lifetime will not pose appreciable risks to human health.

2. *Infants and children*. The toxicology data base for methoxyfenozide included acceptable developmental toxicity studies in both rats and rabbits as well as a 2–generation reproductive toxicity study in rats. The data provided no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to methoxyfenozide. There is a complete toxicity data base for methoxyfenozide an exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Based on the completeness of the data base and the lack of prenatal and postnatal toxicity, EPA determined that an additional safety factor was not needed for the protection of infants and children.

Since no toxicological endpoints were established, acute aggregate risk is considered to be negligible. Using the exposure assumptions, Dow AgroSciences has concluded that aggregate exposure to methoxyfenozide from the proposed new tolerances will utilize 50.9% of the cPAD for infants and children. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

3. *Drinking water*. The EECs for assessing chronic aggregate dietary risk used by the Agency are 3.5 parts per billion (ppb) (in ground water, based on SCI-GROW) and 30 ppb (in surface water, based on the PRZM/EXAMS, long-term mean). The back-calculated drinking water levels of concern (DWLOCs) for assessing chronic aggregate dietary risk range from 501 ppb for the most highly exposed population subgroup (children 1–2 years old) to 2,778 ppb for the U.S. population (total).

The SCI-GROW and PRZM/EXAMS chronic EECs are less than the Agency's level of comparison (the DWLOC value for each population subgroup) for methoxyfenozide residues in drinking water as a contribution to chronic aggregate exposure. Dow AgroSciences thus concludes with reasonable certainty that residues of methoxyfenozide in drinking water will not contribute significantly to the aggregate chronic human health risk and that the chronic aggregate exposure from methoxyfenozide residues in food and drinking water will not exceed the Agency's level of concern (100% of the cPAD) for chronic dietary aggregate exposure by any population subgroup. EPA generally has no concern for exposures below 100% of the cPAD, because it is a level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to the health and safety of any population subgroup. This risk assessment is considered high confidence, conservative, and very protective of human health.

F. International Tolerances

There are no Codex or Canadian maximum residue levels (MRLs) established for residues of methoxyfenozide. Mexican MRLs are established for residues of methoxyfenozide in cottonseed (0.05 ppm) and maize (0.01 ppm). The U.S. tolerances on these commodities are 2.0 ppm and 0.05 ppm, respectively. Based on the current use patterns, the U.S. tolerance levels cannot be reduced to harmonize with the Mexican MRLs, so incompatibility will exist.

[FR Doc. 04–18769 Filed 8–17–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0160; FRL–7364–6]

Glyphosate; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket identification (ID) number OPP–2004–0160, must be received on or before September 17, 2004.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: James A. Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: *tompkins.jim@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2004–0160. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **FederalRegister** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public

docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' andthen key in docket ID number OPP–2004–0160. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to *opp-docket@epa.gov*, Attention: Docket ID number OPP–2004–0160. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information andRecords Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID number OPP–2004–0160.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID number OPP–2004–0160. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior

notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 9, 2004.

Betty Shackleford,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Monsanto Company

PP 0F6195, 1F6273, 1F6274, and 3F6570

EPA has received pesticide petitions (0F6195, 1F6273, 1F6274, and 3F6570) from Monsanto Company, 600 13th St., NW., Suite 660, Washington, DC 20005, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR 180.364 by establishing a regulation to permit residues of the herbicide glyphosate (*N*-phosphonomethyl) glycine in or on the following raw agricultural commodities:Alfalfa, seed at 0.5 parts per million (ppm); rice, grain at 15.0 ppm; and cotton, gin by-products at 150 ppm; wheat, forage at 10.0 ppm, wheat, hay at 10.0 ppm; and the following processed commodities: Rice, bran at 30.0 ppm; andrice, hulls at 25.0 ppm. Monsanto further proposes to delete the entire entries for alfalfa, forage at 175 ppm and alfalfa, hay at 400 ppm as these tolerances are no longer needed, and to revise the entry for grain, cereal group to read: Grain, cereal, group 15 except barley, field corn, grain sorghum, oats, rice and wheat at 0.1 ppm. EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petitions. Additional data may be needed before EPA rules on these petitions.

