ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185, and 186

[OPP–300469; FRL–5598–6]

Glyphosate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes permanent tolerances for residues of the herbicide glyphosate [*N*-(phosphonomethyl)glycine] in or on the raw agricultural commodities (RACs) corn, field, grain; corn, field, stover; corn, field, forage; aspirated grain fractions; sorghum, grain; sorghum, grain, stover; and oats. The residues from the treatment of field corn include residues in or on field corn varieties which have been genetically modified to be tolerant of glyphosate. Monsanto Company submitted petitions to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act of 1996 (Pub L. 104–179) requesting the tolerances.

EFFECTIVE DATES: These regulations become effective April 11, 1997. Written objections must be submitted by June 10, 1997.

ADDRESSES: Written objection and hearing requests, identified by the docket control number, [OPP–300469; PP 8F3672, 8F3673, 5F4555, 6E4645], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing request filed with the Hearing Clerk should be identified by the docket control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to: Rm. 1132, CM#2, 1921 Jefferson Davis Highway., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: oppdocket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [OPP–300469; PP 8F3672, 8F3673, 5F4555, 6E4645]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submission can be found in Unit XIII. of this document.

FOR FURTHER INFORMATION CONTACT: By mail, Philip V. Errico, Product Manager, Registration Division (H7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail address: Rm. 241, CM #2, 1921 Jefferson Davis Highway., Arlington, VA, (703)–305–6027; e-mail: errico.philip@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 24, 1996 (61 FR 67804)(FRL–5576–6), EPA issued a Notice of Filing amending petitions PP 8F3672, 8F3673, 5F4555, 6E4645 to bring the petitions into conformity with the Food Quality Protection Act (FQPA of 1996). The notice contained a summary of the petitions prepared by the petitioner and the summary contained conclusions and arguments to support its conclusion that the petitions complied with FPQA. In that notice Monsanto Company, 700 14th Street, NW., Suite 1100, Washington, DC 20005 proposed amending 40 CFR 180.364 by establishing a regulation to permit residues of the herbicide glyphosate (*N*-(phosphonomethyl)glycine) resulting from the application of the isopropylamine salt and/or the monoammonium salt of glyphosate in or on the raw agricultural commodities (RACs) field corn grain at 1.0 ppm; field corn forage at 1.0 ppm; field corn fodder at 100 ppm; aspirated grain fractions at 200 ppm; grain sorghum at 15 ppm; grain sorghum fodder at 40 ppm; and oats at 20 ppm. The notice stated that PP 5F4555 specifically related to field corn which had been genetically modified to be tolerant to glyphosate.

The Agency received one comment opposing the tolerances. The commentor's objection was based on concerns of (1) Enhanced exposure of the public to glyphosate and other ingredients of the Roundup formulations, (2) greater use of Roundup/glyphosate which will result in adverse effects to the environment and human health, and (3) exposure of the public to Roundup from consumption of the corn or the animal product from animals fed corn. EPA's response to this comment is provided below.

The Agency determined that the terminology for field corn grain, field corn, forage; field corn, fodder; aspirated grain fractions; grain sorghum, and grain sorghum, fodder; should be corrected to read corn, field, grain; corn, field, stover; corn, field, forage; aspirated grain fractions; sorghum, grain; and sorghum, grain, stover; The subject regulation is therefore amended accordingly.

The data submitted in the petitions and other relevant material have been evaluated. The glyphosate toxicological data listed below were considered in support of these tolerances.

I. Toxicological Profile

1. Several acute toxicology studies placing technical-grade glyphosate in Toxicity Category III and Toxicity Category IV. Technical glyphosate is not a dermal sensitizer.

2. A 1–year feeding study with dogs fed dosage levels of 0, 20, 100, and 500 milligrams/kilogram/day (mg/kg/day) with a no-observable-effect level (NOEL) of 500 mg/kg/day.

3. A 2–year carcinogenicity study in mice fed dosage levels of 0, 150, 750, and 4,500 mg/kg/day with no carcinogenic effect at the highest dose tested (HDT) of 4,500 mg/kg/day.

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

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

weight) at 940 mg/kg/day (males) HDT and 457 mg/kg/day (females) based on decreased body weight gain 1,183 mg/kg/day (females) HDT.

