program development which addresses the goals of EPA's wetland program outlined in this document:

- Comprehensive planning of wetland resources, or integration of wetland management into broad watershed protection approaches.
- Development of S/T/LG Wetland Conservation Plans (WCP).
- Development of a framework for assuming CWA Section 404 program or Programmatic General Permits program.
- Development of widely applicable model wetland training programs for S/T/LGs.
- Incorporation of wetlands into water quality standards, or refining criteria to appropriately reflect water quality conditions in wetlands.
- Creation, piloting and refining of wetland and riparian restoration programs.
- Development, piloting and refining of wetland bioassessment programs to evaluate wetland health and performance of protection and restoration activities.
- Facilitation of public-private partnerships to develop wetland restoration, protection or education programs.
- Creation of and/or participation in training that builds watershed and wetland partnership and technical skills (e.g. the Watershed Academy).
- Conducting outreach and education efforts aimed at improving public understanding of wetland protection and regulatory efforts.
- Development of outreach programs to inform owners of potential wetland restoration sites of government assistance programs.
- Creating public education programs which promote wetland information for American Wetlands month.

Appendix C—Grant Coordinators

Region 1: Bob Goetzel, 617/565–3602, *goetzel.robert@epa.gov*
Region 2: John Cantilli, 212/637–3810, *cantilli.john@epa.gov*
Region 3: Alva Brunner, 215/814–2715, *brunner.alva@epa.gov*
Region 4: Sharon Ward, 404/562–9369, *ward.sharon@epa.gov*
Region 5: Cathy Garra, 312/886–0241, *garra.catherine@epa.gov*
Region 6: Sondra McDonald, 214/665–7187, *mcdonald.sondra@epa.gov*
Region 7: Raju Kakarlapudi, 913/551–7320, *kakarlapudi.raju@epa.gov*
Region 8: Ed Stearns, 303/312–6946, *stearns.edward@epa.gov*
Region 9: Cheryl McGovern, 415/744–2013, *mcgovern.cheryl@epa.gov*
Region 10: Anne Robinson, 206/553–6219, *robinson.anne@epa.gov*
Headquarters: Shanna Draheim, 202/260–6218, *draheim.shanna@epa.gov*

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BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[PF–957; FRL–6596–4]

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 control number PF–957, must be received on or before August 24, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the ''SUPPLEMENTARY INFORMATION.'' To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–957 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; 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 affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

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

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number PF–957. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–957 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs

(OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3.*Electronically.* You may submit your comments electronically by e-mail to: *''opp-docket@epa.gov,''* or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–957. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified 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 control 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 Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in 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: July 20, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. 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

0F6130

EPA has received a pesticide petition 0F6130 from Monsanto Company, 600 13th St., NW., Suite 660, Washington, DC 20005 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of glyphosate (*N*-phosphonomethyl)glycine from the application of glyphosate, the isopropylamine salt of glyphoste, the ethanolamine salt of glyphosate, and the ammonium salt of glyphosate in or on the raw agricultural commodity grass forage, fodder, and hay group at 300 parts per million (ppm). These tolerances would replace the existing tolerances for Bahia grass, Bermuda grass, bluegrass, bromegrass, fescue, orchard grass, rye grass, timothy, and wheat grass at 200 ppm, and forage, grasses at 0.2 ppm, grasses forage, at 0.2 ppm, and grasses forage, at 0.1 ppm. The Agency has determined that the petition contains 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 support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* The qualitative nature of the residue in plants is adequately understood. Studies with a variety of plants including corn, cotton, soybeans, and wheat indicate that the uptake of glyphosate or its metabolite, aminomethylphosphonic acid (AMPA), from soil is limited. The material which is taken up is readily translocated. Foliarly applied glyphosate is readily absorbed and translocated throughout the trees or vines to the fruit of apples, coffee, dwarf citrus (calamondin), pears, and grapes. Metabolism via *N*-methylation yields *N*-methylated glycines and phosphonic acids. For the most part, the ratio of glyphosate to AMPA is 9 to 1 but can approach 1 to 1 in a few cases (e.g., soybeans and carrots). Much of the residue data for crops reflects a detectable residue of parent (0.05–0.15 ppm) along with residues below the level of detection (<0.05 ppm) of AMPA. The terminal residue to be regulated in plants is glyphosate per se.

