which have until January 25, 1998, the owner or operator of an affected source, or group of affected sources under common control, shall monitor and record the velocity pressure at the inlet to the packed-bed system and the pressure drop across the scrubber system once each day that any affected source is operating. * * *

* * * * *

(4) * * *

(ii) On and after the date on which the initial performance test is required to be completed under § 63.7, except for hard chromium electroplaters and chromium anodizing operations in California which have until January 25, 1998, the owner or operator of an affected source, or group of affected sources under common control, shall monitor and record the pressure drop across the fiber-bed mist eliminator, and the control device installed upstream of the fiber bed to prevent plugging, once each day that any affected source is operating. * * *

(5) * * *

(ii) On and after the date on which the initial performance test is required to be completed under § 63.7, except for hard chromium electroplaters and chromium anodizing operations in California which have until January 25, 1998, the owner or operator of an affected source shall monitor the surface tension of the electroplating or anodizing bath. * * *

(6) * * *

(ii) On and after the date on which the initial performance test is required to be completed under § 63.7, except for hard chromium electroplaters and chromium anodizing operations in California which have until January 25, 1998, the owner or operator of an affected source shall monitor the foam blanket thickness of the electroplating or anodizing bath. * * *

* * * * *

4. Section 63.347 is amended by revising paragraph (e)(4) to read as follows:

§ 63.347 Reporting requirements.

* * * * *

(e) * * *

(4) For sources that are not required to complete a performance test in accordance with § 63.343(b), the notification of compliance status shall be submitted to the Administrator no later than 30 days after the compliance date specified in § 63.343(a), except the date on which sources in California shall monitor the surface tension of the anodizing bath is extended to January 25, 1998.

* * * * *

[FR Doc. 97–21143 Filed 8–8–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300521; FRL–5732–7]

RIN 2070–AB78

Glyphosate; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of glyphosate, per se in or on dry peas, pea vines, hay, and silage, lentils, and kidney (cattle, goats, horses and sheep). 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, lentils and chickpeas. This regulation establishes a maximum permissible level for residues of glyphosate in this food commodity 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 tolerance will expire and is revoked on August 30, 1998.

DATES: This regulation is effective August 11, 1997. Objections and requests for hearings must be received by EPA on or before October 10, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300521], 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–300521], 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–300521]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Virginia Dietrich, Registration Division 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) 308–9359, e-mail: dietrich.virginia@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 a tolerance for residues of the herbicide *N*-(Phosphonomethyl)glycine, in or on dry peas, pea vines, hay, and silage, lentils, and kidney (cattle, goats, horses and sheep) at 5, 60, 200, 90, 5, and 4, respectively part per million (ppm). These tolerances will expire and are revoked on August 30, 1998. After August 30, 1998, EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

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

discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 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 Exemption for Glyphosate on (Dry Peas, Lentils, and Garbanzo Beans) and FFDCA Tolerances

The Agency determined that an urgent, non-routine situation exists in areas where dense populations of Canada thistle develop in dry pea, chickpea and lentil crops in Idaho, Oregon and Washington. Crop loss of up to 100% may occur in areas heavily infested with Canada thistle. Both pre- and post-emergence herbicides are registered for these crops, but they are ineffective in controlling Canada thistle. Spot treatment with glyphosate to eliminate Canada thistle will not improve dry pea, chick pea and lentil crop yields this year since the application will also destroy the surrounding crop. However, the use of glyphosate will eliminate the Canada thistle pest and future crops are expected to improve. After having reviewed the submission, EPA concurs that emergency conditions exist for this state. EPA has authorized under FIFRA section 18 the use of glyphosate on dry peas, garbanzo beans and lentils) for control of Canada thistle.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of glyphosate in or on dry peas, garbanzo beans and lentils. 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 August 30, 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, garbanzo beans, and lentils 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 glyphosate meets EPA's registration requirements for use on dry peas, garbanzo beans, and lentils or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of glyphosate by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Idaho, Oregon, and Washington to use this pesticide 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 exemption for glyphosate, 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% 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 hundredfold MOE is based on the same rationale as the hundredfold 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 3 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 glyphosate and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of glyphosate on dry peas, pea vines, hay, and silage, lentils, and kidney (cattle, goats, horses and sheep) at 5, 60, 200, 90, 5, and 4 ppm, respectively. 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 glyphosate are discussed below.

