containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

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 29, 1998.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I, part 180 is 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 § 180.438, the table to paragraph (a)(1) is amended by adding entries for alfafa forage; alfalfa hay; aspirated grain fractions; brassica, head and stem subgroup; lettuce, leaf; by revising the entries for poultry, fat; and by removing the entries for sorghum, grain dust; and wheat, grain dust, and broccoli and cabbage, to read as follows:

§ 180.438 Lambda-cyhalothrin; tolerances for residues.

(a) *General.* (1) * * *

Commodity	Parts per million
Alfalfa, forage,	5.0
Alfalfa, hay	6.0
Aspirated grain fractions	2.0
Brassica, head and stem subgroup,.	0.4
* * *	* *
Lettuce, leaf	2.0
* * *	* *
Poultry Fat	0.03
* * *	* *

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[FR Doc. 98–3751 Filed 2–12–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300617; FRL–5771–1]

RIN 2070–AB78

Benoxacor; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of benoxacor (4-(dichloroacetyl)-3,4-dihydro-3-methyl-2*H*-1,4-benzoxazine at 0.01 part per million (ppm) when used as an inert ingredient (safener) in pesticide formulations containing metolachlor in or on raw agricultural commodities for which tolerances have been established for metolachlor. It also removes time limitations for residues of benoxacor on the same commodities that expire on February 14, 1998. Novartis Crop Protection, Incorporated requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104-170).

DATES: This regulation is effective February 13, 1998. Objections and requests for hearings must be received by EPA on or before April 14, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300617], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300617], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300617]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Kerry B. Leifer, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 4W17, Crystal Station #1, 2800 Crystal Drive, Arlington, VA, (703) 308-8811, e-mail: leifer.kerry@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 30, 1992 (57 FR 29031), EPA established time-limited tolerances under section 408 of the FFDCA 21 U.S.C. 346a(d) for residues of benoxacor at 0.01 ppm when used as an inert ingredient (safener) in pesticide formulations containing metolachlor in or on raw agricultural commodities for which tolerances have been established for metolachlor. These time-limited tolerances expired on December 1, 1996. In the **Federal Register** of November 5, 1996 (61 FR 56954) (FRL–5572–8), EPA issued a notice pursuant to section 408 of FFDCA 21 U.S.C. 346a(e) announcing the filing of pesticide petition (PP7E3489) for tolerances by Novartis Crop Protection, Incorporated, P.O. Box 18300, Greensboro, NC 27419. This notice included a summary of the petition prepared by Novartis, the petitioner. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.460 be amended to extend the time-limited tolerances for residues of benoxacor at 0.01 ppm when used as an inert ingredient (safener) in pesticide formulations containing metolachlor in or on raw agricultural commodities for which tolerances have been established for metolachlor from December 1, 1996, to December 1, 1998. On February 21, 1997 (62 FR 7941) (FRL–5583–4), EPA established time-limited tolerances for benoxacor at 0.01 ppm when used as an inert ingredient (safener) in pesticide formulations containing metolachlor in or on raw agricultural commodities for which tolerances have been established for metolachlor with an expiration date of February 14, 1998.

In the **Federal Register** of November 21, 1997 (62 FR 62304) (FRL–5755–4), EPA issued a notice pursuant to section 408 of FFDCA 21 U.S.C. 346a(e) announcing the filing of pesticide petition (PP7E3489) for tolerances by Novartis Crop Protection, Incorporated (formerly Ciba Crop Protection), P.O. Box 18300, Greensboro, NC 27419. This notice included a summary of the petition prepared by the petitioner. There were no comments received in response to the notice of filing.

The petition requested that the time limitation for tolerances established for residues of benoxacor at 0.01 ppm when used as an inert ingredient (safener) in pesticide formulations containing metolachlor in or on raw agricultural commodities for which tolerances have been established for metolachlor be removed based upon the chronic toxicity and oncogenicity data submitted as a condition of registration.

