Commodity	Parts per million
Sheep, meat	0.1
Strawberries	0.1

(b) *Section 18 emergency exemptions.* Time limited tolerances are established for residues of the herbicide terbacil (3-tert-Butyl-5-chloro -6-methyluracil and its three metabolites 3-tert-butyl-5-chloro-6-hydroxymethyluracil, 6-chloro-2, 3-dihydro-7-hydroxymethyl 3,3-dimethyl-5H-oxazolo (3,2-a) pyrimidin-5-one, and 6-chloro-2,3-dihydro-3,3,7-trimethyl-5H-oxazolo (3,2-a) pyrimidin-5-one), calculated as terbacil, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerance is specified in the following table. The tolerance expires and will be revoked by EPA on the date specified in the table.

Commodity	Parts per million	Expiration/ revocation date
Watermelon	0.4	5/30/98

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

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

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180 and 186

[OPP–300496; FRL–5720–4]

RIN 2070–AB78

Bentazon; Pesticide Tolerance for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of the herbicide bentazon and its metabolite(s) in or on the raw agricultural commodity succulent peas in connection with EPA's granting an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on succulent peas in Minnesota and Wisconsin. The tolerance will expire and is revoked on June 30, 1998.

DATES: This regulation becomes effective June 20, 1997. Objections and requests for hearings must be received by EPA on or before August 19, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300496], 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 document control number, [OPP–300496], must be 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 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 number [OPP–300496]. 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: Virginia Dietrich, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Hwy., Arlington, VA (703) 308-8347, e-mail: dietrich.virginia@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 bentazon and its 6- and 8-hydroxy metabolites in or on succulent peas at 3 part per million (ppm). This tolerance will expire and is revoked on June 30, 1998. After June 30, 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 FFDCA, 21 U.S.C. 301 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under 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 CFR 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 Bentazon on Succulent Peas and FFDCA Tolerances

In February and March of 1997, the Departments of Agriculture from Minnesota and Wisconsin each applied for emergency exemptions for the use of bentazon on succulent peas. Bentazon is currently registered for use on succulent peas for the control of Canada thistle. However, to effectively control Canada thistle with bentazon, two applications are needed. The current 30–day preharvest interval (PHI) does not allow for a second application of bentazon. If Canada thistle is not adequately controlled, its buds can be harvested along with the peas because they are similar in size and shape. Growers face docking or rejection of their crop if contaminated with Canada thistle buds. This could result in significant economic loss. Minnesota and Wisconsin therefore have requested an exemption from the 30–day PHI currently required for the use of bentazon in succulent peas to control Canada thistle; requesting a 10–day PHI instead. This exemption was granted on May 9, 1997. They also requested that a time-limited tolerance be established that would accommodate residues greater than those allowed under the current tolerance for succulent peas.

EPA has authorized the use of bentazon on succulent peas for control of Canada thistle under FIFRA section 18. 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 bentazon in or on succulent peas. 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. This tolerance will permit the marketing of succulent peas treated in accordance with the provisions of the section 18 emergency exemption. 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 June 30, 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 succulent peas after that date will not be unlawful, provided the pesticide is applied in a manner that is 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 bentazon meets EPA's registration requirements for use on succulent peas 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 bentazon 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 Minnesota and Wisconsin 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 bentazon, 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. For many of these 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 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 hundreddfold margin of exposure is based on the same rationale as the hundredfold 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 margin of exposure 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.

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. 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 percent 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.

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.

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 bentazon are discussed below.

1. *Acute toxicity.* For acute dietary risk assessment, the Agency selected the NOEL of 100 milligrams per kilogram per day (mg/kg/day), based on developmental effects of increased post-implantation loss and decreased fetal body weight at the lowest effect level (LEL) of 250 mg/kg/day, from the developmental toxicity study in rats. Since there were no maternal findings, but there were developmental findings, at the highest dose tested of 250 mg/kg/day, an MOE of at least 300 is considered appropriate for females 13+ years of age exposed to dietary residues of bentazon.

