

meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.”

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

#### 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 the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a “major rule” as defined by 5 U.S.C. 804(2).

#### List of Subjects in 40 CFR Part 180

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

Dated: September 23, 1998.

**Marcia E. Mulkey,**

*Director, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

#### PART 180—[AMENDED]

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

**Authority:** 21 U.S.C. 346a and 371.

2. By revising § 180.535 to read as follows:

#### § 180.535 Fluroxypyr 1-methylheptyl ester; tolerances for residues.

(a) *General*. Tolerances are established for combined residues of fluroxypyr 1-methylheptyl ester [1-methylheptyl ((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetate] and its metabolite fluroxypyr [((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetic acid] in or on the following raw agricultural commodities.

Commodity	Parts per million
Aspirated grain fractions .....	0.6
Barley, grain .....	0.5
Barley, forage .....	12.0
Barley, hay .....	20.0
Barley, straw .....	12.0
Cattle, fat .....	0.1
Cattle, kidney .....	0.5
Cattle, meat .....	0.1
Cattle, meat byproducts .....	0.1
Goats, fat .....	0.1
Goats, kidney .....	0.5
Goats, meat .....	0.1
Goats, meat byproducts .....	0.1
Hogs, fat .....	0.1
Hogs, kidney .....	0.5
Hogs, meat .....	0.1
Hogs, meat byproducts .....	0.1
Horses, fat .....	0.1
Horses, kidney .....	0.5
Horses, meat .....	0.1
Horses, meat byproducts .....	0.1
Milk .....	0.1
Oats, forage .....	12.0
Oats, grain .....	0.5
Oats, hay .....	20.0
Oats, straw .....	12.0
Sheep, fat .....	0.1
Sheep, kidney .....	0.5
Sheep, meat .....	0.1
Sheep, meat byproducts .....	0.1
Wheat, forage .....	12.0
Wheat, grain .....	0.5
Wheat, hay .....	20.0
Wheat, straw .....	12.0

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the combined residues of fluroxypyr 1-methylheptyl ester and its metabolite fluroxypyr, 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
Corn, field, forage .....	2.0	12/1/99
Corn, field, grain .....	0.05	12/1/99
Corn, field, stover .....	2.5	12/1/99
Corn, sweet, forage .....	2.0	12/1/99
Corn, sweet, K + CWHR .....	0.05	12/1/99
Corn, sweet, stover .....	2.5	12/1/99

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

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

[FR Doc. 98-26002 Filed 9-29-98; 8:45 am]

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[OPP-300721; FRL-6033-3]

RIN 2070-AB78

#### Tebufenozide; Pesticide Tolerances for Emergency Exemptions

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a time-limited tolerance for residues of tebufenozide in or on cranberries. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on cranberries. This regulation establishes a maximum permissible level for residues of tebufenozide in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on September 30, 1999.

**DATES:** This regulation is effective September 30, 1998. Objections and requests for hearings must be received by EPA on or before November 30, 1998.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number, [OPP-300721], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled “Tolerance Petition Fees” and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300721], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov.

Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP-300721]. 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: Stephen Schaible, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-9362, e-mail: [schaible.stephen@epamail.epa.gov](mailto:schaible.stephen@epamail.epa.gov).

**SUPPLEMENTARY INFORMATION:** EPA, on its own initiative, pursuant to sections 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 insecticide tebufenozide, in or on cranberries at 0.5 part per million (ppm). This tolerance will expire and is revoked on September 30, 1999. 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.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL-5572-9).

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is

“safe.” Section 408(b)(2)(A)(ii) defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

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

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

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

## **II. Emergency Exemptions for Tebufenozide on Cranberries and FFDCA Tolerances**

According to the Applicants, outbreak populations of blackheaded fireworms have been observed in recent years, with severe infestations occurring last year. Blackheaded fireworms feed on flowers, growing shoots and developing fruit, causing yield loss to the existing cranberry crop as well as reducing yield to the following year's crop by affecting flower bud formation. The most effective strategy to manage infestations of blackheaded fireworms is to apply insecticides targeting the first instar stage during the second generation. In Washington, the loss of parathion in

1995 has left growers without an effective registered alternative—chlorpyrifos, diazanon, azinphos-methyl and acephate are all currently used, but fail to control the later instars. Growers do not like to use the organophosphate insecticides during the hatch of the second generation of blackheaded fireworm for fear of killing pollinating honeybee colonies which are placed near the beds at this time. The only two products having better safety to bees, *Bacillus thuringiensis* (Bt) and pyrenone, have poor efficacy against fireworm. Tebufenozide is non-toxic to bees and is the only available chemical that can control fireworms during midbloom of the cranberry crop. EPA has authorized under FIFRA section 18 the use of tebufenozide on cranberries for control of blackheaded fireworm in Massachusetts, New Jersey and Washington. 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 tebufenozide in or on cranberries. In doing so, EPA considered the 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 safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on September 30, 1999, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on cranberries after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. 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 tebufenozide meets EPA's registration requirements for use on cranberries 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 tebufenozide 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 Massachusetts, New Jersey and Washington to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for tebufenozide, contact the Agency's Registration Division at the address provided above.

