

DATES: This correction becomes effective January 20, 1999.

FOR FURTHER INFORMATION CONTACT: By mail: Andrea Beard, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-9356; e-mail: beard.andrea@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA published a document on January 20, 1999 (64 FR 3037) (FRL-6051-6), establishing time-limited tolerances for residues of imidacloprid in/on legume vegetables (Crop Group 6, 40 CFR 180.41(c)(6)) and strawberries. This action was 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 legumes and strawberries. This regulation established maximum permissible levels for residues of imidacloprid in/on these food commodities 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 tolerances will expire and are revoked on June 30, 2000. In publishing these tolerances, the tolerance levels for these commodities were listed correctly throughout the document, but were inadvertently transposed in the final table. The correct tolerance levels are 0.1 ppm in/on strawberries, and 1.0 ppm in/on legume vegetables. This document will correct the tolerance levels.

I. Regulatory Assessment Requirements

This final rule does not impose any new requirements. It only implements a technical correction to the Code of Federal Regulations (CFR). As such, this action does not require review by the Office of Management and Budget (OMB) under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not impose any enforceable duty, contain any unfunded mandate, or impose any significant or unique impact on small governments as described in the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require prior consultation with State, local, and tribal government officials as specified by Executive Order 12875, entitled

Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993) and Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), or special consideration of environmental justice related issues under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994). 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), Pub. L. 104-113, section 12(d) (15 U.S.C. 272 note). In addition, since this action is not subject to notice-and-comment requirements under the Administrative Procedure Act (APA) or any other statute, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*).

II. 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 rule in the **Federal Register**. This is a technical correction to the **Federal Register** and 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: March 30, 1999.

James Jones,
Director, Registration Division, Office of Pesticide Programs.

In FR Doc. 99-1253, published on January 20, 1999 (64 FR 3037), make the following correction:

§ 180.472 [Corrected]

On page 3044, in the third column, in § 180.472, in paragraph (b), the table is corrected to read as follows:

§ 180.472 Imidacloprid; tolerances for residues.

* * * * *
(b) * * *

Commodity	Parts per million	Expiration/revocation date
* * *	* *	* *
Legume vegetables	1.0	6/30/00
Strawberry	0.1	6/30/00
* * *	* *	* *

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[FR Doc. 99-9225 Filed 4-13-99; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300835; FRL-6073-5]

RIN 2070-AB78

Glyphosate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of (*N*-phosphonomethyl)glycine resulting from the use of the isopropylamine salt of glyphosate or the monoammonium salt of glyphosate in or on barley, grain; barley, bran; beets, sugar, dried pulp; beets, sugar, roots; beets, sugar, tops; canola, meal; canola, seed; grain crops (except wheat, corn, oats, grain sorghum, and barley); and legume vegetables (succulent and dried) crop group (except soybeans). The residues from treatment of sugar beets and canola include residues in or on sugarbeet and canola varieties which have been genetically altered to be tolerant of glyphosate. Entries for grain crops and sugar beets will replace current entries. Monsanto Company 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 April 14, 1999. Objections and requests for hearings must be received by EPA on or before June 14, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP-300835], 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-300835], 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 be submitted electronically by sending electronic mail (e-mail) to: opp-docket@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 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP-300835]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 237, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703-305-5697; tompkins.jim@epa.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of February 20, 1998 (63 FR 8635) (FR-5768-9), 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) (Pub. L. 104-170) announcing the filing of pesticide petitions (PP) 2E4118 and 7F4886 for tolerance by Monsanto Company, 700 14th Street, Suite 1100, Washington, DC 20005 address. This notice included a summary of the petition prepared by Monsanto Company, the registrant.

There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.364 be amended by establishing tolerances for residues of the herbicide (*N*-(phosphonomethyl)glycine), in or on the imported raw agricultural commodities barley, grain at 20 parts per million (ppm); barley bran and pearled barley at 60 ppm; cereal grains group (except wheat, corn, oats, grain sorghum, and barley) at 0.1 ppm; canola, seed at 10 ppm; canola, meal at 25 ppm; legume vegetables (succulent or dried) group (except soybeans) at 5 ppm (PP 2E4118) and in or on the commodities beets, sugar, tops (leaves) at 10 ppm; beets, sugar, roots at 10 ppm; and beets, sugar, pulp, dried at 25 ppm (PP 7F4886).