6. A developmental toxicity study in rats given doses of 0, 300, 1,000, and 3,500 mg/kg/day with a developmental NOEL of 1,000 mg/kg/day based on an increase in number of litters and fetuses with unossified sternebrae, and decrease in fetal body weight at 3,500 mg/kg/day, and a maternal NOEL of 1,000 mg/kg/day based on decrease in body weight gain, diarrhea, soft stools, breathing rattles, inactivity, red matter in the region of nose, mouth, forelimbs, or dorsal head, and deaths at 3,500 mg/kg/day HDT.

7. A developmental toxicity study in rabbits given doses of 0, 75, 175, and 350 mg/kg/day with a developmental NOEL of 175 mg/kg/day (insufficient litters were available at 350 mg/kg/day to assess developmental toxicity); a maternal NOEL of 175 mg/kg/day based on increased incidence of soft stool, diarrhea, nasal discharge, and deaths at 350 mg/kg/day HDT.

8. A multigeneration reproduction study with rats fed dosage levels of 0, 3, 10, and 30 mg/kg/day with the parental no-observed-effect level/lowest observed effect level (NOEL/LOEL) 30 mg/kg/day HDT. The only effect observed was an increased incidence of focal tubular dilation of the kidney (both unilateral and bilateral combined) in the high-dose male F3b pups. Since the focal tubular dilation of the kidneys was not observed at the 1,500 mg/kg/day level HDT in the rat reproduction study discussed below, but was observed at the 30 mg/kg/day level HDT in the three-generation rat reproduction study the latter was a spurious rather than glyphosate-related effect. Therefore, the parental and reproductive (pup) NOELs are 30 mg/kg/day.

9. A two generation reproduction study with rats fed dosage levels of 0, 100, 500, and 1,500 mg/kg/day with a systemic NOEL of 500 mg/kg/day based on soft stools in F0 and F1 males and females at 1,500 mg/kg/day HDT and a reproductive NOEL 1,500 mg/kg/day HDT.

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

II. Dose Assessment Response

1. *Reference Dose (RfD).* The RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The RfD is determined by using the toxicological end point or the NOEL for the most sensitive mammalian toxicological study. To assure the adequacy of the RfD, the Agency uses an uncertainly factor in deriving it. The factor is usually 100, based on the assumption that certain segments of the human population could be as much as 100 times more sensitive than the species represented by the toxicology. The Agency has determined a RfD of 2.0 mg/kg/day based on the maternal toxicity NOEL of 175 mg/kg/day from the developmental study with rabbits. The LOEL of 350 mg/kg/day HDT was based on treatment related findings of diarrhea, nasal, discharge, and death (62.5% of the does died by gestation day 21). Developmental toxicity was not observed at any dose tested.

2. *Carcinogenicity classification*. The carcinogenic potential of glyphosate was first considered by a panel, then called the Toxicology Branch AD Hoc Committee, in 1985. The Committee, in a consensus review dated March 4, 1985, classified glyphosate as a Group C carcinogen based on an increased incidence of renal tumors in male mice. The Committee also concluded that dose levels tested in the 26–month rat study were not adequate for assessment of glyphosate's carcinogenic potential in this species. These findings, along with additional information, including a reexamination of the kidney slides from the long-term mouse study, were referred to the FIFRA Scientific Advisory Panel (SAP). In its report dated February 24, 1986, SAP classified glyphosate as a Group D Carcinogen (inadequate animal evidence of carcinogenic potential). SAP concluded that, after adjusting for the greater survival in the high-dose mice compared to concurrent controls, that no statistically significant pairwise differences existed, although the trend was significant.

The SAP determined that the carcinogenic potential of glyphosate could not be determined from existing data and proposed that the rat and/or mouse studies be repeated in order to classify these equivocal findings. On reexamination of all information, the Agency classified glyphosate as a Group D Carcinogen and requested that the rat study be repeated and that a decision on the need for a repeat mouse study would be made upon completion of review of the rat study.