2. *Chronic toxicity.* An RfD of 0.03 mg/kg/day was established based on the 1–year dog feeding study with a NOEL of 3.2 mg/kg/day and an uncertainty factor of 100 based on body weight loss and anemia at the LEL of 13.1 mg/kg/day. Due to the extra sensitivity of pups in the rat reproductive toxicity study, an additional modifying factor of 3 should be added to the usual uncertainty factor of 100. The RfD should be, therefore, changed from 0.03 mg/kg/day to 0.01 mg/kg/day for purposes of these section 18's only, resulting in a total uncertainty factor of 300.

3. *Carcinogenicity.* Bentazon has been classified as a Group ''E'' chemical (evidence of non-carcinogenicity in two acceptable animal studies) by the Office of Pesticide Program's Cancer Peer Review Committee.

B. Aggregate Exposure

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.

Bentazon is currently registered for use on food and feed crops and for outdoor residential uses on ornamentals and ornamental turf. Permanent tolerances (see 40 CFR 180.355) for combined residues of bentazon and its 6- and 8- hydroxy metabolites, have been established for over 2 dozen food or feed commodities. Permanent tolerances are also established in animal raw agricultural commodities for bentazon and its metabolite, 2-amino-*N*-isopropyl benzamide.

1. *Acute exposure.* 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 1 day or single exposure. Drinking water is also considered a component of the acute dietary exposure, however, EPA generally will not include residential or other non-dietary exposure as a component of the acute exposure assessment. Theoretically, it is also possible that a residential, or other non-dietary, exposure could be combined with the acute total dietary exposure from food and water. However, the Agency does not believe that aggregating multiple exposure to large amounts of pesticide residues in the residential environment via multiple products and routes for a one day exposure is a reasonably probable event. Additionally, the concept of an acute exposure as a single exposure does not allow for including post-application exposures, in which residues decline over a period of days after application. Therefore, the Agency believes that residential exposures are more appropriately included in the short-term exposure scenario.

The acute dietary (food only) risk assessment used tolerance level residues and assumed 100% crop-treated. The resulting high-end exposure estimate of 0.01125 mg/kg/day, results in a dietary (food only) MOE of 8,888 for females 13+ years old which is considered acceptable.

Using the available monitoring data for groundwater, an exposure estimate of 3×10^{-3} mg/kg/day for adults was calculated. Adding this water exposure to the food exposure resulted in a MOE of 7,000 for females 13+ years.

It should be noted that the acute drinking water component of the risk calculations presented in this document are relevant to sub-populations with high-end exposure within the United States (FL and CA). Because the calculated risk, based on high-end exposure is acceptable, we believe that the overall risk assessment is protective of the whole U.S. population.

In the best scientific judgment of the Office of Pesticide Programs, the aggregate acute risk (food and water) from the currently registered uses and this section 18 use of bentazon does not exceed our level of concern.

2. *Chronic exposure*— i. *Dietary-food exposure.* The chronic dietary (food only) risk assessment used tolerance level residues and assumed 100% crop treated. Therefore, the resulting exposure estimates should be viewed as conservative; further refinement using anticipated residues and percent of crop-treated would result in lower dietary exposure estimates. The existing bentazon tolerances plus the proposed Section 18 use resulted in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to the following percentages of the RfD:

Subpopulation	TMRC(mg/kg/day)	Percent RfD
U.S. Population	0.001079	12
Nursing Infants ..	0.001755	18
Non-Nursing Infants (< 1 year old)	0.003755	39
Children (1-6 years old)	0.002411	24
Children (7-12 years old)	0.001633	15
Hispanics	0.001074	12

The subgroups listed above are: (1) The U.S. population (48 states); (2) those for infants and children; and, (3) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 states).

ii. *Dietary and drinking water exposure.* To account for the exposure from drinking water, the Agency decided to use the Health Advisory level of 20 ppb. This level is a conservative estimate of exposure since it is unlikely that a person would be exposed to this level daily for a lifetime. The following assumptions were made during the calculations: an adult weighs 70 kg and consumes 2 liters of water a day, a child weighs 10 kg and consumes 1 liter of water a day. Using the Health Advisory level of 20 ppb for bentazon in groundwater, and adding the calculated percentage of the RfD based on consumption by adults and children, to the existing percent of the RfD for food consumption, the total percentage of the RfD taken up by food and water consumption is:

Subpopulation	Percent RfD		Total Percent RfD
	Food	Water	
U.S. Population.	12	6	18
Nursing Infants.	18	21	39
Non-Nursing Infants (<1 year old).	39	21	60
Children (1-6 years old).	24	21	45
Children (7-12 years old).	15	21	36
Hispanics	12	6	18

Using these conservative estimates, the sum total of the aggregate chronic risk estimates (food + water) for bentazon for the population subgroup with the largest percentage of the RfD occupied (non-nursing infants less than 1 year old) is 60%. In the best scientific judgement of HED, the bentazon aggregate chronic risk does not exceed our level of concern.

