children (the age at which exposure to clethodim reached a maximum). Adding the worse case potential incremental exposure to infants and children from clethodim in drinking water (0.0024 mg/kg bwt/day) greatly increases the aggregate, chronic dietary exposure and the occupancy of the cPAD by 24% to 46.7% for children (2 years old). 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. It can be concluded that there is a reasonable certainty that no harm will result to infants and children from aggregate, chronic exposure to clethodim residues.

F. International Tolerances

Codex, Canadian, or Mexican maximum residue levels (MRLs) have been established or proposed for residues of clethodim in/on sugar beets (0.1 ppm), potatoes (0.2 ppm), rape seed (0.5 ppm), rape seed oils (0.5 ppm), sunflower seed (0.5 ppm), and sunflower seed oils (0.05 ppm). There are no conflicts between this proposed action and existing international residue limits.

[FR Doc. 02–9323 Filed 4–16–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1079; FRL–6830–5]

Notice of Filing Pesticide Petitions to Establish a Tolerance for Certain Pesticide Chemicals in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by docket control number PF–1079, must be received on or before May 17, 2002.

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–1079 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: James A. 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'' ''Regulations andProposed Rules'' 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–1079. 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–1079 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–1079. 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 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 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 pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals 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 these petitions contain 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: March 28, 2002.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

The Petitioner's summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioner and represent the views of the petitioner. EPA is publishing the petition summaries verbatim without editing them 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

PP 0F6130, PP 0F6195, PP 1F6273, PP 1F6274, PP1F6295

EPA has received several pesticide petitions (PP 0F6130, PP 0F6195, PP 1F6273, PP 1F6274, PP 1F6295) from Monsanto Company, 600 13th Street, NW., 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 part 180 by establishing several tolerances for residues of glyphosate (*N*-(phosphonomethyl) glycine). In the **Federal Register** of July 25, 2000 (65 FR 45769) (FRL–6596–4), EPA issued a notice pursuant to section 408 of the FFDCA announcing the filing of a pesticide petition (PP 0F6130) for tolerance by Monsanto Company; that petition has been amended and is accordingly re-notified. Monsanto requests that 40 CFR 180.364 be amended by establishing tolerances for residues of glyphosate (*N*-(phosphonomethyl) glycine) *per se* resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the potassium salt of glyphosate, and/or the ammonium salt of glyphosate in or on the listed raw agricultural commodities, (RACs) to include: grass, forage, fodder, and hay group at 300 parts per million (ppm); aspirated grain fractions at 100 ppm; corn, field, forage at 6.0 ppm; wheat, forage at 10.0 ppm; wheat, hay at 10.0 ppm; animal feeds, nongrass group at 400 ppm; rice, grain at 15.0 ppm; rice, bran at 30.0 ppm; and rice, hulls at 25.0 ppm and to increase the established tolerance for wheat, grain to 6.0 ppm. In addition, PP 1F6274 requests to revise the present tolerance for cereal grains group to be ''grain, cereal group (except barley, field corn, grain sorghum, oats, rice, and wheat).'' Finally, Monsanto seeks to delete the existing tolerance for soybean, aspirated grain fractions at 50.0 ppm since this tolerance will be included in the ''aspirated grain fractions'' described above, and PP 1F6273 seeks to delete the existing tolerance for animal, feeds, nongrass group (except alfalfa), which will be included in the above proposed ''animal feeds, nongrass group'' tolerance. The tolerances proposed for rice and wheat commodities, and the grass, forage, fodder, and hay group include both conventional and glyphosate tolerant rice, wheat, and creeping bentgrass. EPA has determined that the petitions 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 supports granting of the petitions. Additional data may be needed before EPA rules on the petitions.

A. Residue Chemistry

1. *Plant metabolism*. The nature of the residue in plants is adequately understood and consists of the parent, glyphosate and its metabolite aminomethyl-phosphonic acid (AMPA). Only glyphosate parent is to be regulated in plant and animal commodities since the metabolite AMPA is not of toxicological concern in food. The qualitative nature of the glyphosate residue will not be changed as a result of the proposed tolerance changes.

The qualitative nature of the residue in animals is adequately understood, and will not be affected by the proposed tolerance change. Glyphosate herbicides are not applied directly to livestock, so their only exposure is via plant residues in their diet. The terminal residue to be regulated in livestock 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 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. 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 crops has also been validated by EPA's Analytical Chemistry Laboratory (ACL). The proposed revisions in the tolerance regulation do not change the residue to be analyzed, which remains as glyphosate *per se*.