The petitions request that 40 CFR 180.364 be amended by establishing tolerances for residues of the herbicide glyphosate in or on alfalfa, seed at 0.5 ppm; rice, grain at 15. 0 ppm; rice, bran at 25.0 ppm; rice, hulls at 30.0 ppm; wheat, forage at 10.0 ppm; and wheat, hay at 10.0 ppm, increasing the established tolerance for cotton, gin by-products from 100 ppm to 150 ppm; by deleting the tolerances for alfalfa, forage at 175 ppm and alfalfa, hay at 400ppm, and by revising the grain, cereal group tolerance to ''except rice'' and read as follows: Grain, cereal group 15 except barley, field corn, grain sorghum, oats, rice and wheat at 0.1 ppm. PP 0F6195 has been amended to delete the proposal for wheat, grain at 6 ppm that was announced earlier (May 17, 2002, 67 FR 18894) (FRL–6830–5). ''The tolerances for alfalfa, rice, wheat, and cotton, gin by-products include both conventional and genetically altered crops.'' It is also proposed the 40 CFR 180.364 be amended by replacing the current listing ''Vegetable, legume group (except soybean) at 5.0 ppm with the current crop group'' pea and bean, dried shelled, except soybean, subgroup 6C at 5.0 ppm.

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. . . .''

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

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 acute toxic effects caused by glyphosate are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed in the following Table 2.

TABLE 1.—ACUTE TOXICITY OF GLYPHOSATE TECHNICAL

Guideline No.	Study Type	Results
870.1100	Acute oral	LD_{50} > 5,000 mg/kg Toxicity Category IV
870.1200	Acute dermal	LD_{50} > 5,000 mg/kg Toxicity Category IV
870.1300	Acute inhalation	The requirement for an acute inhalation LC_{50} study was waived
870.2400	Primary eye irritation	Corneal opacity or irritation clearing in 7 days or less Toxicity Category III
870.2500	Primary skin irritation	Mild or slight irritant Toxicity Category IV
870.2600	Dermal sensitization	Not a dermal sensitizer

TABLE 2.—TOXICITY PROFILE OF GLYPHOSATE TECHNICAL

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents mouse	NOAEL = 1,500 mg/kg/day in males and females LOAEL = 4,500 mg/kg/day in males and females based on decreased body weight gain
870.3100	90–Day oral toxicity rodents rat (range-finding)	NOAEL = < 50 mg/kg/day in males and female LOAEL = 50 mg/kg/day in males and females based on increased phosphorus and potassium values
870.3150	90–Day oral toxicity in rodents rat (aminomethyl phosphoric acid plant metabolite of glyphosate)	NOAEL = 400 mg/kg/day in males and females LOAEL = 1,200 mg/kg/day in males and females based on body weight loss and histopathological lesions of the urinary bladder
870.3485	28–Day inhalation toxicity - rat (exposure; 6 hours/day, 5 days/week for 4 weeks)	NOAEL = 0.36 mg/L LOAEL = > 0.36 high dose tested (HDT) mg/L, not established
870.3200	21-Day dermal toxicity - rabbit	NOAEL = 1,000 mg/kg/day in males and females LOAEL = 5,000 mg/kg/day based on slight erythema and edema on intact and abraded skin of both sexes, and decreased food consumption in females
870.3700	Prenatal developmental in rodents-rat	*Maternal* NOAEL = 1,000 mg/kg/day LOAEL = 3,500 mg/kg/day based on inactivity, mortality, stomach hemorrhages and reduced body weight gain *Developmental* NOAEL = 1,000 mg/kg/day LOAEL = 3,500 mg/kg/day based on increased incidence in the number of fetuses and litters with unossified sternebrae and decreased fetal body weight
870.3700	Prenatal developmental in nonrodents-rabbit	*Maternal* NOAEL = 175 mg/kg/day LOAEL = 350 mg/kg/day based on mortality, diarrhea, soft stools, and nasal discharge *Developmental* NOAEL = 350 mg/kg/day LOAEL = > mg/kg/day, not established

