for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

Nothing in this action should be construed as making any determination or expressing any position regarding Colorado's audit privilege and penalty immunity law, sections 13–25–126.5, 13–90–107, and 25–1–114.5, Colorado Revised Statutes (Colorado Senate Bill 94–139, effective June 1,1994), or its impact upon any approved provision in the SIP, including the revision at issue here. The action taken herein does not express or imply any viewpoint on the question of whether there are legal deficiencies in this or any other Clean Air Act program resulting from the effect of Colorado's audit privilege and immunity law. A state audit privilege and immunity law can affect only state enforcement and cannot have any impact on federal enforcement authorities. EPA may at any time invoke its authority under the Clean Air Act, including, for example, sections 113, 167, 205, 211, or 213, to enforce the requirements or prohibitions of the state plan, independently of any state enforcement effort. In addition, citizen enforcement under section 304 of the Clean Air Act is likewise unaffected by a state audit privilege or immunity law.

**List of Subjects**

*40 CFR Part 52*

Environmental protection, Air pollution control, Carbon Monoxide, Intergovernmental relations, Reporting and recordkeeping requirements.

*40 CFR Part 81*

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: February 12, 1999.

**Jack W. McGraw,**

*Acting Regional Administrator, Region VIII.*

Chapter I, title 40, parts 52 and 81 of the Code of Federal Regulations are amended as follows:

## PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

**Authority:** 42 U.S.C. 7401 *et seq.*

## Subpart G—Colorado

2. Section 52.348 is amended by adding paragraph (c) to read as follows:

**§ 52.348 Emission inventories.**

* * * * *

(c) On September 16, 1997, the Governor of Colorado submitted the 1990 Carbon Monoxide Base Year Emission Inventory for Greeley as a revision to the Colorado State Implementation Plan. This inventory addresses carbon monoxide emissions from stationary point, area, non-road, and on-road mobile sources.

3. New section 52.349 is added to read as follows:

**§ 52.349 Control strategy: Carbon monoxide.**

Revisions to the Colorado State Implementation Plan, Carbon Monoxide Redesignation Request and Maintenance Plan for Greeley, as adopted by the Colorado Air Quality Control Commission on September 19, 1996, State effective November 30, 1996, and submitted by the Governor on September 16, 1997.

## PART 81—[AMENDED]

1. The authority citation for part 81 continues to read as follows:

**Authority:** 42 U.S.C. 7401 *et seq* .

2. In § 81.306, the table entitled ''Colorado-Carbon Monoxide'' is amended by revising the entry for ''Greeley Area'' to read as follows:

**§ 81.306 Colorado.**

* * * * *

COLORADO—CARBON MONOXIDE

| Designated area | Designation | | Classification | |
|---|---|---|---|---|
| | Date [1] | Type | Date [1] | Type |
| * * | * | * * | * | * |
| Greeley Area: Weld County (part) ..... Urban boundaries as defined in the North Front Range Regional Transportation Plan, May, 1990.. | ..... May 10, 1999. | Attainment | | |
| * * | * | * * | * | * |

[1] This date is November 15, 1990, unless otherwise noted.

[FR Doc. 99–5661 Filed 3–9–99; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[OPP–300795; FRL–6062–5]**

**RIN 2070–AB78**

## Metolachlor; Pesticide Tolerances for Emergency Exemptions

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a time-limited tolerances for the combined residues of metolachlor 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 tomatoes, tomato puree, and tomato paste. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and

Rodenticide Act authorizing use of the pesticide on tomatoes. This regulation establishes maximum permissible levels for residues of metolachlor in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and are revoked on April 1, 2001.

**DATES:** This regulation is effective March 10, 1999. Objections and requests for hearings must be received by EPA on or before May 10, 1999.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number [OPP–300795], 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–300795], 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, Crystal Mall 2 (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@epa.gov. Copies of electronic 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 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300795]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

**FOR FURTHER INFORMATION CONTACT:** By mail: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 280, (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9367; ertman.andrew@epa.gov.

**SUPPLEMENTARY INFORMATION:** EPA, on its own initiative, pursuant to sections 408 and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a and (l)(6), is establishing a tolerance for combined residues of the herbicide metolachlor 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 tomatoes at 0.1 part per million (ppm), tomato puree at 0.3 ppm, and tomato paste at 0.6 ppm. These tolerances will expire and are revoked on April 1, 2001. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

## I. Background and Statutory Findings

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described in this preamble and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL–5572–9).

