

**List of Subjects in 40 CFR Part 81**

Environmental protection, Air pollution control, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: March 20, 1997.  
**John P. DeVillars,**  
*Regional Administrator, Region I.*  
 Part 81 of chapter I, title 40 of the Code of Federal Regulations is amended as follows:

**Authority:** 42 U.S.C. 7401-7671q.

**Subpart C—Maine**

2. Section 81.320 is amended by revising the table for SO<sub>2</sub> to read as follows:

**PART 81—[AMENDED]**

1. The authority for part 81 continues to read as follows:

**§ 81.320 Maine.**

\* \* \* \* \*

SO<sub>2</sub>

Designated area	Does not meet primary standards	Does not meet secondary standards	Cannot be classified	Better than national standard
AQCR 110 .....	.....	.....	.....	X
AQCR 107 .....	.....	.....	.....	X
AQCR 109 .....	.....	.....	.....	X
AQCR 108-Madawaska .....	.....	.....	X	.....
Rest of region .....	.....	.....	.....	X
AQCR 111 .....	.....	.....	.....	X

\* \* \* \* \*  
 [FR Doc. 97-11483 Filed 5-1-97; 8:45 am]  
 BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-300481; FRL-5713-6]

RIN 2070-AB78

**Clomazone; Pesticide Tolerances for Emergency Exemptions**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a time-limited tolerance for residues of the herbicide clomazone in or on the food commodity watermelons in connection with EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of clomazone on watermelons in Delaware, Virginia, and Maryland. This regulation establishes maximum permissible levels for residues of clomazone on watermelons pursuant to section 408(l)(6) of the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. This tolerance will expire and is revoked on May 30, 1998.

**DATES:** This regulation becomes effective May 2, 1997. Objections and requests for hearings must be received by July 1, 1997.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number, [OPP-300481],

must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300481], should be submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [OPP-300481]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

**FOR FURTHER INFORMATION CONTACT:** By mail: Virginia Dietrich, Registration Division (7505W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA (703) 308-8347, e-mail: dietrich.virginia@epamail.epa.gov.  
**SUPPLEMENTARY INFORMATION:** EPA, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for residues of the herbicide clomazone (2-(2-Chlorophenyl) methyl-4,4-dimethyl-3-isoxazolidinone) in or on watermelons at 0.1 ppm. This tolerance will expire and be revoked by EPA on May 30, 1998. After May 30, 1998, EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

**I. Background and Statutory Authority**

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited

tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 CFR 58135, November 13, 1996) (FRL-5572-9).

New section 408(b)(2)(A)(i) allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that "emergency conditions exist which require such exemption". This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Section 408(l)(6) also requires EPA to promulgate regulations by August 3, 1997, governing the establishment of tolerances and exemptions under section 408(l)(6) and requires that the regulations be consistent with section 408(b)(2) and (c)(2) and FIFRA section 18.

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

In establishing section 18-related tolerances and exemptions during this

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

## II. Emergency Exemptions for Clomazone on Watermelons and FFDCA Tolerances

Between December 30, 1996 and January 24, 1997, Departments of Agriculture from three states (Delaware, Maryland and Virginia) each requested a specific exemption under FIFRA section 18 for the use of clomazone to control weeds in watermelons. These exemptions stated that no herbicides with efficacy similar to clomazone are currently registered for use on watermelons and that without its use, significant economic loss will be expected. After having reviewed their submission, EPA concurs that an emergency condition exists.