Upon receipt and review of the second rat chronic feeding/carcinogenicity study, all toxicological findings for glyphosate were referred to the Health Effects Division Carcinogenicity Peer Review Committee on June 26, 1991, for discussion and evaluation of the weight of evidence on glyphosate with particular emphasis on its carcinogenic potential. The Peer Review Committee classified glyphosate as a Group E (evidence of noncarcinogenicity for humans), based upon lack of convincing carcinogenicity evidence in adequate studies in two animal species. This classification is based on the following findings: (1) None of the types of tumors observed in the studies (pancreatic islet cell adenomas in male rat, thyroid c-cell adenomas and/or carcinomas in male and female rats, hepatocellular adenomas and carcinomas in male rats, and renal tubular neoplasms in male mice) were determined to be compound related; (2) glyphosate was tested up to the limit dose on the rat and up to levels higher than the limit dose in mice; and (3) there is no evidence of genotoxicity for glyphosate.

III. Non-Dietary (Residential and Other Non-Occupational) Exposure Assessment

Glyphosate is registered for use on non-food sites such as around ornamental, shade trees, shrubs, walks, driveways, flowerbeds, home lawns, farmsteads including building foundations, along and in fences, in dry ditches and canals, along ditchbanks, farm roads, shelterbelts, forestry, Christmas trees, and industrial sites and other noncrop or industrial areas such as airports, lumber yards, manufacturing sites, utility substations, parking areas, petroleum tank farms, and pumping station.

Margins of Exposure (MOE's) are determined for non-dietary exposure based on toxicological endpoints and measured or estimated exposures. Since glyphosate is a group E chemical (evidence of non-carcinogenicity for humans), the 21 day dermal study lacked any observable effects at the limit dose, and no adverse effects were observed in developmental toxicity studies in rats up to 1,000 mg/kg/day and rabbits up to 175 mg/kg/day, no toxicological endpoints are applicable. Because available data indicated no evidence of significant toxicity via the dermal or inhalations routes, MOE's were not calculated and risk assessments are not required for non-occupational (residential uses).

Some glyphosate end-use products (non ''homeowner'' uses only) are in Toxicity Categories I and II for dermal and eye irritation and have been associated with illness or injuries related to skin or eye irritation. Under the protective clothing requirements of the Worker Protection Standards (WPS), handlers of these products are expected to be adequately protected.

IV. Dietary Exposure Assessment

The use of a pesticide may result directly or indirectly, in residues in food. Primary residues or indirect/ inadvertent residues in the agricultural commodities harvested from the crop cultured with the aid of pesticide are determined by chemical analysis. To account for the diversity of growing conditions, culture practices, soil types, climatic conditions, crop varieties and method of use of the pesticide, data from studies that represent the resulting commodities are collected and evaluated to determine an appropriate level of the residue that would not be exceeded if the pesticide is used as represented in the studies. Available field trial data for glyphosate support these tolerances. However, because of the recent imposition of additional field trial data for specific geographical representation, additional field trial data are required for corn and grain sorghum. Because insufficient time has elapsed since imposition of these requirements the petitioner is being granted conditional registrations while obtaining the data. The conduct of the field trial and guidelines for determining the residues are given in EPA ''OPPTS Test Guidelines, Series 860, Residue Chemistry, August 28, 1996. See **Federal Register**, 61 FR 44308–44311 for availability of document.

The nature of the residue in plants and animals is adequately understood and consists of the parent, glyphosate. The Agency has decided that only glyphosate parent is to be regulated in plant and animal commodities and that the major metabolite, AMPA (aminomethylphosphonic acid) is not of toxicological concern regardless of its levels in food.

Secondary residues in animal commodities are expected from these uses. However, the established livestock tolerances are adequate to cover secondary residues which may result from feeding field corn (both conventional and genetically modified), and sorghum commodities with residues of glyphosate to animals. Since no U.S. registration has been proposed for oats, it has been concluded that oat feed items are not likely to enter channels of trades in the United States.

V. International Harmonization

Codex MRL's for the residues of glyphosate exist in maize and the straw and fodder, dry cereal grains at 0.1 and 100 ppm respectively. Mexican limits on maize exist at 0.1 ppm. Canadian limits on all other food crops exist at 0.1 ppm. MRL's of 20 ppm, 10 ppm, and 0.1 ppm on oats are established/pending for CODEX, Canada, and Mexico, respectively. Codex MRLS were established based on preplant/ preemergent use of glyphosate and are identical to the existing tolerances for these crops under the same us conditions in the United States. The increased tolerances now being proposed on corn and sorghum are based on new preharvest uses of glyphosate in the United States. The import tolerance being proposed for oats is being proposed to harmonize with other international MRL's. The Agency suggests the petitioner consider providing all relevant studies to Codex once the U.S. tolerances are established in order that the Codex MRLs may be amended to accommodate the use needs of the United States.

