Exhibit 6

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: