Commodity	Parts per million	Expiration/ Revocation Date
* *	*	* *
Beet, sugar, molasses	0.75	None
* *	*	* *
Caneberry subgroup	0.70	None
* *	*	* *
Cattle, fat	6.5	None
Cattle, meat	0.50	None
Cattle, meat byproducts	2.0	None
* *	*	* *
Fig	0.10	None
* *	*	* *
Grape	0.50	None
Grape, raisin	0.70	None
* *	*	* *
Herb, dried, subgroup	22	None
Herb, fresh, subgroup	3.0	None
* *	*	* *
Milk	2.5	None
Milk, fat	27	None
* *	*	* *
Peanut	0.02	None
* *	*	* *
Vegetable, root and tuber, group	0.10	None
* *	*	* *

* * * * *

[FR Doc. 02–24484 Filed 9–26–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0232; FRL–7200–2]

Glyphosate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of glyphosate in or on animal feed, nongrass group; grass, forage, fodder and hay, group and adds the potassium salt of glyphosate to the tolerance expression. Monsanto Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective September 27, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0232, must be received on or before November 26, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0232 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Tompkins (PM 25), 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	Crop production
	112	Animal production
	311	Food manufacturing
	32532	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 homp page at *http://www.epa.gov/*. To access this document, on the home page select ''Laws and Regulations,'' ''Regulations and Proposed 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/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

2. *In person*. The Agency has established an official record for this action under docket ID number OPP–2002–0232. The official record consists of the documents specifically referenced in this action, 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 Hwy., 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.

II. Background

In the **Federal Register** of April 17, 2002 (FR 67 18894) (FRL–6830–5), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170), announcing the filing of pesticide petitions (PP 0F06130, 0F06195, and 0F06273) by Monsanto, 600 13th St., NW., Suite 660, Washington, DC 20005.

The notice included a summary of the petition prepared by Monsanto, the registrant. Comments received in the public docket with respect to the Notice of Filing Pesticide Petitions to Establish a Tolerance for Glyphosate in or on Food (April 17, 2002, 67 FR 18894) are discussed in the section below.

III. Response to Comments

The Northwest Coalition for Alternatives to Pesticides (NCAP) researches and cites studies that are not included in corporate evaluations of their products, and summarizes them in the Journal of Pesticide Reform. The following comments submitted to the Agency by Jill Davies/RiverCare, Martha T. Franks/Taylor Farms and Jeff Schahczenski/Executive Director/ Western Sustainable Agriculture Working Group cite the opinions of the NCAP concerning the information contained within the April 17, 2002 **Federal Register** for glyphosate.

A. Residue Chemistry

The Notice states:

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 the glyphosate parent is to be regulated in plant and animal commodities since the metabolite AMPA is not of toxicological concern in food.

Comment: The metabolite AMPA is of toxicological concern. In subchronic (midterm) tests on rats, AMPA caused an increase in the activity of an enzyme, lactic dehydrogenase, in both sexes; a decrease in liver weights in males at all doses tested; and excessive cell division in the lining of the urinary bladder in both sexes.

Agency response. The subchronic toxicity of AMPA has been investigated in rats and dogs. Treatment-related effects, such as urinary tract irritation, were observed in rats only at very high dosage levels. Gross and histopathologic examinations of these animals did not reveal effects in any other organ. No toxicities occurred in dogs at any dosage level tested. Based on these results, the Agency concluded that the metabolite of glyphosate, AMPA, is not of toxicological concern because the effects observed in subchronic toxicity studies cited above were: (1) Not dose-related, and/or (2) not considered biologically significant.

Comment: The mode of action of the residue in plants is not adequately understood. It is known that glyphosate is a systemic and non-selective herbicide that kills grasses, sedges, and broad-leaved plants, but exactly how it works is not well understood.

Agency response. Residue chemistry/ plant metabolism studies for pesticidal active ingredients are not designed to determine the mode-of-action in plants, but instead are designed to determine the metabolic fate, including the identification of plant metabolites of the active ingredient, when it is systemically present in plants.

Although not relevant to nature of the residue studies, the primary mode of action for glyphosate is well understood and documented. Glyphosate is a member of the phosphono amino acid class of chemicals. These compounds are foliar-applied herbicides that interfere with normal plant amino acid synthesis, resulting in the inhibition of nucleic acid metabolism and protein synthesis. Specifically, glyphosate blocks the activity of 5-enolpyruvylshikimate 3-phosphate synthase (EPSP synthase), an enzyme that is involved in aromatic amino acid biosynthesis (essential for growth) and produced only by green plants. This pathway does not occur in animals, which must eat plants to obtain these essential amino acids. Consequently, glyphosate is toxic to all green plants and essentially nontoxic to other living organisms.

B. Toxicological Profile

The Notice states:

1. *Acute toxicity*. Several acute toxicology studies place technical-grade glyphosate in Toxicity Category III and Toxicity Category IV.

Comment: This is correct, and Toxicity Category III means caution. But most toxicology studies are conducted using glyphosate alone, not the formulations that are in commercial products, which contain so-called inert ingredients. Roundup, which contains glyphosate and the surfactant POEA, is three times as acutely toxic to rats as glyphosate alone. This deficiency in regulation needs to be corrected.

Agency response. This action establishes a tolerance for glyphosate, not the inert polyethylated tallow amines (POEA). POEA is regulated separately under FFDCA and has been approved by the Agency. Additionally, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, registration process, EPA evaluates the potential risks posed by inert ingredients such as the POEA. The Agency requires a full disclosure of inert ingredients for each Roundup formulation to determine acute toxicity such as acute oral, eye, skin, inhalation, and dermal sensitization. The combined effects of active and inert ingredients on a product's acute toxicity properties are reviewed by the Agency and used to define the appropriate personal protective equipment (PPE) and precautionary statements for each pesticide end-use product label that will provide adequate protection to users.

2. *Genotoxicity (mutagencicty)—Comment:* The FR Notice describes assays showing that glyphosate does not cause genetic damage, but other studies have shown that both glyphosate and its commercial products are mutagenic, and the commercial products are more potent mutagens than glyphosate.

Agency response. The mutagenicity studies referred to by the commenters is the *Journal of Pesticide Reform* (JPR), a magazine produced by the Northwest Coalition for Alternatives to Pesticides (NCAP) based in Eugene, OR. JPR has compiled and updated fact sheets on a number of pest-control products, including glyphosate (the active ingredient in Roundup agricultural herbicides).

Based on the negative responses observed in well validated assays conducted according to the required test guidelines and in compliance with USEPA Good Laboratory Practice Standards, the Agency concluded that the active ingredient pesticide, glyphosate, is neither mutagenic or clastogenic.

Several studies have tested herbicide formulations, including Roundup, for mutagenic/genotoxic potential. Although positive responses have been reported, the testing systems used in the cited studies may not be adequate for regulatory purposes for one or more of the following reasons: (1) Un-validated test systems that do not have established predictability based on broad experience using substances of known positive and negative genotoxicity/ mutagenicity; (2) undocumented and uncharacterized test materials; (3) administered doses that cannot be correlated to expected exposures; (4) routes of exposure that vary from the required test protocols; (5) results that address endpoints which do not have a clear accepted relationship to human disease; and/or (6) deficient methodologies.

3. *Reproductive and developmental toxicity—Comment:* A study in Ontario found that father's (mostly farmers) use of glyphosate was associated with an increase in miscarriages and premature births in farm families. Laboratory studies on rats and rabbits have also demonstrated a number of effects from glyphosate on reproduction.

Agency response. Data from studies conducted according to accepted testing methods and reviewed by the Agency, demonstrate that glyphosate is not a

reproductive or developmental toxicant. Glyphosate was evaluated in two multigenerational rat reproduction studies and developmental toxicity studies in rats and rabbits. Results from these studies did not indicate any adverse effects on the animals' ability to mate, conceive, carry or deliver normal offspring. Based on the findings from developmental toxicity studies in rats and rabbits, it can be concluded that glyphosate does not produce birth defects and developmental toxicity is only seen at maternally toxic doses.

The developmental toxicity of the surfactant POEA has been evaluated and found not to be a teratogen or a developmental toxicant in rats. Subchronic toxicity studies with the surfactant and/or Roundup herbicide have also been conducted in rats, rabbits, and dogs. In these studies, gross and microscopic pathology examinations were conducted on several reproductive tissues including ovaries, uterus, testes, and epididymis. No developmental effects or changes in reproductive tissues were found in any of these evaluations. There is no evidence that the surfactant or Roundup herbicide adversely impacts reproductive function.

4. *Subchronic (medium-term) and chronic (long-term) toxicity studies on rats and mice—Comment.* Once again, studies (both subchronic and chronic) other than those cited by Monsanto reflect toxicity from glyphosate, and commercial products are more toxic than just glyphosate.

Agency response. The Agency has determined that the existing data base for glyphosate is adequate according to testing guideline requirements for a food-use registration. There is high confidence in the quality of the existing studies and the reliability of the toxicity endpoints identified for use in risk assessments; there are no data gaps. Based on evaluation of the existing glyphosate data base, the Agency has concluded that the use of glyphosate and glyphosate products do not pose unreasonable risks or adverse effects to humans.

The potential toxicity of POEA has been assessed in subchronic oral studies with rats and dogs. Roundup herbicide has also been evaluated for possible subchronic effects in an inhalation study with rats, a dermal study in rabbits, and an oral study with cattle. It was anticipated most observed effects would be related to the surface-active properties and associated irritation potential of surfactants. These studies confirm that irritation at the site of contact was the primary finding with the test material. In the oral studies conducted with POEA and Roundup, effects secondary to gastrointestinal irritation (emesis and diarrhea) were noted; decreased food consumption and decreased body weight gain. However, these effects were not dose-related in rats and dogs. In the study conducted with cattle in which slight decreases in body weight occurred, dosages of Roundup herbicide were 30 to 100 times greater than the dose typically applied to foliage for agricultural weed control purposes. There was no systemic toxicity in the inhalation and dermal studies conducted with Roundup. No indication of specific target organ toxicity was observed in any of the subchronic toxicity studies.

5. *Animal metabolism.* The Notice states:

> The qualitative nature of the residue in animals is adequately understood.

Comment: This is not true. There are a multitude of established effects on animals, including humans, and the mode of action is not understood at all. Roundup kills beneficial insects (parasitoid wasps, lacewings, ladybugs) and other arthropods that are important in humus production and soil aeration, and affect growth and survival of earthworms. Acute toxicities for fish LC_{50}, the lethal concentration killing 50% of a population of test animals) range from 2 ppm to 55 ppm and increase with increases in water temperature.

Agency response. Animal metabolism studies for pesticide active ingredients do not evaluate toxicological effects, but instead are designed to determine the fate of the molecule within a mammalian metabolic system. The animal metabolism data reviewed by the Agency for glyphosate are adequate and the qualitative nature of the residue in animals is understood.

Environmental consequences of pesticide use are considered in the FIFRA registration process. Based on the current toxicity data, application rates and observance of risk management measures for the active ingredient glyphosate, EPA has determined that the risks for birds, mammals, aquatic organisms, bees and invertebrates are minimal. Glyphosate is no more than slightly toxic to fish and wild birds, and practically non-toxic to aquatic invertebrate animals. There is a very low potential for the compound to build up in the tissues of aquatic invertebrates and other aquatic organisms such as fish. The Roundup formulation is moderately to slightly toxic to freshwater fish and aquatic invertebrate animals. Glyphosate is nontoxic to honeybees. This active ingredient pesticide as well as surfactants in the formulated products have no known effect on soil microorganisms. The reported contact lethal dose (LD_{50}) for earthworms in soil are greater than 5,000 parts per million (ppm) for both the glyphosate trimethylsulfonium salt and Roundup.

6. *Cancer.* Unit C.3.ii. of the Notice states:

> There is no evidence of carcinogenic potential.

Comment: This is false. A recent Swedish Study of hairy cell leukemia (HCL), a form of non-Hodgkin's lymphoma cancer, found that people who were occupationally exposed to glyphosate herbicides had a threefold higher risk of HCL. A similar study of people with non-Hodgkin's lymphoma found exposure to glyphosate was associated with an increase risk of about the same size.

Agency response. The commenters are referring to two epidemiology studies published by Sweden. This type of epidemiologic evaluation does not establish a definitive link to cancer. Furthermore, this information has limitations because it is based solely on unverified recollection of exposure to glyphosate-based herbicides.

The carcinogenic potential of glyphosate has been evaluated in acceptable studies conducted in rats and mice. In June of 1991, the Agency concluded, following a thorough review of all available toxicity data, that glyphosate should be classified in Category E--Evidence of Non-carcinogenicity in Humans. This cancer classification was based upon the observation of no treatment-related tumors at any dose level with glyphosate tested up to the limit in rats and up to dose levels higher than the limit dose in mice, and the lack of evidence of mutagenicity/genotoxicity for glyphosate.

C. Exposure and Risk Assessments

1. *Dietary exposure.* Tolerances have been established (40 CFR 180.364) for the residues 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 also established for animal organs that may be consumed by humans (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 by-products at 1.0 ppm, based on animal-feeding studies and reasonable worst-case livestock diets.

The Notice states:

This analysis showed that the existing livestock tolerances are sufficient for any additional dietary burden arising from the proposed feed tolerances.

Comment: It is not clear what analysis this statement is referring to. In any case, raising the tolerances in feed should result in new meat tolerance studies being done.

Agency response. EPA has conducted an analysis of the reasonable worst-case livestock diets, which include the additional dietary burden from the glyphosate feed tolerances proposed in the FR Notice. Adequate animal feeding studies are available for glyphosate in cattle, swine, and poultry. Based on the existing and proposed tolerances, the total estimated dietary burden derived from treated feed commodities (including those genetically altered to be tolerant to glyphosate) would not result in meat, milk, or egg residues that exceed currently established food tolerances on these commodities.

2. *Drinking water—Persistence in soil—Comment:* Glyphosate is acknowledged to be extremely persistent in the soil under typical application conditions. AMPA (the primary metabolite) is even more persistent than glyphosate. Studies in eight states found that the half-life in soil (the time required for half of the original concentration of a compound to break down or dissipate) was between 119 and 958 days. AMPA has been found in lettuce and barley planted a year after glyphosate treatment.

Agency response. Based on studies conducted both in the laboratory and the field, the Agency has determined that glyphosate is readily degraded by soil microbes to AMPA which is subsequently degraded to CO2. Data from field dissipation trials from eight sites show that the median half-life (DT50) for glyphosate applied at maximum use rates was 13.9 days with a range of 2.6 (Texas) to 140.6 (Iowa). The reported half-lives from the field studies conducted in the coldest climates, i.e., Minnesota, New York, and Iowa were longest at 28.7, 127.8, and 140.6 days, respectively, indicating that the rate of glyphosate degradation is somewhat slower in cooler climates compared to milder ones. Further degradation of AMPA to CO2 occurs at a slower rate than the initial degradation of glyphosate. Because of the strong binding of both glyphosate and AMPA to soil particles, there is very little uptake into plants of either glyphosate or AMPA from soil, even right after application of glyphosate. AMPA was found in only trace levels in lettuce and barley planted a year after application of glyphosate to soil. AMPA has been determined to not be of toxicological concern.

3. *Found in water*. The Notice states:

Glyphosate adsorbs strongly to soil and would not be expected to move vertically below the 6 inch soil layer.

Comment: This is a false assumption. Glyphosate can move into surface water when the soil particles to which it tends to bind are washed into streams or rivers. Glyphosate has been found in both ground and surface water, where it can be toxic to aquatic life for a time.

Agency response. The FR notice statement refers to behavior of glyphosate in soil and its potential for movement to ground water, not its movement into surface water. Glyphosate adsorbs strongly to soil particles, which limits its vertical movement in soil and makes contamination of ground water unlikely to occur.

Glyphosate can potentially occur in surface water from spray drift, runoff, soil particle movement, or by direct application, but at concentrations that are much lower than levels at which toxic effects to aquatic organisms may occur. The Agency has estimated glyphosate levels that could occur in surface water based on presently approved use patterns using computer-modeling methods. Based on toxicological data from acute and chronic tests on fish and other aquatic species, EPA has determined that the potential for environmental effects of glyphosate in surface water is minimal.

The Notice states:

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.

Comment: The Agency had better get monitoring exposure data for drinking water, for both glyphosate and for AMPA.

Agency response. In November 1999, the EPA Office of Water issued a report titled ''A Review of Contaminant Occurrence in Public Drinking Water Systems.'' The data in the report is further discussed in the report ''Occurrence Summary and Use Support Document for the Six-Year Review of National Primary Drinking Water Regulations'' (draft report issued in March 2002). The study is an analysis to date of the occurrence of contaminants in public water systems (PWSs). State data bases of compliance-monitoring data from PWSs were the primary data sources for the analysis. Glyphosate monitoring data of both surface water and ground water sources for 7,800 PWSs were included in the analysis. Occurrences of detectable levels of glyphosate in ground water or surface water were very infrequent. All detections of glyphosate were below 10% of the Maximum Contaminant Level (MCL), which is the health-based maximum permissible level of a contaminant in water that is delivered to any user of a PWS. Only 0.1% of the PWSs reported any detection of glyphosate at a level above 1% of the MCL. These monitoring results are consistent with the modeling predictions discussed above, and reinforce the Agency's conclusion that aggregate exposure to glyphosate via all exposure routes, including drinking water, will not exceed the Agency's level of concern (100% of the cPAD).

4. *Non-dietary exposure*. The Notice states:

iii. Based on the low acute toxicity and the lack of other toxicological concerns, exposures from residential uses (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets) of glyphosate are not expected to pose undue risks.

Comment: There are many toxicological concerns and in California, glyphosate exposure illness among agricultural and landscape workers is common with serious effects reported including blurred vision, peeling of skin, nausea, headache, vomiting, diarrhea, chest pain, dizziness, numbness. How does EPA define undue risks?

Agency response. Some glyphosate end-use products are assigned Toxicity Categories I and II for eye and dermal irritation because they contain POEA surfactants, which have been identified as eye and dermal irritants. For all such formulations, the Agency continues to recommend the addition of personal protective equipment (PPE) and precautionary statements appropriate for labeling of end-use products in Toxicity Categories I and II.

D. Cumulative Effects

The Notice states:

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. For the purposes of this tolerances action, therefore, EPA has not assumed that glyphosate has a common mechanism of toxicity with other substances.

Comment: When the mode of action is not clearly understood, even more uncertainty exists regarding synergistic effects with other substances. Rather

than raising tolerances, EPA should be exercising the Precautionary Principle and lowering them.

Agency response. The herbicidal mode-of-action of glyphosate in plants is well-understood (see Unit A. Residue Chemistry, Agency response of this document) but is not relevant to the determination of whether it shares a common mechanism of toxicity with other substances. Glyphosate does not appear to produce a toxic metabolite that is also produced by other substances that could be grouped together for a cumulative risk assessment, thus at this time, EPA will not include glyphosate in such an assessment.

E. Safety Determination

U.S. population and infants and children—Comment: The mode of action of glyphosate is not understood, synergistic effects are not understood, and a multitude of studies indicate that glyphosate is toxic in all standard categories of toxicological testing. Again, rather than raising tolerances, EPA should be exercising the Precautionary Principle and lowering them.

Agency response: The herbicidal mode-of-action of glyphosate in plants is well-understood (see the previous discussion above) but is not relevant to the determination of whether it shares a common mechanism of toxicity with other substances. Glyphosate does not appear to produce a toxic metabolite that is also produced by other substances that could be grouped together for a cumulative risk assessment, thus at this time, EPA will not include glyphosate in such an assessment. In evaluating these tolerance petitions, EPA has concluded that the proposed tolerances meet the FFDCA standard of reasonable certainty of no harm. This standard requires consideration of aggregate exposure to glyphosate from existing uses as well as exposure from the new uses proposed in the petitions before EPA. EPA requires that toxicological tests conducted with individual active ingredients using validated testing methods be submitted and reviewed in support of its registration decisions. Results from a complete data base of acceptable studies conducted with glyphosate have demonstrated that adverse effects will not occur at expected exposure levels. The Agency is not aware of scientific evidence that demonstrates enhanced potency of glyphosate's toxicological effects that arise through synergistic mechanisms.

F. International Tolerances

Several maximum residue limits (MRLs) for glyphosate have been established by Codex in or on various commodities. The Codex MRL for rice grain is 0.1 ppm. 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. (Unit F of the Notice). Also, the Codex MRL for grass hay is 50 ppm, and that proposed here is 300 ppm; the Codex MRL for field corn is 1 ppm, and that proposed here is 6 ppm and the same statement, that the tolerance cannot be lowered, applies.

Comment: Here is a great example of one of the many detrimental ramifications from the widespread use of GMO's. They drive up the levels of pesticide residues in crops for food and feed, while the majority of society is trying to avoid consumption of pesticides. It is unclear here, who has written this part of the FR Notice, EPA or Monsanto. The phrase, cannot be lowered is an ominous statement. If followed, it means that if a corporation benefits from commercializing a product, all other values and considerations must be cast aside.

Agency response. The rice grain tolerance of 15.0 ppm initially requested by Monsanto Company and cited in the notice of filing pesticide petition to establish a tolerance for glyphosate in or on food (April 17, 2002, 67 FR 18894) is not included in this tolerance petition. In addition, Monsanto Company has amended the tolerance petition by deleting the proposed tolerance increase to 6 ppm for wheat, grain and revising its Roundup UltraMax Herbicide label by removing all instructions related to a preharvest application of this product to Roundup Ready wheat. EPA has determined that the amended use instructions support the existing 5 ppm tolerance level for wheat, grain (40 CFR 180.364).

The pesticide petition process exists so that petitioners can request that EPA establish new food or feed tolerances, or increase existing tolerances, to accommodate new pesticide uses. Petitions are only filed when residue studies have demonstrated that food residues requiring tolerances may occur. Although EPA's approval of such petitions does authorize the potential for increased exposure levels, the existence of food tolerances is not indicative of significant consumer risk. Using worst-case assumptions that: (1) 100% of crops will be treated and (2) that residues will occur at tolerance levels in all cases, EPA has concluded that exposure to glyphosate from food, including all present and proposed tolerances, will utilize only 1.8% 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). Thus, the risk to human health does not exceed the Agency's level of concern (100% of the cPAD).

The phrase cannot be lowered indicates that glyphosate use patterns in the U.S. differ from those that have been considered by Codex, and therefore the new U.S. food and/or feed tolerances are not harmonized with established Codex MRLs. Codex procedures require that new pesticide uses and tolerances must first be approved by national governments before they can be considered by the Codex Committee on Pesticide Residues. As a result, differences between Codex MRLs and U.S. tolerances are anticipated as use patterns evolve. Codex uses the Periodic Review process to periodically update MRLs to reflect the modified use patterns.

G. Conclusions

Comment: In many parts of this FR Notice, it is not possible to tell who has written it, EPA or Monsanto. As a member of an organization working hard to promote an environmentally sound, economically viable, socially just and humane agriculture and food system in this country, I was expecting to see evidence of an agency working to protect human health and our environment, this is very disappointing. Furthermore, there is no consideration given here to the effects the increased use of this pesticide may have on the soil. Lab studies have demonstrated that glyphosate reduces nitrogen fixation associated with legumes and increases the susceptibility of crop plants to a number of diseases. Roundup is toxic to *mycorrhizal* fungi, with effects on some species observed at concentrations of 1 ppm, lower than those found in soil following typical applications.

Agency response. Publication of petitioner-generated summaries is dictated by the FFDCA, 21 U.S.C. 346a(d)(3). The Notice clearly indicates that the petitioner, Monsanto, has written the summary. However, much of this information can be found in the Agency's risk assessment document/ supporting documentation for glyphosate. EPA has conducted a complete and thorough review of the available data for glyphosate. Based on the risk assessments conducted for glyphosate, the Agency determined that there is reasonable certainty that

exposure to glyphosate will not pose unreasonable risks or adverse effects to humans or the environment.

The Agency has received no reports indicating that the use of glyphosate adversely effects nitrogen fixation in legumes or that it increases the disease susceptibility of crops. These type of environmental considerations are more appropriately raised in connection with the FIFRA registration process.

H. Biotechnology Related Issues

Comment: Several comments were received in the public docket that expressed concern over the tolerance approvals for glyphosate that will directly support new uses in glyphosate-tolerant crops, namely wheat, rice and bentgrass. The list of commenters are as follows: Mark Trechock/Staff Director/ Dakota Resource Council, Annie Ray/ Oregon Rural Action, Helge Hellberg/ Marketing Director/California Certified Organic Farmers, Lauran Dundee/ Regional Outreach Coordinator/Partners for Global Justice and Sustainable Communities, Kevin L. Williams/Field Coordinator/Western Organization of Resource Councils, Suzin Kratina/Chair of the Food Safety Task Force/Northern Plains Resource Council, Harriet Ritter and Renata Brillinger.

Agency response. The rice grain tolerance of 15.0 ppm initially requested by Monsanto Company and cited in the Notice of Filing Pesticide Petition to establish a Tolerance for Glyphosate in or on Food (April 17, 2002, 67 FR 18894), is not included in this final rule.

Tolerance actions for glyphosate are considered independently of the other regulatory assessments that a new crop trait must pass before it can be commercialized. Three U.S. Federal agencies regulate crops incorporating traits derived from biotechnology. The Food and Drug Administration (FDA) has responsibility for evaluating the safety of crops derived through biotechnology for use as food and feed. The U.S. Department of Agriculture, Animal Plant Health Inspection Service (USDA APHIS) is responsible for agronomic characteristics and environmental impact. EPA is responsible for the assessment of the human health and environmental risk of pesticide products, including plant-incorporated pesticides, and their registration under FIFRA, as amended. Commercialization by Monsanto of additional glyphosate-tolerant crops, i.e., wheat, rice and bentgrass, cannot occur until such time as the USDA APHIS and the FDA have received and evaluated necessary data from the registrant and granted necessary approvals. As of 2002, Monsanto has submitted a petition to USDA APHIS for GM bentgrass.

Despite the separate nature of the evaluations and approvals, much closer communication has developed between the three agencies in recent years. In early 2001, EPA and USDA APHIS established an interagency work group for products derived from biotechnology. Through this joint working group, EPA consults on a stewardship plan for each new herbicide-tolerant crop that addresses the management of pest resistance and the potential for weedy volunteer crops in their herbicide-tolerant crops and in crop rotations. This stewardship plan is then incorporated into a full environmental impact assessment by USDA APHIS that addresses the potential for development of resistant weed populations through pollen flow, in addition to effects on non- target organisms and agricultural practices. EPA and USDA APHIS have established a strong working relationship through this joint review process that helps ensure that the concerns of both agencies are adequately addressed prior to final approval by either.

Based on the incomplete status of the interagency approval process discussed above, EPA has decided not to register the use of glyphosate in or on herbicide-tolerant wheat or herbicide-tolerant bentgrass at this time.

Some commenters express concern over the potential contamination of organic crops through pollen drift from herbicide-tolerance crop varieties that may be grown on near-by farms. The issue of organic operations in proximity to operations that employ methods that are prohibited under organic rules is discussed in the National Organic Program, Final Rule, available on the USDA Web site at: *http://www.ams.usda.gov/nop/nop2000/Final%20Rule/nopfinal.pdf*.

IV. Statutory Findings

The petition requested that 40 CFR 180.364 be amended by establishing a tolerance for residues of the herbicide glyphosate, in or on animal feed, nongrass, group at 400 part per million (ppm), grass, forage, fodder and hay, group at 300 ppm, wheat, forage at 10 ppm, wheat, hay at 10 ppm, and adding the potassium salt of glyphosate to the tolerance expression.

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).

V. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of glyphosate on animal feed, nongrass, group at 400 ppm, grass, forage, fodder and hay, group at 300 ppm, wheat, forage at 10 ppm, and wheat, hay at 10 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the 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 females 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 (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.

TABLE 2.—TOXICITY PROFILE OF GLYPHOSATE TECHNICAL—Continued

Guideline No.	Study Type	Results
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 = > 350 (HDT) mg/kg/day, not established
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 = > 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/carcinogenicity 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

TABLE 2.—TOXICITY PROFILE OF GLYPHOSATE TECHNICAL—Continued

Guideline No.	Study Type	Results
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* strains	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
870.5550	Other mechanisms - *In vitro* Rec-Assay with *B. subtilis* H17 (rec+) and M45 (rec-)	There was no evidence of recombination in the rec-assay up to 2,000 µg/disk with *B. subtilis* H17 (rec+) and M45 (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 and 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 (acute RfD or chronic RfD) 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 is 100. 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 identified 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
Short-, 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-, intermediate- and long-term dermal (1–30 days, 1–6 months, 6 months–lifetime) (Occupational/Residential)	None	None	Based on the systemic NOAEL of 1,000 mg/kg/day in the 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-, intermediate- and long-term inhalation (1–30 days, 1–6 months, 6 months-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 glyphosate tolerances at 300 and 400 ppm for animal feed, nongrass, group (Crop Group 18) and grass, forage, fodder and hay, group (Crop Group 17), respectively, 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. Furthermore, no impact is expected on the dietary burden to poultry or hogs since grass forage and hay are not feed items for these livestock, and the contribution from alfalfa was already considered. 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 DEEM™ software Version 7.73, which incorporates consumption data from USDA's CSFII, 1989-1992. The 1989–92 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 mg/kg body weight/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™ default processing factors for rice and corn commodities, tolerance levels, 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)	0.031527	1.8
All Infants (< 1 year old)	0.062218	3.6
Children (1–6 years old)	0.068016	3.9
Children (7–12 years old)	0.045529	2.6
Females (13–50 years old)	0.023477	1.3
Males (13–19 years old)	0.031938	1.8
Males (20+ years old)	0.026745	1.5
Seniors (55+ years old)	0.022733	1.3

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 information*. The Agency used tolerance levels and 100% percent crop treated (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 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 percent crop area factor as an 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 %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 section E. (Aggregate Risks and Determination of Safety) of this Unit.

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	AR1 (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, isopropylamine salt 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- 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- 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-/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:
a. 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.
b. Object-to-mouth DFR = 1.62 lb ae/A x 0.20 x (4.54 x 108 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/cm2) x 0.67 cm^3/g= 12.2 µg/g soil.
[4] Potential Dose Rate (PDR; already normalized to body weight of toddler).
a. 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 bw/d.
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 bw/d.
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 bw/d.
[5] MOE = NOAEL/PDR, where the short-term incidental oral NOAEL = 175 mg/kg/d 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 margin of exposure (MOE) analysis or through using uncertainty (safety) factors 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 the USEPA 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, DEEM™ default processing factors for rice and corn commodities, and 100% crop treated data for all proposed commodities and registered uses), EPA has concluded that exposure to glyphosate from food will utilize 1.8% of the cPAD for the U.S. population, 3.6% of the cPAD for [All Infants (less than 1 year old) and 3.9% 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 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	0.031527	1.718473	0.0038	230	60,000
All infants (< 1 year old)	1.75	0.062218	1.687782	0.0038	230	17,000
Children (1–6 years old)	1.75	0.068016	1.681984	0.0038	230	17,000
Children (7-12 years old)	1.75	0.045529	1.704471	0.0038	230	17,000
Females (13-50 years old)	1.75	0.023473	1.726527	0.0038	230	52,000
Males (13-19 years old)	1.75	0.031938	1.718062	0.0038	230	60,000
Males (20+ years old)	1.75	0.026745	1.723255	0.0038	230	60,000
Seniors (55+ years old)	1.75	0.022733	1.727267	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-/intermediate-term aggregate risk (food + residential + water).* In aggregating short-/intermediate-term risk, HED considered background chronic dietary exposure (food + water) and short/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-/intermediate-term food and residential aggregate MOEs are 1,800-2,300. As these MOEs are greater than 100, the short-/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-/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-/intermediate-term aggregate human health risk at the present time. Table 8 summarizes the short-/intermediate-term aggregate exposure to glyphosate residues.