### III. Aggregate Risk Assessment and Determination of Safety

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).

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 tebufenozide and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of tebufenozide on cranberries at 0.5 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 tebufenozide are discussed below.

1. *Chronic toxicity.* EPA has established the Reference dose (RfD) for tebufenozide at 0.018 milligrams/kilogram/day (mg/kg/day). This RfD is based on a No Observed Adverse Effect Level (NOAEL) of 1.8 mg/kg/day, taken from a chronic feeding study in dogs. An uncertainty factor of 100 was used.

2. *Carcinogenicity.* Tebufenozide has been classified by the Agency as a Group E, "no evidence of carcinogenicity for humans," chemical.

#### B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.482) for the residues of tebufenozide, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures and risks from tebufenozide as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. This is not the case with this chemical.

ii. *Chronic exposure and risk.* Using conservative Theoretical Maximum Residue Contribution (TMRC) assumptions, chronic dietary exposure from the published and proposed uses of tebufenozide was calculated to represent 31% of the RfD for the U.S. population; the subgroup most highly exposed, non-nursing infants less than 1 year old, has a TMRC which represents 80% of the RfD. Because of the assumptions that 100% of each commodity will have tebufenozide residues and that these residues will be at tolerance level, the resulting exposure and risk values should be viewed as overestimates.

2. *From drinking water.* Submitted environmental fate studies suggest that tebufenozide is moderately persistent to persistent and mobile. Thus, tebufenozide could potentially leach to groundwater and runoff to surface water under certain environmental conditions. There is no established Maximum Contaminant Level (MCL) for residues of tebufenozide in drinking water, nor have drinking water Health Advisories (HAs) been issued.

Using Generic expected environmental concentration (GENEEC) (surface water) and SCIGROW (groundwater) models, the Agency has calculated Tier I Estimated Environmental Concentrations (EECs) for tebufenozide for use in human health risk assessments. These values represent the upper bound estimates of the concentrations of tebufenozide that might be found in surface and ground water assuming the maximum application rate allowed on the label. Due to the wide range of aerobic soil half-life values, GENEEC and SCIGROW were run based on aerobic half-lives of 66 (California Loam) and 729 (worst case soil with low microbial activity) days.

*Chronic exposure and risk.* Using the GENEEC model, chronic surface water concentrations are 13.3 parts per billion (ppb) and 16.5 ppb for the half-lives of

66 and 729 days, respectively. Chronic groundwater concentrations using the SCIGROW model were calculated to be 0.16 ppb and 1.04 ppb, respectively.

Since there are no acute dietary endpoints for this chemical, drinking water levels of concern (DWLOCs) for tebufenozide in drinking water were calculated for the chronic exposure scenario only. The chronic DWLOCs for tebufenozide were calculated by subtracting from the RfD the chronic exposure attributable to food, multiplying this value by a body weight default, and dividing this multiple by a drinking water consumption value. The Agency assumes that 2 liters of drinking water are consumed each day by adults, and 1 L/day by children. The Agency's default body weights are 70 kg for males, 60 kg for females, and 10 kg for children. Using these assumptions, chronic DWLOCs were calculated to be 480 ppb for adult males, 370 for females 13+ years old and nursing, and 72 ppb for children ages 1 through 6 years old.

3. *From non-dietary exposure.* Tebufenozide is not currently registered for use on any residential non-food sites. Therefore, there is no chronic, short- or intermediate-term exposure scenario.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency considers "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 tebufenozide 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, tebufenozide 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 tebufenozide has a common mechanism of toxicity with other substances. For more 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).

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

1. *Chronic risk.* Using the TMRC exposure assumptions described in Unit II.B. of this preamble, EPA has concluded that aggregate exposure to tebufenozide from food will utilize 31% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants less than one year old (discussed below). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Estimated upper-bound concentrations of tebufenozide in surface water and ground water are below the calculated drinking water levels of concern for all population subgroups of concern.

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

3. *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 tebufenozide residues.

### *D. 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 tebufenozide, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a 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 MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* In both the rat and rabbit studies, there was no evidence of maternal or developmental toxicity; the maternal and developmental toxicity NOAEL in each study was 1,000 mg/kg/day.

iii. *Reproductive toxicity study.* Two 2-generation reproduction studies in rats have been submitted to the Agency. In a 1993 study, the parental systemic NOAEL was 10 ppm (0.8/0.9 mg/kg/day for males and females, respectively) and the LOAEL was 150 ppm (11.5/12.8 mg/kg/day) based on decreased body weight, body weight gain, and food consumption in males, and increased incidence and/or severity of splenic pigmentation. In addition, there was an increased incidence and severity of extramedullary hematopoiesis at 2,000 ppm. The reproductive NOAEL was 150 ppm and the LOAEL was 2,000 ppm (154.8/171.1 mg/kg/day, respectively) based on an increase in the number of pregnant females with increased gestation duration and dystocia. Effects in the offspring consisted of decreased number of pups per litter on postnatal days 0 and/or 4 at 2,000 ppm, with a NOAEL of 150 ppm.

