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]

BILLING CODE 6560–50–F

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]

BILLING CODE 6560–50–F

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

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: Pat Cimino, Registration Division (7505W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA, (703) 308-8328, e-mail: cimino.pat@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 paraquat (1,1′-dimethyl-4,4′-bipyridinium-ion), in or on grain sorghum at 5.0 part per million (ppm), sorghum stover at 10.0 ppm, sorghum forage at 3.0 ppm, aspirated sorghum grain fractions at 50.0 ppm, corn grain at 0.05 ppm, corn forage at 3.0 ppm, corn fodder at 10.0 ppm, corn flour at 0.10 ppm and poultry byproducts at 0.02 ppm. These tolerances will expire and be revoked by EPA on April 14, 1998. After April 14, 1998, EPA will publish a document in the **Federal Register** to remove the revoked tolerances 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 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 FR 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 Exemption for Paraquat on Sorghum and Corn and FFDCA Tolerances

On August 6, 1996, the Louisiana Department of Agriculture Forestry used its authority to declare the existence of a crisis situation within the state, thereby authorizing use under FIFRA section 18 of paraquat on sorghum and corn as a harvest aid for control of weeds. Louisiana stated that above average rainfall has resulted in regrowth and flushes of weeds in corn and sorghum rendering harvest difficult to impossible in the state. This could result in an economic disaster for Louisiana corn and sorghum producers.

As part of its assessment of these crisis declarations, EPA assessed the potential risks presented by residues of paraquat in or on sorghum and corn. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided to allow the crisis uses only after concluding that the necessary tolerances under FFDCA section 408(l)(6) would clearly be consistent with the new safety standard and with FIFRA section 18. These tolerances for paraquat will permit the marketing of corn and sorghum 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 these tolerances 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 April 14, 1998, under FFDCA section 408(l)(5), residues of paraquat not in excess of the amounts specified in the tolerances remaining in or on sorghum and corn 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 these tolerances 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 paraquat meets the requirements for registration under FIFRA section 3 for use on sorghum and corn, or whether permanent tolerances for paraquat for sorghum and corn would be appropriate. This action by EPA does not serve as a basis for registration of paraquat 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 Louisiana to use this product on this crop under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemptions for paraquat, 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 from 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 acceptable by EPA.

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 every crop considered in the analysis is treated with the pesticide being evaluated. 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 crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances and that the entire crop may not have been treated with the pesticide.

IV. Aggregate Risk Assessments, Cumulative Risk Discussion, 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. Paraquat is already registered by EPA for use on various food and feed crops (see 40 CFR 180.205 for specific tolerances). Tolerances exist for most of the food or feed crops affected by these emergency exemptions [0.05 ppm (Non-Detectable) levels for corn (grain, fodder and forage) and sorghum (grain and forage)]; however, they were established for use patterns (primarily as pre-plant herbicide use for reduced-tillage soil conservation farming practices) with much longer pre harvest intervals (PHI) than these emergency exemption harvest-aid/desiccant use patterns.

The pesticide residues from the emergency exemption harvest aid/desiccant use pattern exceed the established tolerances, therefore, new tolerance levels are required. Tolerances exist for meat, milk, poultry and eggs to address the potential for secondary residues resulting from the use of treated commodities as feed. Secondary residues in animal commodities from this section 18 use, resulting from the use of sorghum or corn as feed, are not expected to exceed existing tolerances with the exception of poultry byproducts. The existing tolerance for poultry byproducts is 0.01 ppm. Residues in poultry byproducts are not expected to exceed 0.02 ppm as a result of these emergency exemption uses.

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 time-limited tolerances for residues of paraquat in or on grain sorghum at 5.0 part per million (ppm), sorghum stover at 10.0 ppm, sorghum forage at 3.0 ppm, aspirated sorghum grain fractions at 50.0 ppm, corn grain at 0.05 ppm, corn forage at 3.0 ppm, corn fodder at 10.0 ppm, corn flour at 0.10 ppm and poultry byproducts at 0.02 ppm. Concentration is not expected in other corn processed commodities (grits, oil, meal, and starch). The Agency's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

1. *Chronic toxicity.* The RfD of 0.0045 milligrams per kilogram per day (mg/kg/day) was established by the Agency based on a 1–year dog feeding study with a NOEL of 15 ppm (0.45 mg/kg/day) and an uncertainty factor of 100. Chronic pneumonitis was observed at the next dose of paraquat tested, 30 ppm (0.93 mg/kg/day, expressed as paraquat cation).

2. *Acute toxicity.* Based on the proposed and existing use patterns and tolerances and available toxicological data, there are no acute dietary exposure endpoints of concern for paraquat.

