

Indianapolis, IN 46268, had submitted pesticide petition (PP) 1F3991 to EPA proposing that 40 CFR 180.417 be amended by establishing a regulation to permit the combined residues of the herbicide triclopyr [(3,5,6-trichloro-2-pyridinyl)oxyacetic acid] and its metabolites 3,5,6-trichloro-2-pyridinol and 2-methoxy-3,5,6-trichloropyridine in or on the raw agricultural commodities (RACs) rice grain at 0.3 part per million (ppm) and rice straw at 8.0 ppm, and for triclopyr in poultry meat, poultry fat, and meat byproducts (except kidney) at 0.1 ppm, and eggs at 0.05 ppm.

The petitioner subsequently amended the petition, notice of which appeared in the **Federal Register** of October 21, 1993 (58 FR 54357), by submitting a new Section F proposing to establish a tolerance for the residues of the herbicide triclopyr [(3,5,6-trichloro-2-pyridinyl)oxyacetic acid] and its metabolites 3,5,6-trichloro-2-pyridinol and 2-methoxy-3,5,6-trichloropyridine in or on the raw agricultural commodities (RACs) rice grain at 0.3 part per million (ppm) and rice straw at 10.0 ppm, and for triclopyr in poultry meat, poultry fat, and meat byproducts (except kidney) at 0.1 ppm, and eggs at 0.05 ppm.

There were no comments or requests for referral to an advisory committee received in response to the notices of filing.

The data submitted in the petition and other relevant material have been evaluated. The toxicology data listed below were considered in support of this tolerance.

1. An acute toxicology study placing technical-grade triclopyr in toxicity Category I.

2. A 22-month carcinogenicity study with mice fed dosages of 0, 7.1, 35.7, and 178.5 mg/kg/day with no carcinogenic effects observed under the conditions of the study. The systemic NOEL is 35.7 mg/kg/day based on decreased body weight gain observed in both sexes at the 178.5 mg/kg/day dose.

3. A 2-year chronic toxicity/carcinogenicity study in rats fed dosages of 0, 3, 12, and 36 mg/kg/day with no carcinogenic effects observed under the conditions of the study at levels up to and including 36 mg/kg/day (HDT) and a systemic NOEL of 12 mg/kg/day based on a significant increase in hemoglobin, hematocrit and erythrocyte values, and a significant increase in absolute and relative kidney weights observed at the 36 mg/kg/day dose level in male rats.

4. A 6-month feeding study in dogs fed dosages of 0.1, 0.5, and 2.5 mg/kg/day with a NOEL of 0.5 mg/kg/day based on significant reductions in PSP

excretion rate, absolute and relative kidney weight, and a significant increase in SGOT at 2.5 mg/kg/day.

5. A 1-year feeding study in dogs fed dosages of 0, 0.5, 2.5, and 5.0 mg/kg/day with a NOEL of 0.5 mg/kg/day (LDT) based on significant increases in serum urea nitrogen and creatinine at 2.5 mg/kg/day.

6. A developmental toxicity study in rats fed dosage levels of 0, 50, 100, and 200 mg/kg/day (HDT), with a maternal toxicity NOEL of less than 50 mg/kg/day and a developmental toxicity NOEL of 200 mg/kg/day (HDT).

7. A developmental toxicity study in rabbits fed dosage levels of 0, 10, and 25 mg/kg/day with no developmental effects noted at 25 mg/kg/day (HDT), and a maternal toxicity NOEL of 10 mg/kg/day based on decreases in weight gain observed at 25 mg/kg/day (HDT).

8. A three-generation reproduction study in rats fed dosages of 0, 3, 10, and 30 mg/kg/day (HDT) showed no reproductive effects up to the highest dose tested. The systemic NOEL is equal to or greater than 30 mg/kg/day.

9. Mutagenicity data included gene mutation assays with *E. coli* and *S. typhimurium* (negative); DNA damage assays with *B. subtilis* (negative); an unscheduled DNA synthesis with rat hepatocytes (negative) and a chromosomal aberration test in Chinese hamster cells (negative).

Based on the NOEL of 0.5 mg/kg bwt/day in the 1-year dog feeding study, and using a hundredfold uncertainty factor, the RfD acceptable daily intake (ADI) for triclopyr is calculated to be 0.005 mg/kg bwt/day. The theoretical maximum residue contribution (TMRC) is 0.000356 mg/kg bwt/day for existing tolerances for the overall U.S. population. The current action will increase the TMRC by 0.000127 mg/kg bwt/day (2.54 percent of the ADI). These tolerances and previously established tolerances utilize a total of 7 percent of the ADI for the overall U.S. population. For U.S. subgroup populations, nonnursing infants and children aged 1 to 6, the current action and previously established tolerances utilize, respectively, a total of 26 percent and 16 percent of the ADI, assuming that residue levels are at the established tolerances and that 100 percent of the crop is treated.

There are no desirable data lacking.

This pesticide is useful for the purposes for which the tolerances are sought. The nature of the residues is adequately understood for the purposes of establishing these tolerances. Adequate analytical methodology, high-pressure liquid chromatography, is available for enforcement purposes.

Because of the long lead time from establishing this tolerance to publication, the enforcement methodology is being made available in the interim to anyone interested in pesticide enforcement when requested by mail from: Calvin Furlow, Public Response Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1130A, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

There are currently no actions pending against the registration of this chemical. Based on the data and information submitted above, the Agency has determined that the establishment of tolerances by amending 40 CFR part 180 will protect the public health. Therefore, EPA is establishing the tolerances as described below.

Any person adversely affected by this regulation may, within 30 days after the date of publication in the **Federal Register**, file written objections with the Hearing Clerk, Environmental Protection Agency, at the address given above. 40 CFR 178.20. A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections. 40 CFR 178.25. Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on each issue, and a summary of any evidence relied upon by the objector. 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 a 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested. 40 CFR 178.32.

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f),