3. *Magnitude of residues*. Adequate data concerning glyphosate residues on raw agricultural commodities (RACs) and relevant processed commodities has been submitted to the Agency. Accordingly, the available residue data for glyphosate support the proposed revisions of the tolerance regulation for glyphosate. In addition, any secondary residues occurring in liver, or kidney of cattle, goats, horses, sheep, and meat-by-products of poultry, and eggs, will be covered by existing tolerances. Existing glyphosate tolerances for fish and shellfish will cover any residues occurring in harvestable aquatic species.

B. Toxicological Profile

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

2. *Genotoxicty*. In an *in viro* rec − assay with *B. subtilis* H17 (rec+) and M45 (rec −) and reverse mutation assay using *E. coli* WP2 hcr and *S. typhimurium* strains, there was no evidence of gene toxicity genotoxicity up to the limit dose or cytotoxicity in the presence or absence of metabolic activation.

In an *in vitro* reverse gene mutation assay in *S. typhimurium* bacteria, there was no evidence of induced mutant colonies over background in *Salmonella* strains TA 98, TA 100, TA 1535, and TA 1537 both in the presence and absence of metabolic activation at doses up to cytotoxic levels or the limit dose. In an *in vitro* gene mutation assay in chinese hamster ovary (CHO) cells/hypoxanthine guanine phophoribosyl transferase (HGPRT), there was no evidence of genotoxicity up to cytotoxic levels in the presence or absence of metabolic activation. In a bone marrow chromosome aberrations assay, there was no significant increase in the frequency of chromosome aberrations in bone marrow at the limit dose of 1,000 milligrams/kilograms (mg/kg) in both sexes of Sprague-Dawley rats.

3. *Reproductive and developmental toxicity*. In a prenatal developmental toxicity in rats, the maternal no observe adverse effect level (NOAEL) = 1,000 mg/kg/day based on mortality with a maternal lowest observe adverse effect level (LOAEL) 3,500 mg/kg/day based on mortality, increased clinical signs, and reduced body weight gain. The developmental NOAEL = 1,000 mg/kg/day and the developmental LOAEL = 3,500 mg/kg/day based on decreases in total implantations/dam and nonviable fetuses/dam, increased number of litters and fetuses with unossified sternebrae, and decreased fetal body weight.

In a prenatal developmental toxicity in rabbits the maternal NOAEL = 175 mg/kg/day, the maternal LOAEL = 350 mg/kg/day based on mortality, and clinical signs. The developmental NOAEL = 175 mg/kg/day and the developmental LOAEL = 350 mg/kg/day (insufficient litters available to assess development.

In a reproduction and fertility study with rats the parental/systemic NOAEL = 500 mg/kg/day for males and females, the parental/systemic LOAEL = 1,500 mg/kg/day for males and females based on clinical signs, decreased body weights, decreased weight gain, and decreased food consumption in both sexes. The reproductive/offspring NOAEL = 500 kg/day for males and females and the reproductive/offspring LOAEL = 1,500 mg/kg/day for males and females based on reduced pup weights in both sexes during second and third weeks of lactation.

4. *Subchronic toxicity*. In a 90–day oral toxicity study in rats the NOAEL is less than 50 mg/kg/day for both sexes and the LOAEL = 50 mg/kg/day based on increased phosphorus and potassium in both sexes. In a 90–day oral toxicity study in mice the NOAEL = 1,500 mg/kg/day in both sexes and the LOAEL = 7,500 mg/kg/day in both sexes based on decreased body weight gain in both sexes. In a 21/28–day dermal toxicity study in rabbits, the NOAEL = 1,000 mg/kg/day for males and 5,000 mg/kg/day for females. The LOAEL = 5,000 mg/kg/day in males based on decreased food consumption.

5. *Chronic toxicity*. In a chronic toxicity study in dogs the NOAEL = 500 mg/kg/day highest dose tested (HDT). The LOAEL was greater than 500 mg/kg/day. In a combined chronic toxicity/carcinogenicity study in rats the NOAEL = 362 mg/kg/day in males and 457 mg/kg/day in females, the LOAEL = 940 mg/kg/day in males and 1,183 kg/kg/day in females based on decreased weight gain in females, and increased incidence of cataracts and lens abnormalities, decreased urinary pH, increased absolute liver weight, and increased relative liver weight/brain weight in males. There was no evidence of carcinogenicity. In a carcinogenicity study in mice the NOAEL = 750 mg/kg/day in males and females, the LOAEL = 4,500 mg/kg/day in both sexes based on decreased body weight gains in both sexes, increased incidence of renal proximal tubule epithelial basophilia and hypertrophy in females and increased incidence of interstitial nephritis, hepatocellular hypertrophy and hepatocellular necrosis in males. There was no evidence of carcinogenicity.