The correct tolerance expression for glyphosate is (*N*-(phosphonomethyl)glycine) resulting from the application of the isopropylamine salt of glyphosate and/or the monoammonium salt of glyphosate. The correct terminology for cereal grains; beets, sugar, tops (leaves); and beets, sugar, pulp, dried; is grain crops; beet, sugar, tops; and beets, sugar, dried pulp, respectively. The Agency is correcting the terminology with this rule. During the course of the review the Agency determined that available data support tolerances of 20 ppm for barley bran, 15 ppm for canola, meal and that a tolerance for barley, pearled is not necessary. Concentration in barley, pearled is not expected.

The Agency is amending the proposal to read that 40 CFR 180.364 be amended by establishing tolerances for residues of the herbicide glyphosate (*N*-(phosphonomethyl)glycine) resulting from the application of the isopropylamine salt of glyphosate and/or the monoammonium salt of glyphosate in or the raw agricultural commodities barley, grain at 20 ppm; barley, bran at 30 ppm; grain crops (except wheat, corn, oats, grain sorghum, and barley) at 0.1 ppm; canola, seed at 10 ppm; canola, meal at 15 ppm; beets, sugar, tops at 10 ppm; beets, sugar, roots at 10 ppm; and beets, sugar, dried pulp at 25 ppm; and legume vegetables (succulent and dried) group (except soybeans) at 5.0 ppm.

I. Background and Statutory Findings

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).

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of glyphosate and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of (*N*-(phosphonomethyl)glycine) resulting from the application of the isopropylamine salt of glyphosate and/or the monoammonium salt of glyphosate on barley, bran at 20 ppm; barley, grain at 30 ppm; beets sugar, dried pulp at 25 ppm; beets, sugar, roots at 10 ppm; beets, sugar, tops at 10 ppm; canola, meal at 15 ppm; canola, seed at 10 ppm; grain crops (except wheat, corn, oats, grain sorghum, and barley) at 0.1 ppm; and legume vegetables (succulent and dried) group (except soybeans) at 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 glyphosate are discussed in this unit.

1. Several acute toxicology studies placing technical-grade glyphosate in Toxicity Category III and Toxicity Category IV. Technical glyphosate is not a dermal sensitizer.

2. A 21-day dermal toxicity study rabbits were exposed to glyphosate at levels of 0, 10, 1,000, or 5,000 milligrams/kilogram/day (mg/kg/day). The systemic no observed adverse effect level (NOAEL) was 1,000 mg/kg/day and the lowest observed adverse effect level (LOAEL) was 5,000 mg/kg/day based on decreased food consumption in males. Although serum lactate dehydrogenase was decreased in both sexes at the high dose, this finding was not considered to be toxicologically significant.

3. A 1-year feeding study with dogs fed dosage levels of 0, 20, 100, and 500 milligrams/kilogram/day (mg/kg/day) with a (NOAEL) of 500 mg/kg/day.

4. A 2-year carcinogenicity study in mice fed dosage levels of 0, 150, 750, and 4,500 mg/kg/day with no carcinogenic effect at the highest dose tested (HDT) of 4,500 mg/kg/day.

5. A chronic feeding/carcinogenicity study in male and female rats fed dosage levels of 0, 3, 10, and 31 mg/kg/day (males) and 0, 3, 11, or 34 mg/kg/day (females) with no carcinogenic effects observed under the conditions of the study at dose levels up to and including 31 mg/kg/day (HDT) (males) and 34 mg/kg/day (HDT) (females) and a systemic NOAEL of 31 mg/kg/day (HDT) (males) and 34 mg/kg/day (HDT) (females). Because a maximum tolerated dose (MTD) was not reached, this study was classified as supplemental for carcinogenicity.

6. A chronic feeding/carcinogenicity study in male and female rats fed dosage levels of 0, 89, 362, and 940 mg/kg/day (males) and 1, 113, 457, and 1,183 mg/kg/day (females) with no carcinogenic effects noted under the conditions of the study at dose levels up to and including 940/1,183 mg/kg/day (males/females) (HDT) and a systemic NOAEL of 362 mg/kg/day (males) based on an increased incidence of cataracts and lens abnormalities, decreased urinary pH, increased liver weight and increased liver weight/brain ratio (relative liver weight) at 940 mg/kg/day (males) (HDT) and 457 mg/kg/day (females) based on decreased body weight gain 1,183 mg/kg/day (females) (HDT).

