

shoreline to shoreline, bounded on the west by a line running north to south from points along the shoreline at 38°52'50" N/077°03'25" W, thence to 38°52'49" N/077°03'25" W; and bounded on the east by a line running northwest to southeast from points along the shoreline at 38°52'34" N/077°02'48" W, thence to 38°52'32" N/077°02'46" W (Datum NAD 1983).

(c) *Regulations.* (1) The general regulations governing security zones found in § 165.33 of this part apply to the security zone described in paragraph (b) of this section.

(2) Entry into or remaining in this zone is prohibited unless authorized by the Captain of the Port Baltimore or his designated representative. Except for public vessels and vessels at berth, mooring or at anchor, all vessels in this zone are to depart the security zone.

(3) Persons desiring to transit the area of the security zone must first obtain authorization from the Captain of the Port Baltimore. To seek permission to transit the area, the Captain of the Port Baltimore can be contacted at telephone number (410) 576-2693. The Coast Guard vessels enforcing this section can be contacted on Marine Band Radio, VHF-FM channel 16 (156.8 MHz). Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port Baltimore and proceed at the minimum speed necessary to maintain a safe course while within the zone.

(d) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the zone by Federal, State, and local agencies.

(e) *Enforcement period.* This section will be enforced from 6 a.m. through 11 a.m. on September 11, 2008.

Dated: August 28, 2008.

Brian D. Kelley,

Captain, U.S. Coast Guard, Captain of the Port, Baltimore, Maryland.

[FR Doc. E8-20659 Filed 9-4-08; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2008-0491; FRL-8379-6]

Linuron; Pesticide Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of linuron and its metabolites in or on lentils. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on lentils. This regulation establishes a maximum permissible level for residues of linuron in the food commodity, lentils. The time-limited tolerance expires and is revoked on December 31, 2011.

DATES: This regulation is effective September 5, 2008. Objections and requests for hearings must be received on or before November 4, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION.**

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2008-0491. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the www.regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in www.regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT:

Andrea Conrath, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number:

(703) 308-9356; e-mail address: conrath.andrea@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at <http://www.gpoaccess.gov/ecfr>.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must

identify docket ID number EPA-HQ-OPP-2008-0491 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 4, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2008-0491, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of FFDCA, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing a time-limited tolerance for combined residues of the herbicide linuron, (3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea) and its metabolites convertible to 3,4-dichloroaniline, calculated as linuron, in or on lentils at 0.1 parts per million (ppm). This time-limited tolerance expires and is revoked on December 31, 2011. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the CFR.

Section 408(l)(6) of 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. EPA does not intend for its

actions on section 18 related time-limited tolerances to set binding precedents for the application of section 408 of FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of 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) of FFDCA 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) of FFDCA 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." EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemptions for Linuron on Lentils and FFDCA Tolerance

The applicants from Idaho and Washington petitioned for an emergency exemption, stating that the development of herbicide-resistant biotypes of prickly lettuce and mayweed chamomile has led to an emergency situation. After having reviewed the submissions, EPA determined that emergency conditions exist for these States, and that the criteria for an emergency exemption are met. EPA has authorized under FIFRA section 18 the use of linuron on lentils for control of mayweed chamomile and prickly lettuce in Idaho and Washington.

As part of its evaluation of the emergency exemption applications, EPA assessed the potential risks presented by residues of linuron in or on lentils. In doing so, EPA considered the safety standard in section 408(b)(2) of FFDCA, and EPA decided that the necessary

tolerance under section 408(l)(6) of FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of FFDCA. Although this time-limited tolerance expires and is revoked on December 31, 2011, under section 408(l)(5) of FFDCA, residues of the pesticide not in excess of the amount specified in the tolerance remaining in or on lentils after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this time-limited tolerance at the time of that application. EPA will take action to revoke this time-limited tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this time-limited tolerance is being approved under emergency conditions, EPA has not made any decisions about whether linuron meets FIFRA's registration requirements for use on lentils or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of linuron by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for persons in any State other than Idaho and Washington to use this pesticide on this crop under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for linuron, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of 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) of FFDCA 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) of FFDCA 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...”