2. *Analytical method.* Adequate enforcement methods are available for analysis of residues of glyphosate in or on plant commodities. These methods include 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).

Adequate analytical methods are available for residue data collection and enforcement of the proposed tolerances of glyphosate in or on grass forage, fodder, and hay group.

3. *Magnitude of residues*. The available crop field trial residue data support the establishment of tolerances in grass forage, fodder, and hay at 300 ppm. This new tolerance will be sufficient to replace the existing tolerances for specific grass species at 200 ppm. Any secondary residues occurring in the liver or kidney of cattle, goats, horses, sheep, liver, and kidney of poultry will be covered by existing tolerances, and the available data indicate that residues of glyphosate are not anticipated to occur in any other livestock commodities as a result of this action.

B. Toxicological Profile

1. *Acute toxicity*. Several acute toxicology studies placing technical-grade glyphosate in toxicity category III and toxicity category IV. Technical glyphosate is not a dermal sensitizer.

2. *Genotoxicty*. Mutagenicity data included chromosomal aberration *in vitro* (no aberrations in chinese hamster ovary (CHO) cells were caused with and without S9 activation); DNA repair in rat hepatocyte; *in vivo* bone marrow cytogenetic test in rats; rec-assay with *B. subtilis*; reverse mutation test with *S.typhimurium*; Ames test with *S. typhimurium*; and dominant-lethal mutagenicity test in mice (all negative).

3. *Reproductive and developmental toxicity*. A developmental toxicity study in rabbits given doses of 0, 75, 175, and 350 milligrams/kilograms/day (mg/kg/day) with a developmental no observed adverse effect level (NOAEL) of 175 mg/kg/day (insufficient litters were available at 350 mg/kg/day to assess developmental toxicity); a maternal NOAEL of 175 mg/kg/day based on clinical signs of toxicity and mortality at 350 mg/kg/day highest dose tested (HDT).

A multi-generation reproduction study with rats fed dosage levels of 0, 3, 10, and 30 mg/kg/day with the parental and reproductive (pup) NOAELs at 30 mg/kg/day HDT based on no adverse effects related to dosing at any level tested.

In a 2-generation reproduction study, rats were fed dosage levels of 0, 100, 500, and 1,500 mg/kg/day with a systemic NOAEL of 500 mg/kg/day based on soft stools in Fo and F1 males and females at 1,500 mg/kg/day HDT and a reproductive NOAEL 1,500 mg/kg/day HDT.

4. *Subchronic toxicity*. In a 2-day dermal toxicity study, rabbits were exposed to glyphosate at levels of 0, 10, 1,000, or 5,000 mg/kg/day. The systemic NOAEL was 1,000 mg/kg/day and the lowest observed adverse effect level (LOAEL) was 5,000 mg/kg/day based on decreased food consumption in males. Although serum lactate dehydrogenase was decreased in both sexes at the high dose, this finding was not considered to be toxicologically significant.

5. *Chronic toxicity*. A 1-year feeding study with dogs fed dosage levels of 0, 20, 100, and 500 mg/kg/day with a NOAEL of 500 mg/kg/day. A 2-year carcinogenicity study in mice fed dosage levels of 0, 150, 750, and 4,500 mg/kg/day with no carcinogenic effect at the highest dose tested HDT of 4,500 mg/kg/day.

A chronic feeding/carcinogenicity study in male and female rats fed dosage levels of 0, 3, 10, and 31 mg/kg/day (males) and 0, 3, 11, or 34 mg/kg/day (females) with no carcinogenic effects observed under the conditions of the study at dose levels up to and including 31 mg/kg/day HDT (males) and 34 mg/kg/day HDT (females) and a systemic NOAEL of 31 mg/kg/day HDT (males) and 34 mg/kg/day HDT (females). Because a maximum tolerated dose (MTD) was not reached, this study was classified as supplemental for carcinogenicity.

