ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185 and 186

[OPP–300542; FRL–5739–8]

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 paraquat (1,1′-dimethyl-4,4′-bipyridinium-ion) in or on dry peas and mustard seed. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on dry peas in Idaho, Oregon and Washington, and mustard seed in Washington. This regulation establishes maximum permissible levels for residues of paraquat in these food commodities pursuant to section 408(l)(6) of 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 November 15, 1998.

DATES: This regulation is effective August 29, 1997. Objections and requests for hearings must be received by EPA on or before October 28, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300542], 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–300542], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300542]. 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 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-9357, e-mail: cimino.pat@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, 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 the herbicide/desiccant/defoliant paraquat, in or on dry peas at 0.3 parts per million (ppm) and mustard seed at 5.0 ppm. These tolerances will expire and are revoked on November 15, 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 Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq* . The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996)(FRL-5572-9).

New 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 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) 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.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerance to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemptions for Paraquat on Dry Peas and Mustard Seed and FFDCA Tolerances

The Idaho Department of Agriculture requested a regional emergency exemption for use of paraquat dichloride (Gramoxone Plus Herbicide) for desiccation of weeds infesting green peas grown for seed and dry peas in Idaho, Oregon and Washington in March, 1997. Unusually cold, wet weather delayed the pea planting season resulting in late pea emergence and higher incidence of weed infestations in fields. Continued moist, cool weather has contributed to weeds remaining green at harvest. Weeds plug harvesting equipment delaying harvest and the

delays result in downgraded or unmarketable peas due to shattered pods, bleached and sloughed seed coats and sprouting. There are currently no registered pesticides or alternative methods of control which can provide desiccation of weeds and permit harvest of the crops. After having reviewed the submission, EPA concurs that emergency conditions exist for these states.

The Washington Department of Agriculture requested a specific exemption for use of paraquat (Gramoxone Extra Herbicide) for desiccation of weeds in mustard seed grown for processing (condiment). An early season freeze coupled with continuous cool, early season growing conditions stunted this years' mustard crop and allowed weeds, predominantly Russian thistle, to become established in the crop. Affected growers will be unable to harvest infested mustard fields without the use of a desiccant harvest aid. After having reviewed the submission, EPA concurs that emergency conditions exist for this state.

As part of its assessment of these emergency exemptions, EPA assessed the potential risks presented by residues of paraquat in or on dry peas and mustard seed. In doing so, EPA considered the new 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 new 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 under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on Nov 15, 1998, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on dry peas and mustard seed after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA. 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 dry peas and mustard seed or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of paraquat by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Idaho, Oregon, and Washington for dry peas and Washington for mustard seed to use this pesticide on these crops 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 exemption 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. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal 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. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

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 MOE 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.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide

applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

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, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). 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. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. 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% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey 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 of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup non-nursing infants (less than 1 year old) was not regionally based.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, 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 paraquat (1,1′-dimethyl-4,4′-bipyridinium-ion) on dry peas at 0.3 ppm and mustard seed at 5.0 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 below.

1. *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.

2. *Short - and intermediate - term toxicity.* 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 uses. There are no indoor residential uses of paraquat and based on the nature of the non-food outdoor uses, the Agency does not expect significant exposure from the registered outdoor residential uses (spot treatment of vegetation for ornamental crop production) of paraquat. Therefore, a short- and intermediate-term aggregate risk assessment has not been performed.

3. *Chronic toxicity*. EPA has established the RfD for paraquat at 0.0045 milligrams/kilogram/day (mg/kg/day). This RfD is based on a one 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).

4. *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. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.205) for the herbicide/desiccant/defoliant paraquat (1,1′-dimethyl-4,4′-bipyridinium-ion) , in or on a variety of plant raw agricultural commodities ranging from 0.05 ppm in broccoli to 30 ppm in bean straw, and animal commodities ranging from 0.01 ppm (non-detectable residues) in milk and eggs to 0.30 ppm for cattle kidney. 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. 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.

ii. *Chronic exposure and risk.* 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.

2. *From drinking water.* 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 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. 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 exposure from 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, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

3. *From non-dietary exposure.* Paraquat is registered for use in federal conservation reserve programs and for weed control in ornamental crop production; however, the Agency does not expect significant exposure from these registered outdoor non-food uses.

4. *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.

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

1. *Acute risk.* No acute toxicity effect of concern was identified by the Agency, so this risk assessment is not required.

