

List of Subjects in 40 CFR Part 62

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, and Reporting and recordkeeping requirements.

Dated: September 3, 1998.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

40 CFR Part 62 is amended as follows:

PART 62—[AMENDED]

1. The authority citation for Part 62 continues to read as follows:

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

Subpart B—Alabama

2. Part 62.100 is amended by adding paragraphs (b)(3) and (c)(3) to read as follows:

§ 62.100 Identification of plan.

* * * * *

(b) * * *

(3) Alabama Department of Environmental Management Plan For the Control of Landfill Gas Emissions at Existing Municipal Solid Waste Landfills, submitted on January 6, 1998, by the Alabama Department of Environmental Management.

(c) * * *

(3) Existing municipal solid waste landfills.

3. Subpart B is amended by adding a new § 62.103 and a new undesignated center heading to read as follows:

Landfill Gas Emissions From Existing Municipal Solid Waste Landfills**§ 62.103 Identification of sources.**

The plan applies to existing municipal solid waste landfills for which construction, reconstruction, or modification was commenced before May 30, 1991, that accepted waste at any time since November 8, 1987, or that have additional capacity available for future waste deposition, as described in 40 CFR part 60, subpart Cc.

[FR Doc. 98-26899 Filed 10-7-98; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 62**

[SIPTRAX NO. VA 011-5034a; FRL-6174-7]

Approval and Promulgation of State Air Quality Plans for Designated Facilities and Pollutants; Commonwealth of Virginia; Control of Total Reduced Sulfur Emissions from Existing Kraft Pulp Mills

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule; correction.

SUMMARY: This document corrects an error in the rule language of a final rulemaking action pertaining to EPA's approval of the section 111(d) plan for control of total reduced sulfur (TRS) emissions from kraft pulp mills submitted by the Commonwealth of Virginia.

EFFECTIVE DATE: November 8, 1998.

FOR FURTHER INFORMATION CONTACT:

Artra B. Cooper at (215) 814-2096, or by e-mail at cooper.artra@epamail.gov.

SUPPLEMENTARY INFORMATION: EPA published a document on September 8, 1998 (63 FR 47436) inadvertently adding paragraph (d) under the new § 62.11610. The intent of the document was to add paragraphs (a) through (c) under the new § 62.11610. This document corrects the erroneous amendatory language.

In the final rule (FR Docket 98-23888) published in the **Federal Register** on September 8, 1998 (63 FR 47436), on page 47438 in the first column, remove paragraph (d) from § 62.11610.

Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and, is therefore not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because this corrective rulemaking action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute, it is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

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 correction rule pertaining to Virginia's section 111(d) plan for control of TRS emissions from kraft pulp mills is not a "major rule" as defined by 5 U.S.C. 804(2).

Dated: October 1, 1998.

Thomas Voltaggio,

Acting Regional Administrator, EPA Region III.

[FR Doc. 98-27026 Filed 10-7-98; 8:45am]

BILLING CODE: 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[OPP-300736; FRL 6036-1]

RIN 2070-AB78

Glyphosate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of glyphosate N-(phosphonomethyl) glycine in or on durian, mangosteen, and rambutan. The Interregional Research Project 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective October 8, 1998. Objections and requests for hearings must be received by EPA on or before December 7, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, OPP-300736, 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-300736, 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 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number OPP-300736. 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: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-7610; e-mail: jackson.sidney@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 26, 1998 (63 FR 45487) (6023-5) EPA, issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP) for tolerance by the Interregional Research Project 4. This notice included a summary of the petition prepared by Monsanto Agricultural Group (MAG), 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 glyphosate *N*-(phosphonomethyl) glycine, in or on durian at 0.2 part per million (ppm), mangosteen at 0.2 ppm, and rambutan at 0.2 ppm.

I. Risk Assessment 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 November 26, 1997 (62 FR 62961) (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 tolerances for residues of glyphosate on durian at 0.2 ppm, mangosteen at 0.2 ppm, and rambutan at 0.2 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances 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 below.

