establishing a precedent for any future request for revision to any State implementation plan. Each request for revision to the State implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Under Sections 202, 203, and 205 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must undertake various actions in association with proposed or final rules that include a Federal mandate that may result in estimated costs of $100 million or more to the private sector, or to State, local, or tribal governments in the aggregate.

Through submission of this state implementation plan or plan revision, the State and any affected local or tribal governments have elected to adopt the program provided for under Section 182(b)(2) of the Clean Air Act. These rules may bind State, local and tribal governments to perform certain actions and also require the private sector to perform certain duties. To the extent that the rules being proposed for approval by this action would impose no new requirements; such sources are already subject to these regulations under State law. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action. EPA has also determined that this proposed action does not include a mandate that may result in estimated costs of $100 million or more to State, local, or tribal governments in the aggregate or to the private sector.

This action has been classified as a Table 2 action by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214–2225), as revised by an October 4, 1993, memorandum from Michael H. Shapiro, Acting Assistant Administrator for Air and Radiation. A future notice will inform the general public of these tables. The Office of Management and Budget has exempted this regulatory action from Executive Order 12866 review.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 et. seq., EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. §§ 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under Section 110 and subchapter I, Part D of the Act do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the federal SIP-approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute federal inquiry into the economic reasonableness of state action. The Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co. v. U.S. E.P.A.*, 427 U.S. 246, 256–66 (S.Ct. 1976); 42 U.S.C. 7410 (a)(2).

Also, EPA's limited disapproval of the state request under Section 110 and subchapter I, Part D of the CAA does not affect any existing requirements applicable to small entities. Any pre-existing federal requirements remain in place after this disapproval. Federal limited disapproval of the state submittal does not affect its state-enforceability. Moreover, EPA's limited disapproval of the submittal does not impose any new requirements. Therefore, EPA certifies that this limited disapproval action does not have a significant impact on a substantial number of small entities because it does not remove existing requirements not does it impose any new requirements.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental regulations, Ozone, Reporting and recordkeeping requirements, and Volatile organic compounds.

Authority: 42 U.S.C. 7401–7671q.

Dated: June 26, 1995.

John P. DeVillars,

Regional Administrator, Region I.

[FR Doc. 95–16756 Filed 7–6–95; 8:45 am]

BILLING CODE 6560–50–P

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40 CFR Part 180

[PP 4E4404/P618; FRL–4962–1]

RIN 2070–AC18

Glyphosate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish pesticide tolerances for residues of glyphosate in or on the raw agricultural commodities peppermint and spearmint. The Interregional Research Project No. 4 (IR-4) requested in a petition submitted to EPA pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA) this proposed regulation to establish maximum permissible levels for residues of the pesticide in or on the commodities.

DATES: Comments, identified by the document control number [PP 4E4404/P618], must be received on or before August 7, 1995.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information.'' CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment 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. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: 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. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PP 4E4404/P618]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt L. Jamerson, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington,

DC 20460. Office location and telephone number: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA 22202, (703)-308-8783; e-mail: jamerson.hoyt@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: The Interregional Research Project No. 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903, has submitted pesticide petition (PP) 4E4404 to EPA on behalf of the Agricultural Experiment Station of Washington. This petition requests that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), amend 40 CFR 180.364(d) by establishing tolerances for residues of glyphosate (*N*-(phosphonomethyl)glycine) resulting from the application of the isopropylamine salt of glyphosate, in or on the raw agricultural commodities peppermint and spearmint at 200 parts per million (ppm).

The scientific data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the proposed tolerances include:

1. Several acute toxicology studies placing technical-grade glyphosate in Toxicity Category III (acute oral and dermal).

2. A 1-year chronic feeding study in dogs fed glyphosate in gelatin capsules containing 0, 20, 100, or 500 milligrams (mg)/kilogram (kg)/day with a no-observed-effect level (NOEL) established at 500 mg/kg/day. There were no toxic effects observed under the conditions of the study.

3. A 26-month chronic feeding carcinogenicity study in rats fed diets containing 0, 30, 100, or 300 ppm glyphosate (equivalent to 0/0, 3/3, 10/11, 31/34 mg/kg/day for males/females) with a NOEL for systemic toxicity established at 300 ppm. There were no treatment related systemic effects observed under the conditions of the study. The following findings were observed, however, in the high-dose groups when compared to the concurrent controls: (1) increased incidence of thyroid C-cell carcinomas in females; and (2) increased incidence of interstitial cell (Leydig cell) testicular tumors in males. EPA concluded that these neoplasms were not treatment related, and glyphosate was not considered to be carcinogenic in this study because the incidence of thyroid carcinomas was not statistically significant and the incidence of testicular tumors was within the historical incidence. This study is not considered an acceptable carcinogenic study since the feeding levels were not high enough to assess the carcinogenicity of glyphosate.

4. A 2-year chronic feeding/carcinogenicity study in rats fed diets containing 0, 2,000, 8,000, or 20,000 ppm (equivalent to 0/0, 89/113, 362/457, or 940/1,183 mg/kg/day for males/females) with a NOEL established at 8,000 ppm. Treatment-related systemic effects, which were only observed in the high-dose group, included decreased body weight gains in females, increased incidence of cataracts and lens abnormalities, decreased urinary pH, increased absolute liver weight, and increased liver/brain weight ratio in males. The study also showed slightly increased incidence of (1) pancreatic islet cell adenomas in the low-dose and high-dose males; (2) hepatocellular (liver) adenomas in the low-dose and high-dose males; and (3) thyroid C-cells adenomas in the mid-dose and high-dose male and females. EPA concluded that these adenomas were not treatment related, and glyphosate was not considered to be carcinogenic in this study.