7. A developmental toxicity study in rats given doses of 0, 300, 1,000, and 3,500 mg/kg/day with a developmental (fetal) NOAEL of 1,000 mg/kg/day based on an increase in number of litters and fetuses with unossified sternebrae, and decrease in fetal body weight at 3,500

mg/kg/day, and a maternal NOAEL of 1,000 mg/kg/day based on decrease in body weight gain, diarrhea, soft stools, breathing rattles, inactivity, red matter in the region of nose, mouth, forelimbs, or dorsal head, and deaths at 3,500 mg/kg/day (HDT).

8. A developmental toxicity study in rabbits given doses of 0, 75, 175, and 350 mg/kg/day with a developmental NOAEL of 175 mg/kg/day (insufficient litters were available at 350 mg/kg/day to assess developmental toxicity); a maternal NOAEL of 175 mg/kg/day based on increased incidence of soft stool, diarrhea, nasal discharge, and deaths at 350 mg/kg/day (HDT).

9. A multi-generation reproduction study with rats fed dosage levels of 0, 3, 10, and 30 mg/kg/day with the parental NOAEL/LOAEL 30 mg/kg/day (HDT). The only effect observed was an increased incidence of focal tubular dilation of the kidney (both unilateral and bilateral combined) in the high-dose male F3b pups. Since the focal tubular dilation of the kidneys was not observed at the 1,500 mg/kg/day level (HDT) in the rat reproduction study discussed below, but was observed at the 30 mg/kg/day level (HDT) in the 3-generation rat reproduction study the latter was a spurious rather than glyphosate-related effect. Therefore, the parental and reproductive (pup) NOAELs are 30 mg/kg/day.

10. A 2-generation reproduction study with rats fed dosage levels of 0, 100, 500, and 1,500 mg/kg/day with a systemic NOEL of 500 mg/kg/day based on soft stools in F0 and F1 males and females at 1,500 mg/kg/day (HDT) and a reproductive NOEL 1,500 mg/kg/day (HDT).

11. Mutagenicity data included chromosomal aberration *in vitro* (no aberrations in Chinese hamster ovary cells were caused with and without S9 activation); DNA repair in rat hepatocyte; *in vivo* bone marrow cytogenic test in rats; rec-assay with *B. subtilis*; reverse mutation test with *S. typhimurium*; Ames test with *S. typhimurium*; and dominant-lethal mutagenicity test in mice (all negative).

B. Toxicological Endpoints

1. *Acute toxicity.* No toxicological endpoint attributable to a single dose was identified in oral studies including the rat and rabbit developmental studies. There are no data requirements for acute or subacute neurotoxicity studies since there was no evidence of neurotoxicity in any of the toxicology studies at very high doses and glylyphosate lacks a leaving group.

2. *Short- and intermediate-term toxicity.* No short or intermediate

dermal or inhalation endpoints were identified. In a 21-day dermal toxicity study with rabbits, no systemic or dermal toxicity was seen following repeated applications of glyphosate at 0, 100, 1,000, or 5,000 mg/kg/day. The NOAEL was 1,000 mg/kg/day and the LOAEL was 5,000 mg/kg/day based decreased food consumption in males. In addition, the use of 3% dermal absorption rate (estimated) in conjunction with the oral NOAEL of 175 mg/kg/day established in the rabbit development study yields a dermal equivalent dose of greater than 5,000 mg/kg/day.

Based on the low toxicity of the formulation product (Toxicity Category III and IV) and the physical characteristics of the technical product there is minimal concern for potential inhalation exposure or risk. The acute inhalation study was waived for technical glyphosate. Some glyphosate end-use products are in Toxicity Category I or II for eye or dermal irritation. The Reregistration Eligibility Decision Document for Glyphosate (Sept, 1993) indicates that the Agency is not adding any additional personal protective equipment (PPE) requirements to labels of end-use products, but that it continues to recommend the PPE and precautionary statements required for end-use products in Toxicity Categories I and II.

