(viii) *Hardware and software requirements.* The recipient must be provided with a description of the hardware and software required to access, print, and retain the Form W–2, and the date when the Form W–2 will no longer be available on the website. The recipient must be informed that the Form W–2 may be required to be printed and attached to a Federal, State, or local income tax return.

(4) *Format.* The electronic version of the Form W–2 must contain all required information and comply with applicable revenue procedures relating to substitute statements to recipients.

(5) *Posting.* The furnisher must on or before January 31 of the year following the calendar year to which the Form W–2 relates (or such other date permitted or required for furnishing the Forms W–2) post it on a website accessible to the recipient.

(6) *Notice*—(i) *In general.* The furnisher must on or before January 31 of the year following the calendar year to which the Form W–2 relates (or such other date permitted or required for furnishing the Form W–2) notify the recipient that the Form W–2 is posted on a website. The notice may be delivered by mail, electronic mail, or in person. The notice must provide instructions on how to access and print the statement. The notice must include the following statement in capital letters, ''IMPORTANT TAX RETURN DOCUMENT AVAILABLE.'' If the notice is provided by electronic mail, the foregoing statement should be on the subject line of the electronic mail and sent with high importance.

(ii) *Undeliverable electronic address.* If an electronic notice described in paragraph (j)(6)(i) of this section is returned as undeliverable, and the correct electronic address cannot be obtained from the furnisher's records or from the recipient, then the furnisher must furnish the notice by mail or in person within 30 days after the electronic notice is returned.

(iii) *Corrected Forms W–2.* A furnisher must notify a recipient that it has posted corrected Forms W–2 on a website within 30 days of such posting in the manner described in paragraph (j)(6)(i) of this section. This notice must be furnished by mail or in person if—

(A) An electronic notice of the website posting of an original Form W–2 was returned as undeliverable; and

(B) The recipient has not provided a new e-mail address.

(7) *Retention.* The furnisher must maintain access to the Forms W–2 on the website through October 15 of the year following the calendar year to which the Forms W–2 relate (or the first business day after October 15, if October 15 falls on a Saturday, Sunday, or legal holiday). The furnisher must maintain access to corrected Forms W–2 that are posted on the website through October 15 of the year following the calendar year to which the Forms W–2 relate (or the first business day after such October 15, if October 15 falls on a Saturday, Sunday, or legal holiday) or the date 90 days after the corrected forms are posted, whichever is later.

(k) *Effective date.* Paragraph (j) of this section applies to Forms W–2 required to be furnished under section 6051 after December 31, 2000.

PART 301—PROCEDURE AND ADMINISTRATION

Par. 6. The authority citation for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 7. Section 301.6724–1T is added to read as follows:

§ 301.6724–1T Reasonable cause (temporary).

(a) through (d)(2) [Reserved]. For further information, see § 301.6724–1 (a) through (d)(2).

(d)(3) *Special rule for furnishers of electronic statements.* A filer may seek a waiver for reasonable cause pursuant to § 301.6724–1(c)(6), for failing to timely furnish a statement in the following situation. If the recipient of the statement withdraws a consent to receive the statement in an electronic format, the filer will be deemed to have acted in a responsible manner under § 301.6724–1(d) if the filer furnishes a paper statement on or before the date 30 days after the date the withdrawal of consent is received.

(e) through (n) [Reserved]. For further guidance, see § 301.6724–1(e) through (n).

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

Par. 8. The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

Par. 9. In § 602.101, paragraph (b) is amended by adding entries to the table in numerical order to read as follows:

§ 602.101 OMB Control numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * *	
1.6041–2T	1545–1729
* * * * *	
1.6050S–1T	1545–1729
1.6050S–2T	1545–1729
* * * * *	
31.6051–1T	1545–1729
* * * * *	

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

Approved: January 10, 2001.

Jonathan Talisman,

Assistant Secretary of the Treasury.

[FR Doc. 01–1292 Filed 2–13–01; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301101; FRL–6764–2]

RIN 2070–AB78]

Clomazone; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of clomazone in or on tuberous and corm vegetable (except potato) subgroup crop and cucurbit vegetable crop group. Interregional Research Project Number 4 (IR—4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective February 14, 2001. Objections and requests for hearings, identified by docket control number OPP–301101, must be received by EPA on or before April 16, 2001.