1. *Acute toxicity.* The required battery of acute toxicity studies was submitted and found adequate. The findings were as follows: an acute oral study in rats shows a combined lethal dose (LD)₅₀ of > 5,000 milligram (mg)/kilogram (kg); an acute dermal study in rabbit resulted in a LD₅₀ of > 5,000 mg/kg; a primary dermal irritation and a primary dermal sensitization study essentially showed no irritation and no sensitization, respectively. A primary eye irritation study in the rabbit showed severe irritation for glyphosate acid. However, glyphosate is normally formulated as one of several salts, and eye irritation studies on the salts showed essentially no irritation; a primary dermal irritation study showed essentially no irritation; and a primary dermal sensitization study showed no sensitization.

Based on these results, the Agency concludes that the acute toxicity and irritation potential of glyphosate is low.

2. *Genotoxicity.* A number of mutagenicity studies were conducted and were all negative. These studies included: chromosomal aberration *in vitro* (no aberrations in Chinese hamster ovary cells were caused with or without S9 activation); deoxyribonucleic acid (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. Negative results were obtained when glyphosate was tested in a dominant-lethal mutation assay.

3. *Reproductive and developmental toxicity.* The oral rat and rabbit developmental studies and the oral rat reproduction study demonstrated no indication of increased sensitivity of rats or rabbits to *in utero* and postnatal exposure to glyphosate.

4. *Developmental toxicity study in rats.* Sprague-Dawley rats were dosed by gavage at doses of 0, 300, 1,000, or 3,500 mg/kg/day during days 6-15 of gestation. The maternal (systemic) no-observed adverse effect level (NOAEL) is 1,000 mg/kg/day. The maternal (systemic) lowest-observed effect level (LOAEL) of 3,500 mg/kg/day was based on the following treatment-related effects: diarrhea, decreased mean body weight gain, breathing rattles, inactivity, red matter around the nose and mouth, and on forelimbs and dorsal head, and death (24% of the group). The developmental (fetal) NOAEL is 1,000 mg/kg/day. The developmental (fetal) LOAEL of 3,500 mg/kg/day was based on treatment-related developmental effects observed only in the high-dose group of: decreases in total implantations/dam and inviable fetuses/

dam, increased number of litters and fetuses with unossified sternebrae, and decreased mean fetal body weights.

5. *Developmental toxicity study in rabbit.* Dutch Belted rabbits were gavaged during gestation days 6–27 at doses of 0, 75, 175, or 350 mg/kg/day. The maternal (systemic) NOAEL is 175 mg/kg/day. The maternal (systemic) LOAEL of 350 mg/kg/day was based on treatment-related effects that included: diarrhea, nasal discharge, and death (62.5% of doses died by gestation day 21). The developmental (pup) NOAEL is \geq 175 mg/kg/day (insufficient litters were available at 350 mg/kg/day to assess developmental toxicity). Developmental toxicity was not observed at any dose.

6. *Three-generation reproduction study in rat.* Sprague-Dawley rats were dosed at 0, 3, 10, or 30 mg/kg/day (equivalent to 0, 30, 100 or 300 ppm). The parental NOAEL is \geq 30 mg/kg/day highest dose tested (HDT). The reproductive NOAEL was 10 mg/kg/day based on an increased incidence of focal tubular dilation of the kidney (both unilateral and bilateral combined) in the 30 mg/kg/day group high-dose male F_{3b} pups.

Since the focal tubular dilation of the kidneys was not observed at the 1,500 mg/kg/day level, HDT in the 2-generation rat reproduction (see below), but was observed at the 30 mg/kg/day level HDT in the 3-generation rat reproduction study, the Agency's Reference Dose (RfD) Committee concluded that the latter was a spurious rather than glyphosate-related effect. Therefore, the parental and reproductive (pup) NOAELs are \geq 30 mg/kg/day.

7. *Two-generation reproduction study in rats.* Sprague-Dawley rats were tested at doses of 0, 2,000, 10,000, or 30,000 ppm (100, 500, or 1,500 mg/kg/day). Treatment-related effects observed in the high dose group included: soft stools, very frequent, in the F_0 and F_1 males and females, decreased food consumption and body weight gain of the F_0 and F_1 males and females during the growth pre-mating period, and decreased body weight gain of the F_{1a} , F_{2a} and F_{2b} male and female pups during the second and third weeks of lactation. Focal tubular dilation of the kidneys, observed in the 3-generation study, was not observed at any dose level in this study.

Based on the above findings, the parental and developmental (pup) NOAEL's are 500 mg/kg/day and the parental and developmental (pup) LOAEL's are 1,500 mg/kg/day. There were no adverse reproductive effects at any dose level.

