Dated: February 17, 2000.

Felicia Marcus,

Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

2. Section 52.220 is amended by adding paragraph (c)(239)(i)(F) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(239) * * *

(i) * * *

(F) San Joaquin Valley Unified Air Pollution Control District.

(*1*) Rules 8010, 8020, 8030, 8040, 8060, and 8070 adopted on April 25, 1996.

* * * * *

[FR Doc. 00–5502 Filed 3–7–00; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300978–FRL–6492–7]

RIN 2070–AB78

Bentazon; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of bentazon (3-isopropyl-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one-2,2-dioxide) and its 6- and 8-hydroxy metabolites in or on succulent peas. In addition the tolerance expression for animal commodities (meat, milk, poultry, and eggs) established in 40 CFR 180.355(a) is being corrected to that of the combined residues of bentazon and its metabolite 2-amino-*N*-isopropyl benzamine (AIBA). BASF Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective March 8, 2000. Objections and requests for hearings, identified by docket control number OPP–3000978, must be received by EPA on or before May 8, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300978 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone number: (703) 305–6224; and e-mail address: miller.joanne@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–300978. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of August 17, 1998 (63 FR 43937) (FRL–6018–2), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP) 6F4640 and 3F4270 for a tolerance by BASF Corporation. This notice included a summary of the petition prepared by BASF Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.355(a) be amended by establishing a tolerance for combined residues of the herbicide, bentazon and its 6- and 8-hydroxy metabolites, in or on succulent peas at 3.0 part per million (ppm). Tolerances have been established under 40 CFR 180.355(a) for combined residues of bentazon and its 6- and 8-hydroxy metabolites in/on succulent peas at 0.5 ppm and pea forage at 3 ppm to support a 2 × 1 lb ai/A (pounds active ingredient per acre), 30–day preharvest interval (PHI) use pattern. The new tolerance is proposed to support a 2 × 1 lb ai/A, 10–day PHI use pattern.

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. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. 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 and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for combined residues of bentazon and its 6- and 8-hydroxy metabolites in/on succulent peas at 3.0 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 bentazon are discussed in this unit.

1. Acute toxicity data for bentazon show that this chemical is not acutely toxic by the oral, inhalation, or dermal routes of exposure (Toxicity Categories III and IV). It is moderately irritating to the eye (Toxicity Category II) and slightly irritating to the skin (Toxicity Category IV). Bentazon is also a dermal sensitizer.

2. A 21–day dermal toxicity study in rabbits was conducted at doses of 0, 250, 500, or 1,000 mg/kg/day. The no observed adverse effect level (NOAEL) is 1,000 mg/kg/day, HDT (highest dose tested). The lowest observed adverse effect level (LOAEL) is greater than 1,000 mg/kg/day.

3. A 13–week feeding study in rats was conducted at doses of 0, 400, 1,200, or 3,600 ppm; equivalent to 0, 25.3, 77.8, or 243.3 mg/kg/day for males and 0, 28.9, 86.1, or 258.3 mg/kg/day for females. The NOAEL is 77.8 mg/kg/day. The LOAEL is 243.3 mg/kg/day for males and 258.3 mg/kg/day for females based on depressed mean body weights in females, a slight increase in food consumption in males, increased thromboplastin and prothrombin times (males only), and increased kidney and liver weights.

4. A chronic feeding study in dogs was conducted at doses of 0, 100, 400, or 1,600 ppm; equivalent to 0, 3.2, 13.1, or 52.3 mg/kg/day. The NOAEL is 3.2 mg/kg/day. The LOAEL is 13.1 mg/kg/day based on a dose-dependent presence of feces with red areas in dogs at 13.1 mg/kg/day (400 ppm) and 52.3 mg/kg/day (1600 ppm) and slight to severe anemia at the high dose.

5. A chronic feeding/carcinogenicity study in rats was conducted at doses of 0, 200, 800, or 4,000 ppm; equivalent to 0, 9, 35, or 180 mg/kg/day in males and 0, 11, 45, or 244 mg/kg/day in females. The NOAEL is 9/11 mg/kg/day, in males/females. The LOAEL is 35/45 mg/kg/day, in males/females, based on increased water consumption, changes in urinalysis and hematology/coagulation parameters, and decreased absolute and relative thyroid weight. No evidence of carcinogenicity was observed.

6. A oncogenicity study in mice was conducted at doses of 0, 100, 400, or 2000 ppm; equivalent to 0, 12, 47, or 242 mg/kg/day in males and 0, 12, 48, or 275 mg/kg/day in females. The NOAEL is 12 mg/kg/day. The LOAEL is 47/48 mg/kg/day in males/females, based on increased prothrombin time, increased liver and kidney weights, calcification of the *tunica albuginea*, and islet cell hyperplasia of the pancreas. No evidence of carcinogenicity was observed.

7. A developmental study in rats was conducted at doses of 0, 40, 100, or 250 mg/kg/day. The maternal NOAEL is 250 mg/kg/day (HDT). The maternal LOAEL is greater than 250 mg/kg/day. The developmental NOAEL is 100 mg/kg/day. The developmental LOAEL is 250 mg/kg/day, based on increased postimplantation loss, skeletal variations (incomplete or absent ossification in the phalangeal nucleii of the extremities, the sternebrae and cervical vertebrae), and reduced body weights or fetuses surviving to day 21.

8. A developmental study in rabbits was conducted at doses of 0, 75, 150, or 375 mg/kg/day. The maternal/developmental NOAEL is 150 mg/kg/day. The maternal/developmental LOAEL is 375 mg/kg/day (HDT), based on doe with partial abortion, embryonic resorptions, and no living fetuses.

9. A 2-generation reproduction toxicity study in rats was conducted at doses of 0, 200, 800, or 3,200 ppm; equivalent to 0, 15, 62, or 249 mg/kg/day. The parental systemic NOAEL is 62 mg/kg/day. The parental systemic LOAEL is 249 mg/kg/day, based on increased incidences of kidney mineralization and liver microgranuloma. The reproductive NOAEL is 15 mg/kg/day. The reproductive LOAEL is 62 mg/kg/day, based on reduced pup growth (body weight gain) during lactation.

10. There is no concern for mutagenic activity in several studies, including: Salmonella spp., *in vitro* mammalian cell gene mutation assays, in vivo mouse bone marrow micronucleus assay, and an unscheduled DNA synthesis assay.

11. A rat metabolism study with oral dosing showed that parent bentazon was the major metabolite found in urine, amounting to 77.37–91.02% of the dose. Another metabolism study demonstrated that the absorption and excretion of bentazon or its sodium salt in male rats after oral administration is rapid and essentially equivalent. No sex differences in the absorption, metabolism or excretion of sodium bentazon are apparent based or equivalent excretion half-lives (4 hours), pattern of excretion (greater than 90% in urine) or urinary metabolite identification (greater than 80% as free acid).

12. A dermal penetration study in rats was conducted at doses of 0.12, 1.2, 12, or 120 mg/kg. Single topical application of radioactive sodium bentazon did not appear to significantly penetrate the skin since a maximum of only 1–2% of the radioactivity was recovered (primarily in the urine) at 72 hours. Negligible amounts of dermally applied radioactivity were retained in the liver, kidneys, G.I. tract and carcass. For risk assessment purposes, dermal penetration is estimated to be 1–2%.

B. Toxicological Endpoints

1. *Acute toxicity.* An acute reference dose (aRfD) of 1 mg/kg/day was established for the subpopulation group, females 13–50 years old only, based on a no-observed-adverse-effect level (NOAEL) of 100 mg/kg/day from a developmental toxicity study in the rat. The effects observed at the next higher dose level of 250 mg/kg/day (the highest dose tested) were an increase in postimplantation loss, skeletal variations, and reduced weight of fetuses. These effects are presumed to occur after a single exposure *in utero* and, therefore, are considered to be appropriate. A 10x FQPA safety factor is applied to females 13–50 years old, because there was evidence of increased susceptibility in the developmental toxicity study in rats and in the two-generation reproduction toxicity study in rats. An uncertainty factor of 100 is used to account for inter-species differences and intra-species variability. Therefore, the aPAD (acute population adjusted dose) is 0.1 mg/kg/day for females 13–50 years old. An acute dose and endpoint were not selected for the general U.S. population (including infants and children) because there were no effects observed in oral toxicology studies, including maternal toxicity in the developmental toxicity studies in rats and rabbits, that are attributable to a single exposure (dose).

2. *Short- and intermediate-term toxicity*. A short-term dermal dose/endpoint was not identified since no dermal or systemic toxicity was seen at the limit dose of 1,000 mg/kg/day in a 21-day dermal toxicity study in rabbits. An intermediate-term dermal endpoint was chosen from a one-year feeding study in dogs. A NOAEL of 13.1 mg/kg/day was chosen based on the presence of feces with red areas seen in dogs at weeks 4, 6, and 12 at a LOAEL of 52.3 mg/kg/day. A long-term dermal endpoint was chosen from a one-year feeding study in dogs. A NOAEL of 3.2 mg/kg/day was selected based on a dose-dependent presence of feces with red areas in dogs at the LOAEL of 13.1 mg/kg/day (400 ppm). EPA determined that since oral NOAELs were selected, a dermal absorption (DA) factor of 2%, obtained from a dermal penetration study, should be used for the risk assessment.

No appropriate inhalation studies were available for endpoint selection; therefore, EPA selected oral NOAELs for inhalation exposure risk assessment. For margin of exposure (MOE) calculations, the short-term inhalation exposure NOAEL is 100 mg/kg/day (from a developmental toxicity study in rats, therefore, use 100% inhalation absorption). Dermal exposure can not be combined with inhalation, because a dose/endpoint (hazard) was not identified for short-term dermal exposure risk assessment. The intermediate- and long-term inhalation exposure NOAELs are 13.1 mg/kg/day and 3.2 mg/kg/day, respectively, from a chronic dog study. For intermediate- and long-term inhalation exposure risk assessments, the dermal and inhalation exposures can be combined (using 100% absorption for inhalation and 2% absorption for dermal) because the doses selected are oral equivalent doses and the same toxic effect was observed (feces with red areas).

3. *Chronic toxicity*. EPA has established the Reference Dose (RfD) for at 0.03 milligrams/kilograms/day (mg/kg/day). This is RfD based on the NOAEL of 3.2 mg/kg/day in the one year dog feeding study and an uncertainty factor of 100 (10X for inter-species differences and 10X for intra-species variability). The LOAEL in the study was based on dose-dependent presence of feces with red areas in dogs at 13.1 mg/kg/day (seen at week 33) and at 52.3 mg/kg/day (HDT), and slight to severe anemia at the high dose. Using the 10x FQPA safety factor, the chronic population adjusted dose (cPAD) for bentazon is 0.003 mg/kg/day.

4. *Carcinogenicity*. Bentazon has been classified as a Group ''E'' chemical (evidence of non-carcinogenicity for humans) based upon a lack of evidence of carcinogenicity in two adequate studies (rats and mice).

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.355(a)) for the combined residues of bentazon (3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one-2,2-dioxide) and its 6- and 8-hydroxy metabolites, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from as follows:

A refined chronic dietary exposure analysis (Tier 3) was performed using anticipated residues (ARs) for succulent peas and tolerance level residues for all other commodities for the general U.S. population and all population subgroups. For the chronic analysis, percent crop treated (%CT) information was used for several commodities.

Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent crop treated (PCT) as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used percent crop treated (PCT) information as follows.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to

underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be underestimated. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which bentazon may be applied in a particular area.

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 1-day or single exposure. The acute dietary analysis for females 13–50 years old (the subpopulation of concern) assumed published and proposed tolerance levels and 100% crop treated information for all commodities (Tier I). For all the females 13–50 years old subgroups, 5% or less of the aPAD is occupied by dietary exposure from food. Results of the acute analysis indicate that the acute dietary risk residues in food associated with existing and proposed uses of bentazon do not exceed EPA's level of concern.

ii. *Chronic exposure and risk.* A refined chronic dietary exposure analysis (Tier 3) was performed using anticipated residues for succulent peas and tolerance level residues for all other commodities for the general U.S. population and all population subgroups. For the chronic analysis, percent crop treated information was used for several commodities. The percent chronic population adjusted dose (% cPADs) for all subgroups were less than 100%, with the highest being 28% for the children 1–6 years subgroup. Results of the chronic analysis indicate that the chronic dietary risk from from residues in food associated with the existing and proposed uses of bentazon do not exceed EPA's level of concern.

2. *From drinking water.* SCI-GROW (Screening Concentration in Ground Water) modeling indicates that bentazon residue (bentazon + AIBA) concentrations in groundwater used as drinking water are not likely to exceed 4.25 ppb. The other regulated bentazon metabolites (6-hydroxy and 8-hydroxy bentazon) have not been found in environmental fate studies. Limited monitoring data indicated a range of bentazon concentrations (excluding degradation products) in groundwater of 20 to 120 ppb. Because monitoring data indicate a higher concentration than the SCI-GROW screening model, EPA used the 20 ppb as the environmental exposure concentration (EEC) for both acute and chronic scenarios. The EEC for surface water (from EPA's Pesticide Root Zone Model-EXAMS modeling) is 41 ppb for the peak (acute) and 8 ppb for the 36-year annual mean (chronic). The surface and ground water estimates were used to compare against back-calculated drinking water levels of comparison (DWLOCs) for aggregate risk assessments.

i. *Acute exposure and risk.* For the acute scenario, the DWLOC is 2800 ppb for females (13+/nursing).

ii.*Chronic exposure and risk.* For the chronic scenario, the DWLOCs are 95, 82, 22, 94, and 95 ppb for the US population, females (13+/nursing), children (1–6 years), Hispanics and males (13–19 years), respectively.

3. *From non-dietary exposure.* Because bentazon is registered for consumer use on turf and ornamentals, there is potential for residential exposure to adult applicators and adults and children entering recreational and residential areas treated with bentazon.

Short- and intermediate-term exposure and risk. The handler exposure is expected to be short-term while the post-application exposure is expected for both the short- and intermediate-term. However, since there is no short-term dermal endpoint, the residential post-application exposure cannot be aggregated with the handler exposure. Short-term, non-dietary ingestion exposure for toddlers is not a concern because EPA determined that there is no acute dietary or oral endpoint applicable to infants and children. However, intermediate-term, non-dietary ingestion exposure to toddlers playing on treated turf is possible and was assessed using the intermediate-term endpoint identified from the one-year dog feeding study. Intermediate-term exposure is not expected for the ornamental use. The level of concern for residential exposures to bentazon is for MOE's less than 1,000.

There are no chemical-specific or site-specific data available to determine the potential risks associated with residential exposures from handling bentazon. Therefore, the exposure estimates are based on assumptions and generic data as specified by the December 18, 1997 Draft HED Standard Operating Procedures (SOPs) for Residential Exposure Assessments. Because bentazon is applied no more than twice per year, only short-term exposure is expected for the residential handler. Because a dermal endpoint of concern for the short-term duration was not identified, only inhalation exposure estimates are relevant. Assuming that a homeowner treats his lawn and ornamental plants on the same day, the aggregate inhalation short-term MOE is 500,000 for the residential handler. This estimate indicates that the potential handler risks from residential uses of bentazon do not exceed EPA's level of concern.

Environmental fate data indicate that bentazon is moderately resistant to degradation ($t_{1/2}$ = 24–65 days). Due to the length of time bentazon is expected to remain in the environment, both short- and intermediate-term residential post-application exposures are expected. For toddlers playing on treated turf, the oral intermediate-term endpoint was used to assess toddler incidental ingestion exposures. Based on the residential use pattern, no long-term post-application residential exposure is expected. Short-term, non-dietary oral exposures to the toddler were not assessed because the subgroup of concern was identified as females 13–50 years old. This endpoint is not applicable to the infant and children population subgroups. Intermediate-term, post-application exposure is not expected from the ornamental use of bentazon.