As part of its assessment of these applications for emergency exemption, EPA assessed the potential risks presented by residues of clomazone on watermelons. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided to grant the section 18 exemptions only after concluding that the necessary tolerance under FFDCA section 408(l)(6) would clearly be consistent with the new safety standard and with FIFRA section 18. This tolerance for clomazone will permit the marketing of watermelons treated in accordance with the provisions of the section 18 emergency exemptions. Consistent with the need to move quickly on the emergency exemptions and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e) as provided in section 408(l)(6). Although these tolerances will expire and are revoked on May 30, 1998, under FFDCA section 408(l)(5), residues of clomazone not in excess of the amount specified in the tolerance remaining in or on watermelons after that date will not be unlawful, provided the pesticide is applied during the term of, and in accordance with all the

conditions of the emergency exemptions. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

EPA has not made any decisions about whether clomazone meets the requirements for registration under FIFRA section 3 for use on watermelons or whether permanent tolerance for clomazone for watermelons would be appropriate. This action by EPA does not serve as a basis for registration of clomazone by a State for special local needs under FIFRA section 24(c). Nor does this action serve as the basis for any State other than Delaware, Virginia, and Maryland to use this product on watermelons under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR 180.166. For additional information regarding the emergency exemptions for clomazone, contact the Agency's Registration Division at the address provided above.

## III. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including, but not limited to, reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. For many of these studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the "no-observed effect level" or "NOEL").

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL by the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a "safety factor") of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the

potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered by EPA to pose a reasonable certainty of no harm.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or margin of exposure calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, and other non-occupational exposures, such as where residues leach into groundwater or surface water that is consumed as drinking water. Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. The TMRC is a "worst case" estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100 percent of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of watermelons treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

#### IV. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. Clomazone is not registered by EPA for indoor or outdoor residential use. Existing food and feed use tolerances for clomazone are listed in 40 CFR 180.425. 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 the time-limited tolerance for residues of clomazone in or on watermelons at 0.1 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

##### A. Toxicological Profile

1. *Acute risk.* No appropriate acute dietary endpoint was identified by the Office of Pesticide Programs (OPP).

2. *Chronic risk.* Based on available chronic toxicity data, the OPP has established the RfD for clomazone at 0.043 mg/kg/day. The RfD is based on a 2-year feeding study in rats with a no observed effect level (NOEL) of 4.3 mg/kg/day and an uncertainty factor of 100, based on increased liver weights and serum cholesterol at the Lowest observed effect level (LOEL) of 21.5 mg/kg/day.

3. *Cancer risk.* Clomazone has not been classified by the Office of Pesticide Programs. However, there have been no cancer concerns reported at this time.

##### B. Aggregate Exposure

Tolerances for residues of clomazone are currently expressed as 2-(2-Chlorophenyl)methyl-4,4-dimethyl-3-isoxa-zolidinone. Tolerances currently exist for residues on more than a dozen commodities (see 40 CFR 180.425).

The Agency identified chronic exposure as appropriate for aggregate risk assessment. The aggregate chronic risk is equal to the sum of the chronic risk from exposure from food + water + residential (indoor and outdoor) uses. Clomazone is not registered for any residential uses so no exposure from this route is expected. The Agency estimates that aggregate risk (food plus drinking water) would not exceed the RfD for clomazone.

No short- or intermediate-term non-dietary, non-occupational exposure scenario exists for clomazone, therefore, a short- or intermediate-term aggregate risk assessment is not required. No appropriate acute dietary risk endpoint was identified, thus no acute aggregate risk assessment is required. A cancer aggregate risk assessment is not required

because there are no reported cancer concerns at this time.

For purposes of assessing the potential dietary exposure under this tolerance, EPA assumed tolerance level residues and 100 percent of crop treated to estimate the TMRC from all established food uses for clomazone (for more than a dozen commodities) and the proposed use on watermelons. There are no watermelon animal feed items so no residue levels in animal commodities potentially resulting from feeding of these commodities were considered.

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

There is potential for clomazone to leach to ground water because based on the available studies used in EPA's assessment of environmental risk, clomazone is moderately persistent and potentially mobile. For this reason, exposure to clomazone through drinking water was considered during the risk assessment.

Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for consumption of contaminated water, the ranges the Agency is continuing to examine are all well below the level that would cause clomazone to exceed the RfD if the tolerances 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 tolerances are granted.

#### *C. Cumulative Exposure to Substances with Common Mechanism of Toxicity*

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed). EPA has not made a determination whether clomazone and any other pesticide have a common

mode of toxicity and require cumulative risk assessment. For purposes of these section 18 exemptions, the Agency has considered only risks from clomazone.

