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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300504; FRL–5722–5]

RIN 2070–AB78

Metolachlor; Pesticide Tolerances for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues 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, in or on the raw agricultural commodity tomato, in tomato puree, and in tomato paste, in connection with EPA's granting an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on tomato in Ohio, Indiana, Michigan and Pennsylvania. The tolerances will expire and are revoked on December 31, 1998.

DATES: This regulation becomes effective June 18, 1997. Objections and requests for hearings must be received by EPA on or before August 18, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300504], 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–300504], must be submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), 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. 1132, 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 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–300504]. 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: Olga Odiott, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail: Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. (703) 308-9363, e-mail: odiott.olga@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for residues of the herbicide [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), also referred to in this document as metolachlor, in or on tomato 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 be revoked by EPA on December 31, 1998. After December 31, 1998, EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170) was signed into law August 3, 1996. FQPA amends both the FFDCA, 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under section 408 with a new safety standard and new procedures. These activities are described below 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 tolerance 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 Tomato and FFDCA Tolerances

The 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 the eastern black nightshade. Chloramben (amiben) is the most effective herbicide for this weed, but it 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 Applicants stated that since this weed 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 states. EPA has authorized under FIFRA section 18 the use of metolachlor on tomato for control of Eastern black nightshade. After having reviewed the submissions, EPA concurs that emergency conditions exist for these states.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of metolachlor in or on tomatoes. In doing so, EPA considered the new 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 new safety standard and with FIFRA section 18. These tolerances will permit the marketing of tomatoes treated in accordance with the provisions of the section 18 emergency exemption. 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 December 31, 1998, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on tomatoes after that date will not be unlawful, provided the pesticide is applied during the term of, and in accordance with all the conditions of, section 18 of FIFRA. 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.

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. These tolerances do not 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 Ohio, Indiana, Michigan and Pennsylvania, to use this pesticide on this crop under section 18 of FIFRA without following all provisions of 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 above.

III. Risk Assessment and Statutory Findings

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. For many of these 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.

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. 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.

IV. 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.

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 below.

1. *Acute toxicity.* The EPA has determined that the available data do not indicate the potential for adverse effects after a single dietary exposure.

2. *Short- and intermediate term toxicity.* The EPA has determined that a NOEL of 100 mg/kg/day from a 21-day dermal toxicity study on rats should be used to assess risks from intermediate-term dermal exposures. 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 risk.* Based on the available chronic toxicity data, the EPA has established the RfD for metolachlor at 0.10 mg/kg/day. The RfD was established based on the results of a 1-year feeding study in dogs with a NOEL of 9.7 mg/kg/day, and an uncertainty factor of 100 based on decreased body weight gain at the LEL of 33 mg/kg/day.

4. *Cancer risk.* Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), the EPA has classified metolachlor as a Group C, ''possible human carcinogen'', chemical. The classification as a Group C chemical was based on the increased incidence of adenomas and combined adenomas/carcinomas in female rats, both by pair-wise and trend analysis and the replication of this finding in a second study. The OPP Carcinogenicity Peer Review Committee (CPRC) recommended the quantitation of risk by MOE estimates using a NOEL of 15.7 mg/kg/day from a 2-year feeding study in rats. The structural relationship of metolachlor to acetochlor and alachlor was of concern to the 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 MOE approach.

B. Exposures and Risks

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.368) for the combined residues of 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 in or on a variety of raw agricultural commodities at levels ranging from 0.02 ppm in milk and numerous 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 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. The available data for metolachlor do not indicate the potential for adverse effects after a single dietary exposure.

ii. *Chronic risk.* For the chronic dietary (food only) risk assessment OPP used percent crop-treated data for selected commodities and assumed tolerance level residues. OPP also assumed that 100% of tomatoes were treated. The population subgroups with the largest percentage of the RfD occupied are non-nursing infants less than 1 year old and children 1 to 6 years old, both at 2.3% of the RfD. This risk estimate should be viewed as conservative; further refinement using anticipated residue levels and additional percent crop-treated values analysis would result in lower dietary exposure estimates. Thus, in making a safety determination for these tolerances, EPA is taking into account this conservative exposure assessment.

iii. *Cancer risk.* Based on the OPP CPRC recommendation that the MOE approach be used to assess cancer risk, a quantitative cancer risk assessment was not performed. Human health risk concerns due to long term exposure to metolachlor residues are adequately addressed by the aggregate chronic exposure analysis using the MOE approach.