Changes to the Residential SOPs have been proposed that alter the residential post-application scenario assumptions. The proposed assumptions are expected to better represent residential exposure and are still considered to be high-end, screening level assumptions. Therefore, EPA has deviated from the current Residential SOP assumptions and uses the proposed assumptions to calculate exposure estimates.

The dermal post-application exposure from the turfgrass use for the adult results in an MOE of 9,100. The MOEs for post-application exposures for the toddler are calculated as 6,400 and 3,500 for dermal and hand-to-mouth exposures, respectively. The aggregate intermediate MOE for post-application residential exposure to toddlers is 2,200. Therefore, all residential post-application exposure estimates are well below EPA's level of concern. Because these estimates were calculated using

screening-level assumptions, EPA believes that the actual risks will be lower. For the intermediate-term, typical lawn maintenance practices such as mowing and watering are expected to expedite the dissipation of bentazon on turfgrass. Therefore, with less residue available, potential incidental hand-to-mouth exposures are expected to be substantially lower.

4. *Cumulative exposure to substances with a 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.''

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. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Acute risk.* Acute risk estimates from aggregate exposure to bentazon in food and water are below EPA's level of concern. For Tier 1 acute dietary exposure analysis, EPA assumed that 100% of the crops treated with bentazon and that residues equaled the tolerance level. For all females 13–50 years old subgroups, less than or equal to 5% of the aPAD is occupied by dietary exposure from food. The acute dietary risk from food associated with the existing and proposed uses of bentazon is below EPA's level of concern. The estimated average concentrations of bentazon in surface and ground water are less than EPA's levels of comparison for bentazon in drinking water as a contribution to acute aggregate exposure.

2. *Chronic risk.* Chronic (Non-Cancer) Aggregate Risk estimates are below EPA's level of concern. The chronic dietary exposure analysis for residues in food incorporated anticipated residues for succulent peas and assumed tolerance level residues for all other commodities. Percent CT information was used for several commodities. The %cPADs for all subgroups were less than 100%, with the highest being 28% for the children (1–6 years old) subgroup. Thus, the chronic dietary risk estimates from food associated with existing and proposed uses of bentazon do not exceed EPA's level of concern. For ground and surface water, the estimated average concentrations of bentazon are less than EPA's levels of comparison for bentazon in drinking water as a contribution to chronic aggregate exposure.

3. *Short- and intermediate-term risk.* Aggregate short-term risk estimates are below EPA's level of concern. In aggregating short-term risk, EPA considered background chronic dietary exposure (food + drinking water) and short term inhalation exposures from residential uses. Because a dermal endpoint of concern for the short-term duration was not identified, only inhalation exposure estimates are relevant for the adult handler. Short-term inhalation exposure may occur for a homeowner treating turf and ornamentals on the same day. The total short-term food and residential aggregate MOE value is 220,000. As this MOE is greater than 1,000, the short-term food and residential aggregate risk estimate is below EPA's level of concern. For surface and ground water, the estimated average concentrations of bentazon are less than EPA's levels of comparison for bentazon in drinking water as a contribution to short-term aggregate exposure.

Aggregate intermediate-term risk estimates are below EPA's level of concern for adults. In aggregating intermediate-term risk, EPA considered background chronic dietary exposure (food + drinking water) and intermediate-term dermal exposures from residential uses. For adults, dermal post-application exposures may result from dermal contact with treated turf. For adults, the total food and residential intermediate-term aggregate MOE is 7,600. As this value is greater than 1,000, the intermediate-term aggregate risk estimate is below EPA's level of concern. For surface and ground water, the estimated average concentrations of bentazon are less than EPA's levels of comparison for bentazon in drinking water as a contribution to intermediate-term aggregate exposure.

