from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 petition under FFDCA section 408, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

V. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq*., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of 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: December 2, 1999.

James Jones,

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), 346(a) and 371.

§ 180.142 [Amended]

2. In § 180.142, by amending the table in paragraph (b) by revising the date ''08/31/98'' to read ''12/31/00.''

[FR Doc. 99–32182 Filed 12–10–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300939; FRL–6388–4]

RIN 2070–AB78

Clomazone; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerances for residues of clomazone in or on rice (grain and straw). This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on rice. This regulation establishes a maximum permissible level for residues of clomazone in this food commodity. The tolerance will expire and is revoked on December 31, 2001.

DATES: This regulation is effective December 13, 1999. Objections and requests for hearings, identified by docket control number OPP–300939, must be received by EPA on or before February 11, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the ''SUPPLEMENTARY INFORMATION.'' To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300939 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: David Deegan, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 308–9358; and e-mail address: Deegan.Dave@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 categories and entities may include, but are not limited to:

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under ''FOR FURTHER INFORMATION CONTACT.''

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically*.You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look

up the entry for this document under the ''**Federal Register**--Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–300939. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for residues of the herbicide clomazone, in or on rice, grain and in or on rice, straw at 0.05 part per million (ppm). These tolerances will expire and be revoked on December 31, 2001. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

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. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

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 the Federal Insecticide, Fungicide, and Rodenticide Act (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 the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Clomazone on Rice and FFDCA Tolerances

Several of the rice-producing States in the southern U.S. petitioned EPA to authorize the use of clomazone to control barnyard grass in rice. The applicants chronicled an ongoing problem faced by rice growers, whereby control of barnyard grass is difficult with currently registered alternative products, either due to limited efficacy, resistance development, or unforseen and undesirable environmental repercussions due to their application. EPA has authorized under FIFRA section 18 the use of clomazone on rice for control of barnyard grass in Arkansas, Louisiana, Mississippi, Missouri, and Texas. After having reviewed the submissions, EPA concurs that emergency conditions exist in these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of clomazone in or on rice. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6). Although this tolerance will expire and is revoked on December 31, 2001, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on rice after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. 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.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether clomazone meets EPA's registration requirements for use on rice or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of clomazone 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 Arkansas, Louisiana, Mississippi, Missouri, and Texas to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for clomazone, contact the Agency's Registration Division at the address provided under ''FOR FURTHER INFORMATION CONTACT.''

IV. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of clomazone and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for residues of

clomazone on rice (grain and straw) at 0.05 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

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

B. Toxicological Endpoint

1. *Acute toxicity*. In reviews of the toxicological characteristics of clomazone, no toxicological endpoint was identified for acute oral toxicity. Therefore, no acute aggregate risk assessment is required.

2. *Short- and intermediate-term toxicity*. For short- and intermediate-term MOE calculations, EPA has used the maternal NOAEL of 100 mg/kg/day from the rat oral developmental toxicity study. At the LOAEL of 300 mg/kg/day, there were abdominal stains and decreased locomotion.

3. *Chronic toxicity*. EPA has established the Reference Dose (RfD) for clomazone at 0.043 milligrams/kilograms/day (mg/kg/day). This RfD is based on a 2–year feeding study in rats with a NOAEL of 4.3 mg/kg/day and an uncertainty factor of 100, based on increased liver weights and serum cholesterol at the LOAEL of 21.5 mg/kg/day. For this risk assessment, EPA has also used the chronic PAD (Population Adjusted Dose) of 0.0043 mg/kg/day.

4. *Carcinogenicity*. Clomazone has not been classified by EPA in regards to carcinogenicity. However, there are no reported cancer concerns present at this time, and EPA has reviewed studies indicating that clomazone is negative for cancer in two species.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.425) for the residues of clomazone, in or on a variety of raw agricultural commodities, including snap beans, cottonseed, soybeans, peppers, sweet potatoes, and peas (succulent) at 0.05 ppm and pumpkins, winter and summer squash, cucumbers, and cabbage at 0.1 ppm. A time-limited tolerance for residues of clomazone in/on watermelons at 0.1 ppm is established in conjunction with a previous section 18 emergency exemption authorization. Risk assessments were conducted by EPA to assess dietary exposures and risks from clomazone as follows:

i. *Acute exposure and risk*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. Toxicity observed in oral toxicity studies were not attributable to a single dose or 1 day exposure. Therefore, no toxicological endpoint was identified for acute toxicity and no acute dietary risk assessment is required.

