for a 30-day period before the amendment becomes effective and therefore, the amendment will be immediately effective.

On August 24, 1994, Idaho adopted revisions to its surface water quality standards (Title 1, Chapter 2, section 250 of the Idaho Administrative Code), regarding human health criteria. For all toxic pollutants except arsenic, Idaho adopted by reference EPA's human health criteria. The Office of Water for EPA Region 10 approved the State's human health criteria because they are identical to the federal criteria, and requested that the Agency withdraw the federal criteria applicable to Idaho for which the State now has identical numeric criteria. In a separate action in this issue of the Federal Register, EPA is proposing to withdraw the federal criteria for arsenic applicable to Idaho.

This withdrawal of human health criteria imposes no additional regulatory requirements. Therefore, it has been determined that this rule is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is not subject to OMB review.

Similarly, this action will not result in the annual expenditure of $100 million or more for State, local, and tribal governments, in the aggregate, or to the private sector, and is not a Federal mandate, as defined by the Unfunded Mandates Reform Act of 1995 (UMRA) (P.L. 104–4), nor does it uniquely affect small governments in any way. As such, the requirements of sections 202, 203 and 205 of Title II of the UMRA do not apply to this action.

The Agency has determined that the rule being issued today is not subject to the Regulatory Flexibility Act (RFA), 5 U.S.C. 601, *et seq.*, which generally requires an agency to conduct a regulatory flexibility analysis unless it certifies that the rule will not have a significant economic impact on a substantial number of small entities. By its terms, the RFA applies only to rules subject to notice-and-comment rulemaking requirements under the Administrative Procedures Act (APA) or any other statute.

Today's rule is not subject to notice and comment requirements under the APA or any other statute. As explained in more detail above, EPA is withdrawing its water quality criteria for all toxic pollutants except arsenic for the State of Idaho because the State has adopted its own criteria that are identical to EPA's. In these circumstances, any additional comment on EPA's action in this rulemaking is unnecessary. Consequently, the notice and public procedures provisions of the APA do not apply. 5 U.S.C. 553(b)

Even if the Agency were required to perform a regulatory flexibility analysis, today's rule would not have a significant economic impact on small entities. Any economic impact on small entities is unchanged by today's action because the Idaho criteria are identical to the EPA criteria being withdrawn.

This final rule does not impose any requirement subject to the Paperwork Reduction Act.

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, EPA submitted 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 General Accounting Office prior to publication of the rule in today's Federal Register. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR 131

Environmental protection, Water pollution control, Water Quality Standards.

Dated: November 21, 1996.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble title 40, chapter I, part 131 of the Code of Federal Regulations is amended as follows:

PART 131—WATER QUALITY STANDARDS

1. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 et seq.

§ 131.36—[Amended]

2. Section 131.36(d)(13)(ii) is amended in ''01.b'' use classification, under the listing of applicable criteria, by replacing ''all except #14 and 115'' with ''#2'' for Column D1.

3. Section 131.36(d)(13)(ii) is amended in ''02.a,'' ''02.b,'' and ''02.cc'' use classification, under the listing of applicable criteria, by replacing ''all'' with ''#2'' after ''Column D2''.

4. Section 131.36(d)(13)(ii) is amended in ''03.a'' use classification, under the listing of applicable criteria, by replacing ''all'' with ''#2'' after ''Column D2''.

5. Section 131.36(d)(13)(ii) is amended in ''03.b'' use classification, under the listing of applicable criteria, by replacing ''all'' with ''#2'' after ''Column D2''.

[FR Doc. 96–30310 Filed 11–27–96; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 180

[OPP–300443; FRL–5574–7]

RIN 2070–AB78

Metolachlor Pesticide Tolerance; Emergency Exemption For Use on Spinach

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of the herbicide metolachlor in or on the raw agricultural commodity spinach in connection with EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of metolachlor on spinach in Arkansas, Oklahoma, Texas and Virginia. This regulation establishes a maximum permissible level for residues of metolachlor in this food pursuant to section 408(l)(6) of the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. This tolerance will expire and be revoked automatically without further action by EPA on November 15, 1998.

DATES: This regulation becomes effective November 29, 1996. This regulation expires and is revoked automatically without further action by EPA on November 15, 1998. Objections and requests for hearings must be received by EPA on January 28, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket number, [OPP–300443], 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, Office of Pesticide Programs (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 number, [OPP–300443], should 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 number [OPP–300443]. 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: Margarita Collantes, Registration Division (7505W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA 22202, (703) 308–8347, e-mail: collantes.margarita@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 a tolerance for residues of the herbicide metolachlor, 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-(2-methoxy-1-methylethyl)acetamide in or on spinach at 0.3 part per million (ppm). This tolerance will expire and be revoked automatically without further action by EPA on November 15, 1998.