TABLE 2.—TOXICITY PROFILE OF GLYPHOSATE TECHNICAL—Continued

Guideline No.	Study Type	Results
870.3800	Reproduction and fertility effects rat (3-generation)	*Parental/Systemic* NOAEL = 30 mg/kg/day LOAEL = > 30 HDT mg/kg/day, not established *Reproductive* NOAEL = 30 mg/kg/day LOAEL = > 30 HDT mg/kg/day, not established *Offspring* NOAEL = 10 mg/kg/day LOAEL = 30 mg/kg/day based on focal dilation of the kidney in male F3b pups
870.3800	Reproduction and fertility effects rat (2-generation)	*Parental/Systemic* NOAEL = 500 mg/kg/day in males and females LOAEL = 1,500 mg/kg/day in males and females based on soft stools, decreased body weight gain and food consumption. Focal dilation of the kidney observed at 30 mg/kg/day in the 3-generation study was not observed at any dose level in this study *Reproductive* NOAEL = > 30 1,500 HDT mg/kg/day in males and females LOAEL = > 1,500 HDT mg/kg/day in males and females, not established *Offspring* NOAEL = 500 mg/kg/day in males and females LOAEL = 1,500 mg/kg/day in males and females based on reduced pup weights during the second and third weeks of lactation
870.4100	Chronic toxicity - dogs	NOAEL = 500 HDT mg/kg/day in males and females LOAEL = > 500 mg/kg/day in males and females, not established
870.4300	Chronic/carcinogenic city rats	NOAEL = 362 mg/kg/day in males LOAEL = 940 mg/kg/day in males based on decreased urinary pH, increased incidence of cataracts and lens abnormalities, and increased absolute and relative (to brain) liver weights NOAEL = 457 mg/kg/day in females LOAEL = 1,183 mg/kg/day in females based on decreased body weight gain No evidence of carcinogenicity
870.4300	Carcinogenicity mice	NOAEL = 750 mg/kg/day in males LOAEL = 4,500 mg/kg/day in males based on significant decreased body weight gain, hepatocyte necrosis, and interstitial nephritis NOAEL = 750 mg/kg/day in females LOAEL = 4,500 mg/kg/day in females based on significant decreased body weight gain, increased incidence of proximal tubule epithelial basophilia, and hypertrophy in the kidney of females No evidence of carcinogenicity
870.5100	Gene mutation assay in *S. typhimurium* strains	Negative - non-mutagenic when tested up to 1,000 µg/plate, in presence and absence of activation, in *S. typhimurium* strains TA98, TA100, TA1535 and TA1537
870.5100	Gene mutation assay in *E. coli* WP2hcrA and *S. typhimurium* strain	Negative for reverse gene mutation, both with and without S-9, up to 5,000 µg/plate (or cytotoxicity) with *E. coli* WP2hcrA and *S. typhimurium* TA98, TA100, TA1535, TA1537, and TA1538
870.5300	Gene mutation assay in Chinese hamster ovary (CHO) cells/HGPRT	Negative - non-mutagenic at the HGPRT locus in Chinese hamster ovary cells tested up to cytotoxic concentrations or limit of solubility, in presence and absence of activation
870.5385	Cytogenetics - *In vivo* bone marrow chromosomal aberration assay	Negative - non-mutagenic in rat bone marrow chromosome assay up to 1,000 mg/kg in both sexes of Sprague Dawley rats

TABLE 2.—TOXICITY PROFILE OF GLYPHOSATE TECHNICAL—Continued

Guideline No.	Study Type	Results
870.5550	Other mechanisms - *in vitro* rec-assay with *B. subtilis*	There was no evidence of recombination in the rec-assay up to 2,000 µg/disk with *B. subtilis* H17 (rec+) and M45 H17 (rec+) and M45 (rec-) (rec-)
870.6200	Acute neurotoxicity screening battery in rats	N/A
870.6200	Subchronic neurotoxicity screening battery in rats	N/A
870.6300	Developmental neurotoxicity in rats	N/A
870.7485	Metabolism/pharmacokinetics - rat	Absorption was 30–36% in males and females. Glyphosate was excreted unchanged in the feces and urine (97.5% minimum). The only metabolite present in the excreta was AMPA. Less than 1% of the absorbed dose remained in the carcass, primarily bone. Repeat dosing did not alter metabolism, distribution, and excretion.
870.7600	Dermal penetration	N/A

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD =NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic population adjusted dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE (cancer) = point of departure/exposures) is calculated. A summary of the toxicological endpoints for glyphosate used for human risk assessment is shown in the following Table 3.

TABLE 3.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR GLYPHOSATE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13–50 years old and general population)	None	None	An acute dietary endpoint was not selected for the general population or females 13–50, since an appropriate endpoint attributable to a single exposure was not used in the toxicology data base
Chronic dietary (all populations)	NOAEL = 175 mg/kg/day UF = 100 Chronic RfD = 1.75 mg/kg/day	FQPA SF = 1 cPAD = cRfD FQPA SF = 1.75 mg/kg/day	Developmental toxicity study rabbit LOAEL = 350 mg/kg/day based on diarrhea, nasal discharge and death in maternal animals

TABLE 3.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR GLYPHOSATE FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Short-term, and intermediate term incidental oral (Residential)	NOAEL = 175 mg/kg/day	LOC for MOE = 100	Developmental toxicity study - rabbit LOAEL = 350 mg/kg/day based on diarrhea, nasal discharge and death in maternal animals
Short-term, and long-term dermal (1-30 days, 1-6 months, 6 months - lifetime) (Occupational/Residential)	None	None	Based on the intermediate systemic NOAEL of 1,000 mg/kg/day inthe 21–day dermal toxicity study in rabbits, and the lack of concern for developmental and reproductive effects, the quantification of dermal risks is not required
Short-term, intermediate-term and long-term inhalation (1-30 days, 1-6 months, 6 month-lifetime) (Occupational/Residential)	None	None	Based on the systemic toxicity NOAEL of 0.36 mg/L HDT in the 28–day inhalation toxicity study in rats, and the physical characteristics of the technical (wetcake), the quantification of inhalation risks is not required
Cancer (oral, dermal, inhalation)	Cancer classification (Group E)	Risk assessment not required	No evidence of carcinogenicity