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 VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301101 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection

Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 308–3194; and e-mail address: brothers.shaja@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be 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 codes	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'', ''Regulations and Proposed Rules,'' 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/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301101. 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, 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

In the **Federal Register** of December 6, 2000 (65 FR 76249) (FRL–6755–4), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of pesticide petitions (PP 9E6063 and 7E4865) for tolerance by IR–4, 681 U.S. Highway #1 South, North Brunswick, New Jersey 08902–3390. This notice included a summary of the petitions prepared by FMC Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.425 be amended by establishing tolerances for residues of the herbicide clomazone, [2-(2-chlorophenyl)methyl-4,4-dimethyl-3-isoxazolidinone], in or on tanier, cassava, yams, arracacha, and cucurbit vegetables at 0.05 and 0.1 parts per million (ppm). The petition was subsequently amended to tuberous and corm vegetable (except potato) crop subgroup and cucurbit vegetable crop group at 0.05 ppm.

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....''

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).

III. 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. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of clomazone on the tuberous and corm vegetable (except potato) crop subgroup and cucurbit vegetable crop group at 0.05 ppm. EPA's assessment of 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 the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1. — SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity rat	NOAEL = 135.2/160.9 mg/kg/day, males/females LOAEL = 273/319.3 mg/kg/day, males/females, based on decreased body weight, body weight gains, food consumption and increased absolute and relative liver weights in females and increased absolute liver weights in males
870.3100	90-Day oral toxicity mouse	NOAEL ≥ 1,200 mg/kg/day (limit dose) LOAEL > 1,200 mg/kg/day
870.3700a	Prenatal developmental rat	Maternal NOAEL = 100 mg/kg/day LOAEL = 300 mg/kg/day based on chromorhinorrhea and/or abdominogenital staining Developmental NOAEL = 100 mg/kg/day LOAEL = 300 mg/kg/day based on indications of delayed ossification in the form of either partial ossification or the absence of manubrium, sternebrae 3–4, xiphoid, caudal, and metacarpals
870.3700b	Prenatal developmental rabbits	Maternal NOAEL = 240 mg/kg/day LOAEL = 700 mg/kg/day based on effects seen at 1,000 mg/kg/day, which included mortality, abortions, decreased body weight gain, and decreased defecation or no feces Developmental NOAEL ≥ 700 mg/kg/day highest dose tested (HDT) LOAEL > 700 mg/kg/day
870.3800	2–Generation reproduction and fertility effects	Parental NOAEL = 50 mg/kg/day LOAEL = 100 mg/kg/day based on statistically significantly decreased body weight and body weight gain during pre-mating, and decreased body weight during gestation & lactation male & female. In addition decreased food consumption in females and hydro-nephritic kidneys in males. Offspring NOAEL = 50 mg/kg/day LOAEL = 100 mg/kg/day based on decreased body weight in F2a and F2b litters
870.4100b	Chronic toxicity dogs	NOAEL ≥ 1,038/1,012 mg/kg/day, males/females (HDT) LOAEL > 1,038/1,012 mg/kg/day
870.4300	Chronic toxicity/ Carcinogenicity rats	NOAEL = 84.4/112.9 mg/kg/day, males/females (HDT) LOAEL ≥ 84.4/112.9 mg/kg/day, males/females Classified as a ''not likely human carcinogen''
870.4300	Carcinogenicity mice	NOAEL = 300 mg/kg/day (HDT) LOAEL = > 300 mg/kg/day Classified as a ''not likely human carcinogen''
870.5100	Gene mutation *Salmonella typhimurium* and *Escherichia coli* reverse gene mutation assay)	The test article was assayed up to cytotoxic concentrations (5,000 µg/plate), but in no instance were appreciably increased number of revertants to histidine prototrophy (his+) found in any of the tester strains, either in the presence or absence of metabolic activation.
870.5395	Cytogenetics *In vivo* rat	Negative. The incidence of aberrations and the aberrations/cell were not significantly increased.
870.5550	Other effects *In vitro* UDS assay in primary rat hepatocytes	Clomazone was tested up to cytotoxicity (relative toxicity at 0.10 µL/mL was 88.6%), but in no cultures treated with test article was a significant increase in mean net nuclear counts indicative of UDS recorded.
870.7485	Metabolism and pharmacokinetics	Clomazone is extensively metabolized by the liver and excreted in the urine and feces within 24 hours. Sixteen metabolites, including the parent, were identified; and the predominant route of excretion was in urine.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic

Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q_1*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q_1* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q_1* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a '' point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE cancer = point of departure/exposures) is calculated. A summary of the toxicological endpoints for clomazone used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CLOMAZONE USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary females 13–50 years of age	NOAEL = 100 mg/kg/day UF = 100 Acute RfD = 1.0 mg/kg/day	FQPA SF = 1X aPAD = acute RfD ÷FQPA SF = 1.0 mg/kg/day	Developmental rat LOAEL = 300 mg/kg/day based on delayed ossification.
Acute Dietary general population including infants and children	None	None	A risk assessment is not required for this population subgroup.
Chronic Dietary all populations	NOAEL= 84.4 mg/kg/day UF = 100 Chronic RfD = 0.84 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD ÷ FQPA SF = 0.84 mg/kg/day	2—year rat feeding study LOAEL > 84.4 mg/kg/day (HDT) 90—day oral rat LOAEL = 319.3 mg/kg/day based on based on decreased body weight, body weight gains, food consumption and increased absolute and relative liver weights in females and increased absolute liver weights in males. 2—Generation Reproduction LOAEL = 100 mg/kg/day based on statistically significantly decreased body weight & body weight gain during premating, and decreased body weight during gestation & lactation male & female. In addition decreased food consumption in females and hydro-nephritic kidneys in males.
Oral, Short-Term (1 to 7 days) (Residential)	None	None	No residential uses. An endpoint was not selected.
Oral, Intermediate-Term (1 week to several months) (Residential)	None	None	No residential uses. An endpoint was not selected.
Dermal and Inhalation Short-Term (1 to 7 days) (Residential)	Maternal NOAEL= 100 mg/kg/day Dermal absorption = 100% Inhalation absorption = 100%	LOC for MOE = 100	Developmental rat study Maternal LOAEL = 300 mg/kg/day, based on chromorhinorrhea and abdominogenital staining
Dermal and Inhalation, Intermediate-term (1 week - several months) and Long-Term (several months - lifetime) (Residential)	Oral NOAEL= 84.4 mg/kg/day	LOC for MOE = 100	2–year rat feeding study LOAEL > 84.4 mg/kg/day (HDT) 90–day oral rat

TABLE 2. — SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CLOMAZONE USE IN HUMAN RISK ASSESSMENT— Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
	Dermal Absorption = 100% Inhalation absorption = 100%		LOAEL = 319.3 mg/kg/day based on based on decreased body weight, body weight gains, food consumption and increased absolute and relative liver weights in females and increased absolute liver weights in males 2–Generation Reproduction LOAEL = 100 mg/kg/day based on statistically significantly decreased body weight and body weight gain during premating, and decreased body weight during gestation & lactation male & female. In addition decreased food consumption in females and hydro-nephritic kidneys in males.

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure 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. Risk assessments were conducted by EPA to assess dietary exposures from clomazone in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: A Tier 1 acute analysis was performed for females 13–50 years old using existing and recommended tolerance level residues, 100% crop treated.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM analysis evaluated the individual food consumption as reported by respondents in the USDA (1989–1992) nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A Tier 1 chronic analysis was performed for the general U.S. population and all population subgroups using existing and recommended tolerance level residues, 100% crop treated.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for clomazone in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of clomazone. Clomazone's major environmental degradate, FMC 65317 (*N*-[2- chlorophenol)methyl] -3-hydroxy-2,2-dimethyl propanamide) was also included in the drinking water assessment.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and screening concentration in ground water (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address

total aggregate exposure to clomazone they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models the EECs of clomazone and FMC 65317 for acute exposures are estimated to be 95 parts per billion (ppb) for surface water and 2.4 ppb for ground water. The EECs for chronic exposures are estimated to be 23 ppb for surface water and 2.4 ppb for ground 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, flea and tick control on pets).

Clomazone is not registered for use on any sites that would result in residential exposure.

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.''