6. *Animal metabolism*. The qualitative nature of the residue in animal 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 for 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 toxicology studies discussed above measure numerous endpoints with sufficient sensitivity to detect potential endocrine-modulating activity. No effects have been identified in subchronic, chronic or developmental toxicity or multi-generation reproduction studies to indicate any endocrine-modulating activity by glyphosate. In addition, no adverse was seen 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.

C. Aggregate Exposure

1. *Dietary exposure*. 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, the ammonium salt of glyphosate, and/or the ethanolamine salt of glyphosate, in or on a variety of food and feed commodities. The petitioner proposes to add potassium salt to this list of acceptable salt forms to which the tolerances apply, and to amend or add a number of new animal feed tolerances and one food tolerance. Tolerances are established for cattle, goat, hog, horse,

and sheep kidney at 4.0 ppm, and liver at 0.5 ppm, and for poultry meat at 0.1 ppm, eggs at 0.05 ppm, and poultry meat byproducts at 1.0 ppm, based on animal-feeding studies and reasonable worst-case livestock diets. This analysis showed that the existing livestock tolerances are sufficient for any additional dietary burden arising from the proposed feed tolerances.

Risk assessments were conducted by EPA to assess dietary exposure from glyphosate in food as follows:

2. *Acute exposure—Food.* 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 endpoint and dose was not identified for glyphosate. A review of the rat and rabbit developmental studies did not provide a dose or endpoint that could be used for acute dietary risk purposes. Additionally, there are no data requirements for acute and subchronic rat neurotoxicity studies since there was no evidence of neurotoxicity in any of the toxicology studies at very high doses and glyphosate lacks a leaving group.

3. *Chronic exposure.* i. In conducting this chronic dietary risk assessment the dietary exposure evaluation model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the United States Department of Agriculture (USDA) 1989–1992 nationwide continuing surveys of food intake by individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic dietary exposure analysis was conducted using the reference dose (RfD) of 2.0 mg/kg/day. The RfD is based on the maternal NOAEL of 175 mg/kg/day from a developmental study and an uncertainty factor (UF) of 100 (applicable to all population subgroups). The DEEM analysis assumed tolerance level residues and 100% of the crop treated in/on all commodities with an existing or proposed glyphosate tolerance. These assumptions resulted in the following theoretical maximum residue contributions (TMRC) and percentage RfDs for certain population subgroups. The TMRC for the U.S. population (48 contiguous states) was 0.033727 mg/kg/day or 1.7% of the RfD, 0.029752 mg/kg/day or 1.5% of the RfD for nursing infants (less than 1–year old), 0.094859 mg/kg/day or 4.7% of the RfD for non-nursing infants less that 1–year old; 0.072062 mg/kg/day or 3.6% of the RfD of children (1 to 6 years old); 0.047815 mg/kg/day or 2.4% of the RfD for children (7 to 12 years old); 0.034216 mg/kg/day or 1.7% of the RfD for females (13+/nursing); 0.033234 mg/kg/day or 1.7% of the RfD for non-hispanic whites; 0.034578 mg/kg/day or 1.7% of the RfD for hispanics, and 0.035141 mg/kg/day or 1.7% of the RfD for non-hispanic blacks.

ii. *Cancer.* There is no evidence of carcinogenic potential.

4. *Drinking water.* The available field and laboratory data indicate that glyphosate adsorbs strongly to soil and would not be expected to move vertically below the 6 inch soil layer. Based on non-aged batch equilibrium studies glyphosate and glyphosate residues are expected to be immobile with Kd(ads) values ranging from 62 to 175. The mechanism of adsorption is unclear; however, it is speculated that it may be associated with vacant phosphate sorption sites or high levels of metallic soil cations. The data indicate that chemical and photochemical decomposition is not a significant pathway of degradation of glyphosate in soil and water. However, glyphosate is readily degraded by soil microbes to AMPA, which is degraded to CO_2, although at a slower rate than parent glyphosate. The proposed amendment to permit the use of potassium glyphosate formulations is not expected to change the environmental properties of glyphosate.

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 expected environmental concentration (GENEEC) or the pesticide root zone/exposure analysis modeling system (PRZM/EXAMS) to estimate pesticide concentrations in surface water and the screening concentration and ground water (SCI-GROW) model, 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 percent crop area factor as a possible adjustment to account for the maximum percent crop 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 %RfD or percent of population adjusted dose (%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 the aggregate risk sections below.