3. *Short- and intermediate-term exposure.* 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. Although residential exposure data are not available for ornamentals and ornamental turf uses of bentazon, the Agency notes that large MOEs were calculated for acute aggregate risk (≥ 7,000) and occupational exposure (> 6,000 for the most highly exposed group, aerial mixer loader). Therefore the Agency believes short- and intermediate-term aggregate risk is likely to be below the Agency's level of concern.

C. 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 bentazon 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, bentazon 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 bentazon has a common mechanism of toxicity with other substances.

D. Determination of Safety for U.S. Population

1. *Acute risk.* The acute dietary (food only) risk assessment used tolerance level residues and assumed 100% crop-treated. The resulting high-end exposure estimate of 0.01125 mg/kg/day, results in a dietary (food only) MOE of 8,888 for females 13+ years old, which is considered acceptable.

Using the available monitoring data for groundwater, an exposure estimate of 3×10^{-3} mg/kg/day for adults was calculated. Adding this water exposure to the food exposure resulted in a MOE of 7,000 for females 13+ years.

It should be noted that the acute drinking water component of the risk calculations presented in this document are relevant to sub-populations with high-end exposure within the United States (FL and CA). Because the calculated risk, based on high-end exposure is acceptable, we believe that the overall risk assessment is protective of the whole U.S. population.

The Agency believes that the aggregate acute risk (food and water) from the currently registered uses and this Section 18 use of bentazon does not exceed our level of concern.

2. *Short- and intermediate-term risk.* Although residential exposure data are not available for ornamental lawn uses of bentazon, the Agency notes that large MOEs were calculated for acute aggregate risk (≥ 7,000) and occupational exposure (> 6,000 for the most highly exposed group, aerial mixer loader). In the best scientific judgement of the Agency, short- and intermediate-term aggregate risk will be below the Agncy's level of concern.

3. *Chronic risk.* Using the conservative TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to bentazon from food will utilize 18% of the RfD for the U.S. population. The major identifiable subgroup with the

highest aggregate exposure is non-nursing infants which is discussed below. EPA generally has no concern for exposures below 100 percent of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose 0appreciable risks to human health. Despite the potential for exposure to bentazon and from non-dietary, non-occupational exposure, 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 bentazon residues.

E. Determination of Safety for Infants and Children

In assessing the potential for additional sensitivity of infants and children to residues of bentazon, 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 pesticide exposure during prenatal development to one or both parents. 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 margin of exposure 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 margin of exposure and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold margin of exposure/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 margin of exposure/safety factor.

1. *Developmental toxicity studies*—a. *Rat study.* From the rat developmental toxicity study, the maternal (systemic) NOEL was 250 mg/kg/day, the highest dose tested (HDT). The developmental (fetal) NOEL was 100 mg/kg/day, based on increased post-implantation loss and decreased fetal body weight at the lowest observed effect level (LOEL) of 250 mg/kg/day.

b. *Rabbit study.* From the rabbit developmental toxicity study, the maternal (systemic) NOEL was 150 mg/kg/day, based on abortion and embryonic resorptions at the LOEL of 375 mg/kg/day. The developmental (fetal) NOEL was 375 mg/kg/day, the HDT.

The presence of developmental effects in the absence of maternal effects in the rat developmental toxicity study indicates that there is extra pre-natal sensitivity for infants and children. The significant developmental findings in the rat required an acute dietary risk assessment for females 13+ years of age.