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. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

## II. Emergency Exemption for Metolachlor on Tomatoes and FFDCA Tolerances

Eastern black nightshade (*Solanum nigrum*) is a common annual weed found in tomato fields. Currently registered herbicides for use on tomatoes have little or no effect in controlling eastern black nightshade. Chloramben (*amiben*) is the most effective herbicide for this weed, but has not been manufactured since 1991 and grower's reserves of the herbicide have been depleted. Hand hoeing is utilized, but it does not provide complete control and is very expensive. The Applicant stated that since this weed population is ubiquitous and hand hoeing does not provide complete control, the weed population is increasing and threatening the economic viability of the tomato industry in their state. EPA has authorized under FIFRA section 18 the use of metolachlor on tomatoes for control of nutsedge and nightshade in Virginia. After having reviewed the submission, EPA concurs that emergency conditions exist for this state.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of

metolachlor in or on tomatoes, tomato paste, and tomato puree. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on April 1, 2001, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on tomatoes, tomato paste, and tomato puree after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions EPA has not made any decisions about whether metolachlor meets EPA's registration requirements for use on tomatoes or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of metolachlor by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Virginia to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for metolachlor, contact the Agency's Registration Division at the address provided under the ''ADDRESSES'' section.

## III. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7) .

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 metolachlor and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for combined residues of metolachlor 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 on tomatoes at 0.1 ppm, tomato puree at 0.3 ppm, and tomato paste at 0.6 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 metolachlor are discussed in this unit.

### *B. Toxicological Endpoint*

1. *Acute toxicity*. EPA has determined that available data do not indicate that there is potential for adverse effects after a single dietary exposure. Therefore, acute risk assessments were not conducted.

2. *Short - and intermediate - term toxicity.* For intermediate-term dermal risk assessment, the no observed adverse effect level (NOAEL) of 100 miligrams/kilogram/day (mg/kg/day) from the 21-day dermal toxicity study in rats is to be used. At the lowest effect level (LEL) of 1,000 mg/kg/day, there were dose-related increases in minor histopathological alterations of the skin, in total bilirubin (females), in absolute and relative liver weights (males), and in relative kidney weights (females). An inhalation exposure intermediate-term hazard was not identified. The EPA has determined that the available data do not indicate the potential for adverse effects from short-term dermal or inhalation exposures.

3. *Chronic toxicity*. EPA has established the Reference Dose (RfD) for metolachlor at 0.10 mg/kg/day. This RfD is based on the results from the 1-year feeding study in dogs, with a NOAEL of 9.7 mg/kg/day, and an uncertainty factor of 100, based on decreased body weight gain at the lowest observed effect level (LOEL) of 33 mg/kg/day.

4. *Carcinogenicity*. Under the EPA Guidelines for Carcinogen Risk Assessment, metolachlor has been classified as a Group C Chemical (possible human carcinogen), based on increased incidence of adenomas and combined adenomas/carcinomas in female rats. The structural relationship of metolachlor to acetochlor and alachlor was of concern to the OPP Carcinogenicity Peer Review Committee (CPRC). However, in light of new information on the relative metabolism of these chemicals, and since there was no supportable mutagenicity concern, the CPRC recommended the Margin of Exposure (MOE) approach for estimation of risk, using the NOAEL of 15.7 mg/kg/day from the 2-year rat feeding study.

### *C. Exposures and Risks*

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.368) for the combined residues of metolachlor 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 a variety of raw agricultural commodities, ranging from 0.02 ppm in various animal commodities, to 30 ppm in peanut forage and hay. Risk assessments were conducted by EPA to assess dietary exposures and risks from metolachlor 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 1-day or single exposure. EPA has determined that available data do not indicate that there is potential for adverse effects after a single dietary exposure. Therefore, acute risk assessment is not required.

ii. *Chronic exposure and risk.* In conducting this chronic dietary (food only) risk assessment, the Agency used percent of crop treated data for selected crops, and assumed tolerance level residues in all commodities having metolachlor tolerances. These assumptions result in an overestimate of human dietary exposure, and thus this risk estimate should be viewed as conservative; further refinement using anticipated residue levels and additional percent crop treated values would result in lower exposure estimates. Based on the given

assumptions, EPA has calculated that dietary exposure to metolachlor will utilize 1.1% of the RfD for the overall U.S. population. The major identifiable subgroups with the highest exposure are non-nursing infants <1 year old and children 1 to 6 years old, both at 2.3% of the RfD. This is further discussed below in the section on infants and children. EPA generally has no concern for exposure 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. Despite the potential for exposure to metolachlor in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is reasonable certainty that no harm will result from chronic aggregate exposure to metolachlor residues.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated (PCT) for assessing chronic dietary risk only if the Agency can make the following findings: That the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; that the exposure estimate does not underestimate exposure for any significant subpopulation group; and if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent crop treated as required by the section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used percent crop treated data for selected crops, and assumed tolerance level residues in all commodities having metolachlor tolerances.