ii. *Chronic exposure and risk*. The Agency conducted a chronic dietary exposure analysis and risk assessment. The chronic analysis for exposure to clomazone residues used a chronic PAD of 0.0043 mg/kg/day. The analysis evaluated individual food consumption as reported by respondents in the USDA 1989–92 ''Continuing Surveys of Food Intake by Individuals'' and accumulates exposure to the chemical for each commodity. Tolerance level residues and 100 percent crop treated (%CT) assumptions were made for the proposed commodities of these emergency exemptions, and all other commodities with tolerances for residues of clomazone, in order to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and subgroups of interest. The existing clomazone tolerances (published, pending, and including the necessary time-limited tolerance in support of the emergency exemptions related to this action) result in a TMRC that is equivalent to the following percentages of the chronic PAD:

Summary: Chronic Exposure Analysis by the DEEM System

Population Subgroup	Exposure (mg/kg/day)	Percent Chronic PAD
U.S. Population (48 contiguous States)	0.000079	1.8%
All Infants (<1 year old)	0.000028	6.6%
Nursing Infants (<1 year old)	0.000044	1.0%
Non-Nursing Infants (<1 year old)	0.00039	9.0%
Children (1–6 years old)	0.00015	3.4%
Children (7–12 years old)	0.000095	2.2%

2. *From drinking water*. EPA conducted an assessment of Tier I estimated environmental concentrations (EECs) of clomazone for the highest registered use rate, and in this review EPA concluded that clomazone is metabolized slowly in soil under aerobic conditions and is potentially to relatively mobile. Clomazone is somewhat more labile under anaerobic conditions. The proposed use is expected to pose significant risk to surface water resources.

i. *Ground water*. EPA's clomazone ground water estimated environmental concentration (EEC) is based upon SCI-GROW2 modeling (Screening Concentration In Ground Water). SCI-GROW2 is a prototype model for estimating ''worst case'' ground water concentrations of pesticides. SCI-GROW2 estimates are based on the fate properties of the pesticide, the application rate, and the existing body of data from small-scale ground water monitoring studies. The model assumes that the pesticide is applied at its maximum rate in areas where the ground water is particularly vulnerable to contamination. In most cases, a considerable portion of any use area will have ground water that is less vulnerable to contamination than the areas used to derive the SCI-GROW2 estimates. SCI-GROW2 estimates are biased in that studies where the pesticide is not detected in ground water are not included in the data set. Thus, it is not expected that SCI-GROW2 estimates would be exceeded.

The SCI-GROW2 model estimates that the concentration of clomazone in ground water is not likely to exceed an acute and chronic EEC of 0.97 µg/L for the proposed application rate of 0.6 pound (lb) active ingredient per acre (ai/acre) with a maximum of one application.

ii. *Surface water*. EPA used the Generic Expected Environmental Concentration (GENEEC) model to determine concentrations of clomazone in surface water. GENEEC is used to estimate pesticide concentrations in

surface water for up to 56 days after a single runoff event. GENEEC simulates a 1 hectare by 2 meters deep edge-of-the-field farm pond (with no outlet) which receives pesticide runoff from a treated 10 hectare field. GENEEC provides an upper-bound concentration value. GENEEC can substantially overestimate (by a ≧3-fold factor) true pesticide concentrations in drinking water. GENEEC does have certain limitations and is not the ideal tool for use in drinking water risk assessments. However, it can be used in screening calculations and does provide an upper bound value for the concentration of pesticides that can be found in drinking water. Since GENEEC can substantially overestimate true drinking water concentrations, it will be necessary to refine the GENEEC estimate when the drinking water levels of comparison are exceeded. In those situations where the level of comparison is exceeded and the GENEEC value is a substantial part of the total exposure, EPA can use a variety of methods to refine the exposure estimates. Using the GENEEC model and available environmental fate data, EPA calculated the Tier 1 chronic (56–day) EEC for clomazone would be 16.1 µg/L based on a total annual use rate of 0.6 lb ai/acre (i.e. 1 application at 0.6 lb ai/acre). See IV.D. for discussion of how these exposure values have been addressed in the risk assessment for this tolerance-setting action.

iii. *Chronic exposure and risk*. Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water-related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfDs or acute dietary no observed adverse effect levels (NOAELs)) 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 clomazone 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 clomazone in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

3. *From non-dietary exposure*. Clomazone is currently not registered for use on residential non-food sites. Thus, a residential exposure assessment for clomazone is not required.

4. *Cumulative exposure to substances with a 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.''