3. *Chronic toxicity.* EPA has established the Reference Dose (RfD) for glyphosate at 2.0 mg/kg/day. This RfD is based on the maternal NOAEL of 175 mg/kg/day from a rabbit developmental study and a 100-fold safety factor.

4. *Carcinogenicity.* Glyphosate has been classified as a Group E chemical—no evidence of carcinogenicity in two acceptable animal species.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.364) for the residues of (*N*-phosphonomethyl)glycine and its metabolite aminomethylphosphonic acid resulting from the application of the Isopropylamine salt of glyphosate and/or the monoammonium salt of glyphosate, in or on a variety of raw agricultural commodities. Tolerances are established on kidney of cattle, goats, hogs, horses, and sheep at 4.0 ppm; liver of cattle, goats, hogs, horses, and sheep at 0.5 ppm; and liver and kidney of poultry at 0.5 ppm. Risk assessments were conducted by EPA to assess dietary exposures from glyphosate 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. An acute dietary risk assessment was not performed because no endpoints attributable to single dose were identified in the oral studies including rat and rabbit developmental studies. There are no data requirements for acute and subchronic neurotoxicity studies and no evidence of neurotoxicity in any of the toxicity studies at very high doses. The Agency concludes with reasonable certainty that glyphosate dose not elicit an acute toxicological response. An acute dietary risk assessment is not needed.

ii. *Chronic exposure and risk.* The chronic dietary exposure analysis was conducted using the (RfD) of 2.0 mg/kg/day based on the maternal NOEL of 175 mg/kg/day from a developmental study and an uncertainty factor of 100 (applicable to all population groups) the Dietary Exposure Evaluation Model (DEEM) analysis assumed tolerance levels residues and 100% of the crop treated. These assumptions resulted in the following theoretical maximum residue contributions and % RfDs for certain population subgroups. The TMRC for the US population (48 states) was 0.029960 or 1.5% of the RfD, 0.026051 or 1.3% of the RfD for nursing infants (less than on 1 year old), 0.065430 or 3.3% of the RfD for non-nursing infants less than 1 year old; 0.064388 or 3.2% of the RfD for children (1-6 years old); 0.043017 or 2.2% of the RfD for children (7-12 years old); 0.030928 or 1.5% of the RfD for females (13+/-nursing); 0.030241 or 1.5% of the RfD for non-Hispanic whites; and 0.030206 or 1.5% of the RfD for non-Hispanic blacks.

iii. *Chronic risk-carcinogenic.* Glyphosate has been classified as a group E chemical no evidence of carcinogenicity in two acceptable animal species.

2. *From drinking water.* Generic expected environmental concentration (GENEEC) and Screening concentration and ground water (SCI-GROW) models were run to produce estimates of glyphosate concentrations in surface and ground water, respectively. The drinking water exposure for glyphosate from the ground water screening model, SCI-GROW, yields a peak and chronic Estimated Environmental Concentration (EEC) of 0.0011 ppb in ground water. The GENEEC values represent upper-bound estimates of the concentrations that might be found in surface water due to glyphosate use. Thus, the GENEEC model predicts that glyphosate surface water concentrations range from a peak of 1.64 ppb to a 56 day average of 0.19

ppb. The model estimates are compared to drinking water level of comparison (DWLOC (chronic). The DWLOC (chronic) is the theoretical concentration of glyphosate in drinking water so that the aggregate chronic exposure (food+water+ residential) will occupy no more than 100% of the RfD. Glyphosate is registered for residential products, however, a residential exposure assessment is not required since there are no endpoints selected for either dermal or inhalation exposure. The Agency's default body weights and consumption values used to calculate DWLOCs are as follows: 70 kg/2L (adult male), 60 kg/2L (adult female), and 10 kg/1L (child).

i. *Acute exposure and risk.* An acute dietary endpoint and dose was not identified in the toxicology data base. Adequate rat and rabbit developmental studies did not provide a dose or endpoint that could be used for acute dietary risk purposes. Additionally, there were no data requirements for acute or subchronic rat neurotoxicity studies since there was no evidence of neurotoxicity in any of the toxicology studies at very high doses.