8. *Subchronic toxicity—i.* In a 90-day feeding study in Sprague-Dawley rats at dietary levels of 0, 1,000, 5,000, or 20,000 ppm (50, 250, and 1,000 mg/kg/day) of glyphosate technical, the NOAEL for systemic toxicity was considered less than 1,000 ppm due to increased serum phosphorus and potassium at all treated doses in both sexes and the occurrence of high dose pancreatic lesions in males (pancreas not examined for low and mid-dose groups).

ii. In a 90-day feeding study in CD-1 mice, dietary levels of 750, 1,500, or 7,500 mg/kg/day (8,000, 30,000, or 50,000 ppm) of technical glyphosate resulted in a systemic NOAEL of 1,500 mg/kg/day with the high dose LOAEL based on decreased weight gains of 24% and 18% in males and females, respectively.

iii. In a 21-day dermal toxicity study in New Zealand white rabbits, glyphosate was applied to 10/sex/dose 5 with intact and 5 with abraded skin at levels of 0, 10, 1,000, or 5,000 mg/kg/day. The rabbits were exposed for 6 hours/day, 5 days/week, for 3 weeks. The systemic NOAEL was 1,000 mg/kg/day and the 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.

The required 90-day feeding study in dogs is satisfied by the 1-year dog feeding study.

9. *Chronic toxicity.* A chronic feeding/carcinogenicity feeding study in Sprague-Dawley rats was conducted for 26 months at dietary levels of 0, 30, 100, or 300 ppm (3, 10, or 31 mg/kg/day). There were no systemic effects in any of the parameters examined body weight, food consumption, clinical signs, mortality, clinical pathology, organ weights and histopathology. The systemic NOAEL was established at $>$ 31 mg/kg/day.

10. A second chronic toxicity/carcinogenicity study in Sprague-Dawley rats was conducted at dietary levels of 0, 2,000, 8,000, or 20,000 ppm (89, 362, or 940 mg/kg/day) for males and 113, 457, or 1,183 mg/kg/day for females for 24 months. The systemic NOAEL was established at 8,000 ppm and the LOAEL was identified at 20,000 ppm based on decreased weight gains in the females and increased incidence of cataracts and lens abnormalities, decreased urinary pH, increased absolute liver weight and increased relative liver weight/brain weight in males.

11. In a 1-year chronic toxicity study in beagle dogs, glyphosate technical was administered by gelatin capsule at levels of 0, 20, 100, or 500 mg/kg/day. There were no systemic effects in all examined parameters and the systemic NOAEL was established at $>$ 500 mg/kg/day.

B. Toxicological Endpoints

1. *Acute toxicity.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. In glyphosate studies, an acute dietary endpoint and dose was not identified in the toxicology data base. A review of the 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.

The Agency concludes with reasonable certainty that glyphosate does not elicit an acute toxicological response. An acute dietary risk assessment is not required.

2. *Short - intermediate - and long-term toxicity dermal.* In a 21-day dermal toxicity study in rabbits with technical glyphosate, the NOAEL was 1,000 mg/kg/day and the LOAEL was 5,000 mg/kg/day based on decreased food consumption in females. Although the rabbit developmental study had a maternal toxicity NOAEL of 175 mg/kg/day, use of the 3% dermal absorption with this oral NOAEL of 175 mg/kg/day yields a dermal NOAEL $>$ 5,000 mg/kg/day. A $LD_{50} >$ 2,000 and Toxicity Category III were determined in acute dermal toxicity testing. Doses and endpoints were not identified for dermal and inhalation route of exposure. This risk assessment is not required and a dermal absorption factor is not applicable here in evaluating exposure/risk.

3. *Chronic toxicity.* EPA has established the RfD for glyphosate at 2.0 mg/kg/day. The chronic RfD is based on a NOAEL = 175 mg/kg/day based on death, diarrhea, and nasal discharge at 350 mg/kg/day LOAEL with an uncertainty factor of 100. The data base for RfD determination was developed from multiple species testing.

Groups of 16/dose Dutch Belted rabbits were dosed with technical glyphosate at doses of 0, 75, 175, or 350 mg/kg/day between gestation days 6 to 27. Maternal effects were seen at only the high dose and consisted of diarrhea, nasal discharge and death 10/16.