In a 1995 study, the parental NOAEL was 25 ppm (1.6/1.8 mg/kg/day, for males and females, respectively) and the LOAEL was 200 ppm (12.6/14.6 mg/kg/day), based on histopathological findings in the spleen. Additionally, at 2,000 ppm (126/143.2 mg/kg/day, respectively), treatment-related findings included reduced parental body weight gain and increased incidence of hemosiderin-laden cells in the spleen. Columnar changes in the vaginal squamous epithelium and reduced uterine and ovarian weights were also observed at 2,000 ppm, but the toxicological significance was unknown. For offspring, the systemic NOAEL was 200 ppm, and the LOAEL was 2,000 ppm based on decreased body weight on postnatal days 14 and 21.

iv. *Pre- and post-natal sensitivity.* The Agency has concluded that the submitted studies provide no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to tebufenozide. No maternal or

developmental findings were observed in the prenatal developmental toxicity studies at doses up to 1,000 mg/kg/day in rats and rabbits. In both 2-generation reproduction studies, effects occurred at the same or lower treatment levels in the adults as in the offspring. Based on this information, the Agency has concluded that the 10X factor to account for enhanced sensitivity of infants and children should be removed.

v. *Conclusion.* There is a complete toxicity data base for tebufenozide and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

2. *Chronic risk.* Using the exposure assumptions described above, EPA has concluded that aggregate exposure to tebufenozide from food will utilize 80% of the RfD for non-nursing infants and 60% of the RfD for children ages 1 through 6 years old. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Estimated upper-bound concentrations of tebufenozide in surface water and ground water are below the calculated drinking water levels of concern for all population subgroups of concern.

3. *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 to tebufenozide residues.

## **IV. Other Considerations**

### *A. Metabolism in Plants and Animals*

The metabolism of tebufenozide in/on plants is adequately understood. The residue of concern is the parent compound, tebufenozide per se as specified in 40 CFR 180.482.

### *B. Analytical Enforcement Methodology*

The High performance liquid chromatography using ultra-violet detection (HPLC/UV) method, TR 34-95-19, is considered adequate for enforcement purposes and has been submitted to the FDA for inclusion in PAM II.

The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703-305-5229).

### C. Magnitude of Residues

Residues of tebufenozide are not expected to exceed 0.5 ppm in cranberries as a result of this section 18 use. There are no cattle, poultry, or swine feed items associated with this use; consequently secondary residues of tebufenozide are not expected in animal commodities.

### D. International Residue Limits

There are currently no CODEX, Canadian, or Mexican listings for tebufenozide residues; therefore, there are no harmonization issues for this action.

### E. Rotational Crop Restrictions

Cranberries are not rotated to other crops; therefore a discussion of rotational crop restrictions is not germane to this action.

### V. Conclusion

Therefore, the tolerance is established for residues of tebufenozide in cranberries at 0.5 ppm.

### VI. 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 November 30, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon

by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

### VII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP-300721] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C) Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:  
opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The

official rulemaking record is the paper record maintained at the Virginia address in "ADDRESSES" at the beginning of this document.

### VIII. Regulatory Assessment Requirements

#### A. Certain Acts and Executive Orders

This final rule establishes a tolerance under FFDCA section 408 (l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established under FFDCA section 408 (l)(6), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

#### B. Executive Order 12875

Under Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon

a State, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

#### C. Executive Order 13084

Under Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of

section 3(b) of Executive Order 13084 do not apply to this rule.

#### IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

#### List of Subjects in 40 CFR Part 180

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

Dated: September 22, 1998.

**James Jones,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

#### PART 180—[AMENDED]

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

**Authority:** 21 U.S.C. 346a and 371.

2. In § 180.482 by adding alphabetically an entry for "cranberries," to the table in paragraph (b) to read as follows:

#### § 180.482 Tebufenozide; tolerances for residues.

\* \* \* \* \*

(b) *Section 18 emergency exemptions.*  
\*\*\*

Commodity	Parts per million	Expiration/Revocation Date
* * *	*	*
Cranberries .....	0.5	9/30/99
* * *	*	*
* * *	*	*

[FR Doc. 98-26001 Filed 9-29-98; 8:45 am]

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[OPP-300718; FRL-6032-1]

RIN 2070-AB78

#### Carfentrazone-ethyl; Pesticide Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for combined residues of the herbicide Carfentrazone-ethyl (ethyl-alpha-2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzene-propanoate) and its metabolite: Carfentrazone-ethyl chloropropionic acid (alpha, 2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzene-propanoic acid) in or on these raw agricultural commodities: corn, field, grain at 0.1ppm; corn, field, forage at 0.1ppm; corn, field, fodder at 0.1 ppm; soybean seed at 0.1 ppm; wheat grain at 0.1 ppm; wheat forage at 1.0 ppm; wheat hay at 0.3 ppm; and wheat straw at 0.2 ppm. FMC Corporation requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104-170).

**DATES:** This regulation is effective September 30, 1998. Objections and requests for hearings must be received by EPA on or before November 30, 1998.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number, [OPP-300718], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300718], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall (CM)