Adequate enforcement methods are available for analysis of residues of glyphosate in or on plant commodities. These methods include GLC (Method I in Pesticides Analytical Manual (PAM) II; the limit of detection is 0.05 ppm). and HPLC with fluormetric detection. Use of the GLC method is being discouraged due to lengthiness of the procedure. The HPLC method has undergone successful Agency validation and has been published in PAM II. A GC/MS method for glyphosate in crops has also been validated by the Agency. This method has not yet been submitted for publication in PAM II.

VI. Aggregate Exposure Assessment

1. *Acute dietary*. There is no concern for acute effects due to dietary exposure to glyphosate.

2. *Chronic dietary*. Using the Dietary Risk Evaluation System (DRES), a routine chronic exposure analysis was performed for glyphosate. The chronic analysis for glyphosate is a worst case estimate of dietary exposure with all residues at tolerance levels and 100% of the commodities assumed to be treated with glyphosate.

3. *Drinking water*. In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and exposure through pesticide use in gardens. lawns, or buildings (residential and other indoor uses).

The lifetime health advisory and maximum contaminant level (MCL), for glyphosate are the same and given as 700 parts per billion in the U.S. EPA Office of Drinking Water's ''Drinking Water Health Advisory; Pesticides.'' Environmental Fate data for glyphosate indicate little potential for the7 chemical to migrate to ground water, but some potential for residues to migrate to surface waters. Glyphosate is not highly mobile and not persistent in a soil or water environment. Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water related exposures to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for consumption of contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause glyphosate to exceed the RfD if the tolerances being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with glyphosate in water, even the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

4. *Non occupational (residential) and non-dietary*. Glyphosate is registered for residential uses. As part of the hazard assessment process, the Agency reviews the available toxicological database to determine the endpoints of concern. For glyphosate, the Agency does not have a concern for acute, short-term, or intermediate occupational or residential risk since the available data do not indicate any evidence of significant toxicity by the dermal or inhalation routes, or from a 1 day or single event exposure by the oral route. Therefore, an

acute, a short-term, or intermediate-term occupational or residential risk assessment was not required.

As part of the hazard assessment process it was determined that a chronic residential assessment was not necessary. The exposures which would result from the use of glyphosate were determined to be of an intermittent nature. The frequency and duration of these exposures do not exhibit a chronic exposure pattern. The exposures do not occur often enough to be considered a chronic exposure i.e., a continuous exposure that occurs for at least several months. Therefore, residential exposures were not aggregated with dietary exposures in estimating chronic risk.

6. *Cumulative exposure to substances with 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.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanisms issues can be resolved. These pesticides include pesticides that are toxicologically and structurally dissimilar to existing chemical substances (in which the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

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 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. A condition of the registrations associated with these tolerances will be that the registrant will provide common mechanism data in a timely manner when and if the Agency asks for it. After EPA develops methodologies for more fully applying common mechanism of toxicity issues to risk assessments, the Agency will develop a process (either as a part of the periodic review of pesticides or otherwise) to reexamine those tolerance decisions made earlier.

VII. Determination of Safety for the U.S. Population and Nonnursing Infants

Using the Dietary Risks Evaluation System (DRES) a chronic analysis was based on 100% of the crop treated and all residues at tolerance levels. Based on the dietary risk assessment the proposed uses utilize 0.115% of the RfD for U.S. population; 0.189% of the RfD for non-nursing infants under 1 year old; 0.84 of the RfD for nursing infants under 1 year old; 0.866% of the RfD for children 1 to 6 years old; and 0.443% of the RfD for children 7 to 12 years old. Total aggregate exposure from glyphosate residues in food, taking into account existing and proposed uses, uses 1% of the RfD for the overall U.S. population and nursing infants: 3% of the RfD for nonnursing infants under 1 year old and children 1 to 6 years old; 3%; and 2% of the RfD for children 7 to 12 years old. An additional risk assessment for residential uses was not required because of no evidence of significant toxicology via dermal or inhalation routes. Even though the Agency has not pinpointed the appropriate bounding figure for consumption of contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause glyphosate to exceed the RfD. EPA concluded that there is reasonable certainty that no harm will occur from aggregate exposure to glyphosate.