A second chronic feeding/carcinogenicity study in male and female rats fed dosage levels of 0, 89, 362, and 940 mg/kg/day (males) and 1, 113, 457, and 1,183 mg/kg/day (females) with no carcinogenic effects noted under the conditions of the study at dose levels up to and including 940/1,183 mg/kg/day (males/females) HDT and a systemic NOAEL of 362 mg/kg/day (males) based on an increased incidence of cataracts and lens abnormalities, decreased urinary pH, increased liver weight and increased liver weight/brain ratio (relative liver weight) at 940 mg/kg/day (males) HDT and 457 mg/kg/day (females) based on decreased (bwt) body weight gain 1,183 mg/kg/day (females) HDT. There was no carcinogenic response at any dose level.

6. *Animal metabolism*. The qualitative nature of the residue in animals is adequately understood. Studies with lactating goats and laying hens fed a mixture of glyphosate and AMPA indicate that the primary route of elimination was by excretion (urine and feces). These results are consistent with metabolism studies in rats, rabbits, and cows. The terminal residues in eggs, milk, and animal tissues are glyphosate and its metabolite AMPA; there was no evidence of further metabolism. The terminal residue to be regulated in livestock is glyphosate per se.

7. *Metabolite toxicology*. The metabolite AMPA has been determined to not be of toxicological significance.

8. *Endocrine disruption*. The toxicity studies required by EPA for the registration of pesticides measure numerous endpoints with sufficient sensitivity to detect potential endocrine-modulating activity. No effects have been identified in subchronic, chronic or developmental toxicity studies to indicate any endocrine-modulating activity by glyphosate. In addition, negative results were obtained when glyphosate was tested in a dominant-lethal mutation assay. While this assay was designed as a genetic toxicity test, agents that can affect male reproduction function will also cause effects in this assay. More importantly, the multi-generation reproduction study in rodents is a complex study design which measures a broad range of endpoints in the reproductive system and in developing offspring that are sensitive to alterations by chemical agents. Glyphosate has been tested in two separate multi-generation studies and each time the results demonstrated that glyphosate is not a reproductive toxin.

C. Aggregate Exposure

1. *Dietary exposure—From food and feed uses*. Tolerances have been established (40 CFR 180.364) for the residues of (*N*-(phosphonomethyl)glycine resulting from the application of the isopropylamine salt of glyphosate, and/or the ammonium salt of glyphosate, in or on a variety of raw agricultural commodities. Tolerances are established on the kidney of cattle, goats, hogs, horses, and sheep at 4.0 ppm; liver of cattle, goats, hogs, horses, and sheep at 0.5 ppm; and liver, and kidney of poultry at 0.5 ppm based on animal feeding studies and worst-case livestock diets. Risk assessments were conducted by EPA to assess dietary exposures from glyphosate as follows.

i. *Food*—a. *Acute exposure and risk*. Acute dietary risk assessments are

performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. An acute dietary risk assessment was not performed because no endpoints attributable to single dose were identified in the oral studies including rat and rabbit developmental studies. There are no data requirements for acute and subchronic neurotoxicity studies and no evidence of neurotoxicity in any of the toxicity studies at very high doses. The Agency has concluded with reasonable certainty that glyphosate dose not elicit an acute toxicological response, and that an acute dietary risk assessment is not needed.

b. *Chronic exposure and risk*. The chronic dietary exposure analysis was conduced using the reference dose (RfD) of 2.0 mg/kg/day based on the maternal NOAEL of 175 mg/kg/day from a developmental study and an uncertainty factor of 100 (applicable to all population groups) the Dietary Exposure Evaluation Model (DEEM) analysis assumed tolerance levels residues and 100% of the crop treated. These assumptions resulted in the following theoretical maximum residue contributions and percent RfDs for certain population subgroups. The theoretical maximum residue contribution (TMRC) for the U.S. population (48 contiguous states) was 0.029960 or 1.5% of the RfD; 0.026051 or 1.3% of the RfD for nursing infants (less than on 1-year old); 0.065430 or 3.3% of the RfD for non-nursing infants less than 1–year old; 0.064388 or 3.2% of the RfD for children (1-6 years old); 0.043017 or 2.2% of the RfD for children (7–12 years old); 0.030928 or 1.5% of the RfD for females (13+/nursing); 0.030241 or 1.5% of the RfD for non-hispanic whites; and 0.030206 or 1.5% of the RfD for non-hispanic blacks. These exposure levels are unaffected by the proposed tolerances on grass forage, fodder, and hay group. These commodities are only consumed by livestock, and the existing tolerances in liver and kidney fractions of cattle, goats, horses, sheep, and poultry are considered sufficient to account for any additional dietary burden these animals may encounter.