2. *Reproductive toxicity study.—a.* Rat study. From the rat reproductive study, the parental (systemic) NOEL was 62 mg/kg/day, based on increased incidences of kidney mineralization and liver microgranules at the LOEL of 249 mg/kg/day. The reproductive (pup) NOEL was 15 mg/kg/day, based on decreased pup body weight and weight gain at the LEL of 62 mg/kg/day.

3. *Pre- and post-natal sensitivity.* Based on the results of the reproductive toxicity study in rats, there were developmental (pup) effects in the absence of parental effects. These results indicate extra post-natal sensitivity for infants and children. This finding requires a modifying factor of 3 to be added to the RfD. The RfD should be, therefore, changed from 0.03 mg/kg/day to 0.01 mg/kg/day for purposes of these section 18's only.

4. *Acute risk.* The acute dietary (food only) risk assessment used tolerance level residues and assumed 100% crop-treated. The resulting high-end exposure estimate of 0.01125 mg/kg/day, results in a dietary (food only) MOE of 8,888 for females 13+ years old. If water is considered in the acute exposure, the MOE is 7,000. Exposure estimates (MOEs) for both scenarios are considered acceptable.

5. *Short- or 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. Although residential exposure data are not available for ornamental lawn uses of bentazon, the Agency notes that large MOEs were calculated for acute aggregate risk (≥ 7,000) and occupational exposure (> 6,000 for the most highly exposed group, aerial mixer loader). Therefore the Agency believes short- and intermediate-term aggregate risk is likely to be below the Agency's level of concern.

6. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to bentazon from food and water will utilize no more than 60% of the RfD for non-nursing infants and children, the most highly exposed sub-population. EPA generally has no concern for exposures below 100 percent 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 bentazon from non-dietary, non-occupational exposure, 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 bentazon residues.

V. Other Considerations

1. *Metabolism in plants and animals.* The qualitative nature of the residue in plants is considered to be adequately understood. Radiolabelled studies conducted at rates of up to 2.5 lb active ingredient/acre on beans, corn, soybeans, rice and wheat indicate that bentazon is readily absorbed from foliage, roots and seeds, and translocates in some plant types. Bentazon is rapidly metabolized, conjugated and incorporated into natural plant constituents. Metabolism involves the hydroxylation of bentazon at the 6- and 8-position. The terminal residues of regulatory concern are bentazon, 6-hydroxy bentazon, and 8-hydroxy bentazon (as specified in 40 CFR 180.355 (a)).

2. *Analytical enforcement methodology.* Adequate enforcement methods are available for the determination of residues of bentazon and its 6- and 8-hydroxy metabolites in/on plant commodities. The Pesticide Analytical Manual (PAM) Vol. II lists Method II, a GLC method with flame photometric detection for the determination of bentazon and its hydroxy metabolites in/on corn, rice, and soybeans; the limit of detection for each compound is 0.05 ppm. Method III, modified from Method II, is available for the determination of bentazon and its hydroxy metabolites in/on peanuts and seed and pod vegetables with a limit of detection of 0.05 ppm for each compound.

3. *Magnitude of residues.* Regulable residues of bentazon and its metabolites are not expected to exceed 3 ppm in/on succulent peas as a result of this Section 18 use only.

4. *Rotational crop restrictions.* Confined rotational crop data indicate that bentazon residues may be taken up by rotational crops (39 to 102 day plantback intervals), and that field rotational crop studies are needed for the purposes of reregistration in order to determine if plantback restrictions for bentazon end-use products are needed. The petitioner will need to modify the proposed Basagran label once the field rotational crop studies are submitted by the petitioner and review by the Agency.

5. *International residue limits.* There is a Codex MRL of 0.2 ppm for bentazon and its metabolites established in/on garden peas (young pods), a Canadian MRL for parent only of 0.1 ppm (negligible) established in/on peas, and a Mexican limit for parent (presumed) of 0.05 ppm established in/on green peas. Therefore, a compatibility issue is relevant to the proposed tolerance. Harmonization of the U.S. tolerance will not be possible as the use pattern proposed in this petition will result in residues which greatly exceed the Codex MRL.

VI. Conclusion

Therefore, a tolerance in connection with the FIFRA section 18 emergency exemptions is established for residues of bentazon in succulent peas at 3 ppm. In addition to the tolerance being established for residues of bentazon in succulent peas, EPA is also, removing § 186.375 which contains a tolerance for residues of bentazon on spent mint hay. That tolerance is being transferred to the table in paragraph (a) of § 180.355.