Developmental effects were not seen at any dose tested. Therefore, the NOAEL and LOAEL for maternal toxicity were 175 mg/kg/day and 350 mg/kg/day, respectively. The NOAEL for maternal toxicity in the rabbit developmental study was the lowest NOAEL of all the major studies which include the 24-month mouse carcinogenicity study NOAEL = 750 mg/kg/day, the 1-year dog study NOAEL = 500 mg/kg/day, 2-year chronic/onco rat study NOAEL = 400 mg/kg/day, 2-generation rat reproduction study NOAEL = 500 mg/kg/day and rat developmental study NOAEL = 1000 mg/kg/day.

An uncertainty factor (UF) of 100 was applied to account for inter-(10x) and intra-(10x) species variation. The 10X factor to protect infants and children as required by FQPA was removed, since there was no special sensitivity for infants and children and the database is complete.

4. *Carcinogenicity.* EPA's Cancer Peer Review Committee classified glyphosate as a "Group E" pesticide which shows no evidence for carcinogenicity in rats and mice.

A chronic feeding/carcinogenicity study in Sprague-Dawley rats was performed at doses of 0, 30, 100, or 300 ppm (3, 10, or 31 mg/kg/day) for males and 3, 14, or 34 mg/kg/day for females for 26 months. At the high-dose, in comparison to concurrent controls, the following results were observed: increased incidence of C-cell thyroid carcinomas in females and an increased incidence of interstitial cell Leydig cell testicular tumors. The thyroid tumors were not statistically significant by pairwise comparison to controls and the testicular tumors were within the range of historical controls for studies of comparable duration. It was concluded that the study results were negative for carcinogenicity, but that the dose levels were not high enough to assess carcinogenic potential.

A second chronic feeding/carcinogenicity study was conducted in Sprague-Dawley rats for 24 months at dose levels of 2,000, 8,000, or 20,000 ppm (89, 362, or 940 mg/kg/day) for males and 113, 457, or 1,183 mg/kg/day in females. The results showed increased incidence of pancreatic islet cell adenomas at the low and high dose in males, hepatocellular adenomas at the low and high dose in males, and C-cell thyroid adenomas in both sexes at the mid and high dose group. Each of the tumor types was not considered treatment-related for the following reasons:

i. The pancreatic islet cell tumors had no statistically significant dose-related trend, there was no progression to

carcinomas, and the incidence of pancreatic hyperplasia was not dose-related.

ii. The hepatocellular adenomas were within the range of historical controls, these liver tumors were not statistically significant by pairwise comparison to concurrent controls, there was no progression to carcinoma, and the incidence of hyperplasia was not considered compound-related.

iii. The C-cell thyroid tumors were not statistically significant by pairwise comparison and positive dose-related trend, there was no progression to carcinoma, and there was no statistically significant dose-related increase in either incidence or severity of hyperplasia in either sex.

A carcinogenicity study in CD-1 mice was conducted for 24 months at doses of 0, 150, 750, or 4,500 mg/kg/day (0, 1,000, 5,000, or 30,000 ppm). There were no effects at the low and mid-doses. At the high dose, an increased incidence of renal tubular adenomas was seen in males, but not in females zero incidence for all groups. In males, the incidence was 1, 0, 1, and 3 out of 50/sex/dose. The occurrence of this rare tumor was not statistically significant by pairwise comparison to concurrent controls, but had a statistically significant dose-related trend. There was no tumor associated non-neoplastic lesions in males, but females had an increased incidence of proximal tubule epithelial basophilia and hypertrophy in the absence of any renal tubular neoplasms. In males, there was an increased incidence of interstitial nephritis, hepatocellular hypertrophy and hepatocellular necrosis. There was also statistically significant decreased weight gain in both sexes. The high dose of 30,000 ppm exceeded the limit dose 7,000 ppm for mice. The Agency concluded, based on a weight of the evidence evaluation, that the renal tubular adenomas were not compound related due to the absence of pairwise statistical significance for males, the absence of related non-neoplastic lesion in males, and the presence of related non-neoplastic lesions in females in the absence of renal tubular adenomas. Additionally, the high dose exceeded the limit dose required for testing in mice.

5. *Inhalation exposure general and long-term considerations.* Formulations of glyphosate are Toxicity Category III or IV and technical glyphosate is a wetcake. The acute inhalation study was waived for technical glyphosate. A dose and endpoint were not identified for this risk assessment. This risk assessment is not required.