2. *Chronic risk.* Using the ARC exposure assumptions described above, EPA has concluded that aggregate exposure to paraquat from dietary (food only) sources will utilize 10 % of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants less than 1 year old. The chronic risk for infants and children is discussed below. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to paraquat in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to paraquat residues.

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. There are no indoor residential uses for paraquat and based on the nature of the outdoor non-food uses, the Agency does not expect significant exposure from the registered outdoor residential uses (spot treatment of vegetation for ornamental crop production) of paraquat. Therefore, a short- and intermediate-term aggregate risk assessment has not been performed.

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 mouse and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

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 pre-and post-natal toxicity and the completeness of the database 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 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 inter- and intra-species 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— a. Rats.* The maternal NOEL was 1 mg/kg/day. The maternal LOEL of 5 mg/kg/day (expressed as paraquat cation) was 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 NOEL and LOEL were 1 mg/kg/day and 5 mg/kg/day, respectively.

b. Mice. The maternal NOEL was 1 mg/kg/day expressed as paraquat cation). The maternal LOEL of 5 mg/kg/day was based on a reduction in body weight gain. The NOEL for developmental toxicity was also 1 mg/kg/day. The LOEL of 5 mg/kg/day was based on partially ossified 4th sternebrae.

iii. *Reproductive toxicity study—Rats.* The NOEL for systemic toxicity in the adults was 25 ppm (1.25 mg/kg/day). The LOEL of 75 ppm (3.75 mg/kg/day), expressed as paraquat cation, was based on the increased incidence of alveolar histiocytosis in the parents. The reproductive/developmental toxicity NOEL was considered to be > 150 ppm (7.5 mg/kg/day, expressed as paraquat cation) at the highest dose tested since no reproductive effects were presented in this study.

iv. *Pre- and post-natal sensitivity.* The pre- and post-natal toxicology data base for paraquat is complete with respect to current toxicological data requirements.

In the rat developmental study, the maternal (systemic) NOEL and the developmental NOEL are both 1 mg/kg/day. The LOELs are 5 mg/kg/day for both maternal and developmental effects. The developmental results at 5 mg/kg/day do not indicate any severe effects compared to the maternal effects at the LOEL. In the mouse developmental study, the maternal (systemic) and developmental NOELs were established at 1 mg/kg/day with the LOELs set at 5 mg/kg/day. The developmental effects at the LOEL of 5 mg/kg/day do not demonstrate any special pre-natal sensitivity for infants and children which would require an additional safety factor.

In both studies, maternal and developmental NOEL/LOEL levels and effects at the LOEL suggest that there is no increased sensitivity for infants and children from exposure to paraquat residues in the diet.

In the rat reproduction study the parental (systemic) NOEL was 1.25 mg/kg/day. The pup NOEL was considered to be > 7.5 mg/kg/day at the highest dose tested which suggests that there is no increased post-natal sensitivity to paraquat.

v. *Conclusion.* The effects observed in the mouse and rat developmental studies and the rat reproductive study did not demonstrate any special pre- or post-natal sensitivity for infants and children.

The Agency concludes that reliable data support use of the standard 100-fold uncertainty factor and that an additional uncertainty factor is not needed to protect infants and children.

2. *Acute risk.* No acute effect endpoint of concern was identified by the Agency so this risk assessment is not required.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that the percentage of the RfD that will be utilized from dietary (food only) exposure to paraquat ranges from 12% for nursing infants to 31% for non-nursing infants less than 1 year old. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Under current guidelines, the registered residential uses (weed control in ornamental crop production) do not fall under a chronic scenario. Despite the potential for exposure to paraquat in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. 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 determined. 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 0.3 ppm in/on dry peas and 5.0 ppm in/on mustard seed as a result of these section 18 uses. For the purposes of the dried pea section 18 requests only, the Agency is willing to accept the proposed prohibition for feeding the pea byproducts. No animal feed items are associated with the proposed use on mustard seed.

D. International Residue Limits

No CODEX, Canadian, and/or Mexican MRLs/tolerances have been established for residues of paraquat on peas or mustard seed.

E. Rotational Crop Restrictions.

As noted in the residue chemistry chapter of the Paraquat Reregistration Eligibility Document, no plantback restrictions or field rotational crop studies are required.