Clomazone is a member of the pyridazones/pyridinones class of herbicides. Other members of this class include purazon, norflurazon, fluridone, oxadiazon, fluorochloridone, amitrol, and dithiopyr. EPA does not have, at this time, available data to determine whether clomazone 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, clomazone 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 clomazone has a common mechanism of toxicity with other substances. For more information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Drinking water assessment*. In the absence of drinking water monitoring data, EPA assesses the aggregate dietary risk by using the worst-case scenario of EECs found from either ground or surface water. The EECs reported for clomazone residues in ground water using SCI-GROW2 is 0.97 µg/L. This is much less than the surface water EEC (16.1 µg/L for chronic risk assessment) generated using GENEEC. Therefore, only the surface water EEC for clomazone will be used for purposes of comparing with the calculated drinking water levels of comparison (DWLOC).

2. *Acute risk*. No toxicological endpoint was identified for acute oral toxicity. Therefore, no acute aggregate risk assessment is required.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. No short- or intermediate-term oral toxicological endpoints were identified. Also, clomazone has no residential uses. Thus, no risk assessments were conducted for short- and intermediate-term exposure.

4. *Chronic risk* —i. *Food only*. Using the conservative TMRC exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, EPA has determined that chronic dietary exposure to clomazone residues from food will utilize up to a maximum of 9.0% (for the population subgroup non-nursing infants) of the chronic PAD for subgroups including infants and children (see additional discussion below), and up to a maximum of 2.5% of the chronic PAD for subgroups including adults. Chronic dietary exposure to clomazone residues from food for all other population subgroups results in utilization of a smaller percentage of the chronic PAD.

ii. *Water only*. Based on the chronic dietary (food only) exposure, chronic (non-cancer) DWLOCs were calculated. To calculate the chronic DWLOCs, the chronic dietary food exposure (from the DEEM analysis) was subtracted from the chronic PAD to give the maximum allowable exposure level for drinking water. DWLOCs were then calculated using the default body weights and drinking water consumption figures.

iii. *Food plus water*. The estimated 56–day concentration of clomazone in surface water (16.1 µg/L) is less than EPA's levels of comparison for clomazone in drinking water as a contribution to chronic aggregate exposure (1.5 x 102 µg/L for adult males, 1.3 x 102 µg/L for adult females, and 39 µg/L for infants/children). Therefore, taking into account the registered uses and the use proposed in the emergency exemptions resulting in this tolerance-setting action, EPA concludes with reasonable certainty that residues of clomazone in drinking water (when considered along with other sources of chronic exposure for which EPA has reliable data) would not result in unacceptable levels of chronic aggregate human health risk estimates

for adult and infants/children population subgroups at this time.

EPA bases this determination on a comparison of estimated average concentrations of clomazone in surface water to back-calculated ''levels of comparison'' for clomazone in drinking water. These levels of comparison in drinking water were determined after EPA has considered all other non-occupational human exposures for which it has reliable data, including all currently registered uses, and uses considered in this action. The estimates of clomazone in surface water are derived from water quality models that use conservative assumptions (health-protective) regarding the pesticide transport from the point of application to surface water. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of clomazone in drinking water as a part of the chronic (non-cancer) aggregate risk assessment process.

EPA generally has no concern for exposures below 100% of the chronic PAD because the chronic PAD represents the level at or below which average daily life-time exposure will not pose appreciable risks to human health. Despite the potential for exposure to clomazone in drinking water, EPA does not expect the chronic aggregate exposure to exceed 100% of the chronic PAD for population subgroups which include adults, infants, or children. EPA concludes that there is a reasonable certainty that no harm will result to adults and infants or children from chronic aggregate exposure to clomazone residues.

4. *Aggregate cancer risk for U.S. population*. Clomazone has not been classified by EPA in regards to carcinogenicity. However, there are no reported cancer concerns at this time and clomazone is negative for cancer in two species studies. Thus, a cancer risk assessment was not performed for this chemical.

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

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

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

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined interspecies and intraspecies 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.

