

from *Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 petition under FFDCA section 408, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

V. Submission to Congress and the General Accounting Office

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

rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: November 4, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

§ 180.509 [Amended]

2. In § 180.509, by amending paragraph (b) by revising the date for "barley, bran; barley, flour; barley, grain; barley, hay; barley, pearled; barley, straw; wheat, grain; and wheat, straw" from "2/1/00" to read "12/31/01".

[FR Doc. 99-30410 Filed 11-19-99; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300949; FRL-6392-9]

RIN 2070-AB78

Paraquat; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of paraquat (1,1'-di-methyl-4,4'-bipyridinium-ion) in or on artichokes. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on artichokes. This regulation establishes a maximum permissible level for residues of paraquat in this food commodity. The tolerance will expire and is revoked on December 31, 2000.

DATES: This regulation is effective November 22, 1999. Objections and requests for hearings, identified by docket control number OPP-300949,

must be received by EPA on or before January 21, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the "SUPPLEMENTARY INFORMATION." To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-300949 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Libby Pemberton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 308-9364; and e-mail address: pemberton.libby@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

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

the "Federal Register--Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-300949. 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

EPA, on its own initiative, in accordance with sections 408 (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for residues of the herbicide paraquat, in or on artichokes at 0.05 part per million (ppm). This tolerance will expire and is revoked on December 31, 2000. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable

certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

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

III. Emergency Exemption for Paraquat on Artichokes and FFDCA Tolerances

Simazine has been used in the past to control common chickweed, mustard, Bermuda buttercup, certain grasses and older weeds in artichokes. With the imminent cancellation of simazine on artichokes, the industry purchased all existing stocks. However, growers are expected to deplete the existing stocks of simazine, labeled for artichokes by September of 1999. EPA has authorized under FIFRA section 18 the use of paraquat on artichokes for control of weeds in California. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of paraquat in or on artichokes. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6). Although this tolerance will expire and is revoked on December 31, 2000, under FFDCA

section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on artichokes after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether paraquat meets EPA's registration requirements for use on artichokes or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of paraquat by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than California to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for paraquat, contact the Agency's Registration Division at the address provided under "FOR FURTHER INFORMATION CONTACT."

IV. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of paraquat and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of paraquat on artichokes at 0.05 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity,

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

B. Toxicological Endpoint

1. *Acute toxicity.* An acute reference dose (acute RfD) of 0.03 milligrams per kilogram per day (mg/kg/day) has been identified for females 13+ years old and the general population including infants and children. For females 13+ the acute RfD is based on the maternal no observable adverse effects level (NOAEL) of 3 milligrams/kilogram/day (mg/kg/day) derived from the combined results of two developmental studies in rats. The effects of concern are delayed ossification of the forelimb and hindlimb digits. The maternal NOAEL of 3 mg/kg/day has also been identified as the endpoint of concern for the acute RfD for the general population including infants and children. The effects of concern are based on clinical signs of toxicity, decreased body weight gain, and respiratory distress and histopathology of the lungs. An uncertainty factor (UF) of 100 (10x for inter-species extrapolation and 10x for intra-species variability) is appropriate. The 10x FQPA Safety factor to account for enhanced sensitivity of infants and children as required by FFDCA section 408 (b)(2)(C) was reduced to 1x for acute exposures. The acute Population Adjusted Dose (aPAD) is a modification of the acute RfD to accommodate the FQPA Safety Factor. The aPAD is equal to the acute RfD divided by the FQPA Safety Factor. Therefore, for females 13+ years old and the general population including infants and children the dietary aPAD is 0.03 mg/kg/day.

2. *Short- and intermediate-term toxicity.* The NOAEL of 3.0 mg/kg/day derived from the combined results of two developmental studies in rats was identified as the short- and intermediate-term endpoints for dermal exposures. At lowest observable adverse effects level (LOAEL) of 5.0 mg/kg/day, there were clinical signs of toxicity, decreased body weight gain, and lung histopathology. A 0.3% dermal absorption rate should be used in risk assessments.