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

Population	Short-/Intermediate-Term Exposure Scenario				
	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/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 body weight (kg) ÷ water consumption (L) x 10^{-3} mg/µg (10 kg body weight 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.

VI. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available for analysis of residues of glyphosate in or on plant and livestock commodities. These methods include GLC (Method I in Pesticides Analytical Manual (PAM) II; the limit of detection is 0.05 ppm) and 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 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 tolerances of glyphosate in/on the nongrass animal feed crop group; the grass forage, fodder, and hay crop group; wheat forage and hay; and livestock commodities.

B. 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 a relevant Codex MRL for hay or fodder (dry) of grasses is established at 50 ppm. No Canadian MRLs are established for any grass commodity. A Mexican MRL is established for pasture at 0.2 ppm. Because of the higher residue levels resulting from the proposed use pattern, harmonization of U.S. grass tolerances with existing Codex or Mexican MRLs is not possible.

For wheat-related commodities, relevant Codex MRLs exist for: wheat grain at 5 ppm; unprocessed wheat bran at 20 ppm; wheat flour at 0.5 ppm; wheat wholemeal at 5 ppm; and straw and fodder (dry) of cereal grains at 100 ppm. Canadian MRLs are established for: wheat at 5 ppm and wheat milling fractions (excluding flour) at 15 ppm. A Mexican MRL is established for wheat at 5 ppm. By maintaining the wheat, milling fractions (excluding flour) tolerance at 20 ppm, harmony with international tolerances for wheat processed fractions can be maintained.

There are currently no Codex or Canadian MRLs established for glyphosate for any nongrass animal feed items. A Mexican MRL is established for alfalfa at 200 ppm. Harmonization with this level is not possible due to the higher residue levels found in the submitted field trial studies.

C. Conditions

None.

VII. Conclusion

Therefore, the tolerance is established for residues of glyphosate, in or on animal feed, nongrass, group at 400 ppm and grass forage, fodder and hay, group at 300 ppm and the potassium salt of glyphosate is added to the tolerance expression. Based on the Agency's decision not to register tolerances for glyphosate use in or on herbicide-tolerant wheat, the current tolerances on wheat are not modified.

VIII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2002–0232 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 26, 2002.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing

is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential 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. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket ID number OPP–2002–0232, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IX. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal

officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq*., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: September 18, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.364 is amended by revising the introductory text of paragraph (a) and alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.364 Glyphosate; tolerances for residues.

(a) *General*. Tolerances are established for residues of glyphosate (N-phosphomethyl)glycine) resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate in or on the following food commodities:

Commodity	Parts per million
* *	* * *
Animal feed, nongrass, group	400
* *	* * *
Grass, forage, fodder and hay, group	300
* *	* * *

* * * * *

[FR Doc. 02–24488 Filed 9–26–02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0199; FRL–7200–6]

Triticonazole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of triticonazole, (1RS)-(E)-5-[(4-chlorophenyl)methylene]-2,2-dimethyl-1-(1 *H*-1,2,4-triazol-1-ylmethyl)cyclopentanol, in or on barley, grain; barley, hay; barley, straw; wheat, forage; wheat, grain; wheat, hay; and wheat, straw. Aventis CropScience USA requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). Subsequent to the filing of this petition, Bayer Corporation acquired Aventis CropScience to form Bayer Crop Science. Therefore, the registrant is now Bayer Crop Science.

DATES: This regulation is effective September 27, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0199, must be received on or before November 26, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0199 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Mary L. Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 308–9354; e-mail address: waller. mary@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 and Proposed 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://