*The reference to the FQPA safety factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Tolerances have been established (40 CFR 180.364) for the residues of glyphosate, in or on a variety of raw agricultural commodities. The current proposal to establish tolerances for rice, bran at 30 parts per million (ppm); rice, grain at 15 ppm; rice, hulls at 25 ppm; wheat, forage at 10 ppm; wheat, hay at 10 ppm; and alfalfa, seed at 0.5 ppm, and to increase the established glyphosate tolerance for cotton, gin by-products to 150 ppm, is not expected to result in an increase in the dietary burden for cattle, poultry, and hogs. Respective dietary burdens of 210 ppm and 220 ppm were recently estimated by the Agency for dairy and beef cattle, including a contribution from alfalfa hay as the roughage component of the diet with a tolerance of 400 ppm. Risk assessments were conducted by EPA to assess dietary exposures from glyphosate in food as follows:

i. *Acute exposure*. 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 1–day or single exposure. A review of the toxicity data base, including the developmental toxicity studies in rats and rabbits, did not provide an endpoint that could be used to quantitate risk to the general population and to females 13-50 years old from a single-dose administration of glyphosate. Therefore, no acute dietary analysis was conducted for glyphosate.

ii. *Chronic exposure*. The glyphosate chronic dietary exposure analysis was conducted using the dietary exposure evaluation model (DEEM) software Version 7.87, which incorporates consumption data from the United States Department of Agriculture (USDA) Continuing Survey of Food Intake by Individuals (CSFII), 1989–1992. The 1989–1992 data are based on the reported consumption of more than 10,000 individuals over 3 consecutive days, and therefore, represent more than 30,000 unique person days of data. Foods as consumed (i.e., apple pie) are linked to raw agricultural commodities and their food forms (i.e., apples-cooked/canned or wheat-flour) by recipe translation files internal to the DEEM software. Consumption data are averaged for the entire U.S. population and within population subgroups for chronic exposure assessment, but are retained as individual consumption events for acute exposure assessment.

For chronic dietary exposure and risk assessments, an estimate of the residue level in each food or food-form (i.e., orange or orange-juice) on the commodity residue list is multiplied by the average daily consumption estimate for that food/food form. The resulting residue consumption estimate for each food/food form is summed with the residue consumption estimates for all other food/food forms on the commodity residue list to arrive at the total estimated exposure. Exposure estimates are expressed in milligrams/kilogram body weight day (mg/kg bwt/day) and as a percent of the cPAD for chronic exposure. This procedure is performed for each population subgroup.

The Tier 1 chronic dietary exposure analysis for glyphosate is an upper bound estimate of chronic dietary exposure. The chronic dietary exposure analysis was performed for the general U.S. population and all population subgroups using DEEM assuming tolerance levels residues and 100% crop treated data for the proposed commodities and all registered uses. For chronic dietary risk, the Agency's LOC is less than 100% cPAD. Dietary exposure estimates for representative population subgroups are presented in Table 4. The results of the chronic analysis indicate that the estimated chronic dietary risk as represented by the percent cPAD is below the Agency's LOC (100% cPAD) for the U.S. population and all population subgroups.

TABLE 4.—SUMMARY OF RESULTS FROM CHRONIC DEEM ANALYSIS OF GLYPHOSATE

Subgroup	Exposure (mg/kg/day)	%cPAD
U.S. population (total)	0.033880	1.9
All infants (< 1 year old)	0.075573	4.3
Children (1-6 years old)	0.072077	4.1
Children (7-12 years old)	0.047851	2.7
Females (13-50 years old)	0.025983	1.5
Males (13-19 years old)	0.032773	1.9
Males (20+ years old)	0.028664	1.6
Seniors (55+ years old)	0.023927	1.4

iii. *Cancer*. The HED Cancer Peer Review Committee classified glyphosate as a Group E chemical, negative for carcinogenicity in humans, based on the absence of evidence of carcinogenicity in male and female rats as well as in male and female mice.

iv. Anticipated residue and percent crop treated (PCT) information. The Agency used tolerance levels and 100% PCT data for the proposed commodities and all registered uses.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for glyphosate in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of glyphosate.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/ Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentration in Groundwater (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a PC area factor as an adjustment to account for the maximum PC coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a percent (%) %RfD or %PAD. Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and from residential uses. Since DWLOCs address total aggregate exposure to glyphosate, they are further discussed in section E below.