3. *Chronic toxicity.* EPA has established the chronic RfD for paraquat at 0.0045 mg/kg/day. The chronic RfD is based on the NOAEL of 0.45 mg/kg/day from a one year oral study in dogs. At the LOAEL of 0.93 mg/kg/day the effects

were chronic pneumonitis. An UF of 100 (10x for inter-species extrapolation and 10x for intra-species variability) is appropriate. The 10x FQPA Safety factor to account for enhanced sensitivity of infants and children as required by FFDCA section 408 (b)(2)(C) is not applicable because the endpoint used in deriving the chronic RfD is based on chronic pneumonitis (not developmental or neurotoxic effects) in adult dogs after chronic exposure and thus are not relevant for enhanced sensitivity to infants and children. The chronic Population Adjusted Dose (cPAD) is a modification of the chronic RfD to accommodate the FQPA Safety Factor. The cPAD is equal to the chronic RfD divided by the FQPA Safety Factor. Hence for chronic exposures, the cPAD and chronic RfD are the same (0.0045 mg/kg/day).

4. *Carcinogenicity.* Paraquat is classified as Group E (no evidence of carcinogenicity in humans).

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.205) for the residues of paraquat, in or on a variety of raw agricultural commodities. Tolerances have also been established for fat, kidney, meat, and meat byproducts for cattle, goats, hogs, horses, poultry and sheep as well as tolerances for eggs and milk. Risk assessments were conducted by EPA to assess dietary exposures and risks from paraquat as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–91 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. At the 95th percentile exposure level, assuming 100 percent crop treated and tolerance level residues for all commodities, 13 percent of the aPAD was utilized for the U.S. Population and 23 percent of the aPAD was utilized for children (1-6 years old), the subgroup with the highest exposure. The results of this analysis indicate that the acute dietary risk associated with existing uses and the proposed use of paraquat is below the Agency's level of concern.

ii. *Chronic exposure and risk.* In conducting this chronic dietary risk assessment the DEEM™ analysis evaluated the individual food

consumption as reported by respondents in the USDA 1989–91 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. Assuming tolerance level residues for all commodities and 100 percent crop treated values, 31 percent of the cPAD was utilized for the U.S. Population and 69 percent of the cPAD was utilized for children (1-6 years old), the subgroup with the highest exposure. The results of this analysis indicate that the chronic dietary risk associated with existing uses and the proposed use of paraquat is below the Agency's level of concern.

2. *From drinking water.* Paraquat dichloride binds strongly to soil clay particles and it did not leach from the surface in terrestrial field dissipation studies. There were, however, detections of paraquat in drinking water wells from two states cited in the Pesticides in Ground Water Database (1991). These detections are not considered to be representative of normal paraquat use. Therefore, paraquat is not expected to be a groundwater contaminant or concern based on normal use patterns.

Due to its persistent nature, paraquat could potentially be found in surface water systems associated with soil particles carried by erosion, however, paraquat is immobile in most soils, and at very high application rates (50–1000X), there was no desorption of paraquat from soils. Therefore, based on paraquat's normal use patterns and unique environmental fate characteristics, exposures to paraquat in drinking water are not expected to be obtained from surface water sources.

3. *From non-dietary exposure.* Paraquat is not registered on any use sites which would result in non-dietary, non-occupational exposure. Therefore, EPA expects only dietary and occupational exposure from the use of paraquat.

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 paraquat 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, paraquat 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 paraquat has a common mechanism of toxicity with other substances. For more information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Acute risk.* Acute aggregate exposure takes into account acute dietary food and water exposures plus other indoor and outdoor non-occupational exposure. Since paraquat is not registered on any use sites which would result in non-dietary, non-occupational exposure and exposure to ground or surface water is not expected, the only non-occupational exposure to paraquat is expected through consumption of food. Therefore acute aggregate risk to paraquat is assumed to be the same as estimated risk from food and feed uses: at the 95th percentile exposure level, assuming 100 percent crop treated and tolerance level residues for all commodities, 13 percent of the aPAD was utilized for the U.S. Population.

2. *Chronic risk.* Chronic-term aggregate exposure takes into account chronic dietary food and water plus other indoor and outdoor non-occupational exposure. Since there are no non-dietary, non-occupational exposures expected from the use of this chemical and paraquat is not expected to reach ground or surface water, the only non-occupational exposure to paraquat is anticipated through consumption of food. Therefore chronic aggregate risk to paraquat is expected to be the same as the estimated risk from food and feed uses: assuming tolerance level residues for all commodities and 100 percent crop treated values, 31 percent of the cPAD was utilized for the U.S. Population.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. Paraquat is not registered on any use sites which would result in non-dietary, non-occupational exposure. Therefore no short- and intermediate-term aggregate risk assessments are needed.

4. *Aggregate cancer risk for U.S. population.* Paraquat is classified as Group E (no evidence of carcinogenicity in humans).