3. *Carcinogenicity.* Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), EPA has classified paraquat as Group ''E'' for carcinogenicity (evidence of noncarcinogenicity for humans).

B. Aggregate Exposure

Tolerances have been established (40 CFR 180.205) for the residues of paraquat in or on various food commodities ranging from 0.01 ppm in milk to 30.0 ppm in bean straw.

Other potential sources of exposure of the general population to residues of pesticides besides food are residues in drinking water and residues from non-occupational sources such as indoor and outdoor residential uses. There are no indoor or outdoor residential uses registered for paraquat.

There are no acute dietary exposure or cancer risk endpoints of concern for these uses of paraquat. Aggregate risk has been assessed from chronic exposure to food and drinking water.

1. *Dietary/food risk assessment considerations.* For the purpose of assessing potential chronic dietary exposure from paraquat, EPA assumed tolerance levels for all uses and percent of crop treated refinements for some commodities to estimate the Anticipated Residue Contribution (ARC) from the proposed and existing food uses of paraquat. The use of percent of crop treated data for some of the existing food uses in this analysis results in a more refined estimate of exposure than the TMRC. Percent of crop treated estimates are derived from Federal and private market survey data and are considered to be reliable data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group.

2. *Drinking water considerations.* Review of terrestrial field dissipation data by the Environmental Fate and Effects Division indicates that paraquat is persistent and very soluble in water but has a high affinity to bind to sediment. As noted in ''Pesticides in Groundwater Database'' (EPA 734–12–92–001, Sept 1992), 971 wells were sampled in 5 states from 1983 to 1990. Eleven of the 971 wells exhibited positive hits, up to 0.1 milligram per liter (mg/L) (ppm). However, the two wells that exhibited concentrations at 0.1 mg/L were in Missouri, with a detection limit which was also 0.1 mg/L. The next highest concentration of paraquat was 0.018 mg/L from a well in Virginia, where the detection limit of the analytical method was 0.00001 mg/L 9. Based on the poor analytical methodology used, the Agency believes that the Missouri data are unreliable. There is no established Maximum Concentration Level for residues of paraquat in drinking water. The following health advisory levels for paraquat in drinking water have been established: children (short-term exposure) 0.1 mg/L; children (longer-term exposure) 0.05 mg/L; adult (intermediate-term exposure) 0.2 mg/L; and adult (lifetime exposure) 0.03 mg/L.

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 below the level that would cause paraquat to exceed the RfD if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with paraquat in water, even at the higher levels the Agency is considering as a conservative upper bound for RfD exposure considerations, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

3. *Non-dietary, non-occupational considerations.* Paraquat is not registered for indoor or outdoor residential use.

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 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.

D. Determination of Safety for U.S. Population, Infants and Children

1. *U.S. population.* As discussed above, there are no acute dietary exposure or cancer risk endpoints of

concern for these uses of paraquat and based on currently available methodologies, no common mechanism of toxicity with other substances has been assumed. The safety for the U.S. population from this use has been determined using the aggregate risk assessment from chronic exposure to food and drinking water.

Based on the completeness and reliability of the toxicity data and the ARC dietary exposure assumptions, the Agency has concluded that chronic dietary risk from food accounts for 10% of the RfD. Despite the potential for exposure to paraquat in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD, even at the higher levels the Agency is considering as a conservative upper bound for RfD exposure considerations. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to paraquat residues.

2. *Infants and children.* Safety for infants and children from this use has been determined from: Consideration of the special susceptibilities of infants and children to pesticide residues including neurological differences between infants and children and adults, and effects of *in utero* exposure to pesticides and; aggregate risk assessment from chronic exposure to food and drinking water. As discussed above, there are no acute dietary exposure for these uses of paraquat and based on currently available methodologies, no common mechanism of toxicity with other substances has been assumed. A detailed explanation of the risk assessment follows:

i. *Special susceptibility of infants and children considerations.* 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 rabbit and a 2-year reproductive toxicity study in rats. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during pre-natal development to one or both parents. Reproductive toxicity studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

The results of the rat and mouse developmental studies have been used to assess the potential for additional pre-natal sensitivity to infants and children. In the rat developmental study, the maternal (systemic) NOEL and the developmental (fetus) NOEL are both 1 mg/kg/day. The LOELs are 5 mg/kg/day for both maternal (mother) and developmental (fetus) effects. The maternal NOEL and LOEL were based on clinical signs of thin and hunched appearance and decreased body weight gains. Developmental toxicity was manifested as decreases in fetal body weight and delayed ossification in forelimb and hindlimb digits. The developmental results at 5 mg/kg/day do not indicate any severe effects in comparison to the maternal effects at the LOEL, which would necessitate an acute dietary risk assessment for females 13+.