VII. Objections and Hearing Requests

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

Any person may, by August 19, 1997, file written objections to any aspect of this regulation (including the revocation provision) 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

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket number [OPP–300499] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official rulemaking record is located at the address in **ADDRESSES** at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPP–300499]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

IX. Regulatory Assessment Requirements

This final rule establishes a time-limited tolerance under section 408 of the FFDCA and is related to EPA's granting emergency exemptions under section 18 of the FIFRA. 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). In addition, this final rule does not contain any information collections subject to additional 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, because these tolerances are established without notice and comment rulemaking, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. Nonetheless, 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 significant adverse economic impact associated with these actions (46 FR 24950, May 4, 1981). In accordance with Small Business Administration (SBA) policy, this determination will be provided to the Chief Counsel for Advocacy of the SBA upon request.

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 Parts 180 and 186

Environmental protection, Administrative practice and procedure, Agricultural commodities, Animal feeds, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 2, 1997.

James Jones,

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 180.355 is amended as follows:

i. By adding a paragraph heading to paragraph (a), and revising the phrase ''raw agricultural commodities'' to read ''food commodities''.

ii. By adding alphabetically an entry for ''Mint, spent hay'' to the table in paragraph (a).

iii. In paragraph (b), by transferring and alphabetically adding all of the entries currently in the table to the table in paragraph (a)

iv. By revising the remainder of paragraph (b).

v. By adding and reserving paragraphs (c) and (d).

§ 180.355 Bentazon; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
* * * * *	
Mint, spent hay	4
* * * * *	

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for combined residues of the herbicide bentazon and its metabolites in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/ Revocation Date
Peas, succulent	3	6/30/98

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

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

* * * * *

PART 186—[AMENDED]

2. In part 186:

a.The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C. 342, 348, and 701.

§ 186.375 [Removed]

b. Section 186.375 is removed.

[FR Doc. 97–16215 Filed 6–19–97; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 64

[Docket No. FEMA–7667]

List of Communities Eligible for the Sale of Flood Insurance

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.

SUMMARY: This rule identifies communities participating in the National Flood Insurance Program (NFIP). These communities have applied to the program and have agreed to enact certain floodplain management measures. The communities' participation in the program authorizes the sale of flood insurance to owners of property located in the communities listed.

EFFECTIVE DATES: The dates listed in the third column of the table.

ADDRESSES: Flood insurance policies for property located in the communities listed can be obtained from any licensed property insurance agent or broker serving the eligible community, or from the NFIP at: Post Office Box 6464, Rockville, MD 20849, (800) 638–6620.

FOR FURTHER INFORMATION CONTACT: Robert F. Shea, Jr., Division Director, Program Implementation Division, Mitigation Directorate, 500 C Street SW., room 417, Washington, DC 20472, (202) 646–3619.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Since the communities on the attached list have recently entered the NFIP, subsidized flood insurance is now available for property in the community.

In addition, the Executive Associate Director of the Federal Emergency Management Agency has identified the special flood hazard areas in some of these communities by publishing a Flood Hazard Boundary Map (FHBM) or Flood Insurance Rate Map (FIRM). The date of the flood map, if one has been published, is indicated in the fourth column of the table. In the communities listed where a flood map has been published, Section 102 of the Flood Disaster Protection Act of 1973, as amended, 42 U.S.C. 4012(a), requires the purchase of flood insurance as a condition of Federal or federally related financial assistance for acquisition or construction of buildings in the special flood hazard areas shown on the map.

The Executive Associate Director finds that the delayed effective dates would be contrary to the public interest. The Executive Associate Director also finds that notice and public procedure under 5 U.S.C. 553(b) are impracticable and unnecessary.

National Environmental Policy Act

This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Considerations. No environmental impact assessment has been prepared.

Regulatory Flexibility Act

The Executive Associate Director certifies that this rule will not have a significant economic impact on a substantial number of small entities in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, because the rule creates no additional burden, but lists those communities eligible for the sale of flood insurance.

Regulatory Classification

This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.