Information concerning the possibility of enhanced sensitivity of infants and children when exposed to clomazone has not yet been presented to, and/or reviewed by, EPA. Therefore, EPA has assumed that the FQPA Safety Factor (for enhanced sensitivity of infants and children as required by the FQPA) has been retained and is applicable to all oral endpoints for the purposes of this tolerance-setting action.

ii. *Developmental toxicity studies —a. Rat*. From the rat developmental toxicity study, the maternal (systemic) NOAEL was 100 mg/kg/day, based on decreased locomotion and abdominal staining at the LOAEL of 300 mg/kg/day. The developmental (pup) NOAEL was 100 mg/kg/day, based on delayed ossification at the LOAEL of 300 mg/kg/day.

b. Rabbit. From the rabbit developmental toxicity study, the maternal (systemic) NOAEL was 240 mg/kg/day, based on decreased body weight gain at the LOAEL of 700 mg/kg/day. The developmental (pup) NOAEL was 700 mg/kg/day at the highest dose tested.

iii. *Reproductive toxicity study — Rat*. From the rat reproductive toxicity study, the maternal (systemic) NOAEL was 50 mg/kg/day, based on decreased body weight, food consumption, clinical signs, and organ weight changes at the LOAEL of 100 mg/kg/day. The reproductive (pup) NOAEL was 5 mg/kg/ day, based on decreased pup viability, reduced survival, and decreased body weight at the LOAEL of 50 mg/kg/day.

iv. *Conclusion*. There is a complete toxicity data base for clomazone and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures.

2. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to clomazone from food will utilize (no greater than 9%) of the cPAD for infants and children. EPA generally has no concern for exposures below 100% of the cPAD, because the cPAD 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 clomazone in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

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

V. Other Considerations

A. Metabolism in Plants and Animals

The nature of the residue in plants and animals is adequately understood. The residue of concern is clomazone *per se* as specified in 40 CFR 180.425.

B. Analytical Enforcement Methodology

Adequate enforcement methodology (GLC/NPD or GLC/MS) are available (PAM II) for enforcement of clomazone residues. Additionally, clomazone is adequately recovered (>80%) via the FDA Multiresidue Methods of PAM I (Pestrak, 1990).

C. Magnitude of Residues

1. Residues of clomazone *per se* are not expected to exceed 0.05 ppm in/on rice, grain and rice, straw. Time-limited tolerances are hereby being established at this level.

2. A rice processing study has been reviewed by EPA. In this review, EPA has concluded that residues of clomazone do not concentrate when rice grain containing detectable residues is processed into polished rice, hulls, and

bran. Thus, tolerances are not required for processed rice products.

3. A review of this use concluded that residues in meat, milk, poultry and, eggs are not expected.

D. International Residue Limits

There are no Codex, Canadian or Mexican limits for clomazone in/on rice commodities. Therefore, compatibility problems are not expected from the establishment of a tolerance for clomazone on rice commodities.

E. Rotational Crop Restrictions

Adequate rotational crop restrictions are included on the label for Command 3ME. These restrictions state that cotton, peas, peppers, pumpkins, soybeans, and tobacco may be rotated at anytime. After 9 months the following crops may be rotated: cotton, dry beans, sweet potatoes, corn (filed, pop, seed and sweet), peanuts, tomatoes (transplanted), potatoes, cucurbits, rice, sugar beets, snap beans, and sorghum. After 12 months all crops may be rotated. The label also includes the statement ''do not graze or harvest for food or feed cover crops planted less than 9 months after Command 3ME treatment.''

VI. Conclusion

Therefore, the tolerance is established for residues of clomazone in rice at 0.05 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the 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. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–300939 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 February 11, 2000.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. M3708, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by the docket control number OPP–300939, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a 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(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Regulatory Assessment Requirements

This final rule establishes a time-limited tolerance under FFDCA section 408. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections

subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); 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 or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 petition under FFDCA section 408, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

IX. Submission to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of 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: November 24, 1999.

James Jones,

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), 346(a) and 371.

2. In § 180.425, by alphabetically adding to the table in paragraph (b), the following commodities to read as follows:

§ 180.425 Clomazone; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/revocation date
Rice, grain	0.05	12/31/01
Rice, straw	0.05	12/31/01
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[FR Doc. 99–32183 Filed 12–10–99; 8:45 am]

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NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Part 1815

Requiring Information Other Than Cost or Pricing Data; Correction of Inconsistency

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: This final rule amends the NASA FAR Supplement (NFS) to identify a FAR exception to NASA's prohibition against requesting information other than cost or pricing data in a solicitation when a firm-fixed-price competition is involved.

EFFECTIVE DATE: December 13, 1999.

FOR FURTHER INFORMATION CONTACT: Mr. Joseph Le Cren, NASA Headquarters, Code HK, Washington, DC 20546; Telephone: (202) 358-0444; email: joseph.lecren@hq.nasa.gov.

SUPPLEMENTARY INFORMATION:

A. Background

The NFS coverage at 1815.403–3(b) prohibits requesting information other