VIII. Determination of Safety for Infants and Children

FFCDA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins or exposure (safety) are often referred to as uncertainty (safety) factors. EPA believes that reliable data support using the standard margin of exposure (usually 100x for combined inter- and intra-species variability) and not the additional tenfold margin of exposure when EPA has a complete data base under existing guidelines and when the severity of the effect in infants and children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard margin of exposure.

Risk to infants and children was determined by the use of two developmental toxicity studies in rats and rabbits and the two-generation reproduction study in rats discussed below. The developmental toxicity studies evaluates the potential for adverse effects on the developing organism resulting from exposure during prenatal development. The reproduction study provides information relating to effects from exposure to the chemical on the reproductive capability of both (mating) parents and on systemic toxicity.

The toxicological database for evaluating pre- and post-natal toxicity for glyphosate is considered to be complete at this time. In the rabbits, no developmental toxicity was observed at doses where significant maternal toxicity was noted (death and clinical signs at 350 mg/kg/day, highest dose tested HDT. In the rat developmental toxicity study, maternal (systemic) toxicity was noted at 3,500 mg/kg/day, HDT as diarrhea, decreased mean body weight gain, breathing rattles, inactivity, red matter around the nose and mouth, and on forelimbs and dorsal head, decreases in total implantations/dam and inviable fetuses/dam and death (24% of the group). The developmental (pup) NOEL is 1,000 mg/kg/day. The

developmental (pup) toxicity was exhibited only in the high dose as increased numbers of litters and fetuses with unossified sternebrae, and decreased mean fetal body weights. However, these developmental effects were assumed to be due to the extreme maternal toxicity. No effects on reproductive parameters were observed.

In the rat two-generation reproduction study, parental toxicity was observed at 1,500 mg/kg/day as soft stools, decreased food consumptions and body weight gain. The developmental (pup) toxicity was also only exhibited at 1,500 mg/kg/day as decreased body weight gain of the F1a, F2a, and F2b male and female pups during the second and third weeks of lactation.

The RfD is based on the NOEL for maternal toxicity in the rabbit developmental study. No developmental effects were noted in the study. In the rat developmental study effects were noted only at 20x higher than the NOEL used for the RfD. No pre- or post-natal effects were seen in any study absent maternal toxicity. In the rat reproduction study developmental effects were noted at 5x the NOEL used for the RfD. The Agency does not believe the effects seen in these studies are of such concern to require an additional safety factor. Accordingly, the Agency believes the RfD has an adequate margin of protection for infants and children. The percent RfD utilized by glyphosate is from 1% for nursing infants (less than 1 year old) to 3% for non-nursing infants and children 1 to 6 years old. EPA concluded that there is reasonable certainty that no harm will occur to infants and children from aggregate exposure to glyphosate.

IX. Other Considerations

Endocrine effects. No specific tests have been conducted with glyphosate to determine whether the chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects. However, there are no significant findings in other relative toxicity studies, i.e., teratology and multi-generation reproductive studies which would suggest that glyphosate produces these kinds of effects.

X. Data Gaps

Data desirable but lacking for these tolerances include specific geographic representative grain sorghum and corn field residue trials. Because of insufficient time since the imposition of additional data requirements the Agency is requiring that this data be submitted as a condition of registration.

Based on the information cited above, the Agency has determined that the establishment of these tolerances by amending 40 CFR part 180 will be safe, therefore the tolerances are established as set forth below.

In addition to the time-limited tolerances being amended, since for purposes of establishing tolerances FQPA has eliminated all distinctions between raw and processed food, EPA is combining the tolerances that now appear in §§ 185.3500 and 186.3500 with the tolerances in § 180.364 and is eliminating §§ 185.3500 and 186.3500.

XI. Response to Comment

The one commenter raised several concerns regarding these tolerances.

1. *Increased exposure.* The commenter was concerned that approval of these tolerances would lead to increased exposure to glyphosate because it would enhance Monsanto's ability to market glyphosate-tolerant corn and thus use glyphosate. The commentor argued that therefore approval of the tolerances would not protect the public health rather it would increase risk.