2. *From drinking water.* Based on the available environmental fate studies, metolachlor appears to be moderately persistent and ranges from being mobile to highly mobile in different soils. Data collected from around the United States provides evidence that metolachlor leaches into ground water, occasionally at levels that exceed the Lifetime Health Advisory (HA) Level of 100 ppb. The ''Pesticides in Groundwater Database'' (EPA 734-12-92-001, Sept. 1992), indicates that metolachlor residues were detected in wells in 20 states. Levels exceeded the lifetime HA in three wells located in Wisconsin, New York, and Montana. In eight other states concentrations in some well waters exceeded 10% of the HA. Incident reports submitted under 6(a)2 of FIFRA describe 47 detections of metolachlor in the ground water of seven states at concentrations ranging from 0.11 ppb to 116 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. As part of the risk mitigation in the metolachlor Reregistration Eligibility Document (RED), additional label restrictions designed to minimize ground and surface water contamination are required. Groundwater concerns may be mitigated by adhering to these label restrictions and advisory statements.

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 NOEL'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 tolerances are granted.

3. *From non-dietary exposure.* Metolachlor is registered for outdoor residential lawn use, use on numerous ornamental plants and trees, highway rights-of-way and recreational areas.

i. *Acute risk.* EPA generally will not include residential or other non-dietary exposure 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 aggregating 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 in 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 risk.* The Agency has concluded that a chronic residential exposure scenario does not exit for non-occupational uses of metolachlor.

iii. *Short- and intermediate-term risk.* There are residential uses of metolachlor and EPA acknowledges that there may be shortand 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 (NOEL = 100 mg/kg/day and lowest observed effect level (LOEL) = 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.

C. 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 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.

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. An acute aggregate risk assessment was not conducted.

2. *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 (NOEL = 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.

Since a short-term toxicity endpoint was not identified for metolachlor, a short-term aggregate risk assessment was not conducted.

3. *Chronic risk.* Using the conservative exposure assumptions described above, taking into account the completeness and reliability of the toxicity data, EPA has concluded that aggregate dietary exposure to metolachlor from food will utilize 1.1% of the RfD for the U.S. population. 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, 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 metolachlor residues.

4. *Cancer risk.* 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, the calculated MOE (food only) for the U.S. Population (48 States) is > 20,000. Other than dietary exposure, no chronic exposure scenarios have been identified from registered uses of metolachlor. The chronic dietary risk from the currently registered, and this proposed Section 18 use of metolachlor, do not exceed the Agency's level of concern. The EPA believes that the potential additional exposure in drinking water would not significantly lower the chronic dietary MOE. The Agency concluded that the human health risk concerns due to long-term exposure to metolachlor residues are adequately addressed by the aggregate chronic exposure analysis using the MOE approach.

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

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. 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.

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 two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

1. *Developmental toxicity studies.*—i. *Rat.* The maternal NOEL was 300 mg/kg/day. At the maternal LEL of 1,000 mg/kg/day, there were deaths, increased salivation, lacrimation, convulsions, reduced body weight gain, and reduced feed consumption. The developmental NOEL was also 300 mg/kg/day. The developmental LEL of 1,000 mg/kg/day was based on reduced mean fetal body weight, reduced number of implantations/dam with resulting decreased litter size, and a slight increase in resorptions/dam with resulting increase in post-implantation loss.

ii. *Rabbit.* The maternal NOEL was 120 mg/kg/day. The maternal LEL of 360 mg/kg/day was based on lacrimation, miosis, reduced food consumption and decreased body weight gain. The developmental NOEL was ≥360 mg/kg/day at the highest dose tested (HDT).*

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

3. *Pre- and post-natal sensitivity.* Based on current toxicological data requirements, the data base for metolachlor relative to pre- and post-natal toxicity is complete. The developmental toxicity NOELs of 300 mg/kg/day (in rats) and ≥360 mg/kg/day (HDT in rabbits) demonstrate that there is no 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 NOELs are more than 30- and 37-fold higher in the rats and rabbits, respectively, than the NOEL of 9.7 mg/kg/day from the 1-year feeding study in dogs, which is the basis of the RfD.