The Agency believes that the 3 conditions, discussed in section 408 (b)(2)(F) in this unit concerning the Agency's responsibilities in assessing chronic dietary risk findings, have been met. The PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. 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 the PCT, the Agency is reasonably certain that the percentage of the food treated is not likely to be underestimated. The regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which metolachlor may be applied in a particular area.

2. *From drinking water.* Environmental fate studies indicate that metolachlor appears to be moderately persistent and ranges from being mobile to highly mobile in different soils. Data collected from around the U.S. provides evidence that metolachlor leaches into ground water, occasionally at levels that exceed the Lifetime Health Advisory (HA) level of 100 parts per billion (ppb). Metolachlor is not yet formally regulated under the Safe Drinking Water Act; therefore, no enforcement Maximum Contaminant Level (MCL) has been established for it. Metolachlor also has relatively high health advisory levels (1-10 day HA level of 2,000 ppb and lifetime HA level of 100 ppb). Based on available data, it appears highly unlikely that maximum or short-term average metolachlor concentrations will exceed the 1-10 day HA levels of 2,000 ppb, or that annual average metolachlor concentrations will exceed the lifetime HA of 100 ppb anywhere. Additionally, to mitigate risk, additional label restrictions are being required under the Reregistration process, designed to minimize ground and surface water contamination.

*Chronic exposure and risk.* Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water-related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOAEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for exposure from contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause metolachlor to exceed the RfD if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with metolachlor in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

3. *From non-dietary exposure.* Metolachlor is currently registered for use on a number of residential non-food sites including ornamental plants and grasses, highway rights of way, and recreational areas. No indoor uses are registered.

i. *Acute exposure and risk.* EPA generally will not include residential or other non-dietary exposures as a component of the acute exposure assessment. Theoretically, it is also possible that a residential, or other non-dietary, exposure could be combined with the acute total dietary exposure from food and water. However, the Agency does not believe that aggregate multiple exposure to large amounts of pesticide residues in the residential environment via multiple products and routes for a one day exposure is a reasonably probable event. It is highly unlikely that, in one day, an individual would have multiple high-end exposures to the same pesticide by treating their lawn and garden, treating their house via crack and crevice application, swimming in a pool, and be maximally exposed by the food and water consumed. Additionally, the concept of an acute exposure as a single exposure does not allow for including post-application exposures, in which residues decline over a period of days after application. Therefore, the Agency believes that residential exposures are more appropriately included in the short-term exposure scenario discussed below.

ii. *Chronic exposure and risk.* The Agency has concluded that a chronic residential exposure scenario does not exist for non-occupational uses of metolachlor.

iii. *Short- and intermediate-term exposure and risk.* There are residential uses of metolachlor and EPA acknowledges that there may be short and intermediate-term non-occupational

exposure scenarios. The EPA has identified a toxicity endpoint for intermediate-term residential risks. However, no acceptable reliable exposure data to assess the potential risks are available at this time. Based on the high level of the intermediate-term toxicity endpoint (NOAEL of 100 mg/kg/day, and LOEL of 1,000 mg/kg/day), the Agency does not expect the intermediate-term aggregate risk to exceed the level of concern. A short-term non-dietary toxicity endpoint was not identified for metolachlor.

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.''

EPA does not have, at this time, available data to determine whether metolachlor 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, metolachlor 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 metolachlor has a common mechanism of toxicity with other substances. For more information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Acute risk*. The available data for metolachlor do not indicate the potential for adverse effects from acute dietary exposures. Therefore, an acute aggregate risk assessment was not conducted.

2. *Chronic risk*. Using the conservative exposure assumptions described in this unit, EPA has concluded that aggregate exposure to metolachlor from food will utilize 1.1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants <1 year old, and children 1 to 6 years old, both at 2.3% of the RfD; this is further discussed below. 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. Despite the potential for exposure to metolachlor in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure.

Based on the low percentage of the RfD occupied by the chronic dietary exposure (<3% for all population subgroups) and the high level of the intermediate-term toxicity endpoint (NOAEL and LOEL of 100 and 1,000 mg/kg/day, respectively), in the best scientific judgment of EPA, the intermediate-term aggregate risk will not exceed the Agency's level of concern. Despite the potential for exposure to metolachlor in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD. Since a short-term toxicity endpoint was not identified for metolachlor, a short-term aggregate risk assessment was not conducted.