Using available environmental fate parameters and assuming two applications with a retreatment interval of 90 days at a rate of 5 lbs. active ingredient/arce (3.75 lbs active ingredient/acre), the ground water EEC from glyphosate using SCI-GROW was 0.0038 parts per billion (ppb). The current label allows multiple applications of 0.37 - 5 lbs active ingredient/acre up to a maximum of 10.6 lbs active ingredient/acre/year. The ground water EECs generated by SCI-GROW are based on the largest 90–day average recorded during the sampling period. Since there is relatively little temporal variation in ground water concentrations compared to surface water, the concentrations can be considered as acute and chronic values.

The GENEEC model was used to estimate surface water concentrations for glyphosate resulting from its maximum use rate on crops. GENEEC is a single event model (one runoff event), but can account for spray drift from multiple applications. GENEEC represents a 10 hectare field immediately adjacent to a 1 hectare

pond that is 2 meters deep with no outlet. The pond receives a spray drift event from each application plus one runoff event. The runoff event moves a maximum of 10% of the applied pesticide into the pond. This amount can be reduced due to degradation on the field and by soil sorption. Spray drift is estimated as 5% of the application rate. The GENEEC values represent upper-bound estimates of the concentrations that might be found in the surface water due to glyphosate use. Thus, the GENEEC model predicts that glyphosate surface water EECs range from a peak of 21 ppb to a 56–day average of 2.5 ppb. For comparison purposes, EPA guidance suggests dividing the 56–day GENEEC EEC value by 3 before comparison to the calculated DWLOC chronic value (''Interim Guidance for Incorporating Drinking Water Exposure into Aggregate Risk Assessments,'' August 1, 1999, SOP 99.5). Thus, 2.5 divided by 3 or 0.83 ppb is the predicted surface water EEC value resulting from glyphosate treatment of crops.

To estimate the possible concentration of glyphosate in surface water resulting form direct application to water, EPA assumed application to a water body 6 feet deep. At an application rate of 3.75 lbs active ingredient/acre, the estimated peak concentration is 230 ppb. Using this peak value in a first-order dissipation model with a half-life for glyphosate in water of 7.5 days, the resulting 56–day average is 54.6 ppb. Following the EPA guidance, as described above, the 56–day average value divided by 3, or 15.4 ppb, is the predicted surface water EEC resulting from direct application to water. Because the glyphosate water-application estimate is greater than the crop-application estimate, 15.4 ppb is the appropriate chronic value to compare to the calculated DWLOC chronic value for aggregate risk considerations.

Based on the GENEEC and SCI-GROW models the EECs of glyphosate for chronic exposures are estimated to be 15.4 ppb for surface water and 0.004 ppb for ground water.

5. *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). Glyphosate is currently registered for use on the following residential non-dietary sites:

i. Ornamentals, greenhouses, residential areas, lawns, and industrial rights of way.

ii. Glyphosate is formulated in liquid and solid forms and it is applied using ground or aerial equipment.

iii. Based on the low acute toxicity and the lack of other toxicological concerns, 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's 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 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)(FRL–5754–7), **Federal Register** of November 26, 1997).

E. Safety Determination

1. *U.S. population*. To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs that are used as a point of comparison against the model estimates of a pesticide's concentration in water. 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 population adjusted dose (PAD)) is available for exposure through drinking water, e.g., allowable chronic water exposure (mg/kg/day) = chronic population adjusted dose (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's 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, the Office of Pesticide Programs (OPP) concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP 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, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

i. *Acute risk*. No appropriate toxicological endpoint for a single dose exposure was identified in oral toxicity studies with glyphosate. Therefore, an acute RfD was not established, and there is no expectation of acute dietary risk from food and water.

ii. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to glyphosate from food using present tolerances and all proposed new tolerances, will utilize 1.7% of the cPAD for the U.S. population, 3.8% of the cPAD for all infants less than 1–year old and 3.6% of the cPAD for children (1 to 6 years old). These dietary exposure levels take into account all existing and proposed tolerances for glyphosate. 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 and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD. DWLOCs for the U.S.

population, infants less than 1–year old, and children (1 to 6) are 69,000 ppb, 19,000 ppb, and 19,000 ppb, respectively, compared with EECs of 0.004 ppb and 15.4 ppb for ground and surface water, respectively.