Based on the GENEEC and SCI-GROW models, the EECs of glyphosate for acute exposures are estimated to be 21 parts per billion (ppb) for surface water and 0.0038 ppb for ground water. The EECs for chronic exposures are estimated to be 0.83 ppb for surface water and 0.0038 ppb for ground water, based on glyphosate treatment crops. To estimate the possible concentration of glyphosate in surface water resulting from direct application to water, the Agency assumed application to a water body 6 feet deep. At an application rate of 3.75 lb acid equivalent (ae)/A, the estimated concentration is 230 ppb. Because the glyphosate water-application estimate is greater than the crop application estimate, 230 ppb is the appropriate value to use in the chronic risk estimate.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

i. *Non-occupational (recreational) exposures*. Glyphosate is currently registered for use on the following residential non-dietary sites: Recreational areas, including parks and golf courses for control of broadleaf weeds and grasses, and lakes and ponds, including reservoirs for control of nuisance aquatic weeds. Based on the registered uses, adult and child golfers are anticipated to have short-term post-application dermal exposure at golf courses. Swimmers (adults, children and toddlers) are anticipated to have short-term post-application dermal and incidental ingestion exposures. However, since the Agency did not select dermal endpoints, no post-application dermal assessment is included; only a post-application incidental ingestion exposure assessment (swimmers) is included. Risk estimates for incidental ingestion by swimmers (adults, children, and toddlers) ranged from 7,600 to 36,000. It should be noted however, that glyphosate is used for non-selective weed control on emerged aquatic weeds. In this use pattern, it is unlikely that swimmers would be present in waterbodies with floating weeds present. Thus, the inclusion of the swimmer incidental ingestion exposure assessment is considered by the Agency to be conservative. Table 5 presents a summary of assumptions used to

estimate the exposure to adult and toddler child swimmers and the corresponding risk estimates.

TABLE 5.—ASSUMPTIONS AND RISK ESTIMATES FOR POST-APPLICATION SWIMMER EXPOSURE ASSESSMENTS FOR GLYPHOSATE, ISOPROPYLAMINE SALT

Exposure Scenario	AR[1] (lb a.e./A)	Maximum Concentration in water (mg/L)[2]	Potential Dose Rate (PDR; oral mg/kg bw/day)[3]	Short-term MOE[4]
Incidental oral ingestion, adult-female	3.75	1.38	0.00493	36,000
Incidental oral, toddler			0.023	7,600

[1]Application rate from registered labels for aquatic weed control using glyphosate IPA salt (ex. label = EPA Reg. No. 524–343; max rate = 7.5 pints/A containing 4 lb ae glyphosate/gal. x 1 gal./4 pints = 3.75 lb ae/A.
[2]Maximum concentration in water (top 1 ft.) = 3.75 lb ae/A x 1A/43,560 ft^2 x 454,000 mg/lb x 1/ft x ft^3 /28.32 L = 1.38 mg/L.
[3]PDR, incidental oral exposure = concentration, Cw (mg/L) x ingestion rate, IgR (L/hr) x exposure time, ET (hrs/d) x 1/BW (adult-female = 60 kg; toddler = 15 kg).
[4]MOE = NOAEL/PDR; short-term incidental oral NOAEL = 175 mg/kg bw/d; The LOC for adult females and toddlers for short-term, incidental oral exposures is MOEs < 100.

The MOEs presented in Table 5 for post-application exposure by swimmers to glyphosate in aquatic weed control applications are greater than 100 and do not exceed the Agency's LOC for short-term non-occupational (recreational) exposures (MOEs less than 100).

ii. *Residential exposures*. Glyphosate is also registered for broadcast and spot treatments on home lawns and gardens by homeowners and by lawn care operators (LCOs). Based on the registered residential use patterns, there is a potential for short-term dermal and inhalation exposures to homeowners who apply products containing glyphosate (residential handlers). Additionally, based on the results of environmental fate studies, there is also a potential for short- and intermediate-term post-application dermal exposures by adults and toddlers and incidental ingestion exposures by toddlers. However, since the Agency did not select short-term or intermediate-term dermal or inhalation endpoints, no residential handler or post-application dermal assessment is included; only a post-application toddler assessment for incidental ingestion exposures is included. Risk estimates for toddler post-application incidental ingestion exposures ranged from 7,200 to greater than 10^6. All recreational and residential exposures assessed do not exceed the Agency's level of concern (MOEs less than 100). Table 6 provides a summary of the short-term and intermediate-term risk estimates for post-application incidental ingestion exposures to toddlers.