From the mouse developmental study, the maternal (systemic) and developmental (fetus) NOELs were established at 1 mg/kg/day with the LOELs set at 5 mg/kg/day. Maternal toxicity was observed at 5 mg/kg/day and above as reduction in body weight gain. Developmental toxicity was observed at 5 mg/kg/day as partially ossified 4th sternebrae. The developmental effects at the LOEL of 5 mg/kg/day do not demonstrate any special pre-natal sensitivity.

In both developmental toxicity studies, maternal (mother) and developmental (fetus) NOEL/LOEL levels and effects at the LOEL suggest that there is no special pre-natal sensitivity for infants and children from exposure to paraquat residues in the diet.

The results of the 2-generation rat reproduction study have been used to assess the potential for additional post-natal sensitivity. In the rat reproduction study the parental (systemic) NOEL was 1.25 mg/kg/day and the LOEL was 3.75 mg/kg/day based on increased incidence of alveolar histiocytosis. No reproductive effects were observed; therefore, the pup NOEL was considered to be >7.5 mg/kg/day, the highest dose tested. This result indicates that there are no special pre- or post- natal sensitivities to paraquat residues for infants and children.

ii. *Safety factor considerations.* FFDCA section 408 provides that EPA shall apply an additional 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 data base unless EPA concludes, based on reliable evidence, that a different safety factor is protective of infants and children. EPA believes that reliable data support using a different safety factor (usually 100x) and not the additional safety 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 traditional safety factors. Based on current toxicological data requirements, the data base for paraquat relative to pre- and post-natal toxicity is complete. As described above, NOEL/LOEL levels and effects at the LOEL, from the developmental and the reproductive studies, suggest that there is no special pre- or post-natal sensitivity for infants and children from exposure to paraquat residues in the diet. The Agency has concluded that reliable data support use of the standard uncertainty factor as protecting the safety of infants and children and that an additional tenfold margin of exposure is unnecessary.

iii. *Chronic risk.* Based on ARC exposure estimates for food, as described above, EPA has concluded that the percentage of the RfD that will be utilized by dietary (food only) exposure to residues of paraquat ranges from 15% for children 7 to 12 years old, up to 31% for non-nursing infants. Despite the potential for exposure to paraquat in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD, even at the higher levels the Agency is considering as a conservative upper bound for RfD exposure considerations. 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

The nature of the residue in plants and animals is adequately understood for these tolerances. Codex maximum residue levels (MRL) are established for residues of paraquat for corn grain at 0.1 ppm and for sorghum grain at 0.5 ppm. The proposed tolerances for corn grain at 0.05 ppm and sorghum grain at 5.0 ppm differ from the Codex MRLs based on field residue data generated in the United States for these uses (Pesticide Petitions 5F1625 and 5H5088 for corn grain and 5F1591 for sorghum grain). These data indicate that use of the pesticide according to good agricultural practices and under the terms of the FIFRA emergency exemption will not result in residues in corn grain greater than 0.05 ppm or in sorghum grain greater than 5.0 ppm. Differences in use patterns and pre-harvest intervals may account for the differences between the Codex MRLs and the tolerance values generated from the pesticide residue trials in the United States. For purposes of these section 18 uses, the time-limited tolerances will be established at 0.05 ppm for corn grain and 5.0 ppm for sorghum grain. Harmonization of the U.S. tolerances with the Codex MRLs will be addressed if permanent tolerances and registrations are requested. Adequate enforcement

methodology, method I of PAM, Vol. II (spectrophotometric), is available to enforce the tolerance expression. 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 Highway, Arlington, VA (703) 305-5805.

VI. Conclusion

Therefore, tolerances in connection with the FIFRA section 18 emergency exemptions are established for residues of paraquat in or on grain sorghum at 5.0 part per million (ppm), sorghum stover at 10.0 ppm, sorghum forage at 3.0 ppm, aspirated sorghum grain fractions at 50.0 ppm, corn grain at 0.05 ppm, corn forage at 3.0 ppm, corn fodder at 10.0 ppm, corn flour at 0.10 ppm and poultry byproducts at 0.02 ppm. These tolerances will expire and be revoked by EPA on April 14, 1998.

VII. Objections and Hearing Requests

The new FFDCA 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 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–300479] (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 FFDCA 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.

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 17, 1997.

Stephen L. Johnson,

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. 346a and 371.

2. Section 180.205 is amended as follows:

a. In paragraph (a) by adding a paragraph heading, and new entries in alphabetical order to the table.

b. By redesignating paragraph (b) as paragraph (c) and adding a new paragraph (b).

c. In newly designated paragraph (c) by adding a paragraph heading.

d. By adding and reserving paragraph (d).

e. By revising the phrase ''raw agricultural'' to read ''food'' throughout the section.