The basis for the time-limited tolerances that expire February 14, 1998, was given in the February 21, 1997 issue of the **Federal Register** (62 FR 7941). These time-limited tolerances were predicated on the expiration of pesticide product registrations that were made conditional due to the lack of certain chronic/oncogenicity data. The rationale for using time-limited tolerances was to encourage pesticide manufacturers to comply with the conditions of registration in a timely manner. There is no regulatory requirement to make tolerances time-limited due to the conditional status of a product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended. It is current EPA policy to no longer establish time limitations on tolerances if none of the conditions of registration have any bearing on human dietary risk. The current petition action meets that condition and thus the expiration dates associated with the crop tolerances are being deleted.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1–7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because

of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1–7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup, non-nursing infants less than one year old, was not regionally based.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of benoxacor and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of benoxacor when used as an inert ingredient (safener) in pesticide formulations containing metolachlor in or on raw agricultural commodities for which tolerances have been established for metolachlor at 0.01 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by benoxacor are discussed below.

1. *Acute toxicity*. A rat acute oral study with an LD_{50} >5,000 milligram/kilogram (mg/kg), a rabbit acute dermal study with an LD_{50} >2,010 mg/kg, a rat inhalation study with an LC_{50} >2,000 mg/liter, a primary eye irritation study in the rabbit showing moderate eye irritation, a primary dermal irritation study in the rabbit showing benoxacor is not a skin irritant, and a skin sensitization study which showed benoxacor to be a skin sensitizer in the Guinea pig. Results of a dermal absorption study show a maximum of 55.7% of benoxacor is absorbed by the rat following a 24-hour dermal exposure.

2. *Genotoxicity*. Benoxacor did not induce point mutations in vitro at limit (cytotoxic) concentrations in a *Salmonella* /mammalian microsome test or show any mutagenic activity in the Chinese hamster V79 mammalian point mutation test and is neither clastogenic nor aneugenic in the Chinese hamster at doses up to the limit dose of 5,000 mg/kg. Benoxacor did not induce unscheduled DNA synthesis in isolated rat hepatocytes at cytotoxic concentrations up to 20 micrograms/ml.

3. *Subchronic toxicity*—i. *Dogs*. In a subchronic feeding study in dogs (5 dogs/sex/dose), benoxacor was administered at doses of 0, 0.25, 1, 5, 50, 150, or 400 milligram/kilograms/day (mg/kg/day) for 90 days. The NOEL was 5 mg/kg/day and the lowest observed effect level (LOEL) 50 mg/kg/day based on increased liver and gallbladder weights.

ii. *Mice*. In a subchronic feeding study, CD-1 mice were administered dietary concentrations of 0, 50, 500, 2,000, and 6,000 ppm (approximately 0, 7.14, 70.7, 290, and 1,100 mg/kg/day for males and 0, 9.53, 99.8, 382, and 1,470 mg/kg/day for females) of benoxacor for 13 weeks. The systemic toxicity NOEL was 500 ppm (70.7 and 99.8 mg/kg/day in males and females respectively) and the systemic toxicity LOEL was 2,000 ppm (290 and 382 mg/kg/day in males and females respectively) based on increased incidence of renal cortex fibrosis and calcifications in males, and increases in water consumption, platelet counts, and liver and kidney weights in both males and females.

iii. *Rats*. In a subchronic feeding study in rats, six groups of 15 male and 15 female Sprague Dawley rats were fed benoxacor at dietary concentrations of approximately 0, 0.5, 5, 15, 50, or 300 mg/kg/day for 13 weeks. The NOEL was 5 mg/kg/day and the LOEL was 15 mg/kg/day based on increased incidence of kidney nephrosis.

4. *Dermal toxicity study*. In a 21-day dermal toxicity study, benoxacor was repeatedly applied daily to the shaved skin of 5 male and 5 female New Zealand white rabbits at dose levels of 0, 1, 500, or 1,010 mg/kg for 6/hours/day . The NOEL was >1,010 mg/kg/day.

5. *Developmental toxicity study*—i. *Rabbits*. In an oral developmental toxicity study, rabbits were administered benoxacor at doses of 0, 0.5, 2.5, 12.5,and 62.5 mg/kg/day. The systemic maternal NOEL was 12.5 mg/kg/day and the systemic maternal LOEL was 62.5 mg/kg/day based on decreased consumption values. The developmental toxicity NOEL was 12.5 mg/kg/day and the developmental toxicity LOEL was 62.5 mg/kg/day based on increased frequency of vertebral anomalies with or without associated rib anomalies.

ii. *Rats*. In an oral developmental toxicity study, rats were administered benoxacor at doses of 0, 1, 100, and 400 mg/kg/day. The systemic maternal NOEL was 100 mg/kg/day and the systemic maternal LOEL was 400 mg/kg/day based on increased maternal gross pathology findings, and decreased body weight gain. The developmental toxicity NOEL was 100 mg/kg/day and the developmental toxicity LOEL was 400 mg/kg/day based on decreased fetal weight, number of live fetuses, decreased uterine weight and increased early resorptions, and fetal visceral variations, malformations, and skeletal variations.