c. *Chronic risk-carcinogenic*. Glyphosate has been classified as a group E chemical no evidence of carcinogenicity in two acceptable animal species.

ii. *Drinking water*. Generic Expected Environmental Concentration (GENEEC) and Screening Concentration and Groundwater (SCI-GROW) models were run by EPA to produce maximum estimates of glyphosate concentrations in surface and ground water, respectively. The drinking water exposure for glyphosate from the ground water screening model, SCI-GROW, yields a peak and chronic estimated environmental concentration (EEC) of 0.0011 parts per billion (ppb) in ground water. The GENEEC values represent upper-bound estimates of the concentrations that might be found in surface water due to glyphosate use. Thus, the GENEEC model predicts that glyphosate surface water concentrations range from a peak of 1.64 ppb to a 56-day average of 0.19 ppb. The model estimates are compared directly to drinking water levels of comparison (DWLOC) (chronic). The DWLOC (chronic) is the theoretical concentration of glyphosate in drinking water so that the aggregate chronic exposure (food + water + residential) will occupy no more than 100% of the RfD. This assessment does not take into account expected reductions in any glyphosate concentrations in water arising from water treatment of surface water prior to releasing it for drinking purposes. The Agency's default body weights (bwts) and consumption values used to calculate DWLOCs are as follows: 70 kg/2 liter (L) (adult male), 60 kg/2L (adult female), and 10 kg/1L (child).

a. *Acute exposure and risk*. An acute dietary endpoint and dose was not identified in the toxicology data base. Adequate rat and rabbit developmental studies did not provide a dose or endpoint that could be used for acute dietary risk purposes. Additionally, there were no data requirements for acute or subchronic rat neurotoxicity studies since there was no evidence of neurotoxicity in any of the toxicology studies at very high doses.

b. *Chronic exposure and risk*. The DWLOC (chronic, non-cancer) risk is calculated by multiplying the allowed chronic water exposure (mg/kg/day) x bwt/kg divided by the consumption (L) x 10^3 µg/mg. The DWLOCs are 69,000 µg/L for the U.S. population in 48 contiguous states, males (13+), non-hispanic whites, and non-hispanic blacks; and 19,000 for non-nursing infants (less than 1–year old) and children (1-6 years). Although the GENEEC and SCI–GROW models are known to produce worst-case estimates, the resulting average concentrations of glyphosate in the surface and ground water are more than 10,000–fold less than the DWLOC (chronic). Therefore, taking into account present uses and uses proposed in this action, Monsanto concludes with reasonable certainty that no harm will result from chronic aggregate exposure to glyphosate.

2. *Non-dietary exposure*. Glyphosate is currently registered for use on the following residential non-food sites: Around ornamentals, shade trees, shrubs, walks, driveways, flower beds, and home lawns. Based on the registered uses of glyphosate, the potential for residential exposures exists. However, based on the low acute toxicity and lack of other toxicological concerns, glyphosate does not meet the Agency's criteria for residential data requirements and a residential exposure assessment is not required since there are no toxicological endpoints selected for either dermal or inhalation exposure. Exposures from residential uses are not expected to pose undue risks or harm to public health.

i. *Acute exposure and risk*. There are no acute toxicological concerns for glyphosate. Glyphosate has been the subject of numerous incident reports, primarily for eye and skin irritation injuries, in California. Some glyphosate end-use products are in toxicity categories I and II for eye and dermal irritation. The reregistration eligibility decision document for glyphosate (SEP–1993) indicated that the Agency is not adding additional personal protective equipment (PPE) requirements to labels of end-use products, but that it continues to recommend the PPE and precautionary statements required for end-use products in toxicity categories I and II.