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 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 were discussed in detail in the final rule establishing a tolerance for an emergency exemption for use of propiconazole on sorghum (61 FR 58135, Nov. 13, 1996).

New section 408(b)(2)(A)(i) 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, 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) 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. Section 408(l)(6) also requires EPA to promulgate regulations by August 3, 1997, governing the establishment of tolerances and exemptions under section 408(l)(6) and requires that the regulations be consistent with section 408(b)(2) and (c)(2) and FIFRA section 18.

Section 408(l)(6) allows EPA to establish tolerances or exemptions from the requirement for a tolerance, in connection with EPA's granting of FIFRA section 18 emergency exemptions, without providing notice or a period for public comment. Thus, consistent with the need to act expeditiously on requests for emergency exemptions under FIFRA, EPA can establish such tolerances or exemptions under the authority of section 408(e) and (l)(6) without notice and comment rulemaking.

In establishing section 18-related tolerances and exemptions during this interim period before EPA issues the section 408(l)(6) procedural regulation and before EPA makes its broad policy decisions concerning the interpretation and implementation of the new section 408, EPA does not intend to set precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Rather, these early section 18 tolerance and exemption decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further rulemaking and policy development. EPA intends to act on section 18-related tolerances and exemptions that clearly qualify under the new law.

II. Emergency Exemptions for Metolachlor on Spinach and FFDCA Tolerances

On September 13, 1996, the Texas Department of Agriculture availed itself of the authority to declare the existence of a crisis situation within the State, thereby authorizing use under FIFRA section 18 of metolachlor on spinach for control of various weeds. The States of Arkansas, Oklahoma, and Virginia have also requested specific exemptions for use of metolachlor on spinach in those States to control various weeds. Emergency conditions are determined to exist due to the loss of Antor 4E, diethatyl ethyl, a herbicide used on spinach. NOR-AM Chemical Company no longer manufactures Antor and stocks were exhausted from 1993 production. Furthermore, at the present there is no preemergence herbicide registered to control annual weeds in spinach. Roneet E6 is the only herbicide registered for use on spinach at planting; however, it has proven ineffective as a preemergence control for weeds.

As part of its assessment of these applications for crisis declaration and emergency exemptions, EPA assessed the potential risks presented by residues of metolachlor on spinach. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided to grant the section 18 exemptions only after concluding that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. This tolerance for metolachlor will permit the marketing of spinach treated in accordance with the provisions of the section 18 emergency exemptions. Consistent with the need to move quickly on the emergency exemptions and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e) as provided in section 408(l)(6). Although this tolerance will expire and be

revoked automatically without further action by EPA on November 5, 1998, under FFDCA section 408(l)(5), residues of metolachlor not in excess of the amount specified in the tolerance remaining in or on spinach after that date will not be unlawful, provided the pesticide is applied during the term of, and in accordance with all the conditions of, the emergency exemptions. EPA will take action to revoke this tolerance 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 the requirements for registration under FIFRA section 3 for use on spinach or whether a permanent tolerance for metolachlor for spinach would be appropriate. This action by EPA does not serve as a basis for registration of metolachlor by a State for special local needs under FIFRA section 24(c). Nor does this action serve as the basis for any States other than those listed above to use this product on spinach 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 exemptions 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 percent or less of the RfD) is generally considered acceptable by EPA.

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 margin of exposure (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, and other non-occupational exposures, such as where residues leach into groundwater or surface water that is consumed as drinking water. 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 percent 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.

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. Metolachlor is already registered by EPA for numerous food and feed uses, as well as use on outdoor residential lawn, numerous ornamental plants and trees, highway rights-of-way and recreational area use. EPA has also assessed the toxicology data base for metolachlor in its evaluation of applications for registration on spinach. Thus, 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 the time-limited tolerances for residues of metolachlor on spinach at 0.3 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

1. *Chronic toxicity.* Based on the available chronic toxicity data, the Office of Pesticide Programs (OPP) has established the RfD for metolachlor at 0.10 milligrams(mg)/kilogram(kg)/day. The RfD for metolachlor is based on a 1–year feeding study in dogs with a NOEL of 9.7 mg/kg/day and an uncertainty factor of 100. Decreased body weight gain was the effect observed at the Lowest Effect Level (LEL) of 33 mg/kg/day.

2. *Acute toxicity.* OPP has determined that data do not indicate the potential for adverse effects after a single dietary exposure.

3. *Short-term toxicity.* OPP has determined that an intermediate term risk assessment is appropriate for occupational and residential routes of exposure. OPP recommends that the NOEL of 100 mg/kg/day, taken from the 21–day dermal toxicity study, be used for these MOE calculations. Effects observed at the lowest observed effect level (LOEL) of 1,000 mg/kg/day are dose-related increases in minor histopathological alterations of the skin, total bilirubin (females), absolute and relative liver weights (males), and relative kidney weights (females). However, no acceptable reliable dermal exposure data to assess these potential risks are available at this time. OPP did

not identify an inhalation exposure intermediate-term hazard.