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

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

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

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined interspecies and intraspecies variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* In a developmental study in rats, the maternal NOAEL is 8 mg/kg/day (HDT). No LOAEL was identified and there were no maternal or developmental effects observed in the study.

In another developmental study in rats, the maternal NOAEL is 1 mg/kg/day based on thin and hunched appearance, decreased body weight gain, and histological changes in the lungs and kidneys of non-survivors at 5

mg/kg/day (LOAEL). The developmental NOAEL is 1 mg/kg/day based on delayed ossification in the fore- and hindlimb digits at 5 mg/kg/day (LOAEL). (The overall maternal and developmental NOAEL for the rat is considered 3 mg/kg/day based on the results from two developmental studies.)

In a developmental study in mice, the maternal NOAEL is 5 mg/kg/day based on statistically significant decreases in body weight gain at 10 mg/kg/day (LOAEL). The developmental NOAEL is 5 mg/kg/day based on statistically significant decreases in body weight gain at 10 mg/kg/day (LOAEL).

In another developmental study in mice, the maternal NOAEL is 15 mg/kg/day based clinical signs, death, decreased body weight gain, decreased body weight, increased organ weight (lung w/ trachea, kidney), dark red lung lobes, and possible decrease in pregnancy rate at 25 mg/kg/day (LOAEL). The developmental NOAEL is 15 mg/kg/day based on decreased mean fetal weight, retarded ossification of occipital, increased number with extra 14th ribs, increased number with unossified astragalus in the hindlimb, and an increased number with ≤ 6 caudal centra.

iii. *Reproductive toxicity study.* In a 2-generation reproductive study in rats, the NOAEL for paternal toxicity is 1.25 mg/kg/day based on increased incidence of alveolar histiocytes, discolored lungs, fibrosis, edema at the LOAEL of 3.75 mg/kg/day. There were no reproductive effects seen in this study therefore, the reproductive NOAEL/LOAEL is 7.5 mg/kg/day (HDT).

iv. *Prenatal and postnatal sensitivity.* The Agency has determined that there is no indication of additional sensitivity to young rats or mice following pre-and/or postnatal exposure to paraquat.

v. *Conclusion.* There is a complete toxicity data base for paraquat and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Data provided no indication of increased sensitivity of rats or mice to *in utero* and/or postnatal exposure to paraquat. Based on this, EPA concludes that reliable data support the use of the standard 100-fold uncertainty factor, and that an additional uncertainty factor is not needed to protect the safety of infants and children.

2. *Acute risk.* Acute aggregate exposure takes into account acute dietary food and water exposures plus other indoor and outdoor non-occupational exposures. Since paraquat is not registered on any use sites which would result in non-dietary, non-

occupational exposure and is not expected in ground or surface water, the only non-occupational exposure to paraquat is expected through consumption of food. Therefore acute aggregate risk to paraquat is assumed to be the same as estimated risk from food and feed uses; at the 95th percentile exposure level, assuming 100 percent crop treated and tolerance level residues for all commodities, 23 percent of the aPAD was utilized for utilized for children, 1-6 years old, the major identifiable subgroup with the highest aggregate exposure.

3. *Chronic risk.* Chronic-term aggregate exposure takes into account chronic dietary food and water plus other indoor and outdoor non-occupational exposure. Since there are no non-dietary, non-occupational exposures expected from the use of this chemical and paraquat is not expected to reach ground or surface water, the only non-occupational exposure to paraquat is expected through consumption of food. Therefore chronic aggregate risk to paraquat is assumed to be the same as the estimated risk from food and feed uses; assuming tolerance level residues for all commodities and 100 percent crop treated values, 69 percent of the cPAD was utilized for children, 1-6 years old, the major identifiable subgroup with the highest aggregate exposure.

4. *Short- or intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. Paraquat is not registered on any use sites which would result in non-dietary, non-occupational exposure. Therefore no short- and intermediate-term aggregate risk assessments are needed.

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

V. Other Considerations

A. Metabolism in Plants and Animals

The qualitative nature of the residue in plants and animals has been understood. The residue of concern is the parent compound, paraquat, only, as specified in 40 CFR 180.205.

B. Analytical Enforcement Methodology

Method I of PAM, Vol. II (spectrophotometric), is adequate for tolerance enforcement purposes. In addition, the Agency concluded that

Method 1B adequately recovers paraquat cation residues from samples of potatoes and soybeans treated with radiolabeled paraquat.