ii. *Chronic exposure and risk.* The DWLOC (chronic) (non-cancer) risk is calculated by multiplying the chronic water exposure (mg/kg/day) x (body weight) divided by the consumption (L) x 10⁻³ mg/ug. The DWLOCs are 69,000 µg/L for the U.S. population in 48 states, males (13+), non-Hispanic whites, and non-Hispanic blacks; and 19,000 for non-nursing infants (less than 1 year old) and children (1-6 years). The GENEEC and SCI-GROW estimated that average concentrations of glyphosate in the surface and ground water are less than the DWLOC (chronic). Therefore, taking into account present uses and uses proposed in this action, the Agency concludes with reasonable certainty that no harm will result from chronic aggregate exposure to glyphosate.

3. *From non-dietary exposure.* Glyphosate is currently registered for use on the following residential non-food sites: Around ornamentals, shade trees, shrubs, walk, driveways, flower beds and home lawns. Based on the registered uses of glyphosate, the potential for residential exposures exists. However, based on the low acute toxicity and lack of other toxicological concerns, glyphosate does not meet the Agency's criteria for residential data requirements. Exposures from residential uses are not expected to pose undue risks or harm to public health.

i. *Acute exposure and risk.* There are no acute toxicological concerns for glyphosate. Glyphosate has been the subject of numerous incident reports,

primarily for eye and skin irritation injuries, in California. Some glyphosate end-use products are in Toxicity Categories I and II for eye and dermal irritation. The Reregistration Eligibility Decision Document for Glyphosate (SEP-1993) indicates the Agency is not adding additional personal protective equipment (PPE) requirements to labels of end-use products, but that it continues to recommend the PPE and precautionary statements required for end-use products in Toxicity Categories I and II.

ii. *Chronic exposure and risk.* Although there are registered residential uses for glyphosate, glyphosate does not meet the Agency's criteria for residential data requirements, due to the lack of toxicological concerns. Incidental acute and/or chronic dietary exposures from residential uses of glyphosate are not expected to pose undue risks to the general population, including infants and children.

iii. *Short- and intermediate-term exposure and risk.* EPA identified no toxicological concerns for short-intermediate- and long-term dermal or inhalation routes of exposures. The Agency concludes that exposures from residential uses of glyphosate are not expected to pose undue risks.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA does not have, at this time, available data to determine whether glyphosate 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, glyphosate 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 glyphosate 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.* There was no acute dietary endpoint identified, therefore there are no acute toxicological concerns for glyphosate.

2. *Chronic risk.* Using the TMRC exposure assumptions described in this unit, EPA has concluded that aggregate exposure to glyphosate from food will utilize 1.5% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants (less than 1 year) and children (1-6) as discussed below. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to glyphosate in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to glyphosate residues.

3. *Short- and intermediate-term risk.* Short- and intermediate-term dermal and inhalation risk is not a concern due to the lack of significant toxicological effects observed with glyphosate under these exposure scenarios.

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.

4. *Aggregate cancer risk for U.S. population.* Glyphosate has been classified as a Group E chemical, with no evidence of carcinogenicity for humans in two acceptable animal studies.

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 glyphosate 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 glyphosate, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation.

Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a 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 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. *Pre- and post-natal sensitivity.* The oral perinatal and prenatal data demonstrated no indication of increased sensitivity of rats or rabbits to *in utero* and postnatal exposure to glyphosate.

iii. *Conclusion.* There is a complete toxicity database for glyphosate and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures. Based on these data, there is no indication that the developing fetus or neonate is more sensitive than adult animals. No developmental neurotoxicity studies are being required at this time. A developmental neurotoxicity data requirement is an upper tier study and required only if effects observed in the acute and 90-day neurotoxicity studies indicate concerns for frank neuropathy or alterations seen in fetal nervous system in the developmental or reproductive toxicology studies. The Agency believes that reliable data support the use of the standard 100-fold uncertainty factor, and that a tenfold (10x) uncertainty factor is not needed to protect the safety of infants and children.

2. *Acute risk.* There are no acute toxicological endpoints for glyphosate. The Agency concludes that establishment of the proposed tolerances would not pose an unacceptable aggregate risk.

