methyl] benzoate 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 bensulfuron methyl-2[[[[[(4,6-dimethoxy-pyrimidin-2-yl) amino] carbonyl] amino] sulfonyl] methyl] benzoate residues.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure.

An acute and intermediate-term risk assessment is not required as appropriate endpoints were not identified for bensulfuron methyl.

E. Aggregate Cancer Risk for U.S. Population

A carcinogenic risk assessment is not required as there is no evidence of carcinogenicity for bensulfuron methyl in the mouse or rat or dog.

F. 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 bensulfuron methyl-2[[[[[(4,6-dimethoxy-pyrimidin-2-yl) amino] carbonyl] amino] sulfonyl] methyl] benzoate, 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 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 uncertainty factor (usually 100 for combined inter- and intra-species variability)) and not the additional tenfold MOE/uncertainty 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 MOE/safety factor.

ii. *Developmental and reproductive toxicity studies.* The prenatal developmental toxicity data demonstrated no indication of increased sensitivity of rabbits to in utero exposure to bensulfuron methyl. In addition, the multigeneration reproduction study data did not identify any increased sensitivity of rats to in utero or postnatal exposure. In both studies, the maternal LOEL was less than or equivalent to the NOEL for effects in the offspring. Minor

ossification variations were observed in a developmental study in rats, but only at a dose of 1,320 mg/kg/day which exceeds the limit dose of 1,000 mg/kg/day as specified in Guideline Sec. 93-3a.

For chronic dietary risk assessment, the Agency determined that based on a complete database the 10x factor to account for enhanced sensitivity of infants and children (as required by FQPA) should be removed. Removal of the 10x is based on a complete database. The present UF of 100 (10X each for inter-and intra-species variability) is adequate to ensure protection of these population subgroups from exposure to bensulfuron methyl for reasons stated below:

(a) There is no indication of increased sensitivity to young animals following pre- and/or post-natal exposure to bensulfuron methyl.

(b) There is no increased sensitivity to fetuses as compared to maternal animals following in utero exposures in rats and rabbits.

(c) There is no increased sensitivity to pups as compared to adults in a multi-generation reproduction toxicity study in rats.

(d) Considering the overall toxicity profile of bensulfuron methyl, it was noted that toxic effects were only observed at or near the Limit Dose with all short- and long-term studies.

2. *Acute risk*. An acute risk assessment is not required as an appropriate endpoints were not identified for bensulfuron methyl.

3. *Chronic risk*. Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to bensulfuron methyl-2[[[[[(4,6-dimethoxy-pyrimidin-2-yl) amino] carbonyl] amino] sulfonyl] methyl] benzoate from food will utilize <1% of the RfD for infants and children. 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 bensulfuron methyl-2[[[[[(4,6-dimethoxy-pyrimidin-2-yl) amino] carbonyl] amino] sulfonyl] methyl] benzoate 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 to infants and children from aggregate exposure to bensulfuron methyl-2[[[[[(4,6-dimethoxy-pyrimidin-2-yl) amino] carbonyl] amino] sulfonyl] methyl] benzoate residues.

4. *Short- or intermediate-term risk*. EPA has concluded that available evidence does not indicate any evidence of significant toxicity from short and intermediate term exposure.

III. Other Considerations

A. Metabolism In Plants and Animals

The metabolism of bensulfuron methyl in plants and animals is adequately understood for purposes of this tolerance. Due to very low levels of residues with a small percentage of metabolites, these metabolites need not be regulated.

B. Analytical Enforcement Methodology

An adequate analytical method, high-pressure liquid chromatography using a photo conductivity detector, is available for enforcement purposes. The analytical method for enforcing these tolerances has been submitted for published in the Pesticide Analytical Manual, Vol II (PAM II). Because of the long lead time from establishing these tolerances to publication of the enforcement methodology in PAM, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, 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. Office location and telephone number: Rm. 119FF, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703–305–5229).

C. Magnitude of Residues

The nature of the residue in plants is adequately understood for the purpose of this tolerance. Based on the results of animal metabolism studies it is unlikely that significant residues would occur in secondary animal commodities from this use.

D. International Residue Limits

There are no established CODEX, Canadian or Mexican residue limits for bensulfuron methyl in/on rice (grain and straw) and crayfish. Thus, harmonization of the proposed tolerances with CODEX, Canada and Mexico are not an issue for these petitions.

E. Rotational Crop Restrictions

No tolerances for inadvertent residues of bensulfuron methyl are required in rotational crops. The rotational crop restrictions contained on the current Londax DF label (EPA 352-325) are adequate.

IV. Conclusion

Therefore, the tolerances are established for residues of bensulfuron methyl in/or on crayfish at 0.05 ppm and increase tolerance on rice straw from 0.05 to 0.3 ppm.

V. 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 April 27, 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 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.

VI. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300603] (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 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 Hwy., 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.

VII. Regulatory Assessment Requirements

This final rule establishes tolerances 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).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances 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.

VIII. Submission to Congress and the Comptroller General

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 recordkeeping requirements.

Dated: February 9, 1998.

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. Section 180.445 is revised to read as follows:

§ 180.445 Bensulfuron methyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide bensulfuron methyl (methyl-2[[[[[(4,6-dimethoxy-pyrimidin-2-yl) amino] carbonyl] amino] sulfonyl] methyl] benzoate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Crayfish	0.05
Rice	0.02
Rice, straw	0.3

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300607; FRL–5767–6]

RIN 2070–AB78

Thiabendazole; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of thiabendazole in or on lentils. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on lentils. This regulation establishes a maximum permissible level for residues of thiabendazole in this food commodity