4. *Carcinogenicity*. Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), the Carcinogenicity Peer Review Committee (CPRC) has classified metolachlor as a Group C chemical, possible human carcinogen, based on (a) 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, (b) negative mutagenicity studies, and (c) comparative metabolism studies indicating that metolachlor has a different metabolic profile than acetochlor and alachlor with regard to the quinone imine metabolite. Based on these findings, the CPRC recommended that the NOEL of 15.7 mg/kg/day, from the 2–year feeding study [MRID#: 00129377] in rat, and the MOE approach be used for quantification of risk.

B. Aggregate Exposure

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(a), (b), and (c)).

For the purpose of assessing chronic dietary exposure from metolachlor, EPA assumed tolerance level residues and percent of crop treated refinements to estimate the Anticipated Residue Contribution (ARC) from the proposed and existing food uses of metolachlor. The use of percent of crop treated data for most of the existing food uses in this analysis results in a more refined estimate of exposure than the TMRC.

Other potential sources of exposure of the general population to residues of pesticides are residues in drinking water and exposure from non-occupational sources. Based on the available studies used in EPA's assessment of environmental risk, 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 parts per billion (ppb). The ''Pesticides In Groundwater Database'' (EPA 734–122–92–001, 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 percent of the HA. Incident reports submitted under 6(a)(2) of FIFRA describe 47 detections of metolachlor in the groundwater of 7 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 Concentration Level (MCL) has been established for it. Metolachlor also has relatively high health advisory levels (1 to 10 day HA level of 2,000 ppb and lifetime HA level of 100 ppb).

Although residue levels of metolachlor exceeding the lifetime HA of 100 ppb have been measured, the 1 to 10 day HA level of 2,000 is not exceeded in any well measured and residues over time in these wells are highly unlikely to exceed the lifetime HA of 100 ppb anywhere. As part of the risk mitigation in the metolachlor Registration 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.

Previous experience with persistent and mobile pesticides for which there have been available data to perform quantitative risk assessments have demonstrated that drinking water exposure is typically a small percentage of the total exposure when compared to the total dietary exposure. This observation holds even for pesticides detected in wells and drinking water at levels nearing or exceeding established MCLs. Based on this experience and OPP's best scientific judgement, and considering the low percent of the RfD occupied by dietary exposure estimates including spinach (0.6 percent RfD for U.S. population), EPA does not anticipate that combined exposure from drinking water and dietary exposure would result in an ARC that exceeds 100 percent of the RfD. Therefore, the EPA concludes that potential metolachlor residues in drinking water are not likely to pose a human health concern.

There are residential uses of metolachlor and EPA acknowledges that there may be short-, intermediate-, and long-term non-occupational exposure scenarios. OPP has identified a toxicity endpoint for an intermediate-term residential risk assessment. However, no acceptable reliable exposure data to assess these potential risks are available at this time. Given the time-limited nature of this request, the need to make emergency exemption decisions quickly, and the significant scientific uncertainty at this time about how to aggregate non-occupational exposure with dietary exposure, the Agency will make its safety determination for this tolerance based on those factors which it can reasonably integrate into a risk assessment.

At this time, the Agency has not made a determination that metolachlor and other substances that may have a common mode of toxicity would have cumulative effects. Given the time limited nature of this request, the need to make emergency exemption decisions quickly, and the significant scientific uncertainty at this time about how to define common mode of toxicity, the Agency will make its safety determination for this tolerance based on those factors which it can reasonably integrate into a risk assessment. For purposes of this tolerance only, the Agency is considering only the potential risks of metolachlor in its aggregate exposure.

C. Safety Determinations For U.S. Population

Based on the completeness and reliability of the toxicity and consumption data, EPA has concluded that dietary exposure to metolachlor will utilize 0.6 percent of the RfD for the U.S. population. As mentioned before, EPA does not expect that chronic exposure from drinking water would result in an aggregate exposure which would exceed 100 percent of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to metolachlor residues.

As discussed earlier, quantitation of cancer risk using the MOE approach was recommended by the CPRC using the NOEL of 15.7 mg/kg/day from the 2–year feeding study in rats. However, as noted in the metolachlor RED, because the RfD is set on a NOEL of 9.7 mg/kg/day from the 1 year feeding study in dogs, dietary cancer concerns are adequately addressed by the chronic exposure analysis using the RfD.