1. *Acute toxicity.* No endpoint of concern was identified by the Office of Pesticide Programs .

2. *Short - and intermediate - term toxicity.* No effects were observed in a 21–day dermal toxicity study at the limit dose. No adverse effects were observed in the developmental toxicity study in rats up to 1,000 mg/kg/day and in rabbits at up to 175 mg/kg/day.

3. *Chronic toxicity.* EPA has established the RfD for glyphosate at 2 milligrams/kilogram/day (mg/kg/day). This RfD is based on the maternal toxicity NOEL of 175 mg/kg/day from a rabbit developmental toxicity study using an uncertainty factor (UF) of 100. The lowest observed effect level (LOEL) of 350 mg/kg/day (highest dose tested) was based on treatment-related findings of diarrhea, nasal discharge, and death (62.5% of does died by gestation day 21). Developmental toxicity was not observed at any dose tested.

4. *Carcinogenicity.* Glyphosate has been classified as a Group E chemical (evidence of non-carcinogenicity for humans) by the Office of Pesticide Programs. The classification was based on a lack of convincing evidence of carcinogenicity in adequate studies with two animal species, rat and mouse.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.364, 185.3500, 186.3500) for the combined residues of glyphosate and its metabolite aminomethylphosphonic acid in or on certain raw agricultural commodities ranging from 0.1 ppm in peanuts to 200 ppm in alfalfa. This regulation also establishes a tolerance for secondary residues in kidney (cattle, goats, horses, and sheep). Risk assessments were conducted by EPA to assess dietary exposures and risks from glyphosate as follows:

i. *Acute exposure and risk.* No endpoint was identified for this duration of exposure, therefore no assessment was necessary. Acute dietary risk assessments are performed for a food-use pesticide only if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure.

ii. *Chronic exposure and risk.* In conducting this exposure assessment, EPA has made very conservative assumptions—that 100% of dry peas, lentils, and chickpeas and all other commodities having glyphosate tolerances would contain glyphosate residues and that those residues would be at the level of the respective tolerances—which result in an overestimate of human dietary exposure. Thus, in making a safety determination for this tolerance, EPA is taking into account this conservative exposure assessment.

All the glyphosate tolerances (published, pending, and including these Section 18 tolerances) result in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to the following percentages of the RfD:

Subgroups	Percentage of RFD
U.S Population	1.2
Nursing Infants	1.2
Non-Nursing Infants (<1 year old).	3.3
Children (1-6 years old)	2.6
Children (7-12 years old)	1.8
Western Region	1.3

The subgroups listed above are: (1) the U.S. population (48 states); (2) those for infants and children; and, (3) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 states).

iii. *Cancer risk.* Glyphosate has been classified as a Group E chemical (evidence of non-carcinogenicity for humans) by the Office of Pesticide Programs Cancer Peer Review Committee.

2. *From drinking water.* Based on information in the EPA's files, glyphosate is not persistent and not mobile. A Maximum Contaminant Level has been established by the Agency's Office of Water (OW) for residues of glyphosate in drinking water at 0.7 ppm. OW has also established Health Advisory levels for glyphosate in drinking water at the following levels:

Child, 10 kg of body weight.	
1–day	20 mg/L
10–day	20 mg/L
longer-term	1 mg/L
Adult, 70 kg of body weight.	
lifetime	0.7 mg/L

i. *Acute exposure and risk.* No endpoint of concern was identified by the Agency so this risk assessment was not required.

ii. *Chronic exposure and risk.* 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 glyphosate 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 glyphosate 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.* Glyphosate is registered for uses on outdoor non-food sites such as turf and ornamentals. These uses may result in non-occupational exposures. However, since no toxicological endpoints for non-dietary exposures have been identified, the resulting risks cannot be assessed, therefore these exposures have not been estimated.

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 glyphosate 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, glyphosate 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 glyphosate has a common mechanism of toxicity with other substances.

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

1. *Acute risk.* Since no toxicological endpoint of concern was identified, there is a reasonable certainty that no harm will result from aggregate acute exposures to glyphosate residues.