3. *Chronic risk.* Using the exposure assumptions described in this unit, EPA

has concluded that aggregate exposure to glyphosate from food will utilize 3.0% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to glyphosate in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk.*

Short-term and intermediate-term dermal and inhalation risk is not a concern due to the lack of significant toxicological effects observed with glyphosate under these exposure scenarios.

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 to glyphosate residues.

III. Other Considerations

A. Metabolism In Plants and Animals

The qualitative nature of the residue in plants is adequately understood. Studies with a variety of plants including corn, cotton, soybeans, and wheat indicate that the uptake of glyphosate or its metabolite, aminomethylphosphonic acid (AMPA), from soil is limited. The material which is taken up is readily translocated. Foliarly applied glyphosate is readily absorbed and translocated throughout the trees or vines to the fruit of apples, coffee, dwarf citrus (calamondin), pears and grapes. Metabolism via *N*-methylation yields *N*-methylated glycines and phosphonic acids. For the most part, the ratio of glyphosate to AMPA is 9 to 1 but can approach 1 to 1 in a few cases (e.g., soybeans and carrots). Much of the residue data for crops reflects a detectable residue of parent (0.05 - 0.15 ppm) along with residues below the level of detection (<0.05 ppm) of AMPA. The terminal residue to be regulated in plants is glyphosate *per se*.

The qualitative nature of the residue in animals is adequately understood. Studies with lactating goats and laying hens fed a mixture of glyphosate and AMPA indicate that the primary route of elimination was by excretion (urine and feces). These results are consistent with metabolism studies in rats, rabbits, and cows. The terminal residues in eggs, milk, and animal tissues are glyphosate and its metabolite AMPA; there was no evidence of further metabolism. The

terminal residue to be regulated in livestock is glyphosate *per se*.

B. Analytical Enforcement Methodology

Adequate enforcement methods are available for analysis of residues of glyphosate in or on plant commodities. These methods include GLC (Method I in *Pesticides Analytical Manual (PAM) II*; the limit of detection is 0.05 ppm) and High performance liquid chromatography (HPLC) with fluorometric detection. Use of the GLC method is discouraged due to the lengthiness of the experimental procedure. The HPLC procedure has undergone successful Agency validation and was recommended for inclusion in PAM II. A GC/MS method for glyphosate in crops has also been validated by EPA's Analytical Chemistry Laboratory (ACL).

Adequate analytical methods are available for residue data collection and enforcement of the proposed tolerances of glyphosate in or on barley, bran, barley, grain; cereal grains (except wheat, corn, oats, grain sorghum, and barley); canola seed, canola meal, and legume vegetables group.

C. Magnitude of Residues

The available crop field trial residue data support the establishment of tolerances in barley, bran at 30 ppm; barley, grain at 20 ppm; beets, sugar, dried pulp at 25 ppm; beets, sugar, roots at 10 ppm; beets, sugar, tops at 10 ppm; canola, meal at 15 ppm; canola, seed at 10 ppm; and legume vegetable (succulent and dried) group (except soybeans) at 5 ppm. These entries for sugar beets will replace the current entry for beets, sugar at 0.2 ppm.

The available data support deleting the current entry for grain crops (except wheat, corn, oats, and grain sorghum) at 0.01 ppm and replacing it with grain crops (except wheat, corn, oats, grain sorghum and barley) at 0.1 ppm.

D. International Residue Limits

Codex Maximum residue levels (MRLs) exist for barley, dry peas, dry beans, and canola seed at 20, 5, 2, and 10 ppm respectively. Canadian MRLs exist for barley, barley milling fractions, peas, beans, and lentils at 10, 15, 5, 2 and 4 ppm respectively. Mexican MRLs exist for barley, peas, and beans at 0.1, 0.2, and 0.2 ppm, respectively. The Mexican and Canadian MRLs are lower than needed to cover residues from the proposed use patterns in the U.S. The tolerances to be established for group (excluding soybeans), barley, grain, and canola seed agree with Codex MRLs in place. The legume vegetable group tolerance includes tolerances for peas,

beans, and lentils. The crop group tolerance on legume vegetables is necessary to cover use patterns in the United States.

No Codex, Canadian or Mexican MRLs exist for sugar beets or canola meal, therefore harmonization is not an issue.