Consistent with the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure expected as a result of this emergency exemption request and the time-limited tolerance for combined residues of linuron on lentils at 0.1 ppm. EPA's assessment of exposures and risks associated with establishing the time-limited tolerance follows.

A. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for linuron used for human risk assessment can be found at <http://www.regulations.gov> in the document *Linuron Human Health Risk Assessment to Support a Section 18 Emergency Exemption for Use on Lentils in Washington and Idaho*, page 6 in docket ID number EPA-HQ-OPP-2008-0491.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to linuron, EPA considered exposure under the time-limited tolerance established by this action as well as all existing linuron tolerances in (40 CFR 180.184). EPA assessed dietary exposures from linuron in food as follows:

i. *Acute exposure.* In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, for blended commodities, an average of the field trial data corrected for the maximum percent of crop treated (PCT) was used in the assessment. For non-blended or partially-blended commodities, all values from the field trials were included along with the use of maximum PCT. For the new use on lentils, field trial values were included and 100 PCT was assumed. For all commodities, residues reported at or below the analytical method limit of quantitation (LOQ) were incorporated into the assessment at the LOQ level. Concentration/reduction factors were incorporated for some commodities based on empirical data; for all other processed commodities, default processing factors were used. A single high end modeled peak surface water estimated drinking water concentration (EDWC) of 38 ppb was used as a point estimate for drinking water, and directly incorporated into the assessment. There were no significant toxicological effects attributable to a single exposure (dose) for the general population or any other population subgroups other than the population subgroup of females 13–49

years old. Therefore, only this subgroup was included in this assessment.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. For the chronic assessment, an average of the field trial data and PCT information were used to derive anticipated residue values. For the new use on lentils, the average of the field trial data was used and 100 PCT was assumed. Concentration/reduction factors were incorporated for some commodities based on empirical data; for all other processed commodities, default processing factors were used. The annual mean surface water estimate of 18 ppb was used as a chronic exposure estimate for drinking water and was directly incorporated into the dietary assessment.

iii. *Cancer.* Linuron has been classified as Group C chemical and quantification of human cancer risk is not required; therefore a cancer dietary risk assessment was not conducted.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
 - Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
 - Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.
- In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as

required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

For the acute assessment the maximum PCT was used as follows: sorghum and soybean at 2.5%, and wheat and lentils at 100%. For the chronic assessment, the average PCT was used as follows: sorghum and soybean at 1%, and wheat and lentils at 100%. Although usage on wheat is likely negligible, since there were no usage data reported for this crop, a default of 100 PCT was used for both acute and chronic assessments, which is likely an overestimate.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.B.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to

which linuron may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for linuron in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of linuron. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentration (EDWC) of linuron for acute exposures is estimated to be 38 ppb for surface water. For chronic exposures for non-cancer assessments the EDWC is estimated to be 18 ppb for surface water. Groundwater sources were not included in this assessment, as the EDWCs for this water source are minimal in comparison to surface water (0.7 ppb for both acute and chronic concentrations). Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For acute dietary risk assessment, the water concentration value of 38 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration value of 18 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Linuron is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found linuron to share a common mechanism of toxicity with any other substances, and linuron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that linuron

does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative>.

C. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The data from the multi-generation reproduction study in rats show that linuron has weak affinity for androgen receptors and causes dose-related alterations in androgen-dependent reproductive organ development in male rats. While there is evidence of increased susceptibility seen in rats, the anti-androgenic effects of linuron are well established and there is a clear NOAEL for the effects. Further, the toxicity endpoint selected for risk assessment is protective of both the hematological effects seen (increased methemoglobin levels, selected as the chronic endpoint) as well as the anti-androgenic effects of linuron. EPA has determined that the available linuron database is adequate for assessing the potentially increased susceptibility of the young to linuron exposure and the possible need for a FQPA safety factor to protect the young from the effects of linuron.