2. *Chronic risk.* Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to glyphosate from food will utilize 1.2 percent of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants, which is further 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 glyphosate 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 glyphosate 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.

An Ad Hoc Toxicology Endpoint Selection Committee concluded that this risk assessment is not required, based on the lack of any observable effects in a 21–day dermal toxicity study at the limit dose and the observation of no adverse effects in a developmental toxicity study in rats up to 1,000 mg/kg/day and rabbits up to ≥ 175 mg/kg/day. Therefore, EPA concludes that there is a reasonable certainty that no harm will result from aggregate short- and inermediate-term exposure to glyphosate residues.

D. Aggregate Cancer Risk for U.S. Population

As noted above, glyphosate has been classified as a Group E chemical (evidence of non-carcinogenicity for humans).

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

1. *Safety factor for infants and children—a. In general.* In assessing the potential for additional sensitivity of infants and children to residues of glyphosate, EPA considered data from developmental toxicity studies in the rat and rabbit 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.

b. *Developmental toxicity studies —i. Rat.* In the rat developmental toxicity study, the maternal (systemic) NOEL is 1,000 mg/kg/day. The maternal (systemic) LOEL of 3,500 mg/kg/day was based on the following treatment-related effects: diarrhea, decreased mean body weight gain, breathing rattles, inactivity, red matter around the nose and mouth, and on forelimbs and dorsal head, decreases in total implantations/dam and non-viable fetuses/dam, and death (24% of the group). The developmental (fetal) NOEL is 1,000 mg/kg/day. The developmental (fetal) LOEL of 3,500 mg/kg/day was based on treatment-related developmental effects observed only in the high-dose group of: increased number of litters and fetuses with unossified sternebrae, and decreased mean fetal body weights.

ii. *Rabbit.* In the rabbit developmental toxicity study, the maternal (systemic) NOEL is 175 mg/kg/day. The maternal (systemic) LOEL of 350 mg/kg/day was based on treatment-related effects that included: diarrhea, nasal discharge, and death (62.5% of does died by gestation day 21). The developmental (fetal) NOEL is ≥ 175 mg/kg/day (insufficient litters were available at 350 mg/kg/day to assess developmental toxicity). Developmental toxicity was not observed at any dose tested.

c. *Reproductive toxicity study—i. Rat.* A three-generation reproductive toxicity study was conducted with Sprague-Dawley rats, the parental NOEL/LOEL is ≥ 30 mg/kg/day (highest dose tested). The only effect observed was an increased incidence of focal tubular dilation of the kidney (both unilateral and bilateral combined) in the high-dose male F_{3b} pups.

Since the focal tubular dilation of the kidneys was not observed at the 1,500 mg/kg/day level (HDT) in the 2-generation rat reproduction (see below),

but was observed at the 30 mg/kg/day level (HDT) in the 3-generation rat reproduction study, the OPP Developmental Peer Review Committee concluded that the latter was a spurious rather than glyphosate-related effect. Therefore, the parental and reproductive (pup) NOELs are ≥ 30 mg/kg/day.

ii. *Rat.* A two-generation reproductive toxicity study was conducted with Sprague-Dawley rats. Treatment-related effects observed in the high dose group included: soft stools, very frequent, in the Fo and F1 males and females, decreased food consumption and body weight gain of the Fo and F1 males and females during the growth (premating) period, and decreased body weight gain of the F1a, F2a and F2b male and female pups during the second and third weeks of lactation. Focal tubular dilation of the kidneys, observed in the 3-generation study, was not observed at any dose level in this study. Based on the above findings, the parental and developmental (pup) NOEL's are 500 mg/kg/day and the parental and developmental (pup) LOEL's are 1,500 mg/kg/day. The reproductive toxicity NOEL is ≥ 1,500 mg/kg/day.

d. *Pre- and post-natal sensitivity.* Based on the developmental toxicity studies discussed above, for glyphosate there does not appear to be an extra sensitivity for pre-natal effects. The developmental rat study only had developmental findings above 1,000 mg/kg/day in the presence of severe maternal effects [death, etc.] at the highest dose tested of 3,500 mg/kg/day. In rabbits, developmental effects above the NOEL of 175 mg/kg/day were unable to be identified due to severe maternal effects [death, etc.] at 350 mg/kg/day [highest dose tested]. Based on the reproductive toxicity study discussed above, for glyphosate there does not appear to be an extra sensitivity for post-natal effects. The pup and adult NOELs of 500 mg/kg/day and LOELs of 1,500 mg/kg/day do not demonstrate any post-natal extra sensitivity for infants and children because the dose levels, respectively, are the same for pups and adults and the effects are similar as well.

e. *Conclusion.* Therefore, the Agency concludes that no additional 10X safety factor is necessary to protect infants and children.