TABLE 6.—SUMMARY OF TODDLER INCIDENTAL INGESTION EXPOSURES AND RISK ESTIMATES FOR RESIDENTIAL USE OF GLYPHOSATE, ISOPROPYLAMINE SALT[1]

Activity	AR (lbs a.e./A)[2]	Residue Estimate[3]	PDR (mg/kg bw/d)[4]	Short-term/Intermediate-term MOE[5]
Hand-to-mouth	1.62	DFR: 0.908 μg/cm^2	0.0242	7,200
Object-to-mouth		DFR: 3.63 μg/cm^2	0.00605	29,000
Soil ingestion		Soil residue: 12.2 μg/g soil	8.13 x 10^{-5}	10^{-6}

[1]Sources: Standard Operating Procedures for Residential Exposure Assessments, Draft, December 17, 1997 and Exposure SAC Policy No. 11, February 22, 2001: Recommended Revisions to the SOPs for Residential Exposure.
[2]AR = maximum application rate on Roundup ProDry label (EPA Reg. No. 524–505) for residential lawn treatment.
[3]Residue estimates based on the following protocol from the Residential SOPs:
Hand-to-mouth DFR = 1.62 lb ae/A x 0.05 x (4.54 x 10^{-8} μg/lb ae) x (2.47 x 10^{-8} A/cm^2) = 0.908 g/cm^2.
Object-to-mouth DFR = 1.62 lb ae/A x 0.20 x (4.54 x 10^8 μg/lb ae) x (2.47 x 10^{-8} A/cm^2 = 3.63 μg/cm^2.
Soil Residue = 1.62 lb ae/A x fraction of residue in soil (100%)/cm x (4.54 x 10^8 μg/lb ae) x (2.47 x 10^{-8} A/cm^2) x 0.67 cm^3/g = 12.2 μg/g soil.
[4]Potential Dose Rate (PDR; already normalized to body weight of toddler).
Hand-to-mouth PDR = (0.908 g/cm^2 x 0.50 x 20 cm^2/event x 20 events/hr x 10^{-3} mg/μg x 2 hrs/d)/15 kg = 0.0242 mg/kg bwt/day.
Object-to-mouth PDR = (3.63 g/cm^2 x 25 cm^2 /d x 10^{-3} mg/μg)/15 kg = 0.00605 mg/kg bwt/day.
Soil Ingestion PDR = (12.2 μg/g soil x 100 mg soil/d x 10^{-6} g/μg)/15 kg = 8.13 x 10^{-5} mg/kg bwt/day.
[5]MOE = NOAEL/PDR, where the short-term incidental oral NOAEL = 175 mg/kg/day the Agency's LOC is for MOEs < 100 (short-term residential).

All MOEs calculated for post-application toddler exposures do not exceed the Agency's level of concern for residential exposures (MOEs less than 100).

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether 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. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general*. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure 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 UFs (safety) in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. The toxicology data base for glyphosate is adequate according to the Subdivision F Guideline requirements for a food-use chemical. Acceptable developmental toxicity studies in the rat and rabbit are available, as is an acceptable 2-generation reproduction study in the rat. Based on the available data, the Agency determined that there is no evidence of either a quantitative or qualitative increased susceptibility following *in utero* glyphosate exposure to rats and rabbits, or following prenatal/postnatal exposure in the 2-generation reproduction study in rats.

3. *Conclusion*. There is a complete toxicity data base for glyphosate and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The Agency determined that the FQPA safety factor to protect infants and children can be removed (reduced from 10X to 1X) for all population subgroups and exposure scenarios because:

1. The toxicology data base is complete.

2. A developmental neurotoxicity study is not required.

3. The dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by EPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute aggregate risk (food + drinking water)*. The Agency did not identify an appropriate acute dietary endpoint that is the result of a single-dose administration of glyphosate. Accordingly, glyphosate is not expected to pose an acute risk.

2. *Chronic aggregate risk (food + drinking water)*. Using the exposure assumptions described in this unit for chronic exposure (tolerance level residues and 100% crop treated data for all proposed commodities and registered uses), EPA has concluded that exposure to glyphosate from food will utilize 1.9% of the cPAD for the U.S. population, 4.3% of the cPAD for all infants (less than 1–year old) and 4.1% of the cPAD for children 1-6 years old. The results of the chronic analysis (Table 4 in this unit) indicate that the chronic dietary risk estimates for the general U.S. population and all population subgroups associated with the existing and proposed uses of glyphosate do not exceed the Agency's LOC (less than 100% of the cPAD). Based on the use pattern, chronic residential exposure to residues of glyphosate is not expected. In addition, there is potential for chronic dietary exposure to glyphosate in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 7 below:

TABLE 7.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO GLYPHOSATE

Scenario/Population Subgroup	cPAD,mg/kg/day	Chronic Food Exposure mg/kg/day	Maximum Chronic Water Exposure[1], mg/kg/day	Ground Water EEC, ppb	Surface Water EEC, ppb	Chronic DWLOC[2], ppb
U.S. population	1.75	0.033880	1.716120	0.0038	230	60,000
All infants (< 1–year old)	1.75	0.075573	1.674427	0.0038	230	17,000
Children (1-6 years old)	1.75	0.072077	1.677923	0.0038	230	17,000

TABLE 7.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO GLYPHOSATE—Continued

Scenario/Population Subgroup	cPAD,mg/kg/day	Chronic Food Exposure mg/kg/day	Maximum Chronic Water Exposure[1], mg/kg/day	Ground Water EEC, ppb	Surface Water EEC, ppb	Chronic DWLOC[2], ppb
Children (7-12 years old)	1.75	0.047851	1.702149	0.0038	230	17,000
Females (13-50 years old)	1.75	0.025983	1.724017	0.0038	230	52,000
Males (13-19 years old)	1.75	0.032773	1.717227	0.0038	230	60,000
Males (20+ years old)	1.75	0.028664	1.721336	0.0038	230	60,000
Seniors (55+ years old)	1.75	0.023927	1.726073	0.0038	230	60,000

[1]Maximum chronic water exposure (mg/kg/day) = cPAD (mg/kg/day) - chronic food exposure from DEEM™ (mg/kg/day).
[2]The chronic DWLOCs were calculated as follows: DWLOC (μg/L) = maximum water exposure (mg/kg/day) x body weight (kg)/consumption (L/day) x 0.001 mg/μg.

3. *Short-term/intermediate-term aggregate risk (food + residential + water).* In aggregating short-term-/intermediate-term risk, HED considered background chronic dietary exposure (food + water) and short-term/intermediate-term incidental oral exposures (see Tables 6 and 7). Because the incidental oral ingestion exposure estimates for toddlers from residential turf exposures (Table 7) exceeded the incidental oral exposure estimates from post-application swimmer exposures (Table 6), the Agency conducted this risk assessment using exposure estimates from just the worst-case situation. No attempt was made to combine exposures from the swimmer and residential turf scenarios due to the low probability of both occurring.

The total short-term/intermediate-term food and residential aggregate MOEs are 1,800–2,300. As these MOEs are greater than 100, the short-term/intermediate-term aggregate risk does not exceed the Agency's LOC. For surface water and ground water, the EECs of glyphosate are less than the DWLOCs for glyphosate in drinking water as a contribution to short-term/intermediate-term aggregate exposure. Therefore, the Agency concludes with reasonable certainty that residues of glyphosate in drinking water do not contribute significantly to the short-term/intermediate-term aggregate human health risk at the present time. Table 8 summarizes the short-term/intermediate-term aggregate exposure to glyphosate residues.

TABLE 8.—SHORT-TERM/INTERMEDIATE-TERM AGGREGATE RISK AND DWLOC CALCULATIONS FOR EXPOSURE TO GLYPHOSATE RESIDUES SHORT-TERM/INTERMEDIATE-TERM EXPOSURE SCENARIO

Population	Aggregate MOE (food+ residential)[1]	Aggregate Level of Concern (LOC) or Target MOE[2]	Surface Water EEC[3] (ppb)	Ground Water EEC[3] (ppb)	Short-Term/ Intermediate-Term DWLOC[4], (ppb)
All Infants <1 year old)	1,900	100	230	0.0038	17,000
Children (1-6 years old)	1,800	100	230	0.0038	17,000
Children (7-12 years old)	2,300	100	230	0.0038	17,000

[1]Aggregate MOE = NOAEL/(Average food exposure + Residential exposure).
[2]Basis for the target MOE: interspecies and intraspecies uncertainty factors totaling 100.
[3]The glyphosate use producing the highest level was used.
[4]DWLOC (μg/L or ppb) = maximum water exposure (mg/kg/day) x bwt (kg) / water consumption (L) x 10^{-3} mg/μg (10 kg bwt assumed).

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

F. Analytical Enforcement Methodology

Adequate enforcement methods are available for analysis of residues of glyphosate in or on plant and livestock commodities. These methods include Gas Liquid Chromatography (GLC) (Method I in Pesticides Analytical Manual (PAM) II; the limit of detection is 0.05 ppm) and High Performance Liquid Chromatography (HPLC) with fluorometric detection. Use of the GLC method is discouraged due to the lengthiness of the experimental procedure. The HPLC procedure has undergone successful Agency validation and was recommended for inclusion in PAM II. A Gas Chromatography/Mass Spectrometry (GC/MS) method for glyphosate in crops has also been validated by EPA's Analytical Chemistry Laboratory (ACL). Thus, adequate analytical methods are available for residue data collection and enforcement of the proposed tolerance changes for glyphosate.