EPA response. Approval of these tolerances may lead to higher exposure the glyphosate residues. That is the case when ever EPA approves a new tolerance. The question before EPA in ruling on a tolerance petition is whether the tolerance meets the FFDCA's safety standard. As detailed above, EPA has concluded that these tolerances do meet the reasonable certainty of no harm standard. This standard requires consideration of exposure to glyphosate from existing uses as well as exposure from the uses covered by the tolerances in the petition before EPA.

2. *Glyphosate residues in foods derived from animals.* The commenter asked EPA to confirm that the major route of exposure resulting from these tolerances would be from foods derived from animals. The commenter also asked how the tolerances would effect the level of glyphosate residues in animal feeds and what percentage of glyphosate treated corn would be consumed by humans.

EPA response. The nature of glyphosate residue in plants and animals has been explored by various studies that have been reviewed by the Agency. A separate peer review committee ''Metabolism Committee'' evaluated glyphosate plant and animal commodities and decided that the major metabolite is not of toxicological concern regardless of its level in food. Due to the use pattern of glyphosate, secondary residues in animal commodities are expected. Corn grain, forage, fodder, and aspirated grain fractions are animal feed items. Based on the proposed tolerances on aspirated grain fractions, corn stover, forage, and grain, the dietary burden of at most 78 ppm glyphosate residue in/on corn commodities, (if all corn commodities (including corn genetically altered to be tolerant to glyphosate) are fed)) will be covered by the tolerances currently established on meat, milk, eggs, and livestock commodities including the recently (April 5, 1996, 61 FR 15192)(FRL–5351–1), established tolerances on kidney of cattle, goats, hogs, horses, poultry, and sheep at 4 ppm. A chronic (long-term) dietary exposure analysis (DRES) was performed for the use of glyphosate in/on corn. The Agency used the following conservative (worst-case) assumptions: all corn (including genetically altered corn) would have the same tolerance level residues, and that 100 percent of the crop is treated. It is not believed that actual residues would reach tolerance levels, or that 100 percent of the total corn crop would be treated with glyphosate. The Agency feels that the risk to human health does not exceed a level of concern (100%) due to the percent of the RfD using the ''worst case'' assumptions. These dietary risk numbers include corn consumed directly by humans, plus meat, milk and eggs from which animals consumed corn raw agricultural commodities as feed. Published and proposed glyphosate tolerances result in the following percents of the RfD used: 1% for the overall U.S. population and nursing infants, 2% for children (7 to 12 years old), and 3% non-nursing infants less than 1 year old and children (1 to 6 years old).

3. *Toxicology concerns.* The commenter challenged Monsanto's assertions that glyphosate was of low toxicity. The commenter cited the fact that glyphosate ranked number 3 in California for acute illnesses in agriculture from 1984–1990. The commenter claimed that glyphosate is a skin and eye irritant, a possible carcinogen, a mutagen, and a reproductive toxicant. In support of glyphosate's carcinogenicity, the commenter claimed that one of the metabolites or breakdown products of glyphosate is formaldehyde and the commenter asserted that formaldehyde is a carcinogen, mutagen, and reproductive toxicant.

Additionally, the commenter claimed that a study showed that glyphosate decreased lung function and that studies showed that glyphosate inhibits enzymes involved in the detoxification of chemicals.

4. *Acute illnesses and skin and eye irritation—EPA response.* Data indicate that technical-grade glyphosate is in Toxicity Category III and Toxicity Category IV and that technical glyphosate is not a dermal sensitizer. Some formulations of glyphosate are in Category I and II where skin and eye irritation were associated with acute illnesses. Some of these formulations are being phased out of the U.S. market. Handlers and users of remaining formulations in Category I and II are expected to be adequately protected by the protective clothing requirements of the Worker Protection Standards (WPS). Data reviewed by the Agency on current formulations place these formulations in Toxicity Category III and IV.

5. *Carcinogen, mutagen and reproductive toxicity—EPA response.* Data indicate that glyphosate is a group E carcinogen (evidence of noncarcinogenicity for studies in humans, causes no pre- or post-natal effects in any study absent maternal toxicity, and is not a mutagen (refer to toxicology discussion above for a detailed discussion of carcinogenicity, reproductive, developmental and mutagenicity testing).