4. *Aggregate cancer risk for U.S. population.* A cancer risk assessment was not done. Bentazon is classified as a Group E chemical (evidence of non-carcincinogenicity for humans) based upon lack of evidence of carcinogenicity in rats and mice.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to bentazon residues.

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 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 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 prenatal and postnatal toxicity and the completeness of the data base 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 (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 interspecies and intraspecies 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 toxicity studies.* Two studies were described in Toxicology Profile (see Unit III.A. Tox profile).

iii. *Reproductive toxicity study.* A reproductive toxicity study was described in the Toxicology Profile (see Unit III.A. Tox profile).

iv. *Prenatal and postnatal sensitivity.* The toxicological data base for evaluating prenatal and postnatal toxicity of bentazon is complete with respect to current data requirements.

There was evidence of increased susceptibility following*in utero* exposure to bentazon in the prenatal developmental toxicity study in rats and there was quantitative evidence of increased susceptibility following pre-/postnatal exposure to bentazon in the 2-generation reproduction study in rats.

v. *Conclusion*. There is a complete toxicity data base for bentazon and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The FQPA Safety Factor for protection of infants and children will be retained at 10x for bentazon due to the increased pre-/postnatal susceptibility. The FQPA Safety Factor for bentazon is applicable to females 13–50 years old only for acute dietary and residential exposure assessments because increased susceptibility was demonstrated in the developmental study in rats which is designed to evaluate chemical effects on the mother and fetus from the time of implantation of the fertilized egg in the uterus through the end of gestation. The safety factor is also applicable to all population subgroups for chronic dietary and residential exposure assessments because increased susceptibility was demonstrated in the 2-generation reproduction study (which is designed to assess the effects of the pesticide on male and female reproductive processes, from egg and sperm production and mating through pregnancy, birth, nursing, growth and development, and maturation).

2. *Acute risk*. An acute endpoint was not identified and this risk assessment was not required.

3. *Chronic risk*.Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to bentazon from food will utilize 28% of the chronic PAD for children (1–6 years old). EPA generally has no concern for exposures below 100% of the chronic PAD because the chronic PAD 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 in drinking water and from non- dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the chronic PAD.

4. *Short- or intermediate-term risk.* Although bentazon a registered herbicide for use on turf and ornamentals, short-term non-dietary ingestion exposure for toddlers is not assessed because EPA determined that there is no acute dietary or oral endpoint applicable to infants and children.

Aggregate intermediate-term risk estimates are below EPA's level of concern for infants and children. In aggregating intermediate-term risk, EPA considered background chronic dietary exposure (food + drinking water) and intermediate-term, non-dietary oral and dermal exposures from residential uses. For toddlers, dermal and non-dietary oral postapplication exposures may result from dermal contact with treated turf as well as hand-to-mouth transfer of residues from turfgrass. For infants and children, the total food and residential intermediate-term aggregate MOE is 2,000. As this value is greater than 1,000, the intermediate-term aggregate risk estimate is below EPA's level of concern. For surface and ground water, the estimated average concentrations of bentazon are less than EPA's levels of comparison for bentazon in drinking water as a contribution to intermediate-term aggregate exposure.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure bentazon to residues.

IV. Other Considerations

A. 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 ai/A 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-positions. The terminal residues of regulatory concern are bentazon, 6-hydroxy bentazon, and 8-hydroxy bentazon. As there are no livestock feed items associated with succulent peas, issues pertaining to the nature of the residue in animals are not germane to this regulation.

B. 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 gas liquid chromatography (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.

C. Magnitude of Residues

Ten field residue trials were conducted in seven different states with a distribution which corresponds well with the suggested growing region for succulent garden peas. The data indicated that combined residues of bentazon and its 6- and 8-hydroxy metabolites will not exceed the proposed tolerance. BASF provided data only on green peas. The raw agricultural commodity (RAC) analyzed in these trials was the succulent seeds with the pods. At the time these trials were conducted in 1993, succulent seeds with pods was the appropriate RAC. In 1995, the guidelines were revised and the RAC was redefined as edible-podded peas and succulent shelled peas. Thus, the submitted field trials do not fulfill current guidelines. BASF is required to perform three (3) edible-podded pea trials. The additional studies will satisfy the new guidelines and provide EPA with confirmatory data. EPA is proceeding with this tolerance while the additional trials are conducted because the available data are adequate to make a safety determination.