In the two-generation reproductive toxicity study in rats, the reproductive/developmental toxicity NOEL of 23 mg/kg/day was less than the parental (systemic) toxicity NOEL of >76 mg/kg/day. The reproductive/developmental NOEL was based on decreased pup body weight during late lactation and the NOEL occurred at a level which is below the NOEL 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 3x uncertainty factor was added to the RfD.

The TMRC value for the most highly exposed infant and children subgroup (non-nursing infants <1 year old) occupies 6.9% of the RfD (with the additional 3x safety factor). This estimate should be viewed as conservative, since is based on percent 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. Therefore, this risk assessment is an over-estimate of dietary risk.

4. *Acute risk.* The available data for metolachlor do not indicate the potential for adverse effects from acute dietary exposures.

5. *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. 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 3x safety factor) for non-nursing infants less than 1 year old (the most highly exposed population subgroup). Based on the low percentage of the RfD occupied by the chronic dietary exposure and the high level of the intermediate-term toxicity endpoint (NOEL = 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.

6. *Chronic risk.* 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 ranges from 6.9 % for non-nursing infants less than one year old, down to 1.8 % for nursing infants less than one year old (using an additional 3x safety factor). 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. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to metolachlor residues.

V. 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).

2. *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; GC-NPD) and Method II (animals; GC-MS).

3. *Magnitude of residues.* Regulable residues of metolachlor are not expected to exceed 0.1 ppm in/on tomatoes as a result of this Section 18 use. A time-limited tolerance should be established at this level. Residues of metolachlor appear to concentrate in the tomato processed commodities of tomato puree (3x) and paste (6x). Regulable residues of metolachlor are not expected to exceed 0.3 ppm in tomato puree and 0.6 ppm in tomato paste a result of this Section 18 use. Time-limited tolerances should be established at these levels. Secondary residues are not expected in animal commodities as no feed items are associated with this Section 18 use.

4. *International residue limits.* There are no CODEX or Mexican residue limits for metolachlor on tomatoes. There is a Canadian residue limit of 0.1 ppm for the parent compound.

5. *Rotational crop restrictions.* Rotational crop restrictions are stated on the DUAL and DUAL 8E product labels.

VI. Conclusion

Therefore, tolerances in connection with the FIFRA section 18 emergency exemptions are established for residues of the herbicide [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) also referred to in this document as metolachlor, in or on tomato at 0.1 part per million (ppm), in tomato puree at 0.3 ppm and in tomato paste at 0.6 ppm.

VII. 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 August 18, 1997, file written objections to any aspect of this regulation (including the revocation provision) 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 Confidential Business Information (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.

VIII. Public Docket

A record has been established for this rulemaking under docket control number [OPP–300504]. A public version of this record, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

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 address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

This final rule establishes a time-limited tolerance under section 408 of the FFDCA and is related to EPA's granting emergency exemptions under section 18 of the FIFRA. 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). In addition, this final rule does not contain any information collections subject to additional 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, because these tolerances are established without notice and comment rulemaking, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nonetheless, 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 significant adverse economic impact associated with these actions (46 FR 24950, May 4, 1981). In accordance with Small Business Administration (SBA) policy, this determination will be provided to the Chief Counsel for Advocacy of the SBA upon request.

X. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted 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 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: June 5, 1997.

James Jones,

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 180.368 is amended as follows:

i. In paragraph (a) by adding the heading.

ii. In paragraph (b) by transferring and alphabetically adding the entries in the table to the table in paragraph (a) and by removing the remaining text.

iii. In paragraph (c) by adding the heading.

iv. By adding a heading and reserving new paragraph (d).

v. By redesignating paragraph (e) as paragraph (b) and revising newly redesignated paragraph (b).

§ 180.368 Metolachlor; tolerances for residues.