C. Magnitude of Residues

Residues of paraquat are not expected to exceed 0.05 ppm in/on artichokes as a result of this section 18. No animal feed items are associated with the proposed use.

D. International Residue Limits

No CODEX, Canadian, and/or Mexican MRLs/tolerances have been established for residues of paraquat on artichoke. Therefore, there are no issues of international harmonization associated with this action.

E. Rotational Crop Restrictions

Artichokes are a perennial crop and are not normally rotated; therefore, a discussion of rotational crop requirements is not germane to this petition.

VI. Conclusion

Therefore, the tolerance is established for residues of paraquat in artichokes at 0.05 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP-300949 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 January 21, 2000.

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

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

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

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

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of

Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by the docket control number OPP-300949, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Regulatory Assessment Requirements

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

Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 petition under FFDCA section 408, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various

levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

IX. Submission to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: November 4, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. In § 180.205, the table to paragraph (b) is amended by adding alphabetically an entry for "artichokes" to read as follows:

§ 180.205 Paraquat; tolerances for residues.

*	*	*	*
*			

(b) *Section 18 emergency exemptions.*

Commodity	Parts per million	Expiration/revocation date
Artichokes	0.05	12/31/00

* * * *

[FR Doc. 99-30411 Filed 11-19-99; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL-6476-8]

National Oil and Hazardous Substance Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Notice of partial deletion of the Materials Technology Laboratory (MTL)—Watertown Arsenal Development Corporation Parcel and Commander's Quarters parcel (also known as Zones 1-4) from the National Priorities List (NPL).

SUMMARY: The Environmental Protection Agency (EPA) Region I announces the partial deletion of the Materials Technology Laboratory—Watertown Arsenal Development Corporation Parcel and Commander's Quarters parcel (jointly known as Zones 1-4) from the National Priorities List (NPL). Zones 1 through 4 of MTL include a portion of Operable Unit (OU) No. 1 and OU No. 3. The NPL constitutes appendix B of 40 CFR part 300, which is the National Oil and Hazardous Substance Pollution Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended by the

Superfund Amendments and Reauthorization Act. After consultation with the Commonwealth of Massachusetts, EPA has determined that all appropriate actions under CERCLA have been implemented. Moreover, EPA and the Commonwealth have determined that remedial activities conducted to date at OU No. 1 (Zones 1 through 4) and OU No. 3 have been protective of human health, welfare and the environment. Institutional controls, which have been established as part of the remedy, will ensure continued protectiveness in the future. Institutional controls are provided for in a Grant of Environmental Restriction and Easement. The Charles River Park parcel and the Charles River Operable Unit, are still undergoing investigation/remedial actions and are not to be removed from the NPL at this time.

EFFECTIVE DATE: November 22, 1999.

FOR FURTHER INFORMATION CONTACT: Meghan Cassidy, Remedial Project Manager, U.S. EPA Region I, 1 Congress St., Suite 1100 (HBT), Boston, MA 02114-2023, (617) 918-1387.

SUPPLEMENTARY INFORMATION: The site to be partially deleted from the NPL is: Watertown Arsenal Development Corporation Parcel and Commander's Quarters parcel (also known as Zones 1-4) of the Materials Technology Laboratory (MTL) in Watertown, Massachusetts.

A Notice of Intent to Delete for these parcels at this site was published on August 16, 1999, 64 FR 44454. The closing date for comments on the Notice of Intent to Delete was September 15, 1999. EPA received no comments.

EPA identifies sites that appear to present a significant risk to public

health, welfare, or the environment and maintains the NPL as the list of these sites. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund Response Trust Fund (Fund). Pursuant to § 300.425(e)(3) of the NCP, any site (or portion thereof) deleted from the NPL are eligible for further remedial actions should future conditions warrant such action.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous Waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: October 8, 1999.

John P. DeVillars,

Regional Administrator, Region 1.

For the reasons set out in the preamble, 40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601-9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923; 3 CFR, 1987 Comp., p. 193.

2. Table 2 of Appendix B to Part 300 is amended by revising the entry for "Materials Technology Laboratory (USARMY)", Watertown, Massachusetts to read as follows:

Appendix B to Part 300—National Priorities List

* * * *

TABLE 2.—FEDERAL FACILITIES SECTION

St	Site name	City/county	Notes(a)
MA	Materials Technology Laboratory (USARMY)	Watertown	P

(a) * * *

P = Sites with partial deletion(s).