#### *D. Safety Determination for U.S. Population*

Based on the completeness and reliability of the toxicity data and the conservative TMRC dietary exposure assumptions, EPA has concluded that dietary exposure from food to clomazone will utilize <1 percent of the RfD for the U.S. population. EPA generally has no concern for exposures below 100 percent of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Whatever reasonable bounding figure the Agency eventually decides upon for the contribution from water, that number is expected to be well below 99% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to clomazone residues.

#### *E. Safety Determination for Infants and Children*

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety factor) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. EPA believes that reliable data support using the standard margin of exposure (usually 100x for combined inter- and intra-species variability) and not the additional tenfold margin of exposure 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 margin of exposure. Based on current toxicological data requirements, the database for clomazone relative to pre- (provided by rat and rabbit developmental studies) and post-natal (provided by the rat reproduction study) toxicity is complete.

In assessing the adequacy of the standard uncertainty factor for 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 pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

Developmental toxicity was not observed in developmental studies using rats and rabbits. In the rat developmental toxicity study, the maternal and developmental NOELs and LELs occurred at the same dose levels of 100 and 300 mg/kg/day, respectively, and the developmental findings did not indicate a need for an acute dietary risk assessment. The rabbit developmental study had no developmental findings up to 700 mg/kg/day (highest dose tested).

The Agency's review, completed in 1986, of the rat reproductive toxicity study indicates that there may be a special post-natal sensitivity for infants and children. The parental NOEL and LOEL were 50 and 100 mg/kg/day, respectively, based on decreased body weight, decreased food consumption, increased clinical signs and increased organ weights. The pup NOEL and LOEL were 5 and 50 mg/kg/day, respectively, based on decreased survival, decreased viability, and decreased body weight.

However, upon rereview of this study for this section 18 exemption, the Agency has discovered discrepancies between the conclusions presented in the review and the data provided in its summary tables. However, based on our review, the Office of Pesticide Programs believes that the standard uncertainty factor is adequate to protect infants and children and that an additional uncertainty factor is not necessary.

In any event, given the low percentage (< 1%) of the RfD occupied for infants and children, which was calculated using very conservative aggregate risk estimates, aggregate exposure estimates for infants and children would not exceed the Agency's level of concern even if an additional uncertainty factor were to be added.

Despite the potential for exposure through drinking water, EPA has concluded that the percentage of the RfD that will be utilized by dietary exposure (including drinking water exposure) to residues of clomazone does not exceed 100% for any of the population subgroups. Considering food only, the population subgroup with the largest percentage of the RfD occupied is the non-nursing infants (< 1 year old) at < 1% of the RfD. Therefore, taking into account the completeness and reliability of the toxicity data and the conservative exposure assessment, 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

The metabolism of clomazone in plants is adequately understood for the purposes of this tolerance. There are no Codex, Canadian, or Mexican international maximum residue levels established for residues of clomazone on watermelons. There is a practical analytical method (Method I, Pesticide Analytical Manual, Volume II) for detecting and measuring levels of clomazone in or on food with a limit of detection that allows monitoring of food with residues at or above the level set by the clomazone tolerance. EPA has provided information on this method to FDA. The method is available to anyone who is interested in pesticide residue enforcement from: By mail, Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Crystal Mall #2, Rm 1128, 1921 Jefferson Davis Hwy., Arlington, VA 703-305-5805.

#### VI. Conclusion

Therefore, tolerances in connection with the FIFRA section 18 emergency exemptions are established for residues of clomazone in or on watermelons at 0.1 p.m.