C. Exposures and Risks

1. From food and feed uses.

Tolerances have been established (40 CFR 180.364) for the residues of glyphosate, in or on a variety of raw agricultural commodities. Existing glyphosate tolerances are numerous with values ranging from a low of 0.1 to a high of 200 ppm. Glyphosate residues could possibly be transferred to meat and milk. However, in feeding studies, no residues of glyphosate were found in milk or fat at any dosing level and only minimal residues were found in eggs and muscle (at the highest dose of 400 ppm). Significant residue levels were found in animal liver and kidney, however, secondary residues are not expected to exceed currently established animal tolerances. Risk assessments were conducted by EPA to assess dietary exposures from glyphosate as follows:

Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a "worst case" estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances.

The Agency's dietary risk evaluation system (DRES) analysis was used for the chronic dietary exposure estimate for glyphosate. Using permanent and time-limited tolerances, dietary exposure to residues of glyphosate resulted in a TMRC equivalent to $\leq 3\%$ of the RfD for all population subgroups. No percent crop treated or anticipated residue data were used in the analysis. By using the TMRC, the Agency is reasonably certain that exposure is not underestimated for any significant subpopulation. An uncertainty factor of 100 is used for all subgroups. The proposed tolerances are for uses considered as Low Dietary Intake (LDI) crops since the total acreage for all three crops is less than 100 acres.

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of

a one day or single exposure. An acute dietary endpoint and dose was not identified in the toxicology data base. A review of the 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 chronic dietary exposure analysis from food sources was conducted using the reference dose (RfD) of 2.0 mg/kg/day. The RfD is based on the maternal NOAEL of 175 mg/kg/day in female rabbits from the developmental study in rabbits, and an uncertainty factor of 100 which is applicable to all population subgroups.

Durian, mangosteen, and rambutan all qualify as Low Dietary Intake (LDI) crops since the total acreage for all three is less than 100 acres. Consequently, no data on these tropical fruits are included in the current version of the DRES system. In conducting this chronic dietary risk assessment, the Agency has assumed that inclusion of these tropical fruits would not significantly change the resulting % RfD values because glyphosate currently has tolerances on a large number of non-LDI crops. In addition, EPA would note the exposure estimate for existing tolerances is in an overestimate of human dietary exposure due to the conservative assumptions built into the system.

The existing glyphosate tolerances result in a TMRC that is equivalent to the following percentages of the RfD:

For subgroups, U.S. population (48 states), nursing infants (<1 year old) and non-nursing infants (<1 year old) the % RfD is 1.2, 1.2, and 3.3, respectively. For the subgroups, children (1–6 years old), children (7–12 years old), and males (13–19 years old) the % RfD is 2.6, 1.8, and 1.2, respectively.

2. *From drinking water.* The GENECC model and the SCI-GROW model were run to produce estimates of glyphosate concentrations in surface and ground water, respectively. The primary use of these models is to provide a coarse screen for sorting out pesticides for which EPA has a high degree of confidence that the true levels of the pesticide in drinking water will be less than the human health drinking water levels of concern (DWLOCs). A human health DWLOC is the concentration of a pesticide in drinking water that would be acceptable as an upper limit in light of total aggregate exposure to that chemical from food, water, and non-occupational (residential) sources.

DWLOC_{chronic} is the concentration in drinking water as part of the aggregate chronic exposure that results in a negligible cancer risk. The Agency's default body weights and consumption values used to calculate DWLOCs are as follows: 70 kg/2L (liter) (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.

The Agency concludes that no harm to public would result due to acute risk for the proposed uses of glyphosate.

ii. *Chronic exposure and risk.* For chronic (non-cancer) exposure to glyphosate in surface and ground water, the drinking water levels of concern are 69,000 µg/L for males (13 yrs+), 59,000 µg/L for females (13 yrs+) and 19,000 µg/L for children (1–6 yrs). To calculate the DWLOC for chronic (non-cancer) exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from DRES) was subtracted from the RfD to obtain the acceptable chronic (non-cancer) exposure to glyphosate in drinking water. DWLOCs were then calculated using default body weights and drinking consumption figures.

Estimated average concentrations of glyphosate in surface and ground water are 0.063 ppb (after adjustment for the highly conservative nature of the GENECC model) and 0.0011 ppb, respectively. The estimated average concentrations of glyphosate in surface and ground water are less than EPA's level of concern for glyphosate in drinking water as a contribution to chronic aggregate exposure. Therefore, taking into account present uses and uses proposed in this action, EPA concludes with reasonable certainty that residues of glyphosate in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time.

