

The proposed regulation to establish maximum permissible levels for residues of the herbicide was requested in petitions submitted by the Interregional Research Project No. 4 (IR-4).

DATES: Comments, identified by the document control number, [PP 0E3882 and PP 4E4286/P598], must be received on or before March 17, 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). Information so marked 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 p.m., Monday through Friday, excluding legal holidays.

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 Hwy., Arlington, VA 22202, (703)-308-8783.

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) 0E3882 and PP 4E4286 to EPA on behalf of the named Agricultural Experiment Stations. These petitions request 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 180.368 by establishing tolerances for combined residues (free and bound) of the herbicide metolachlor [2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide], and its metabolites, determined as the derivatives, 2-[(2-ethyl-6-

methylphenyl)amino]-1-propanol, and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound in or on certain raw agricultural commodities as follows:

1. *PP 0E3882.* Petition submitted on behalf of the Experimental Stations of California, Florida, and Texas proposing a tolerance for celery at 0.1 part per million (ppm).

2. *PP 4E4286.* Petition submitted on behalf of the Experimental Stations of Arkansas, Michigan, New Jersey, New York, Oklahoma, and Texas proposing a tolerance for dry bulb onion at 1.0 ppm. The petitioner proposed that use of metolachlor on dry bulb onion be limited to onion production areas east of the Rocky Mountains based on the geographical representation of the residue data submitted. Additional residue data will be required to expand the area of usage. Persons seeking geographically broader registration should contact the Agency's Registration Division at the address provided above.

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

1. A 1-year feeding study with dogs fed diets containing 0, 100, 300, or 1,000 ppm with a systemic no-observed-effect-level (NOEL) of 300 ppm (9.7 mg/kg/day) based on decreased body weight in females.

2. A 2-year feeding/carcinogenicity study with rats fed diets containing 0, 30, 300, 1,000 or 3,000 ppm (equivalent to 0, 1.5, 15, 50, or 150 mg/kg/day) with a compound-related increase in liver adenomas and combined adenomas/carcinomas in female rats at the high-dose level. This study was classified as supplemental data due to inadequate clinical chemistry determinations and dietary preparation records.

3. A 2-year feeding/carcinogenicity study with rats fed diets containing 0, 30, 300, or 3,000 ppm (equivalent to 0, 1.5, 15, or 150 mg/kg/day) with a systemic NOEL of 300 ppm based on decreased body weight at the 3,000-ppm dose level. A statistically significant increase in liver neoplasia was found in female rats at the 3,000-ppm dose level, as well as evidence for a neoplastic response in the nasal turbinates of both sexes.

4. A 2-year carcinogenicity study in mice fed diets containing 0, 300, 1,000 and 3,000 ppm (highest dose level equivalent to 428 mg/kg/day) with no treatment-related carcinogenic effects observed under the conditions of the study.

5. A second 2-year carcinogenicity study in mice fed diets containing 0, 300, 1,000, or 3,000 ppm with no treatment-related carcinogenic effects observed under the conditions of the study.

6. A two-generation reproduction study in rats fed diets containing 0, 30, 300, or 1,000 ppm with a reproductive NOEL of 300 ppm (equivalent to 23.5-26 mg/kg/day) based on reduced pup weights in the F1a and F2a litters at the 1,000-ppm dose level (equivalent to 75.8 to 85.7 mg/kg/day). The NOEL for parental toxicity is equal to or greater than the 1,000-ppm dose level.

7. A developmental toxicity study in rabbits given gavage doses at 0, 36, 120, or 360 mg/kg/day on gestation days 6 to 18. The NOEL for maternal toxicity was established at 120 mg/kg/day based on lacrimation, miosis, reduced food consumption, and body weight gain. There was no developmental toxicity observed under the conditions of the study.

8. A developmental toxicity study in rats given gavage doses of 0, 60, 180, or 360 mg/kg/day on gestation days 6 to 15. There were no signs of maternal or developmental toxicity observed under the conditions of the study.

9. A second developmental toxicity study in rats given gavage doses of 0, 30, 100, 300, or 1,000 mg/kg/day on gestation days 6 to 15. The NOEL's for maternal and developmental toxicity were established at 300 mg/kg/day. The NOEL for maternal toxicity was based on deaths, salivation, lacrimation, convulsions, reduced body weight, and food consumption at the 1,000-mg/kg/day dose level. The NOEL for developmental toxicity was based on reduced mean fetal body weight, reduced number of implantations/dam with resulting decreased litter size, and a slight increase in resorptions/dam with resulting increase in post-implantation loss.

10. Metolachlor was not found to be mutagenic in any tests. Mutagenicity data include gene mutation assays in *Salmonella* and mouse lymphoma cells; structural chromosome aberration tests including an in vivo micronucleus assay in Chinese hamsters and a dominant lethal assay in mice; and other genotoxic activity tests including DNA damage/repair assays in rat hepatocytes and in human fibroblasts, and an in vivo/in vitro unscheduled DNA synthesis assay.

11. Several metabolism studies have been performed with metolachlor, and the available data indicate the compound is readily absorbed after oral dosing and excreted in approximately equal amounts in urine and feces.