2. *Acute risk.* No endpoint was selected by the Agency so this risk assessment was not conducted.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to glyphosate from food will utilize no more than 3.3% of the RfD for non-nursing infants, the most highly exposed sub-group. 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 glyphosate 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 glyphosate residues.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants and animals is adequately understood. The current tolerances established under 40 CFR 180.364 include glyphosate and its metabolite aminomethylphosphonic acid (AMPA). The Office of Pesticide Programs Metabolism Committee has concluded that AMPA need not be regulated and should be dropped from the tolerance regulation. The residue of concern is the parent compound, glyphosate, only.

B. Analytical Enforcement Methodology

Adequate enforcement methodology (GLC and HPLC/fluorometric) are available (PAM, Vol. II, Method I) to enforce the tolerance expression.

C. Magnitude of Residues

Residues of glyphosate, per se, are not expected to exceed the following levels as a result of this Section 18 use. Time-limited tolerances should be established at these levels: pea, dry at 5 ppm; lentil at 5 ppm; pea, field vines at 60 ppm; pea, field hay at 200 ppm; pea, field silage at 90 ppm; kidney, cattle, goats, horses, and sheep at 4 ppm.

With the exception of the proposed increase in the kidney tolerance noted above, secondary residues in animal commodities are not expected to exceed existing tolerances as a result of this Section 18 use. The dietary burden for livestock will not exceed that from the use on grasses.

D. International Residue Limits

A CODEX MRL has been established for residues of glyphosate, per se, on dry peas at 5 ppm. Canadian tolerances have been established for residues of glyphosate and AMPA on peas at 5 ppm and lentils at 4 ppm.

E. Rotational Crop Restrictions

For this proposed Section 18 use, a 30–day plant-back interval for crops on which glyphosate is not registered is being required.

VI. Conclusion

Therefore, the tolerance is established for residues of glyphosate in dry peas, pea vines, hay, and silage, lentils, and kidney (cattle, goats, horses and sheep) at 5, 60, 200, 90, 5, and 4, ppm, respectively.

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 11, 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–300521] (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 Hwy., 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 tolerances under FFDCA section 408(l)(6). 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 (l)(5), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. 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 acations 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 in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Animal feeds, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 29, 1997.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I 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. Section 180.364 is amended by adding text to paragraph (b) to read as follows:

§ 180.364 Glyphosate; tolerances for residues.

(a) *General* . * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for combined residues of the herbicide glyphosate, per se in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Cattle, kidney	4	August 30, 1998
Goats, kidney	4	August 30, 1998
Horses, kidney	4	August 30, 1998
Lentils	5	August 30, 1998
Pea, hay	200	August 30, 1998
Pea, vines	60	August 30, 1998
Peas, dry	5	August 30, 1998
Sheep, kidney	4	August 30, 1998
Silage, hay	90	August 30, 1998

* * * * *

[FR Doc. 97–21144 Filed 8–8–97; 8:45 am]
BILLING CODE 6560–50–F

GENERAL SERVICES ADMINISTRATION

41 CFR Part 301–8

[FTR Amendment 66]

RIN 3090–AG41

Federal Travel Regulation; Reimbursement of Higher Actual Subsistence Expenses in Special or Unusual Circumstances; Correction

AGENCY: Office of Governmentwide Policy, GSA.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to the final rule, which was published in the **Federal Register** of Tuesday, June 3, 1997, (62 FR 30279). The final rule related to reimbursement of higher actual subsistence expenses in special or unusual circumstances.

DATES: Effective on May 1, 1997.

FOR FURTHER INFORMATION CONTACT: Jane E. Groat, 202–501–1538.

