

Metolachlor was evaluated by the Office of Pesticide Programs' Peer Review Committee in 1991 and classified as a Group C (possible carcinogen) with a recommendation for the quantification of estimated potential human risk using a linearized low-dose extrapolation (Q¹). This recommendation was based on the finding of liver tumors in female rats at the 3,000-ppm dose level in both rat studies and the apparent induction of a small number of nasal turbinate tumors in both sexes of rats at the 3,000-ppm dose level. Nasal turbinate tumors have also been associated with dietary administration of acetochlor and alachlor, structurally related herbicides that are classified as Group B2 carcinogens (probable human carcinogens).

The Peer Review Committee's decision was presented to the FIFRA Scientific Advisory Panel on September 18, 1991. The Panel concluded that liver tumors were benign and hyperplasia was evident in rats of both sexes. The Panel also concluded that the occurrence of nasal turbinate tumors in rats was low and not statistically significant, but of concern since metolachlor is structurally related to acetochlor and alachlor. The Panel considered the carcinogenicity evidence to be minimal but sufficient for the classification of metolachlor as a Group C carcinogen.

The Office of Pesticide Programs' Health Effect Division Carcinogenicity Peer Review Committee met on July 27, 1994, to reevaluate the weight-of-the-evidence on metolachlor, with particular reference to its carcinogenicity, based on newly submitted metabolism and mutagenicity studies. The registrant submitted data to show that the metabolism of metolachlor is substantially different from the metabolism of acetochlor and alachlor. Metolachlor does not metabolize to form a reactive quinone imine, which is presumed to be the carcinogenic metabolite of acetochlor and alachlor. There was also no evidence for mutagenic potential of metolachlor. Based on these data and in consideration of the full weight-of-the-evidence, the Carcinogenicity Peer Review Committee concluded that the classification of metolachlor should remain as a Group C carcinogen, but recommended that the RfD approach should be used for quantification of human risk.

A NOEL of 15 mg/kg/day from the 2-year rat feeding study was determined to be appropriate for use in the Margin of Exposure carcinogenic risk assessment. The chronic reference dose

(RfD) is currently based on a systemic NOEL of 9.7 mg/kg/day from the 1-year feeding study in dogs, and any cancer concerns from chronic exposure are already addressed by the lower NOEL, which is the basis for the current RfD.

The Reference Dose (RfD) is established at 0.1 mg/kg of body weight (bwt)/day, based on a NOEL of 9.7 mg/kg/day and an uncertainty factor of 100. Available information on anticipated residues and/or percent of crop treated were used to estimate the Anticipated Residue Contribution (ARC) from residues of metolachlor in the human diet. The ARC from established tolerances and the proposed tolerances for celery and onions is estimated at 0.0006 mg/kg bwt/day and utilizes 0.6 percent of the RfD for the U.S. population. The ARC for non-nursing infants (the subgroup most highly exposed) utilizes 2 percent of the RfD. EPA believes these uses of metolachlor pose a negligible cancer risk to humans.

An adequate analytical method, gas chromatography, is available for enforcement purposes. The analytical method for enforcing this tolerance has been published in the Pesticide Analytical Manual, Vol. II (PAM II). The nature of the residue in plants is adequately understood. There is no reasonable expectation that secondary residues will occur in milk, eggs, or meat of livestock and poultry since there are no livestock feed items associated with this action.

There are currently no actions pending against the continued registration of this chemical.

Based on the information and data considered, the Agency has determined that the tolerances established by amending 40 CFR part 180 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.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [PP 0E3882 and PP 4E4286/P597]. All written comments filed in response to these petitions will be available in the Public Response and Program Resources Branch, at the

address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

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: January 30, 1995.

Stephen L. Johnson,

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.