5. A carcinogenicity study in mice fed diets containing 0, 150, 750, or 4,500 mg/kg/day for 18 months with a systemic NOEL established at 750 mg/kg/day. The following findings were observed in the high-dose group: (1) decreased body weight gain in males and females; (2) increased incidence of hepatocellular hypertrophy, hepatocellular necrosis and interstitial nephritis in males; (3) increased incidence of proximal tubule epithelial basophilia and hypertrophy in females; and (4) slightly increased incidence of renal tubular adenomas in males. EPA concluded that the occurrence of the renal tubular adenomas in male mice was spontaneous rather than compound induced because the incidence of these in males was not statistically significant when compared with the concurrent controls. Glyphosate was not considered to be carcinogenic in this study.

6. A developmental toxicity study in rats given gavage doses of 0, 300, 1,000, or 3,500 mg/kg/day of glyphosate during days 6 through 19 of gestation with a NOEL for developmental toxicity established at 1,000 mg/kg/day. There was an increase in the number of litters and fetuses with unossified sternebrae and a decrease in the fetal body weight at the 3,500-mg/kg/day dose.

7. A developmental toxicity study in rabbits given gavage doses of 0, 75, 175, or 350 mg/kg/day of glyphosate during days 6 through 27 of gestation. Developmental toxicity was not observed at any dose tested. The NOEL for developmental toxicity was established at 175 mg/kg/day. Due to high maternal mortality (10 of 16 females rabbits died) at the 350-mg/kg/day dose level, too few liters were available to adequately assess developmental toxicity at the high dose.

8. A three-generation reproductive study in rats fed diets containing 0, 3, 10, or 30 mg/kg/day with a systemic and reproductive NOEL of 30 mg/kg/day and a developmental NOEL of 10 mg/kg/day. 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.

9. A two-generation reproductive study in rats fed diets containing 0, 100, 500, or 1,500 mg/kg/day of glyphosate with systemic and developmental NOEL's of 500 mg/kg/day and a reproductive NOEL of 1,500 mg/kg/day. Treatment-related effects, which were observed only in the high-dose group, include soft stools in the F0 and F1 males and females, decreased food consumption and body weight gain of the F0 and F1 males and females; and decreased body weight gain of the F1a, F2a, and F2b male and female pups during the second and third week of lactation.

10. A battery of mutagenicity studies including: gene mutation assay (Ames Test and assay in mammalian cells), negative; structural chromosomal aberration assay (cytogenic in vivo), negative; and other genotoxicity assays (rec-assay using *Bacillus subtilis* and reverse mutation assay using *Escherichia coli*), negative.

11. Metabolism studies in rats show that glyphosate is excreted in the urine and feces as the parent compound. Aminomethylphosphonic acid was the only metabolite excreted. Less than 1.0 percent of the absorbed dose remained in the tissues and organs, primarily in the bone tissue.

The dietary risk assessment for glyphosate indicates that there is minimal risk from established tolerances and the proposed tolerances for peppermint and spearmint. A cancer risk assessment is not appropriate for glyphosate since the pesticide is assigned to ''Group E'' (no evidence of carcinogenicity) of EPA's cancer classification system. Dietary risk assessments for the pesticide were conducted using the Reference Dose (RfD) to assess chronic exposure.

The RfD is calculated at 2 mg/kg/ of body weight/day based on a NOEL of 175 mg/kg/day from the rabbit developmental toxicity study and an uncertainty factor of 100. The theoretical maximum residue

contribution (TMRC) from existing tolerances and the proposed tolerances utilizes l percent of the RfD for the general population, or 3 percent of the RfD for non-nursing infants less than 1 year old (the subgroup population most highly exposed).

The nature of the residue is adequately understood in plants and animals. An adequate analytical method utilizing highpressure liquid chromatography, is available for enforcement purposes. An analytical method for enforcing this tolerance has been published in the Pesticide Analytical Manual (PAM), Vol. II. No secondary residues in meat, milk, poultry, or eggs are expected since peppermint and spearmint are not considered livestock feed commodities.

There are currently no actions pending against the continued registration of this chemical. EPA concludes that all uses of currently registered products containing the isopropylamine and sodium salts of glyphosate, when used in accordance with the labeling specified in the Reregistration Eligibility Document (RED), issued September 1993, will not pose unreasonable risks of adverse effects to humans or the environment and are eligible for reregistration.

Based on the information and data considered, the Agency has determined that the tolerances established by amending 40 CFR 180.364 would protect the public health. Therefore, it is proposed that the tolerances be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this notice in the **Federal Register** that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDCA.

A record has been established for this rulemaking under docket number [PP 4E4404/P618] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

opp-Docket@epamail.epa.gov

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

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 all comments 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 address in ''ADDRESSES'' at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines ''significant'' as those actions likely to lead to a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not ''significant'' and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

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

Dated: June 23, 1995.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be 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 (d) is amended by adding and alphabetically inserting the entries for peppermint and spearmint, to read as follows:

§ 180.364 Glyphosate; tolerances for residues.

* * * * *

(d) * * *

Commodity	Parts per million
* * * * *	
Peppermint	200
Spearmint	200
* * * * *	

[FR Doc. 95–16753 Filed 7–6–95; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 439

[FRL–5227–2]

RIN 2060–AC49

Pharmaceutical Manufacturing Industry; Comment Period Extension and Public Hearing

AGENCY: Environmental Protection Agency.

ACTION: Notice of comment period extension and public hearing.

SUMMARY: The Environmental Protection Agency (EPA) is announcing extension of the comment period for the proposed regulations, and a formal public hearing regarding proposed pretreatment standards that will apply to the pharmaceutical manufacturing industry. The proposed pretreatment standards and effluent limitations guidelines were published in the **Federal Register** on May 2, 1995 (60 FR 21592). EPA is sponsoring this public hearing to