VI. Conclusion

Therefore, tolerances are established for paraquat (1,1′-dimethyl-4,4′-bipyridinium-ion) in/on dry peas at 0.3 ppm and mustard seed at 5.0 ppm in 40 CFR 180.205. In addition, § 180.205 was restructured in a final rule published in the **Federal Register** on May 2, 1997 (62 FR 24045)(FRL-5713-2) to combine the tolerances for food and feed commodities and raw agricultural commidities into the same section. At that time the food and feed additive tolerances in §§ 185.4700 and 186.4700 were combined with the tolerances in § 180.205(a). Therefore, §§ 185.4700 and 186.4700 are no longer necessary and are removed in this rule.

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 October 28, 1997, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300542] (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 Information and Records Integrity Branch, Information Resources and Services 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 Virginia address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

This final rule establishes a time limited tolerance on EPA's own initiative, under FFDCA section 408(d). 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) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or 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 in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the time limited 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. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

X. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory

Enforcement Fairness Act of 1996, the Agency has 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 this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 180

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

40 CFR Part 185

Environmental protection, Food additives, Pesticides and pests.

40 CFR Part 186

Environmental protection, Animal feeds, Pesticides and pests.

Dated: August 18, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I, parts 180, 185, and 186 is amended as follows:

PART 180—[AMENDED]

1. In part 180:

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

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

b. In § 180.205, the table in paragraph (b) is amended by ordering alphabetically the existing entries, and by adding alphabetically entries for ''peas, (dry),'' and ''mustard, seed,'' to read as follows:

§ 180.205 Paraquat; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/Revocation Date
* *	* * *	
Peas (dry)	0.3	November 15, 1998
Mustard, seed	5.0	November 15, 1998
* *	* * *	

* * * * *

PART 185—[AMENDED]

2. In part 185:

a. The authority citation for part 185 continues to read as follows:

Authority : 21 U.S.C. 346a and 348.

§ 185.4700 [Removed]

b. Section 185.4700 is removed.

PART 186—[AMENDED]

3. In part 186:

a. The authority citation for part 186 continues to read as follows:

Authority : 21 U.S.C. 346a and 348.

§ 186.4700 [Removed]

b. Section 186.4700 is removed.

[FR Doc. 97–23094 Filed 8–28–97; 8:45 am]

BILLING CODE 6560–50–F

LEGAL SERVICES CORPORATION

45 CFR Part 1602

Procedures for Disclosure of Information Under the Freedom of Information Act

AGENCY: Legal Services Corporation.

ACTION: Final rule.

SUMMARY: This final rule makes technical revisions to the Legal Services Corporation's (''Corporation'' or ''LSC'') rule concerning the disclosure of information under the Freedom of Information Act by revising the Corporation's address and deleting outdated references to regional offices. Other minor technical revisions are also made.

EFFECTIVE DATE: This final rule is effective on August 29, 1997.

FOR FURTHER INFORMATION CONTACT: Office of the General Counsel, (202) 336–8817.

SUPPLEMENTARY INFORMATION: Pursuant to the Freedom of Information Act, the Corporation is required to publish current information in the **Federal Register** that provides guidance to the public regarding how to obtain information about and from the Corporation. See 5 U.S.C. 552. The Corporation's Operations and Regulations Committee (''Committee'') of the Corporation's Board of Directors (''Board'') met on July 13, 1997, in Los Angeles, California, and voted to recommend technical changes to the rule so that it would conform to this FOIA requirement. On July 14, 1997, the changes were recommended to the Board, which adopted the revisions and directed that they be published as final with an effective date on the date of publication.

This final rule makes several technical revisions to the Corporation's FOIA regulation to correct inaccurate and misleading information, so that the Corporation is in compliance with the FOIA. The corrections include changing the Corporation's address to reflect its current location and deleting references to regional offices that no longer exist. Related stylistic and grammatical changes are also made. None of the changes are substantive, and therefore the changes do not require a public notice and comment period. The revisions are effective on the date of publication.

List of Subjects in 45 CFR Part 1602

Grant programs, Legal services.

For the reasons set forth in the preamble, LSC amends 45 CFR part 1602 to read as follows:

PART 1602—PROCEDURES FOR DISCLOSURE OF INFORMATION UNDER THE FREEDOM OF INFORMATION ACT

1. The authority citation for part 1602 is revised to read as follows:

Authority: 5 U.S.C. 552 and 42 U.S.C. 2996d(g).

2. Section 1602.4 is revised to read as follows:

§ 1602.4 Index of records.

The Corporation will maintain a current index identifying any matter within the scope of § 1602.5(b) (1) through (3) which has been issued, adopted, or promulgated by the Corporation, and other information