D. Determination of Safety for Infants and Children.

In assessing the potential for additional sensitivity of infants and children to residues of metolachlor, EPA considered pre- and post-natal toxicity data. EPA notes that the developmental toxicity NOELs of 300 mg/kg/day (in rats) and greater than or equal to 360 mg/kg/day (HDT in rabbits) demonstrate

that there is no developmental (prenatal) toxicity present for metolachlor in the absence of maternal toxicity. EPA notes that 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 2–generation reproductive toxicity study in the rat, the reproductive/developmental toxicity NOEL of 15 mg/kg/day was less than the parental (systemic) toxicity NOEL of greater than 50 mg/kg/day. The reproductive/developmental NOEL was based on decreased pup body weight during late lactation. The NOEL for post-natal pup effects occurred at a level which is below the NOEL for maternal toxicity. This finding suggests that post-natal development in pups is more sensitive and that infants and children may have a greater sensitivity to metolachlor than adult animals. EPA notes that the NOELs are 1.5–fold (reproductive) and greater than 5–fold higher (parental) than the NOEL of 9.7 mg/kg/day from the 1–year feeding study in dogs, which is the basis of the RfD. The reproductive/developmental LEL of 50 mg/kg/day was based on reduced pup body weight at postnatal days 14 and 21 for the first generation (F1 pups) and at post natal days 4, 14, and 21 for the second generation (F2 pups). Because the second generation (F2) pups are in the offspring of adults that have been exposed throughout their lifetime, including *in utero* exposure, there is the possibility that body weight decreases observed in these second generation offspring are an indication of increased susceptibility.

EPA has concluded that the percent of the RfD that will be utilized by chronic dietary exposure to residues of metolachlor ranges from 1.0 percent for children 7 to 12 years old, up to 2.1 percent for non-nursing infants (<1 year old). However, this calculation assumes tolerance level residues for all commodities and is therefore an over-estimate of dietary risk. Refinement of the dietary risk assessment by using anticipated residue data would reduce dietary exposure. As mentioned before, the addition of potential exposure from metolachlor residues in drinking water is not expected to result in an exposure which would exceed the RfD. EPA therefore concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to metolachlor.

As mentioned above, dietary cancer concerns for infants and children are adequately addressed by the chronic exposure analysis using the RfD.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the data base. Should an additional uncertainty factor be deemed appropriate, when considered in conjunction with a refine exposure estimate, it is unlikely that the dietary risk will exceed 100 percent of the RfD. Therefore, EPA concludes that this tolerance will not pose an unacceptable risk to infants and children.

V. Other Considerations

The metabolism of metolachlor in plants and animals is adequately understood for the purposes of this tolerance. There are no Codex maximum residue levels established for residues of metolachlor on spinach. Adequate methods for purposes of data collection and enforcement of tolerance 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).

VI. Conclusion

Therefore, a tolerance in connection with the FIFRA section 18 emergency exemptions is established for residues of metolachlor in spinach at 0.3 ppm. This tolerance will expire and be automatically revoked without further action by EPA on November 15, 1997.

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 January 28, 2996 file written objections to any aspect of this regulation (including the automatic 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 number [OPP–300443]. 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, is kept in paper form. Accordingly, in the event there are objections and hearing

requests, 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. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and, since this action does not impose any information collection requirements as defined by the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Under 5 U.S.C. 801(a)(1)(A) of the Administrative Procedure Act (APA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104–121, 110 Stat. 847), EPA submitted 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 General Accounting Office prior to publication of the rule in today's Federal Register. This rule is a ''major rule'' as defined by 5 U.S.C. 804(2) of the APA as amended.

Because FFDCA section 408(l)(6) permits establishment of this regulation without a notice of proposed rulemaking, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act, 5 U.S.C. 604(a), do not apply.

List of Subjects in 40 CFR Part 180

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

Dated: November 20, 1996.

Daniel M. Barolo,

Director, 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. In § 180.368, by adding and reserving paragraph (d) and adding a new paragraph (e) to read as follows:

§ 180.368 Metolachlor; tolerances for residues

* * * * *

(d) [Reserved]

(e) A time-limited tolerance is 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 tolerance expires and is automatically revoked on the date specified in the table without further action by EPA.

Commodity	Parts per million	Expiration/Revocation Date
Spinach	0.3	November 15, 1998

[FR Doc. 96–30468 Filed 11–27–96; 8:45 am]
BILLING CODE 6560–50–F

40 CFR Part 180

[OPP–300445; FRL–5575–1]

RIN 2070–AB78

Imidacloprid Pesticide Tolerance; Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of the insecticide imidacloprid in or on the raw agricultural commodity garden beets roots and tops and turnip roots and greens in connection with EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of imidacloprid on garden beet roots and tops and turnip roots and greens in California. This regulation establishes maximum permissible levels for residues of imidacloprid on turnips and beets 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 be revoked automatically without further action by EPA on November 29, 1997.

DATES: This regulation becomes effective November 29, 1996. This regulation expires and is revoked automatically without further action by EPA on November 29, 1997. Objections and requests for hearings must be received by EPA on January 28, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300445], 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 number, [OPP–300445], should 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