3. *Conclusion.* EPA concludes that the FQPA safety factor of 10X is not warranted, and it is reduced to 1X for the following reasons:

EPA has determined that reliable data show that the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for understanding the toxicity of linuron is complete.

ii. The information on linuron's effects on differentiating male reproductive system (antiandrogenic action) is well established, and the dose levels where these effects occur are known. A clear NOAEL was established for the effects on the reproductive system. At this time, the point of departure for risk assessment purposes is protective of the linuron's action on this target tissue (differentiating male reproductive system) as well as the hematological effects described in Unit IV.C.2.

iii. The linuron database does not show any neurotoxicity in all the submitted and published studies at doses as high as 100 mg/kg. The current developmental neurotoxicity (DNT) study focuses on the neurobehavioral and brain histological changes and will not provide additional information for understanding the toxicity of linuron; therefore, this study is no longer required.

iv. Exposure estimates are unlikely to underestimate risk.

v. There are no residual uncertainties identified in the exposure databases. For estimation of exposure, the analysis incorporated PCT estimates, which are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA believes that using these estimates will not underestimate the exposure and risks. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to linuron in drinking water. These assessments will not underestimate the exposure and risks posed by linuron.

D. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate UFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure

estimates from acute dietary consumption of food and drinking water. There were no significant toxicological effects attributable to a single exposure (dose) for the general population other than the population subgroup Females 13–49 Years Old; therefore only this population subgroup was included in this assessment. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to linuron will occupy 6.0% of the aPAD at the 99.9th percentile of exposure distribution for Females 13–49 Years Old.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to linuron from food and water will utilize 22% of the cPAD for All Infants, the population subgroup receiving the greatest exposure. There are no residential uses for linuron. For the general U.S. population the existing and new uses for linuron resulted in an estimated chronic dietary exposure and risk equivalent to 7% of the cPAD.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Linuron is not registered for any use patterns that would result in residential exposure. Therefore, the short-term aggregate risk is the sum of the risk from exposure to linuron through food and water and will not be greater than the chronic aggregate risk.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Linuron is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to linuron through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population.* Linuron has been classified as Group C carcinogen and quantification of human cancer risk is not required.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to linuron residues.

V. Other Considerations

A. Analytical Enforcement Methodology

The Pesticide Analytical Manual (PAM) Vol. II lists a colorimetric method (Method I) and a paper chromatographic method (Method II) for the enforcement of tolerances for linuron residues. Residues of diuron may interfere in Method I. A modified version of Method I (H. L. Pease, *Journal of Agric. and Food Chem.*, 1962, Vol. 10, p. 279), which includes a cellulose column step to separate linuron from diuron, has been used for tolerance enforcement purposes. Both these methods determine linuron and all metabolites hydrolyzable to 3,4-dichloroaniline and have limits of detection of 0.05 ppm and are adequate to enforce the tolerance expression.

B. International Residue Limits

There are no Codex MRLs for linuron on lentils.

VI. Conclusion

Therefore, a time-limited tolerance is established for combined residues of linuron, (3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea) and its metabolites convertible to 3,4-dichloroaniline, calculated as linuron, in or on lentil at 0.1 ppm. This tolerance expires and is revoked on December 31, 2011.

VII. Statutory and Executive Order Reviews

This final rule establishes tolerances under sections 408(e) and 408(l)(6) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income*

Populations (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established in accordance with sections 408(e) and 408(l)(6) of FFDCA, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: August 22, 2008.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.184 revise paragraph (b) to read as follows:

§ 180.184 Linuron; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for combined residues of the herbicide linuron (3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea) and its metabolites convertible to 3,4-dichloroaniline, calculated as linuron, in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. The tolerance expires and is revoked on the date specified in the table.

Commodity	Parts per million	Expiration/revocation date
Lentil	0.1	12/31/2011

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2008-0549; FRL-8378-2]

Chlorantraniliprole; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of chlorantraniliprole in or on various sweet corn commodities and in milk. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal

Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on sweet corn. This regulation establishes maximum permissible levels for residues of chlorantraniliprole in or on these food commodities. The time-limited tolerances expire and are revoked on December 31, 2011.

DATES: This regulation is effective September 5, 2008. Objections and requests for hearings must be received on or before November 4, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2008-0549. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Marcel Howard, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6784; e-mail address: howard.marcel@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or