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 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. Safety Factor for Infants and Children

1. *Safety factor for infants and children*—i. *In general*. 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 on toxicity and exposure 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.

ii. *Prenatal and postnatal sensitivity*. The prenatal and postnatal toxicology data base for clomazone is complete with respect to FQPA considerations. There is no quantitative or qualitative evidence of increased susceptibility of rats or rabbit fetuses to *in utero* exposure in developmental studies. Although there was a suggestion of susceptibility in the rat developmental study based on the presence of delayed ossification in the fetuses, the EPA concluded that the fetal effects were no more severe than the maternal effects because: There is no dose response relationship for delayed ossification (i.e., absence of increased incidence with increase in dose); low fetal/litter incidences; delayed ossifications were not considered to be severe; and no visceral or skeletal malformations were seen.

iii. *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. The FQPA factor was reduced to 1X because of the following reasons: There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure; a developmental neurotoxicity study is not required; and the dietary (food and drinking water) exposure assessments will not under estimate the potential exposures for infants and children (there are currently no registered residential uses).

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD − (average food + residential exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the US EPA Office of Water are used to calculate DWLOCs: 2Liters (L)/70kilograms (kg) (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP 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, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. A Tier 1 acute dietary exposure analysis for clomazone was performed using existing and proposed tolerance level residues, 100 CT for all commodities, and DEEM default processing factors. The acute analysis was performed for females 13–50 years old. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to clomazone will occupy <1% of aPAD for females 13–50 years and older at the 95th percentile. In addition, there is potential for acute dietary exposure to clomazone in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO CLOMAZONE

Scenario/Population Subgroup	aPAD, mg/kg/day	% aPAD (Food)	Surface Water, ppb	Ground Water, ppb	DWLOC ppb
Females 13–50 yrs old	1	1%	95	2.4	30,000

2. *Chronic risk.* A Tier 1 chronic dietary exposure analysis for clomazone was performed using existing and proposed tolerance level residues, 100% CT for all commodities, and DEEM default processing factors. The chronic analysis applied to the U.S. population and all population subgroups. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to clomazone from food will utilize <1% of the cPAD for the U.S. population and all population subgroups. There are no residential uses for clomazone that result in chronic residential exposure to clomazone. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 4:

TABLE 4. — AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO CLOMAZONE

Scenario/Population Subgroup	cPAD, mg/kg/day	% cPAD (Food)	Surface Water, ppb	Ground Water, ppb	DWLOC, ppb
U.S. Population	0.84	<1	23	2.4	29,000
All infants (< 1 year old)	0.84	<1	23	2.4	8,400
Children (1–6 years old)	0.84	<1	23	2.4	8,400
Children (7–12 years old)	0.84	<1	23	2.4	8,400
Females (13–50 years old)	0.84	<1	23	2.4	25,000

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

Clomazone is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *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, and to infants and children from aggregate exposure to clomazone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available for the determination of the residues of clomazone in plants. Briefly, samples are acid hydrolyzed, hexane extracted, Na_2CO_3 washed, and cleaned-up with a FlorisilR column. The resulting samples are analyzed by gas chromatography (GC) using a nitrogen phosphorus detector (NPD) or mass spectrometer (MS). The limit of quantitation (LOQ) for this method is 0.05 ppm. A confirmatory procedure (GC/MS-SIM) is available (Method I, PAM II).

B. International Residue Limits

There is neither a Codex proposal, nor Canadian or Mexican limits for residues of clomazone in/on the subject crops. Therefore, a compatibility issue is not relevant to the proposed tolerance.

V. Conclusion

Therefore, tolerances are established for residues of clomazone, [2-(2-chlorophenyl)methyl-4,4-dimethyl-3-isoxazolidinone], in or on the tuberous and corm vegetable (except potato) crop subgroup and cucurbit vegetable crop group at 0.05 ppm.

VI. 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–301101 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 April 16, 2001.

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, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, 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, 1200 Pennsylvania Ave., NW., 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, 1200 Pennsylvania Ave., NW., 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 VI.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 docket control number OPP–301101, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., 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 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).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) 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). 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 petition under FFDCA section 408(d), 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).

VIII. 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: January 18, 2001.

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. Section 180.425 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.425 Clomazone; tolerances for residues.

(a) *General.** * *

Commodity	Parts per million
* * * *	*
Vegetable, cucurbit, group	0.05
Vegetable, tuberous and corm, except potato, subgroup	0.05

* * * * * *

[FR Doc. 01–3619 Filed 2–13–01; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[WT Docket No. 99–168; CS Docket No. 98–120; MM Docket No. 00–39; FCC 01–25]

Clearing of the 740–806 MHz Band; Conversion to Digital Television

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission adopts mechanisms and makes determinations intended to facilitate the clearing of the 740–806 MHz band to allow for the introduction of new wireless services, and to promote the early transition of analog television licensees to digital television service (''DTV''). The Commission adopts rules and policies that allow the private sector to determine the band-clearing mechanisms that will best suit broadcasters' and potential new 700 MHz licensees' needs. By this action, the Commission also builds upon the policies adopted in the Memorandum Opinion and Order and Further Notice of Proposed Rule Making in this proceeding (''*700 MHz MO&O and FNPRM*'') in which it provided guidance regarding its review of regulatory requests filed in connection with voluntary private agreements that would accelerate the DTV transition and open the 700 MHz band for new uses.