ii. *Chronic exposure and risk*. Although there are registered residential uses for glyphosate, glyphosate does not meet the Agency's criteria for residential data requirements, due to the lack of toxicological concerns. Incidental acute and/or chronic dietary exposures from residential uses of glyphosate are not expected to pose undue risks to the general population, including infants and children.

iii. *Short- and intermediate-term exposure and risk*. EPA identified no toxicological concerns for short-, intermediate-, and long-term dermal or inhalation routes of exposures for glyphosate. The Agency has concluded that exposures from residential uses of glyphosate are not expected to pose undue risks.

D. Cumulative Effects

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 residue 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 produce a toxic metabolite that is also produced by other substances. For the purposes of this tolerance action, therefore, EPA should assumed that glyphosate does not have 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) (FRL–5754–7).

E. Safety Determination

1. *U.S. population*—i. *Acute risk*. There was no acute dietary endpoint identified, therefore there are no acute toxicological concerns for glyphosate.

ii. *Chronic risk*. Using the TMRC exposure assumptions described in this unit, EPA has concluded that aggregate exposure to glyphosate from food will utilize 1.5% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants (less than 1-year) and children (1–6) as 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, the aggregate exposure will not exceed 100% of the RfD. EPA has previously concluded that there is a reasonable certainty that no harm will result from aggregate exposure to glyphosate residues at this level.

iii. *Short- and intermediate-term risk*. Short- and intermediate-term dermal and inhalation risk is not a concern due to the lack of significant toxicological effects observed with glyphosate under these exposure scenarios. 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.

iv. *Aggregate cancer risk for U.S. population*. Glyphosate has been classified as a group E chemical, with no evidence of carcinogenicity for humans in two acceptable animal studies.

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

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

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

ii. *Prenatal and postnatal sensitivity*. The oral perinatal and prenatal data demonstrated no indication of increased sensitivity of rats or rabbits to *in utero* and postnatal exposure to glyphosate.

iii. *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. Based on these data, there is no indication that the developing fetus or neonate is more sensitive than adult animals. No developmental neurotoxicity studies have been required at this time. A developmental neurotoxicity data requirement is an upper tier study and is required only if effects observed in the acute and 90-day neurotoxicity studies indicate concerns for frank neuropathy or alterations seen in fetal nervous system in the developmental or reproductive toxicology studies. The Agency has concluded that reliable data support the use of the standard 100–fold uncertainty factor for glyphosate, and that a ten-fold (10x) uncertainty factor is not needed to protect the safety of infants and children.

iv. *Acute risk*. There are no acute toxicological endpoints for glyphosate. The Agency has concluded that establishment of the proposed tolerances would not pose an unacceptable aggregate risk.

v. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to glyphosate from food utilizing present tolerances will utilize 3.0.% of the RfD for infants and children. 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. These dietary exposure levels are unaffected by the proposed tolerances on grass forage, fodder, and hay group, because these commodities are only consumed by livestock, and the existing tolerances in liver and kidney fractions of cattle, goats, horses, sheep, and poultry are considered sufficient to account for any additional dietary burden these animals may encounter. Although there is a low likelihood, potential exposure to glyphosate in drinking water and from non-dietary, non-occupational exposure, EPA has previously concluded that the aggregate exposure is not expected to exceed 100% of the RfD.

vi. *Short- or intermediate-term risk*. Short-term and intermediate-term dermal and inhalation risk is not a concern due to the lack of significant toxicological effects observed with glyphosate under these exposure scenarios.

vii. *Determination of safety*. Based on these risk assessments, EPA has previously concluded that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to glyphosate residues at these levels.

F. International Tolerances

A Codex Maximum Residue Level exists for ''hay or fodder (dry) of grasses'' at 50 ppm.

[FR Doc. 00–18794 Filed 7–24–00; 8:45 am]

BILLING CODE 6560–50–F