(a) *General.* * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for 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 in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerance is specified in the following table. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/ Revocation Date
Spinach	0.3	11/15/98
Tomato paste	0.6	12/31/98
Tomato puree	0.3	12/31/98
Tomatoes	0.1	12/31/98

(c) *Tolerances with regional registrations.** * *

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

[FR Doc. 97–15981 Filed 6–17–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300486B; FRL–5724–9]

RIN 2070–AB78

Bromoxynil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes the following time-limited tolerances, to expire on January 1, 1998, for the residues of the herbicide bromoxynil (3,5-dibromo-4-hydroxybenzonitrile) and its metabolite DBHA (3,5-dibromo-4-hydroxybenzoic acid) resulting from the application of octanoic and heptanoic acid esters of bromoxynil to cotton: undelinted cottonseed at 7 parts per million (ppm), cotton gin byproducts at 50 ppm, and cotton hulls at 21 ppm. (Active ingredient codes are 35302 for the octanoic acid ester, and 128920 for the heptanoic acid ester. CAS Reg. Nos. are 1689–99–2 for the octanoic acid ester, and 56634–95–8 for the heptanoic acid ester.) In addition, this document revises tolerances for the residues of bromoxynil, resulting from the application of octanoic and heptanoic acid esters of bromoxynil to cotton, in or on cattle, hogs, horses, goats, and sheep to 0.5 ppm in meat, 3.0 ppm in meat by-products, and 1.0 ppm in fat. Further, this document establishes tolerances for residues of bromoxynil, resulting from the application of octanoic and heptanoic acid esters of bromoxynil to cotton, at 0.1 ppm in milk; at 0.05 ppm in eggs; and at 0.05 ppm in poultry meat, meat by-products, and fat. The tolerances for the cotton commodities will expire and are revoked on January 1, 1998. After January 1, 1998, EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations. Rhone-Poulenc AG Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act as amended by the Food Quality Protection Act of 1996 requesting a tolerance on cottonseed.

EFFECTIVE DATE: This rule becomes effective June 18, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300486B], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the docket control number and submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), 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. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 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 in 5.1 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–300486B]. 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.

Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Jim Tompkins, Product Manager (PM) 25, 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. 241, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–6027, e-mail: tompkins.jim@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 24, 1995 (60 FR 27414), EPA established a time-limited tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, for residues of the herbicide bromoxynil, (3,5-dibromo-4-hydroxybenzonitrile) on cottonseed. This tolerance expired on April 1, 1997. The tolerance was established in response to a petition filed by the Rhone-Poulenc AG Company, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709.

In the **Federal Register** of December 24, 1996 (61 FR 67807) (FRL–5576–8), EPA issued a notice of filing that stated that the Rhone-Poulenc AG Company had submitted a pesticide petition to EPA proposing to extend the time-limited tolerance on cottonseed. Comments in response to the notice of filing were received from the Union of Concerned Scientists, the Pesticide Action Network, the Edmonds Institute, Friends of the Earth, the Environmental Defense Fund, and many individuals.

In the **Federal Register** of May 2, 1997 (62 FR 24065) (FRL–5617–5), EPA issued a proposed rule for establishment of tolerances on cotton commodities and poultry, and revision of tolerances on animal commodities. The Agency issued this proposed rule because, after review of the petition, the Agency determined that as a result of bromoxynil use on cotton: (1) A higher tolerance will be needed for cottonseed; (2) existing tolerances for bromoxynil on animal commodities (meat, meat byproducts, and fat) need to be raised; and (3) additional tolerances will be needed for other cotton commodities (undelinted cottonseed and cotton gin byproducts) and other animal commodities (poultry meat, meat by-products, fat; eggs; and milk).

Written comments on the proposed rule were to be received within 17 days of issuance of the **Federal Register** notice. Under section 408 of the FFDCA, the Agency is required to provide a 60–day comment period on proposed rules unless EPA finds for good cause that it would be in the public interest to provide a shorter period. The Agency shortened the comment period on the bromoxynil tolerances to 17 days because notice had been provided on the intention of establishing a tolerance permitting use of bromoxynil on cotton, and cotton growers faced a potential hardship if a decision was not made expeditiously.

Following publication of the May 2 proposed rule, several environmental and public interest groups requested that EPA extend this comment period from 17 to 60 days. In their request for an extension, these groups cited a number of health issues and questions regarding interpretation of the FFDCA safety standard. EPA was not convinced that the comment period was inadequate to address the issues raised by these groups. Nonetheless, in a