6. *Formaldehyde—EPA response.* Available rat metabolism data, residue data, and environmental data indicate that the major metabolite of glyphosate is AMPA which is further degraded by soil microbes to CO_2. The Agency has determined that AMPA is not of toxicological concern. (Glyphosate Reregistration Eligibility Decision (RED) issued by EPA September 1993). Available data do not indicate that formaldehyde is a metabolite or a degradate of glyphosate.

7. *Decreased lung function—EPA response.* Data reviewed by the Agency for glyphosate formulations for acute inhalation place most glyphosate formulations in Toxicity Category III and IV for acute inhalation. The Agency believes that handlers of these formulations and any formulations that may be Toxicity Category I or II are expected to be adequately protected by the protective clothing required by WPS.

8. *Interference with enzymes—EPA response.* The mode of action for glyphosate does involve interference with enzymes that result in the death of plants by inhibiting the biosynthesis of aromatic amino acids which along with other biochemical changes results in the death of plants. This is a common mode of action for various pesticides, but the Agency has no information that indicates that the handling or ingestion of glyphosate in small amounts result in interference with enzymes in the human body.

9. *Inert Ingredients.* The commentor also contended that EPA must examine the toxicity of the inert ingredients in glyphosate products in setting these tolerances.

EPA response. These tolerances establish maximum legal levels of residues of the active ingredient glyphosate that can be present in certain foods. These tolerances do not legalize any inert ingredients in glyphosate products. If a pesticide product also contains inert ingredients, those inert ingredients must have tolerances or exemptions from the requirement or their presence in food will render the food adulterated. Before approving a pesticide registration under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 et seq., EPA checks to make sure that all needed tolerances or exemptions are in place. All inerts present in current glyphosate formulations for use on food crops either have tolerances or exemptions from tolerances. Additionally, under the FIFRA registration process, EPA evaluates the potential risks posed by inert ingredients. The Agency requires a full disclosure of inert ingredients for each Roundup formulation to determine acute toxicity such as acute eye, skin, inhalation, and dermal sensitization. Refer to previous discussions on skin, eye, and acute inhalation for discussion of formulations.

10. *Persistence in soil.* The commenter claimed that glyphosate persists in soils from 3 to 141 days.

EPA response. Data from background 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) days. Acceptable aerobic soil, aerobic aquatic, and anaerobic aquatic metabolism studies demonstrate that under those conditions at 25 °C in the laboratory, glyphosate degrades rapidly with half-lives of approximately 2,7, and 8 days respectively. The reported half-lives from the field studies conducted in the coldest climates, i.e. Minnesota, New York, and Iowa, were the longest at 28.7 days, 127.8 days, and 140.6 days respectively indicating that glyphosate residues in the field are somewhat more persistant in cooler climates as opposed to milder ones (Georgia, California, Arizona, Ohio, and Texas. AMPA was the major degradate in all studies. AMPA has been determined to not be of toxicological concern. (Glyphosate Reregistration Eligibility Decision (RED) issued by EPA September, 1993).

11. *Environmental effects.* The commenter also claimed that data was lacking regarding glyphosate's toxicity to soil invertebrates, reptiles, and amphibians.

EPA response. Environmental Effects are considered under FIFRA. In examining glyphosate under FIFRA the Agency required several tests with mammals; acute tests to birds, fish, aquatic invertebrates, and bees; subacute dietary testing on birds; avian reproduction; and chronic testing on freshwater fish and freshwater invertebrates. Data submitted to and reviewed by the Agency indicate that effects to birds, mammals, fish, and invertebrates are minimal. (Glyphosate Registration Eligibility Decision (RED) issued by EPA September, 1993).

XII. Objections and Hearing Requests

The new FFDCA section 408 (g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under the new section 408 (e) and (1)(6) as was provided in the old section 408 and section 409. However, the period for filing objections is 60 days rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person adversely affected by this regulation may, by June 10, 1997, file written objections to any aspect of this regulation (including the automatic revocation provision) and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given below (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which the hearing is requested, the requestor's contentions on each such issue, and a summary of any evidence relied upon by the objector (40 CFR 178.27). 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 issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested. (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any or all of that information as ''Confidential Business Information'' (CBI). Information marked as CBI 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.

XIII. Public Docket

EPA has established a record for this rulemaking under docket number [OPP–300469; PP 8F3672, 8F3673, 5F4555, 6E4645] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in **ADDRESSES** at the beginning of this document.