4. *Aggregate cancer risk for U.S. population*. Based on the CPRC recommendation that the MOE approach be used to assess cancer risk, a quantitative cancer risk assessment was not performed. Based on the aggregate chronic dietary analysis (food only), the calculated MOEs for the U.S. population and infants/children are 15,000 and 6,800, respectively. Other than dietary exposure, no chronic exposure scenarios have been identified from registered uses of metolachlor. The EPA believes that the potential additional exposure in drinking water would not significantly lower the chronic dietary MOEs. The EPA has not yet established what an adequate MOE should be for chemicals having a non-linear mechanism for carcinogenicity. At this time, and for the purpose of this action only, the Agency concludes that the MOEs given above are adequate to ensure that there is a reasonable certainty that no harm to the U.S. population or to infants and children, will result from aggregate exposure to residues of metolachlor. When the Agency reaches a conclusion on the science policy issue of adequate MOEs for non-linear carcinogens, it is possible that the risk assessment for metolachlor may need to be revised.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to metolachlor residues.

*E. 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 metolachlor, 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 during 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 margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*. In the rat developmental study, the maternal NOAEL was 300 mg/kg/day; mortality, increased salivation, lacrimation, convulsions, reduced body weight gain, and reduced food consumption were observed at the LEL of 1,000 mg/kg/day. The developmental NOAEL was also 300 mg/kg/day, with reduced mean fetal body weight, reduced number of implantations, and a slight increase in resorptions, seen at the LEL of 1,000 mg/kg/day.

In the rabbit developmental study, the maternal NOAEL was 120 mg/kg/day, with lacrimation, miosis, reduced food consumption, and decreased body weight gain seen at the LEL of 360 mg/kg/day. No developmental effects were

observed at the levels tested, and therefore the developmental NOAEL was greater than 360 mg/kg/day the highest dose tested (HDT).

iii. *Reproductive toxicity study*. In the 2-generation rat reproductive study, the reproductive/developmental toxicity NOAEL of 23 mg/kg/day was less than the parental (systemic) toxicity NOAEL of >76 mg/kg/day HDT. The reproductive/developmental NOAEL was based on decreased pup body weight during late lactation.

iv. *Pre- and post-natal sensitivity*. Based on current toxicological data requirements, the database for metolachlor relative to pre- and post-natal toxicity is complete. The developmental toxicity NOAELs of 300 mg/kg/day (in rats) and >360 mg/kg/day (HDT tested in rabbits) demonstrate that there is not increased sensitivity to metolachlor by the developing fetus (pre-natal) in the presence of maternal toxicity. There was developmental toxicity in rats at 1,000 mg/kg/day (but not in rabbits). The developmental NOAELs are more than 30- and 37-fold higher in the rats and rabbits, respectively, than the NOAEL of 9.7 mg/kg/day from the 1-year feeding study in dogs, which is the basis of the RfD.

In the 2-generation reproductive toxicity study in rats, the reproductive/developmental toxicity NOAEL of 23 mg/kg/day was less than the parental (systemic) toxicity NOAEL of >76 mg/kg/day. The reproductive/developmental NOAEL was based on decreased pup body weight during late lactation and the NOAEL occurred at a level which is below the NOAEL for parental toxicity (>76 mg/kg/day). This finding suggests that pups are more sensitive to metolachlor than adult animals. For purposes of this section 18 only, an additional 3-fold uncertainty factor was added to the RfD for infants and children.

v. *Conclusion*. The TMRC value for the most highly exposed infant and children subgroups (non-nursing infants <1 year old, and children 1 to 6 years old) occupies 6.9% of the RfD for both groups (with the additional 3-fold safety factor). This estimate should be viewed as conservative, since it is based on percent of crop treated data for selected crops and tolerance level residues for all commodities. Refinement of the dietary risk assessment by using additional percent crop treated and anticipated residue data would reduce dietary exposure estimates. Therefore, this risk assessment is an over-estimate of dietary risk.