2. *Infants and children*. In general, FFDCA Section 408 provides that EPA shall apply an additional ten-fold margin of safety (MOS) 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 MOS 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 UF (usually 100 x for combined interspecies and intraspecies variability) and not the additional ten-fold MOE/UF when EPA has a complete data base under existing guidelines and when the severity of the effects 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.

i. *Prenatal and postnatal sensitivity*. There is no evidence of increased susceptibility in rats and rabbits to *in utero* and/or postnatal exposure to glyphosate.

ii. *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. EPA determined that the 10X SF to protect infants and children should be removed. The FQPA factor is removed because:

- The toxicology data base is complete.
- There is no indication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to glyphosate (in the prenatal developmental toxicity study in rats, effects in the offspring were observed only at or above treatment levels which resulted in evidence of appreciable parental toxicity).
- The use of generally high quality data, conservative models and/or assumptions in the exposure assessment provide adequate protection of infants and children.

F. International Tolerances

Several maximum residue limits (MRLs) for glyphosate have been established by CODEX in or on various commodities. These limits are based on the residue definition of glyphosate *per se*, without reference to the cation used in product formulations. Based on toxicological considerations, EPA has determined that AMPA no longer needs to be regulated and has deleted AMPA from the U.S. tolerance expression, so that the U.S. residue definition is harmonized with that of CODEX. The proposed rice grain tolerance of 15.0 ppm, is based on crop field trial data obtained using glyphosate-tolerant rice and therefore cannot be lowered to maintain harmonization with the CODEX MRL of 0.1 ppm, for residues of glyphosate in or on this commodity. A CODEX MRL exists for ''hay or fodder (dry) of grasses'' at 50.0 ppm, and on ''maize forage'' at 1.0 ppm, however the proposed U.S. tolerance for ''grass, forage, fodder, and hay group'' at 300 ppm, and ''corn, field, forage'' at 6.0 ppm, are based on higher application rates than those used in the residue studies considered by CODEX, so that harmonization cannot be maintained in these cases. Other than for these specific commodities, the agreement between U.S. tolerances and Codex international residue standards is unaffected by this action.

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ENVIRONMENTAL PROTECTION AGENCY

[FRL–7172–4]

Guidance on the CERCLA Section 101(10)(H) Federally Permitted Release Definition for Certain Air Emissions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is publishing as an appendix to this notice a guidance on the CERCLA section 101(10)(H) federally permitted release definition for certain air emissions.

FOR FURTHER INFORMATION CONTACT: Visit the OECA Docket Web Site at www.epa.gov/oeca/polguid/enfdock.html or contact the RCRA/UST, Superfund and EPCRA Hotline at (800) 424–9346 or (703) 412–9810 in Washington, DC area. For general questions about this guidance, please contact Lynn Beasley at (703) 603–9086 and for enforcement related questions, please contact Ginny Phillips at (202) 564–6139 or mail your questions to: U.S. EPA, 1200 Pennsylvania Ave., NW., Washington DC 20460, attention Lynn Beasley, mail code 5204G.

SUPPLEMENTARY INFORMATION:

Purpose of this Notice

Today's guidance discusses the federally permitted release definition, which is an exemption to the reporting requirements under two federal emergency response and public right to know laws: section 103 of the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA''), as amended, 42 U.S.C. 9603 and section 304 of the Emergency Planning and Community Right-to-Know Act (''EPCRA''), 42 U.S.C. 11004. Federally permitted releases are defined in CERCLA section 101(10), which specifically identifies certain releases that are permitted or controlled under several environmental statutes and exempts these releases from the notification requirements of CERCLA section 103 and EPCRA section 304. CERCLA section 101(10)(H) identifies releases that are exempt from reporting because they are subject to permits and regulations under the Clean Air Act (''CAA'').

This guidance reflects our consideration of the general concerns raised by previous **Federal Register** notices on the definition of federally permitted release, the comments submitted on the Interim Guidance and our own experience in implementing the reporting requirements under CERCLA section 103 and EPCRA section 304. This guidance also considers several administrative adjudication decisions on federally permitted releases.

This guidance does not impose new reporting requirements or change the types of releases which are required to be reported under CERCLA section 103 and EPCRA section 304 or the implementing regulations at 40 CFR parts 302 and 355. The legal authority for the reporting requirements arises from those statutory and regulatory provisions, as well as the statutory provisions on federally permitted releases, not from this guidance. This guidance has no effect on CAA permit requirements.

The CAA provides EPA and states the authority to impose a wide variety of permits, regulatory limits and control requirements on emission sources. Whether a particular air release of a hazardous substance or extremely hazardous substance is exempt from CERCLA section 103 and EPCRA section 304 reporting requirements requires a case-by-case determination based on the specific permit language or applicable control requirement. As a consequence, it is difficult to establish a ''bright line'' for when releases qualify for the