3. *From non-dietary exposure.* Glyphosate is currently registered for use on the following residential non-food sites: non-food crops and a variety of other uses including ornamentals, greenhouses, residential areas, lawns, and industrial rights of way. Glyphosate is formulated in liquid and solid forms

and it is applied using ground or aerial equipment. Based on the registered uses of glyphosate, the potential for occupational and residential exposures exists. However, based on the low acute toxicity and the lack of other toxicological concerns, glyphosate does not meet the Agency's criteria for occupational and residential data requirements. The Agency believes that no significant harm to public health would result due to non-dietary exposure from proposed uses of glyphosate.

i. *Acute exposure and risk.* There are no acute toxicological concerns for glyphosate.

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 determined that 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 November 26, 1997 (62 FR 62961) (FRL 6023-5).

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

1. *Acute risk.* There was no acute dietary endpoint identified, therefore no acute toxicological concerns for glyphosate.

2. *Chronic risk.* Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to glyphosate from food will utilize 1.2% 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 old, which utilizes 3.3% of the RfD. 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.

3. *Short- and 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.

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 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 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 oral rat and rabbit developmental studies and the oral rat reproduction study demonstrated no indication of increased sensitivity of rats or rabbits to *in utero* and postnatal exposure to glyphosate. In the rat developmental study, the developmental NOAEL was 1,000 mg/kg/day and the maternal NOAEL was 1,000 mg/kg/day. Therefore, there was no prenatal developmental toxicity in the absence of maternal toxicity. Similarly in rabbits, the prenatal developmental NOAEL was 350 mg/kg/day and the maternal NOAEL was 175 mg/kg/day. Therefore, prenatally exposed fetuses were not more sensitive to the effects of glyphosate than maternal animals.

iii. *Reproductive toxicity study.* In a rat reproduction study, the parental NOAEL of 10,000 ppm was identical to the pup NOAEL of 10,000 ppm and decreased body weight was seen in both pup and parental animals. This finding demonstrates that there are no extra sensitivities with respect to pre- and post-natal toxicity between adult and infant animals.

iv. *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.

v. *Conclusion.* There is a complete toxicity database for glyphosate and exposure data are complete or 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.* Although there are no acute toxicological endpoints for glyphosate, there exist an adequate exposure database to assess potential adverse effects on infants and children, the most highly exposed subgroup which utilize 3.3% of the RfD. The Agency concludes that the establishment of the proposed tolerances would not pose an unacceptable aggregate risk.

3. *Chronic risk.* Using the exposure assumptions described above, EPA has concluded that aggregate exposure to glyphosate from food will utilize 3.3% of the RfD for infants and children. For the general population, aggregate exposure to glyphosate from food is 1.2% of the RfD. 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 of 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 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 durian, mangosteen, and rambutan.

C. Magnitude of Residues

Residue studies for glyphosate were not submitted for review with this petition. However, the Agency believes that data submitted previously in support of petitions may be used to support proposed uses.

The proposed use for glyphosate is for orchard floor treatment. The registrant referenced extensive experience and data with glyphosate in/on tree fruit and nuts crops which show that when orchard floor applications are made, no detectable residues of the herbicide are recovered in the harvested fruit. Based on these data EPA expects no detectable residues of glyphosate in durian, mangosteen or rambutan when glyphosate is applied in a similar manner. Glyphosate is known to be a water soluble chemical and does not rapidly transport into trees from soil. Residues are expected to be mainly due to contamination (e.g., spray drift). Therefore, significant amounts of residues are not expected to be detected in tree crops.

Tolerances for the combined residues of glyphosate and its metabolite, aminomethylphosphonic acid (AMPA), have been established at 0.2 ppm on a number of tree fruit and nuts, as well as a variety of tropical fruit: acerola, atemoya, avocado, banana, breadfruit, canistel, carambola, cherimoya cocoa beans, coconuts, dates, figs, genip, jaboticaba, jackfruit, longan, lychee, mango, mayhaw, passion fruit, persimmon, pomegranate, sapodilla, sapote, soursop, sugar apple and tamarind. Any secondary residues occurring in milk, eggs, meat, fat, liver and kidney of cattle, goats, horses, hogs, poultry and sheep are covered by existing tolerances.