2. *Acute risk*. The available data for metolachlor do not indicate the potential for adverse effects from acute dietary exposures. Therefore, no acute risk assessment was conducted.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to metolachlor from food ranges from 6.9% for non-nursing infants <1 year old, down to 1.8% for nursing infants <1 year old (using an additional 3 fold safety factor) of the RfD for infants and children. 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. Despite the potential for exposure to metolachlor in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. A short-term non-dietary toxicity endpoint was not identified for metolachlor. Using the conservative exposure assumptions described above, EPA has concluded that the percent of the RfD that will be utilized by aggregate exposure to residues of metolachlor is 6.9% (using an additional 3 fold safety factor) for non-nursing infants <1 year old and children 1 to 6 years old (the most highly exposed population subgroups). Based on the low percentage of the RfD occupied by the chronic dietary exposure and the high level of the intermediate-term toxicity endpoint (NOAEL = 100 mg/kg/day and LOEL = 1,000 mg/kg/day), in the best scientific judgment of EPA, the intermediate-term aggregate risk will not exceed the Agency's level of concern. Despite the potential for exposure to metolachlor in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to metolachlor residues.

## IV. Other Considerations

### *A. Metabolism In Plants and Animals*

The nature of the residue in plants and animals is adequately understood. Tolerances for residues of metolachlor in or on food/feed commodities are currently expressed in terms of the 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 (40 CFR § 180.368)

### *B. Analytical Enforcement Methodology*

Adequate methods for purposes of data collection and enforcement of tolerances for metolachlor residues are available. Methods for determining the combined residues of metolachlor and its metabolites, as the derivatives CGA-37913 and CGA-49751, are described in PAM, Vol. II, as Method I (plants; Gas Chromatograpy (GC) with Nitrogen Phosphorus Detection (NPD)) and Method II (animals; GC-Mass Spectroscopy).

### *C. Magnitude of Residues*

Residues of metolachlor are not expected to exceed 10 ppm in/on forage and 0.2 ppm in/on the hay of grass grown for seed, as a result of this section 18 use. Secondary residues in animal commodities are not expected to exceed existing tolerances as a result of this section 18 use.

### *D. International Residue Limits*

There are no established CODEX, Canadian, or Mexican residue limits for metolachlor on grass commodities.

### *E. Rotational Crop Restrictions*

Rotational crop restrictions are stated on the Dual Magnum product label.

## V. Conclusion

Therefore, the tolerance is established for combined residues of metolachlor and its metabolites, each expressed as the parent compound in tomatoes at 0.1 ppm, tomato puree at 0.3 ppm, and tomato paste at 0.6 ppm.

## VI. 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 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 May 10, 1999, 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 under the ''ADDRESSES'' section (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). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

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.

## VII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300795] (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 Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:
opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit 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 record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

## VIII. Regulatory Assessment Requirements

### *A. Certain Acts and Executive Orders*

This final rule establishes a tolerance under section 408 of the FFDCA. 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 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 tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(l)(6), such as the tolerance 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 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.

### *B. Executive Order 12875*

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of

Executive Order 12875 do not apply to this rule.

*C. Executive Order 13084*

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

### IX. 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 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 26, 1999.

**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. 321(q), 346a and 371.

2. In § 180.368, paragraph (b), by revising the following commodities in the table to read as follows:

**§ 180.368 Metolachlor.**

* * * * *

(b) * * *

| Commodity | Parts per million | Expiration/ revocation date |
|---|---|---|
| * * | * | * * |
| Tomato paste .. | 0.6 | 4/1/01 |
| Tomato puree .. | 0.3 | 4/1/01 |
| Tomatoes ..... | 0.1 | 4/1/01 |
| * * | * | * * |

* * * * *

[FR Doc. 99–5963 Filed 3–9–99; 8:45 am]

BILLING CODE 6560–50–F

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[OPP–300796; FRL–6064–1]**

**RIN 2070–AB78**

### Maleic hydrazide; Extension of Tolerances for Emergency Exemptions

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation extends time-limited tolerances for combined residues of the herbicide maleic hydrazide and its metabolites in or on rice, grain at 105 parts per million (ppm); rice, straw at 75 ppm; rice, hulls at 240 ppm; and rice, bran at 180 ppm. In addition, this rule extends time-limited tolerances for secondary residues in milk at 1.0 ppm; at 2.5 ppm in meat, 7 ppm in liver, 32 ppm in kidney, and 3 ppm in fat of cattle, goats, hogs, horses and sheep; at 0.5 ppm in meat, liver, and fat of poultry; 1.4 ppm in poultry meat byproducts; and 0.5 ppm in eggs. All of these time-limited tolerances are extended for an additional 1-year period. These tolerances will expire and are revoked on September 30, 2000. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on rice. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18.

**DATES:** This regulation becomes effective March 10, 1999. Objections and requests for hearings must be received by EPA, on or before May 10, 1999.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number [OPP–300796], 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–300796], 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, Crystal Mall 2 (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@epa.gov. Copies of electronic 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 or ASCII file format. All copies of