D. International Residue Limits

There is a Codex Maximum Residue Limit (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 3.0 ppm U.S. tolerance will not be possible as the use pattern proposed on the Basagran Herbicide label will result in residues which greatly exceed the Codex MRL. EPA thus suggests that BASF submit the residue data and Good Agricultural Practice (GAP) to Codex once the U.S. registration and tolerance are approved.

E. Rotational Crop Restrictions

Currently, there are no plantback restrictions on the Basagran Herbicide label. 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.

If plantback restrictions are needed based upon these studies then the Herbicide label will be revised.

V. Conclusion

Therefore, the tolerance is established for combined residues of bentazon and its 6- and 8-hydroxy metabolites in pea, succulent at 3.0 ppm. In addition, the tolerance expression for animal commodities in 40 CFR 180.355(a) is corrected as the combined residues of bentazon and its metabolite 2-amino-*N*-isopropyl benzamide (AIBA).

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–300978 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before May 8, 2000.

1. Filing the request. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). 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.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C-400 , Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

Pursuant to FFDCA section 408(m)(1), EPA is authorized to waive any fee requirement ''when in the judgment of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. N.W., Washington, DC 20460.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A.1., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–300978, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a 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(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance 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) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); 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 or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and*

Safety Risks (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Because tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

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 this final rule in the **Federal Register**. This final 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 24, 2000.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), (346a) and 371.

2. Section 180.355 is amended in paragraph (a) by revising the introductory text and redesignating it as paragaph (a)(1), by revising the entry for ''pea, succulent'' in the table in newly designated paragraph (a)(1), by removing from the table in newly designated paragraph (a)(1) the entries for cattle, fat; cattle, meat byproducts; cattle, meat; egg; goats, fat; goats, mbyp; goats, meat; hogs, fat; hogs, mbyp; hogs, meat; milk; poultry, fat; poultry, meat byproducts; poultry, meat; sheep, fat; sheep, mbyp; and sheep, meat, and by adding new paragraph (a)(2). The additions and revision read as follows:

§ 180.355 Bentazon; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the herbicide bentazon (3-isopropyl-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one-2,2-dioxide) and its 6- and 8-hydroxy metabolites in or on the following food commodity:

Commodity	Parts per million
* * * * *	
Pea, succulent	3.0
* * * * *	

(2) Tolerances are established for the combined residues of the herbicide bentazon (3-isopropyl-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one-2,2-dioxide) and its metabolite 2-amino-*N*-isopropyl benzamide (AIBA) in or on the following food commodities:

Commodity	Parts per million
Cattle, fat	0.05
Cattle, mbyp	0.05
Cattle, meat	0.05
Eggs	0.05
Goats, fat	0.05
Goats, mbyp	0.05
Goats, meat	0.05
Hogs, fat	0.05
Hogs, mbyp	0.05
Hogs, meat	0.05
Milk	0.02
Poultry, fat	0.05
Poultry, mbyp	0.05
Poultry, meat	0.05
Sheep, fat	0.05
Sheep, mbyp	0.05
Sheep, meat	0.05

* * * * *

[FR Doc. 00–5634 Filed 3–7–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300977; FRL–6492–3]

RIN 2070–AB78

Diclosulam; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of diclosulam, *N*-(2,6-dichlorophenyl)-5-ethoxy-7-fluoro[1,2,4]triazolo[1,5-*c*]pyrimidine-2-sulfonamide], in or on soybean seed and peanut nutmeat. Dow AgroSciences requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective March 8, 2000. Objections and requests for hearings, identified by docket control number OPP–300977, must be received by EPA on or before May 8, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300977 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703)