6. *Reproductive toxicity study*. In a two-generation reproduction study, Sprague-Dawley rats were fed in the diet with benoxacor at doses of 0, 10, 50, 100, 500, and 1,000 ppm for two generations. For parental/systemic toxicity, the NOEL was 50 ppm (3.55 mg/kg/day in the male and 4.51 mg/kg/day in the females) and the LOEL was 500 ppm (34.84 mg/kg/day in males and 41.21 mg/kg/day in females) based on decreased body weight and body weight gain in both sexes and both generations. For reproductive toxicity the NOEL was 50 ppm (3.55 mg/kg/day in the male and 4.51 mg/kg/day in the female) and the LOEL was 500 ppm (34.84 mg/kg/day in males and 41.21 mg/kg/day in females) based on decreased pup body weight on lactation day 21 in both generations.

7. *Chronic toxicity study*. In a 52-week feeding study, benoxacor was administered orally to male and female beagle dogs (4/sex/group) at doses of 0, 1, 5, 40, or 80 mg/kg/day. The NOEL was 5 mg/kg/day and the LOEL was 40 mg/kg/day based upon decreases in mean body weight gain in males and increases in adjusted liver and kidney weights and increased lipofuscin deposition in the kidney in both sexes.

8. *Carcinogenicity study*. In a carcinogenicity study, CD-1 mice were fed benoxacor (50/sex/group) at dietary levels of 0, 10, 30, 600, and 1,200 ppm (0, 1.2, 3.7, 75, and 167 mg/kg/day for males and 0, 1.6, 4.7, 93, and 201 mg/kg/day for females) for 18 months. There was evidence of carcinogenicity at the two highest doses tested. Statistically ($p<0.05$) significant increases of squamous cell papillomas and combined papillomas/carcinomas were seen in the nonglandular stomach (forestomach) in both sexes at the highest dose tested. There were also statistically significant positive trends for carcinomas in male mice and for papillomas and combined papilloma/carcinoma in both sexes. For chronic toxicity, the NOEL was 30 ppm (3.7 mg/kg/day and 4.7 mg/kg/day in males and females, respectively) and the systemic LOEL was 600 ppm (75 mg/kg/day and 93 mg/kg/day in males and females, respectively) based on increased liver/body weight ratios in both sexes. The NOEL for mouse forestomach tumors was 3.7 mg/kg/day in males and 4.7 mg/kg/day in females with tumors occurring at 75 and 93 mg/kg/day in males and females. Dosing was considered adequate to assess the carcinogenic potential of benoxacor based on body weight reduction in males, treatment-related increased liver/body weight ratios in both sexes, and other treatment-related increased incidences of tumor and nontumor findings in the forestomach.

9. *Chronic/oncogenicity study*. In a combined chronic/oncogenicity study, Crl:CD BR rats (70 /sex/group) were fed benoxacor dosed at dietary levels of 0, 10, 50, 500, and 1,000 ppm (0, 0.4, 2.0, 20.6, and 41 mg/kg/day for males and 0, 0.6, 2.8, 28.2, and 59 mg/kg/day for females) for two years. Statistically significant ($p<0.01$) increasing trends were seen in male rats for forestomach squamous cell papillomas and papillomas and/or carcinomas combined. There was also a statistically significant ($p<0.05$) increasing trend for forestomach squamous cell carcinomas in male rats. There were significant differences in the pair-wise comparisons of the male high-dose group with the controls for forestomach squamous cell papillomas ($p<0.05$) and for papillomas and/or carcinomas combined ($p<0.01$). Statistically significant ($p<0.01$) increasing trends, and differences in the pair-wise comparisons of the high-dose group with the controls, were seen in female rats for forestomach squamous cell papillomas and papillomas and/or carcinomas combined. For chronic toxicity, the NOEL was 10 ppm (0.4 mg/kg/day and 0.6 mg/kg/day in males and females, respectively) and the systemic LOEL is 50 ppm (2.0 mg/kg/day in males) based on centrolobular hepatic enlargements with or without hepatocytic vacuolation in male rat livers. At a dose level of 2.6 mg/kg/day, hyperkeratosis of the forestomach in females was observed. The NOEL for rat forestomach tumors was 20.6 mg/kg/day in males and 28.2 in females with tumors occurring at 41 and 59 mg/kg/day in males and females.

