were insufficient to induce a toxic response and a maximum tolerated dose (MTD) was not achieved. This study must be repeated.

6. In a second supplemental chronic feeding/carcinogenic study with rats fed dosages of 0, 18.2/23.0, and 55.9/71.8 mg/kg/day (males/females) with no carcinogenic effects observed under the conditions of the study at dose levels up to and including 55.9/71.8 mg/kg/day (HDT) (males/females) and a systemic NOEL greater than or equal to 55.9/71.8 mg/kg/day (males/females). The doses used were insufficient to induce a toxic response and failed to achieve an MTD or define a Lowest Effect Level (LEL). Slight decreases in body weights in the final quarter of the study, although not biologically significant, can support a free-standing NOAEL of 55.9/71.8 mg/ kg/day (males/females).

7. A developmental toxicity study in rats fed dosages of 0, 50, 180, 650, and 1,000 mg/kg/day with a maternal NOAEL of 180 mg/kg/day and a maternal LEL of 650 mg/kg/day (irregular gait, decreased activity, excessive salivation, and anogenital staining); and a developmental NOAEL of 180 mg/kg/day and a developmental LEL of 650 mg/kg/day (21 to 22 percent decrease in fetal weights, filamentous tail and lack of tail due to the absence of sacral and/or caudal vertebrae, and delayed ossification in the hyoids. vertebral centrum and/or transverse processes, sternebrae and/or metatarsals, and pubes).

8. A developmental toxicity study in rabbits fed doses of 0, 80, 160, 320, and 400 mg/kg/day with a maternal NOEL of 320 mg/kg/day and a maternal lowest observable effect level (LOEL) of 400 mg/kg/day (37 percent reduction in body weight gain without significant differences in group mean body weights, and decreased food consumption during dosing); and a developmental NOEL greater than 400 mg/kg/day (HDT).

9. A two-generation reproduction study with rats fed dosage levels of 0, 150, 600, and 3,000 ppm (approximately 0, 7.5, 30, and 150 mg/kg/day) with no reproductive effects observed at 3,000 ppm (approximately 150 mg/kg/day) (HDT). However, the Agency considers this study usable for regulatory purposes and has established a freestanding NOEL of 3,000 ppm (approximately 150 mg/kg/day).

10. Mutagenicity studies included: Ames Assays, which were negative for *Salmonella typhimurium* strains TA98, TA100, TA1535, and TA 1537, with and without metabolic activity; sethoxydim did not cause structural chromosomal aberrations at doses up to 5,000 mg/kg in Chinese hamster bone marrow cells in vivo; a Host Mediated Assay (mouse) with *4S. typhimurium* was negative at 2.5 grams/kg/day of chemical, and recombinant assays and forward mutations in *Bacillus subtilis, Escherichia coli*, and *S. typhimurium* were all negative at concentrations of greater than or equal to 100%; a in vitro Unscheduled DNA Synthesis Assay in Primary Rat Hepatocytes had a negative response for DNA repair (UDS) in primary rat hepatocyte cultures exposed up to insoluble (greater than 101 micrograms per milliliter (mL)) and cytotoxic (507 ug/mL) doses.

11. In a rat metabolism study, excretion was extremely rapid and tissue accumulation was negligible, assuming DMSO vehicle does not affect excretion or storage of NP-55 (78 percent excreted into urine and 20.1 percent excreted in feces).

The reference dose (RFD), based on a NOEL of 8.86 mg/kg bwt/day in the 1year feeding study in dogs and an uncertainty factor of 100, was calculated to be 0.09 mg/kg bwt/day. The theoretical maximum residue contribution (TMRC) for the overall U. S. population is 0.031961 mg/kg bwt/ day or 35.9% of the RfD for existing tolerances for the overall use population. The current action will increase the TMRC by 0.000380 mg/kg bwt/day. These tolerances and previously established tolerances utilize a total of 35.9 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 61.8 percent and 72.6 percent of the ADI, assuming that residue levels are at the established tolerances and that 100 percent of the crop is treated.

Desirable data lacking based on review of data under current guidelines include a carcinogenicity in mice study and a chronic feeding/carcinogenicity in rats study. Because the current studies, although unacceptable by current guidelines, provide useful information and these tolerances utilize 3 percent of the RfD, the Agency believes there is little risk from establishment of these tolerances. Any additional tolerance proposals will be considered on a caseby-case basis.

The pesticide is useful for the purposes for which these tolerances are sought and capable of achieving the intended physical or technical effect. The nature of the residue is adequately understood, and adequate analytical methods (gas chromatography using sulfur-specific flame photometric detection) are available for enforcement purposes. The method is listed in the Pesticide Analytical Manual, Volume II (PAM II), as Method I.

There are currently no actions pending against the registration of this chemical. Any secondary residues occuring in meat, fat, meat byproducts and milk of cattle, goats, hogs, horses and sheep will be covered by existing tolerances. There are no residues expected to occur in poultry meat, meat byproducts, fat, or eggs from these tolerances.

Based on the information and data considered, the Agency has determined that the tolerances established by amending 40 CFR part 180 will protect the public health, and the establishment of a feed additive regulation by amending 40 CFR part 185 will be safe. Therefore, they are eablished as set forth 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 obctions submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objection. 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 sue(s) on which a hearing is requested, the requestor's intentions on each issue, and a summary of any evidence relied upon by the objector. 40 CFR 178.27. A request for hearing will be granted if the Administrator determines at 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 aims 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 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