E. Rotational Crop Restrictions

Glyphosate labels currently bear a 30-day minimum plant back interval for crops on which the use of glyphosate is not registered.

IV. Conclusion

Therefore, the tolerance is established for residues of (*N*-phosphonomethyl)glycine resulting from the application of the isopropylamine salt of glyphosate and/or the monoammonium salt of glyphosate in or on the raw agricultural commodities barley, grain to 20 ppm; barley bran at 30 ppm; beets, sugar, dried pulp at 25 ppm; beets, sugar, roots at 10 ppm; beet, sugar, tops at 10 ppm; canola, meal at 15 ppm; canola, seed at 10 ppm; grain crops (except wheat, corn, oats, grain sorghum, and barley) at 0.1 ppm; and legume vegetables (succulent and dried) group (except soybeans) at 5 ppm. The entries for grain crops and beets, sugar replace current entries for these commodities.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to "object" to a tolerance regulation 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 June 14, 1999, 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 under the "ADDRESSES" section (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 regulation. 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). EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5697; tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

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

VI. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP-300835] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available

for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at: opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit 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 record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in "ADDRESSES" at the beginning of this document.

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

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

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCFA 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. Nevertheless, the Agency 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 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.

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: March 30, 1999.

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. 321(q), 346a, and 371.

2. Section 180.364 is amended, by removing from the table in paragraph (a)(1), the commodities "beets, sugar" and "grain crops (except wheat, corn, oats, and grain sorghum)" and by alphabetically adding new paragraph (a)(3) to read as follows:

§180.364 Glyphosate; tolerances for residues.

(a) * * *

(3) Tolerances are established for residues of glyphosate, (N-(phosphonomethyl)glycine) resulting from the applicaiton of the isopropylamine salt of glyphosate and/or the monoammium salt of glyphosate in or on the following food commodities.

Commodity	Parts per million
Barley, bran	30
Barley, grain	20
Beets, sugar, dried pulp	25
Beets, sugar, roots	10
Beets, sugar, tops	10
Canola, meal	15
Canola, seed	10
Grain crops (except wheat, oats, grain sorghum and barley).	0.1
Legume vegetables (succulent and dried) group (except soybeans).	5

* * * * *

[FR Doc. 99-9317 Filed 4-13-99; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300842; FRL-6075-2]

RIN 2070-AB78

Dimethomorph; Extension of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends a time-limited tolerance for residues of the fungicide dimethomorph in or on

squash, cantaloupe, watermelon, and cucumber at 1 part per million (ppm) for an additional 1½-year period. This tolerance will expire and is revoked on September 30, 2001. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on squash, cantaloupe, watermelon, and cucumber. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act 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 FIFRA section 18.

DATES: This regulation becomes effective April 14, 1999. Objections and requests for hearings must be received by EPA, on or before June 14, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP-300842], 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-300842], 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 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic 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 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP-300842]. No Confidential Business Information (CBI) should be submitted through e-

mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Libby Pemberton, 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: Rm. 280, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703 308-9364, pemberton.libby@epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a final rule, published in the **Federal Register** of February 18, 1998 (63 FR 8134) (FRL-5767-8), which announced that on its own initiative under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a and (l)(6), as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170) it established a time-limited tolerance for the residues of dimethomorph in or on squash, cantaloupe, watermelon, and cucumber at 1.0 ppm, with an expiration date of March 31, 2000. EPA established the tolerance because 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 FIFRA section 18. Such tolerances can be established without providing notice or period for public comment.

EPA received a request to extend the use of dimetomorph on squash, cantaloupe, watermelon, and cucumber for this years growing season due to the continued need for control of crown rot (*Phytophthora capsici*) in Georgia. After having reviewed the submission, EPA concurs that emergency conditions exist. EPA has authorized under FIFRA section 18 the use of dimethomorph on squash, cantaloupe, watermelon, and cucumber for control of crown rot in Georgia.

EPA assessed the potential risks presented by residues of dimethomorph in or on squash, cantaloupe, watermelon, and cucumber. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. The data and other relevant material have been evaluated and discussed in the final rule of February 18, 1998 (63 FR 8134) (FRL-5767-8). Based on that data and information considered, the Agency