B. Toxicological Endpoints

1. *Acute toxicity*. An acute dietary risk assessment for the general population, including infants and children, is not required because no treatment-related effects attributable to a single exposure (dose) were seen in oral studies conducted with benoxacor.

2. *Short- and intermediate-term toxicity*. A short- and intermediate-term risk assessment is not required for benoxacor. There was no systemic toxicity at 1,010 mg/kg/day (highest dose tested) in a 21-day dermal toxicity study in rabbits.

3. *Chronic toxicity*. EPA has established the RfD for benoxacor at 0.004 mg/kg/day. This RfD is based on a 2-year feeding study in rats with a NOEL of 0.4 mg/kg/day. An uncertainty factor of 100 was used in calculating the RfD to account for interspecies extrapolation and intra-species variability.

4. *Carcinogenicity*. EPA's Health Effects Division Carcinogenicity Peer Review Committee (CPRC) has determined that, in accordance with the EPA proposed Guidelines for Carcinogenic Risk Assessment (April 23, 1996), benoxacor's carcinogenic potential be characterized as ''cannot be determined, but suggestive'' based on increases in forestomach tumors in both sexes of mice and rats. The consensus of the CPRC was that these tumors have little or no relevance to humans. For cancer risk assessment purposes, the CPRC recommended using a threshold (MOE) approach based on the most sensitive precursor forestomach lesions. It was further recommended that the NOEL for rat forestomach lesions of 0.4 mg/kg/day be used as the point of departure for MOE calculations.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.460) for the residues of benoxacor in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to

assess dietary exposures and risks from benoxacor as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. Since there are no acute toxicological concerns for benoxacor, an acute dietary risk assessment was not required.

ii. *Chronic exposure and risk.* For the purpose of assessing chronic dietary exposure from benoxacor, EPA considered the proposed benoxacor tolerance of 0.01 ppm and the raw agricultural commodities for which tolerances have been established for metolachlor. There are no other established U.S. tolerances for benoxacor, and there are no other registered uses for benoxacor on food or feed crops in the United States. In conducting this exposure assessment, EPA assumed tolerance level residues and 100% crop treated, resulting in a large overestimation of dietary exposure and protective of any chronic dietary exposure scenario. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Review of this regional data allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Based on the chronic dietary exposure TMRC's of 0.000205 mg/kg/day for the U.S. population and 0.000828 mg/kg/day for the most highly exposed population subgroup (non-nursing infants less than one year old), this chronic dietary risk assessment resulted in the use of 5.13% of the RfD for the U.S. population and 20.7% of the RfD for the most highly exposed population subgroup. A cancer dietary MOE was calculated to be 1,950.

2. *From drinking water.* For the purposes of assessing chronic exposure in drinking water, EPA has considered the registered uses and the available data on persistence and mobility for benoxacor. The Agency has determined through a qualitative risk assessment that the physical and chemical characteristics of benoxacor are such that it is not expected to impact water resources. While benoxacor is mobile, it is not persistent (half-life in soil of 49 days under aerobic conditions and 70 days anaerobically). In light of these findings, EPA believes that benoxacor's use will not impact ground water or surface water resources, and therefore, is not expected to lead to exposure to humans through drinking water. If new uses are added in the future, OPP will reassess the potential impacts of benoxacor on drinking water as a part of the aggregate risk assessment process.

3. *From non-dietary exposure.* All registered metolachlor products to which benoxacor is added as a safener are commercial agricultural products not registered for residential use. The potential for non-occupational exposure to benoxacor by the general population is therefore unlikely except for the potential residues in food crops discussed above.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether benoxacor has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, benoxacor does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that benoxacor has a common mechanism of toxicity with other substances.

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* Since there are no acute toxicological concerns for benoxacor, EPA has no cause for concern for acute aggregate exposure.

2. *Chronic risk.* Using the TMRC exposure assumptions described above, EPA has concluded that aggregate chronic exposure to benoxacor from food and water will utilize 5.13% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants less than one year old (utilizing 20.7% of the RfD). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to benoxacor residues.