#### VII. Objections and Hearing Requests

The new FFDC section 408(g) provides essentially the same process for persons to "object" to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by July 1, 1997, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be

submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

#### VIII. Public Docket

EPA has established a record for this rulemaking under docket number [OPP-300481] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

#### IX. Regulatory Assessment Requirements

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

Because FFDC section 408(l)(6) permits establishment of this regulation without a notice of proposed rulemaking, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act, 5 U.S.C. 604(a), do not apply. Nonetheless, the Agency has previously assessed whether establishing tolerances or exemptions from tolerance, raising tolerance levels, or expanding exemptions adversely impact small entities and concluded, as a generic matter, that there is no adverse impact. (46 FR 24950, May 4, 1981).

Under 5 U.S.C. 801(a)(1)(A) of the Administrative Procedure Act (APA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104-121, 110 Stat. 847), EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2) of the APA as amended.

**List of Subjects in 40 CFR Part 180**

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

Dated: April 18, 1997.

**Peter Caulkins,**

*Director, Office of Pesticide Programs.*

Therefore, 40 CFR Chapter I is amended as follows:

**PART 180—[AMENDED]**

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

**Authority:** 21 U.S.C. 346a and 371.

2. Section 180.425 is amended as follows

- i. By designating the existing text as paragraph (a) "General".
- ii. By adding paragraph (b).
- iii. By adding and reserving paragraphs (c) and (d).

**§ 180.425 Clomazone; tolerances for residues.**

(a) *General.* \* \* \*

(b) *Section 18 emergency exemptions.* Time limited tolerances are established for residues of the herbicide clomazone (2-(2-Chlorophenyl) methyl-4,4-dimethyl-3-isoxazolidinone) in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerance is specified in the following table. The tolerance expires and will be revoked by EPA on the date specified in the table.

Commodity	Parts per million	Expiration/Revocation Date
Watermelons .....	0.1	5/30/98

(c) *Tolerances with regional registrations.* [Reserved]

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

[FR Doc. 97-11505 Filed 5-01-97; 8:45 am]

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-300474A; FRL-5714-5]

RIN 2070-AB78

**Propiconazole; Pesticide Tolerances for Emergency Exemptions; Correction**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule; correction.

**SUMMARY:** EPA published in the **Federal Register** of April 11, 1997, a document establishing time-limited tolerances for combined residues of the pesticide propiconazole in or on the food commodities almonds and cranberries. The tolerance level for cranberries was listed incorrectly. This document corrects the amount.

**EFFECTIVE DATE:** This correction is effective May 2, 1997.

**FOR FURTHER INFORMATION CONTACT:** By mail: Olga Odiott, Registration Division (7505W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA, 703-308-6418, e-mail: odiott.olga@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** EPA published a document on April 11, 1997 (62 FR 17710) (FRL-5600-5), establishing time-limited tolerances for combined residues of the pesticide propiconazole in or on the food commodities almonds and cranberries. The tolerance level for cranberries was listed incorrectly. This document corrects the amount.

**List of Subjects in 40 CFR Part 180**

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

Dated: April 23, 1997.

**Stephen L. Johnson,**

*Acting Division Director, Office of Pesticide Programs.*

In FR Doc. 97-9371 published on April 11, 1997 (62 FR 17710), make the following correction:

**§ 180.434 [Corrected]**

On page 17717, in § 180.434(b), in the table, the entry for cranberries, in the second column, parts per million is corrected to read "1.0".

[FR Doc. 97-11506 Filed 5-1-97; 8:45 am]

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-300479; FRL-5713-2]

RIN 2070-AB78

**Paraquat; Pesticide Tolerances for Emergency Exemptions**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances for residues of the herbicide paraquat in or on the food commodities sorghum grain, sorghum forage, sorghum stover, sorghum aspirated grain fractions, corn grain, corn forage, corn fodder, corn flour, and poultry byproducts in connection with EPA's granting of an emergency exemption under the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of paraquat on sorghum and corn in Louisiana. This regulation establishes maximum permissible levels for residues of paraquat in these foods pursuant to the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and are revoked on April 14, 1998.

**DATES:** This regulation becomes effective May 2 1997. Objections and requests for hearings must be received by EPA on or before July 1, 1997.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number, [OPP-300479], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300479], must also be submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA. A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov.

Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [OPP-300479]. No Confidential