EPA has determined that AMPA should be dropped from the tolerance expression. Tolerances that are the subject of this notice are based solely on residues of glyphosate.

D. International Residue Limits

There are no CODEX, Canadian, or Mexican tolerances for glyphosate residues on durian, mangosteen, or rambutan. Therefore, international harmonization is not an issue at this time.

IV. Conclusion

Therefore, the tolerance is established for residues of glyphosate *N*-(phosphonomethyl) glycine in durian commodity at 0.2 ppm, mangosteen at 0.2 ppm, and rambutan at 0.2 ppm.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to "object" to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural

regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by December 7, 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 or a fee waiver request as specified prescribed by 40 CFR 180.33. If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number OPP-300736 (including any comments and data submitted electronically). A public version of this

record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

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

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

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

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

accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

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

VIII. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: September 29, 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 § 180.364, paragraph (a), by designating the text following the paragraph heading as paragraph (a)(1), and by adding paragraph (a)(2) to read as follows:

§ 180.364 Glyphosate; residues for tolerances.

(a) * * *

(2) Tolerances are established for residues of glyphosate *N*-(phosphonomethyl) glycine in or on the commodities list in the table as follows:

Commodity	Parts per million
Durian	0.2
Mangosteen	0.2
Rambutan	0.2

* * * * *

[FR Doc. 98-26906 Filed 10-7-98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300739; FRL-6034-1]

RIN 2070-AB78

Sethoxydim; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of sethoxydim (2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one) and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on apricots, cherries (sweet and sour), nectarines, peaches, succulent beans, bean forage, soybeans, grapes, raisins, cilantro, leafy vegetable (except Brassica) crop group, tuberous and corm vegetable subgroup, garden beets,

caneberry crop sub group, and globe artichoke. This regulation also deletes the established tolerances for raisin waste, grape pomace, celery, head lettuce, leaf lettuce, spinach, endive(escarole), potato, sweet potato, and raspberry. BASF Corporation and Interregional Research Project Number (IR-4) requested these tolerances 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 October 8, 1998. Objections and requests for hearings must be received by EPA on or before December 7, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP-300739], 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-300739], 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-300739]. 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 or Hoyt Jamerson, 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, Jim Tompkins (703) 305 5697, Hoyt Jamerson (703) 308 9368, e-mail: Tompkins.jim or Jamerson.hoyt@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 16, 1997 (62 FR 27028)(FRL-5717-6) and August 5, 1998(63 FR 41829)(FRL-5799-6), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP) for tolerance by BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709, and Interregional Research Project Number 4 (IR-4), New Jersey Agricultural Experimental Station, Rutgers University, New Brunswick, New Jersey 08903. These notices included a summary of the petitions prepared by BASF Corporation, the registrants, and IR-4. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.412 be amended by establishing tolerances for combined residues of the herbicide sethoxydim (2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one and its metabolites containing the 2-cyclohexen moiety (calculated as the herbicide), in or on 9F3408 (62 FR 27028) apricots at 0.2 part per million (ppm), cherries (sweet and sour) at 0.2 ppm, nectarine at 0.2 ppm, and peaches at 0.2 ppm; 6F4695 (63 FR 41829) grapes at 1.0 ppm, succulent beans at 15.0 ppm; bean forage at 15.0 ppm, soybeans at 16.0 ppm, and raisins at 2.0 ppm; 6E4953 (63 FR 41829) leafy vegetable (except Brassica) crop group at 4.0 ppm and cilantro at 4.0 ppm; 6E4725 (63 FR 41829)--tuberous and corm vegetable subgroup at 4.0 ppm and garden beet at 1.0 ppm; 6E4698 (63 FR 41829) artichokes at 5.0 ppm; and 6E4697(63 FR 41829) caneberry crop subgroup at 5.0 ppm.

The notice issued August 5, 1998 (63 FR 41829) for 6F4695 proposed deleting the established tolerances for raisin waste at 1.0 ppm and grape pomace at 6.0 ppm since they are considered insignificant animal feed commodities and are no longer of regulatory concern.

The August 5, 1998 notice also proposed to remove or delete the established tolerances for celery at 1.0 ppm, head lettuce at 1.0 ppm, leaf lettuce at 2.0 ppm, spinach at 4.0 ppm, endive(escarole) at 2.0 ppm (6E4753); potato at 4.0 ppm, and sweet potato at