DATES: Effective February 14, 2001.

FOR FURTHER INFORMATION CONTACT: Nese Guendelsberger or Bill Huber of the Auctions and Industry Analysis Division at (202) 418–0660 (voice), (202) 418–7233 (TTY), or Martin Liebman or Stanley Wiggins of the Policy Division at (202) 418–1310 (voice), (202) 418–7233 (TTY), Wireless Telecommunications Bureau.

SUPPLEMENTARY INFORMATION: This is a summary of a Third Report and Order (''*Third R&O*'') in WT Docket No. 99–168, adopted on January 18, 2001, and released on January 23, 2001. The complete text of the *Third R&O* is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY–A257), 445 12th Street, SW, Washington, DC. It may also be purchased from the Commission's copy contractor, International Transcription Services, Inc. (ITS, Inc.), 445 12th Street, SW, Room CY–B400, Washington, DC 20554, (202) 314–3070. The *Third R&O* is also available on the Internet at the Commission's web site: *http://www.fcc.gov/Bureaus/Wireless/Orders/2001/fcc01025.* Alternative formats (computer diskette, large print, audio cassette and Braille) are available to persons with disabilities by contacting Martha Contee at (202) 418–0260, TTY (202) 418–2555, or at mcontee@fcc.gov.

Synopsis of the Third Report and Order

1. By this *Third R&O*, the Commission adopts mechanisms and makes determinations intended to facilitate the clearing of the 740–806 MHz band to allow for the introduction of new wireless services, and to promote the early transition of analog television licensees to DTV. The 746–806 MHz band at issue has historically been used exclusively by television stations (Channels 60–69). The incumbent television broadcasters are permitted by statute to continue operations until their markets are converted to digital television, which is not scheduled to occur until December 31, 2006, and that date may be extended under certain circumstances. Congress has, however, mandated that the Commission commence competitive bidding for the commercial licenses well before the scheduled termination date of the DTV transition. In the *700 MHz MO&O and FNPRM*, (65 FR 42879 and 65 FR 42960, July 12, 2000), the Commission provided guidance on its review of applications for approval of regulatory requests associated with voluntary agreements accelerating the transition of incumbent analog television licensees and opening these bands for new 700 MHz licensee use. The *Third R&O* announces additional policies to facilitate voluntary band clearing agreements among incumbent broadcasters and new wireless licensees.

2. *Cost-Sharing Rules.* The Commission concludes that it is not necessary or appropriate to adopt cost-sharing rules to assist in clearing the 700 MHz band. Based on the record, the Commission finds that the new 700 MHz commercial wireless licensees should be able to enter into cost-sharing agreements without Commission rules. Therefore, the Commission leaves all cost-sharing arrangements to negotiations among successful auction bidders in this band.

3. *Three-Way Voluntary Transition Agreements.* The Commission adopts a general presumption, standards of review, and policies for three-way agreements among incumbent Channel 59–69 broadcasters and new 700 MHz wireless licensees that are similar to those adopted in the *700 MHz MO&O and FNPRM* for bilateral agreements between broadcasters and new 700 MHz wireless licensees. Three-way band clearing agreements would provide for TV incumbents in the 700 MHz band to relocate their operations to lower band TV channels that would be voluntarily cleared by the lower band TV incumbents. The Commission finds that adopting guidelines for three-way agreements similar to those established for bilateral agreements should help negotiating parties and serve the public interest by providing a measure of certainty regarding the conditions under which a regulatory request to implement a three-way agreement may be approved. The presumption the Commission will apply to three-way agreements will be the same as the presumption adopted for bilateral agreements. Thus, the Commission will presume that the public interest is substantially furthered when an applicant demonstrates that the grant of its request will both result in certain specific benefits and avoid specific detriments. To obtain this presumption, an applicant must first demonstrate that grant of its request would result in one of the following: (i) Make new or