G. International Residue Limits

Codex and Mexican maximum residue limits (MRLS) are established for residues of glyphosate (glifosato) per se and Canadian MRLs are established for combined residues of glyphosate and AMPA in a variety of raw agricultural, processed, and animal commodities. Currently no relevant Codex MRL for cotton gin by-products is established. The proposed ''rice, grain'' tolerance of

15.0 ppm is based on crop field trial data obtained when using glyphosate-tolerant rice and thus cannot be lowered to maintain harmonization with the CODEX MRL of 0.1 ppm for residues of glyphosate in or on this commodity. This petition proposes no additional numerical changes that would effect agreement between United States tolerances and Codex MRLs.

[FR Doc. 04–18770 Filed 8–17–04; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than September 10, 2004.

A. Federal Reserve Bank of Cleveland (Cindy C. West, Banking Supervisor) 1455 East Sixth Street, Cleveland, Ohio 44101–2566:

1. KEYCORP and KC Subsidiary, Inc. both in Cleveland, Ohio; to merge with Evertrust Financial Group, Inc., and thereby indirectly acquire Evertrust Bank, both in Everett, Washington.

Board of Governors of the Federal Reserve System, August 12, 2004.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 04–18895 Filed 8–17–04; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Request for Ambulatory Care CAHPS® (ACAHPS) Test Sites

AGENCY: Agency for Healthcare Research and Quality (AHRQ), DHHS.

ACTION: Notice of request.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is soliciting volunteer sites for the testing of a draft Ambulatory CAHPS® (ACAHPS) instrument. This instrument will be part of a suite of standardized patient surveys that are reliable, valid, and provide a flexible, modular approach to measurement. This goal is in direct response to requests from stakeholders to revise the CAHPS® tool in order to measure different levels of ambulatory health care to provide practical information for quality improvement for multiple and more varied audiences. The result will be data derived from patients' perspectives that are more actionable for quality improvement than the current CAHPS® instrument.

AHRQ has initiated the redesign of the CAHPS instrument to include different levels of ambulatory health care delivery, i.e., services provided by individual primary care clinicians (such as physicians, physician assistants, or nurse practitioners), sites of care (that is a particular geographic location or facility from which care is delivered) or group practices (where two or more practitioners legally organize as a medical group to deliver care under certain conditions), and health plans (the payor of health care services in either fee-for-service or managed care arrangements). These levels are not necessarily relevant to all survey users. The modular approach to the ACAHPS instrument allows users to assess the quality of ambulatory care in their particular market while maintaining comparability to the CAHPS survey users in other markets.

AHRQ will respond to stakeholder input to provide users with a flexible and modular approach to assess the quality of ambulatory care for all of the functions at each of the delivery levels listed above, using instruments specific to plans, groups or sites, or physicians. Presently, we are interested in soliciting volunteers to be test sites for the ACAHPS instrument. The instrument will be tested beginning in 2004 and continuing into 2005.

Testing the ACAHPS Instrument

Survey Method Issues

The following are some examples to methodological studies that AHRQ plans to address during the pilot test of the ACAHPS instrument, and which you may be willing to participate in:

1. Testing of mode effects (mail versus telephone) within levels of ambulatory care. Because ACAHPS will be fielded by both mail and telephone it is a primary concern to test and revise the instrument in these two modes in order to ensure comparability across these modes.

2. Testing in other modes. We are also interested in testing ACAHPS administration in other modes to assess mode effect and response rates.

3. Testing the use of screener items versus non- screener items. CAHPS® surveys traditionally use some screener items to establish whether the respondent falls within a particular category to determine whether a question is appropriate or whether the response in meaningful. Through additional testing of the draft instrument, it can be determined whether screeners are necessary and appropriate.

4. Assessing the impact on measurement of similar concepts when using a reference period of care versus visit-specific care. Some surveys at the physician level and group level use a visit-specific reference for survey items. Others use a reference period (e.g., the last six months).

5. Testing the adequacy of different response scales. We wish to test the benefits of scales of differing lengths (e.g., four vs. six points).

6. Assessing supplemental item placement. We wish to test the effects of embedding additional questions within the ACAHPS instrument.

7. Testing the equivalence of the English and Spanish versions of the draft instrument.

8. Assessing the correlation of survey measures with clinical measures of quality.

9. Testing the effect on response rate of different survey materials, taking into account incremental changes in cost. There is some evidence in the survey research literature that response rate can