§ 180.205 Paraquat; tolerances for residues

(a) *General.* * * *

Commodity	Parts per million
* * * *	*
Hops, dried	0.2
* * * *	*
Mint, hay, spent	3.0
Sunflower, seed hulls	6.0
* * * *	*

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the desiccant, defoliant, and herbicide paraquat (1,1′-dimethyl-4,4′-bipyridinium-ion) derived from applications of either the bis (methyl sulfate) or the dichloride salt (both calculated as the cation) in connection with use of the pesticide under section 18 emergency exemptions granted by EPA in or on the following food commodities:

Commodity	Parts per million	Expiration/ Revocation Date
Sorghum grain	5.0	4/14/98
Sorghum stover	10.0	4/14/98
Sorghum forage	3.0	4/14/98
Sorghum, aspirated grain fractions	50.0	4/14/98
Corn grain	0.05	4/14/98
Corn forage	3.0	4/14/98
Corn fodder	10.0	4/14/98
Corn flour	0.10	4/14/98
Poultry, mbyp	0.02	4/14/98

(c) *Tolerances with regional registrations.* * * *

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

[FR Doc. 97–11507 Filed 5–1–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 244

[FRL–5814–7]

Solid Waste Programs; Management Guidelines for Beverage Containers, and Resource Recovery Facilities Guidelines; Removal of Obsolete Guidelines

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Partial withdrawal of direct final rule.

SUMMARY: On December 31, 1996, the Environmental Protection Agency (EPA) published a direct final rule (61 FR 69032) removing from the Code of Federal Regulations (CFR) two guidelines pertaining to solid waste management which are obsolete. This action was published without prior proposal. Because EPA has received adverse comment with respect to the removal of 40 CFR Part 244, Solid Waste Management Guidelines for Beverage Containers, EPA withdraws the removal of this Part from the direct final rule. The withdrawal of this Part does not affect the removal of 40 CFR Part 245 which became effective March 3, 1997.

EFFECTIVE DATE: March 3, 1997.

FOR FURTHER INFORMATION CONTACT: Deborah Gallman (703) 308–8600, U.S. EPA, Office of Solid Waste and Emergency Response, 401 M Street, SW, (5306W), Washington, D.C. 20460, or the RCRA Superfund Hotline, phone (800) 424–9346 or (703) 412–9810 in the Washington, DC, metropolitan area.

SUPPLEMENTARY INFORMATION: On December 31, 1996, EPA published in the **Federal Register** a direct final rule to remove two guidelines pertaining to solid waste management which the Agency believes to be obsolete, 40 CFR Part 244, Solid Waste Management Guidelines for Beverage Containers, and Part 245, Resource Recovery Facilities Guidelines. The activities addressed in these 1976 guidelines have been included in numerous state and local statutes and regulations and other Federal rules, or have been superseded by such Presidential actions as Executive Order 12873. The direct final rule was published without prior proposal in the **Federal Register** but with a provision for a 30 day comment period. In addition, EPA published a proposed rule, also on December 31, 1996 (61 FR 69059). EPA announced in both rules that, should EPA receive adverse comment on the direct final rule, the Agency would withdraw the direct final rule and address the comments received in a subsequent final rule based on the related proposed rule. EPA received adverse comment within the prescribed comment period specifically addressing the removal of 40 CFR Part 244. EPA did not receive adverse comments addressing the removal of 40 CFR Part 245. With today's action, EPA is withdrawing the removal of 40 CFR Part 244 from the December 31, 1996 direct final rule (61 FR 69032). The withdrawal of Part 244 from the direct final rule does not affect the removal of Part 245 which became effective March 3, 1997, as indicated in the direct final rule. The comments received regarding the removal of 40 CFR Part 244 will be addressed in a subsequent final rule based on the related proposed rule (61 FR 69059).

List of Subjects in 40 CFR Part 244

Environmental protection, Waste treatment and disposal, Recycling, Government property.

Dated: April 16, 1997.

Timothy Fields, Jr.,

Acting Assistant Administrator, Office of Solid Waste and Emergency Response.

For the reasons set forth in the preamble, the amendment removing 40 CFR Part 244 published at 61 FR 69032 (December 31, 1996) is withdrawn and part 244 is added as follows:

PART 244—SOLID WASTE MANAGEMENT GUIDELINES FOR BEVERAGE CONTAINERS

Subpart A—General Provisions

Subpart B—Requirements

Appendix to Part 244—Recommended Bibliography

Authority: Secs. 1008 and 6004 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6907, 6964).

Subpart A—General Provisions

§ 244.100 Scope.

(a) The ''Requirement'' sections contained herein delineate minimum actions for Federal agencies for reducing beverage container waste.

(b) Section 211 of the Act and Executive Order 11752 make the ''Requirements'' section of the