E. Aggregate Cancer Risk for U.S. Population

The carcinogenic risk from food uses of benoxacor for the general U.S. population was calculated by comparing the dietary exposure from benoxacor to the NOEL identified for use with the cancer risk assessment. Based on the NOEL selected by the CPRC for cancer risk characterization of 0.4 mg/kg/day, the cancer risk was estimated to result in a MOE of 1,950 contributed through all the published, pending and new uses for benoxacor. Based upon the extreme conservatism of the dietary exposure estimates and the fact that tumors were

observed only at dose levels far in excess of the selected NOEL, this MOE is at a level which the Agency does not consider raising a concern for excess lifetime cancer.

F. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*—i. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of benoxacor, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In either case, EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the NOEL in the animal study appropriate to the particular risk assessment. This 100–fold uncertainty (safety) factor/MOE (safety) is designed to account for inter-species extrapolation and intra-species variability. EPA believes that reliable data support using the 100–fold uncertainty factor rather than the 1,000–fold margin/factor, when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children, the potency or unusual toxic properties of a compound, or the quality of the exposure data do not raise concerns regarding the adequacy of the standard margin/factor.

ii. *Developmental toxicity studies*. See Toxicological Profile in Unit II.A. of this preamble.

iii. *Reproductive toxicity study*. See Toxicological Profile in Unit II.A. of this preamble.

iv. *Pre- and post-natal sensitivity*. There is no evidence of increased sensitivity to young rats or rabbits following pre- or post-natal exposure to benoxacor.

v. *Conclusion*. The toxicological data base for evaluating pre- and post-natal toxicity for benoxacor is complete with respect to current data requirements. Because both developmental and reproductive effects occurred in the presence of parental (systemic) toxicity, these data do not suggest an increased pre- or post-natal sensitivity of children and infants to benoxacor exposure. Based on the above, EPA concludes that reliable data support use of a 100–fold MOE/uncertainty factor, rather than the standard 1,000–fold margin/factor to protect infants and children. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to benoxacor residues.

2. *Acute risk*. Since there are no acute toxicological concerns for benoxacor, EPA has no cause for concern for acute aggregate exposure.

3. *Chronic risk*. Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to benoxacor from food will range from 3.69% of the RfD for females 13+ years, to 20.7% of the RfD for non-nursing infants less than one year old. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to benoxacor residues.

4. *Cancer risk*. Carcinogenic risk to infants and children from food uses of benoxacor is addressed under Aggregate Cancer Risk for U.S. Population under Unit II.E. of this preamble.

III. Other Considerations

A. Metabolism In Plants and Animals

The metabolism of benoxacor in plants and animals is adequately understood for purposes of these tolerances.

B. Analytical Enforcement Methodology

Adequate enforcement methodology, GC/NPD, is available to enforce the tolerance expression. An analytical methodology for the determination of benoxacor and its metabolites in plant and animal commodities (Ciba Analytical Method AG536(C)) is available from: Calvin Furlow, Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 119FF, CM#2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703) 305-5229.

C. Magnitude of Residues

The magnitude of the residue in plants is adequately understood for the purposes of these tolerances.

D. International Residue Limits

No Codex Maximum Residue Levels have been established for residues of benoxacor on commodities for which a tolerance for metolachlor exist.

IV. Conclusion

Therefore, the tolerances are established for benoxacor (4-(dichloroacetyl)-3,4-dihydro-3-methyl-2*H*-1,4-benzoxazine) at 0.01 ppm when used as an inert ingredient (safener) in pesticide formulations containing metolachlor in or on raw agricultural commodities for which tolerances have been established for metolachlor.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by April 14, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, 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 issues on which a hearing is requested, the requestor's

contentions on such issues, and a summary of any evidence relied upon by the requestor (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 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 issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information 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.

VI. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300617] (including any comments and data submitted electronically). 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 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Electronic comments may 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 any copies of objections and hearing requests 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 Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels, or expanding exemptions

might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. *801 et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: February 10, 1998.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is 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. Section 180.460 is revised to read as follows:

§ 180.460 Benoxacor; tolerances for residues.

(a) *General* . Tolerances are established for residues of the inert ingredient (safener) benoxacor (4-(dichloroacetyl)-3,4-dihydro-3-methyl-2*H*-1,4-benzoxazine) at 0.01 ppm when used in pesticide formulations containing metolachlor in or on raw agricultural commodities for which tolerances have been established for metolachlor.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

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