SUPPLEMENTARY INFORMATION:

Background

The final rule that is the subject of these corrections amended the Federal Travel Regulation (FTR) (41 CFR chapters 301–304) to allow an agency to authorize or approve travel up to 300 percent of the prescribed maximum per diem rate on an actual subsistence expense basis under certain special or unusual circumstances.

Need for correction

As published, the final rule contains information, which may prove to be misleading, and needs to be clarified.

List of Subjects in 41 CFR Part 301–8

Government employees, Travel, Travel allowances, Travel and transportation expenses.

Accordingly, 41 CFR Part 301–8 is corrected by making the following correcting amendments:

PART 301–8—REIMBURSEMENT OF ACTUAL SUBSISTENCE EXPENSES

1. The authority citation for part 301–8 continues to read as follows:

Authority: 5 U.S.C. 5707.

§ 301–8.3 [Corrected]

2. Section 301–8.3 is amended in paragraphs (a)(1) and (b)(1)(i) to remove the phrase ''150 percent'' where it appears and to replace it with the phrase ''300 percent''; by revising paragraph (b)(1)(ii) to read ''The amount established by the Departments of Defense and State for travel outside CONUS.''; by removing paragraph (c); by redesignating paragraph (d) as (c); by amending newly redesignated paragraph (c) to remove the phrase ''paragraphs (a) through (c) of this section'' where it appears and to replace it with the phrase ''paragraphs (a) and (b) of this section''.

3. Section 301–8.3(a)(2) is revised to read as follows:

* * * * *

(a) * * *

(1) * * *

(2) *Travel outside CONUS.* For travel outside CONUS, the maximum daily rate for subsistence expenses shall not exceed the amount prescribed by:

(i) The Department of Defense, Per Diem, Travel and Transportation Allowance Committee, for nonforeign areas, as set forth in Civilian Personnel Per Diem Bulletin No. 194; and

(ii) The Department of State, for foreign areas, as set forth in section 925, a per diem supplement to the U.S. Department of State Standardized Regulations (Government Civilians, Foreign Areas).

* * * * *

Dated: August 5, 1997.

Peggy Wood,

Acting Director, Travel and Transportation Management Policy Division.

[FR Doc. 97–21051 Filed 8–8–97; 8:45 am]
BILLING CODE 6820–34–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 0

[DA 97–1505]

Freedom of Information Act

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Federal Communications Commission is modifying a section of the Commission's rules that implements the Freedom of Information Act (FOIA) fee schedule. This modification pertains to the charge for recovery of the full, allowable direct costs of searching for and reviewing records requested under the FOIA and the Commission's rules, unless such fees are restricted or waived. The fees are being revised to correspond to modifications in the rate of pay approved by Congress.

EFFECTIVE DATE: September 10, 1997.

FOR FURTHER INFORMATION: Judy Boley, Freedom of Information Act Officer, Office of Performance Evaluation and Records Management, Room 234, Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554, (202) 418–0210.

SUPPLEMENTARY INFORMATION: The FCC is modifying § 0.467(a) of the Commission's rules. This rule pertains to the charges for searching and reviewing records requested under the Freedom of Information Act (FOIA). The FOIA requires federal agencies to establish a schedule of fees for the processing of requests for agency records in accordance with fee guidelines issued by the Office of Management and Budget (OMB). In 1987, OMB issued its Uniform Freedom of Information Act Fee Schedule and Guidelines. However, because the FOIA requires that each agency's fees be based upon its direct costs of providing FOIA services, OMB did not provide a unitary, government-wide schedule of fees. The Commission based its FOIA fee schedule on the grade level of the employee who processes the request. Thus, the fee schedule was computed at a Step 5 of each grade level based on the General Schedule effected January 1997. The instant revisions correspond to modifications in the rate of pay recently approved by Congress.

Regulatory Procedures

This final rule has been reviewed under Executive Order No. 12866 and has been determined not to be a ''significant rule'' since it will not have an annual effect on the economy of $100 million or more.

In addition, it has been determined that this final rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 47 CFR Part 0

Freedom of information.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

Rule Changes

Part 0 of title 47 of the Code of Federal Regulations is amended as follows:

PART 0—COMMISSION ORGANIZATION

1. The authority citation for part 0 continues to read as follows:

Authority: 47 U.S.C. 155, 255, unless otherwise noted.