XIV. Regulatory Assessments Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and, since this action does not impose any information collection requirements subject to approval under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty, or contain any ''unfunded mandates'' as described in Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special consideration as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because tolerances established on the basis of a petition under section 408(d) of FFDCA do not require issuance of a proposed rule, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act (RFA), 5 U.S.C. 604(a), do not apply. Prior to the recent amendment of the FFDCA, EPA had treated such rulemakings as subject to the RFA; however, the amendments to the FFDCA clarify that no proposal is required for such rulemakings and hence that RFA is inapplicable. Nonetheless, the Agency has previously assessed whether establishing tolerances or exemptions from tolerance, raising tolerance levels, or expanding exemptions adversely impact small entities and concluded, as a generic matter, that there is no adverse impact. (46 FR 24950, May 4, 1981).

Pursuant to 5 U.S.C. 801 (a)(1)(A), EPA submitted 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 General Accounting Office prior to publication of this rule in today's **Federal Register**. This rule is not a major rule as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agriculatural commodities, Pesticides and pest, Reporting and recordkeeping requirements.

40 CFR Part 185

Environmental protection, Food additives, Pesticides and pests.

40 CFR Part 186

Environmental protection, Animal feeds, Pesticides and pests.

Dated: March 28, 1997.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, chapter I of title 40 of the Code of Federal Regulations is amended as follows:

PART 180—[AMENDED]

1. In part 180:

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

Authority: 21 U.S.C. 346a and 371.

b. Section 180.364 is amended as follows:

i. By adding a paragraph heading to paragraph (a), and in the table by revising the entry ''Grain crops (except wheat)'' and alphabetically adding the commodities: aspirated grain fractions; corn, field, forage; corn, field, grain; corn, field, stover; oats; sorghum, grain; and sorghum, grain, stover.

ii. In paragraph (b) by transferring the entries in the table and alphabetically adding them to the table in paragraph (a), by removing the remaining text of paragraph (b), by adding a paragraph heading and reserving paragraph (b).

iii. In paragraph (d) by transferring the entries in the table and alphabetically adding them to the table in paragraph (a), by removing the remaining text of paragraph (d).

iv. In paragraph (c) is amended by adding a paragraph heading, ''Indirect and inadvertent residues'', and redesignating the amended paragraph (c) as new paragraph (d), and by adding a heading and reserving new paragraph (c).

§ 180.364 Glyphosate, tolerances for residues.

(a) *General.* * * *

Commodity	Parts Per Million (ppm)
* * * * *	
Aspirated grain fractions	200.0
* * * * *	
Corn, field, forage	1.0
Corn, field, grain	1.0
Corn, field, stover	100.0
* * * * *	
Grain crops (except wheat, corn, oats, and grain sorghum)	0.010
* * * * *	
Oats, grain	20.0
* * * * *	
Sorghum, grain	15.0
Sorghum, grain, stover	40.0

Commodity				Parts Per Million (ppm)
*	*	*	*	*

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* * * *

PART 185—[AMENDED]

2. In part 185:

a. The authority citation for part 185 continues to read.

Authority: 21 U.S.C. 346a and 348.

§ 185.3500 [Removed]

b. In § 185.3500 by transferring the entries in the tables to paragraphs (a)(1), (2), and (3), and alphabetically adding them to the table in paragraph (a) of § 180.364, and by removing the remainder of § 185.3500.

PART 186—[AMENDED]

3. In part 186:

a. The authority citation for part 185 continues to read.

Authority: 21 U.S.C. 342, 348 and 701.

§ 186.3500 [Removed]

b. In § 186.3500 by transferring the entries in the tables to paragraphs (a) and (b) and alphabetically adding them to the table in paragraph (a) of § 180.364, and by removing the remainder of § 186.3500.

[FR Doc. 97–9231 Filed 4–10–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185 and 186

[OPP–300466; FRL–5597–9]

RIN 2070–AC78

Myclobutanil; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of the fungicide myclobutanil in or on the raw agricultural commodity strawberries in connection with EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of myclobutanil on strawberries in Florida. This regulation establishes a maximum permissible level for residues of myclobutanil in this food pursuant to section 408(l)(6) of the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and be revoked by EPA on March 31, 1998.

DATES: This regulation becomes effective April 11, 1997. Objections and requests for hearings must be received by EPA on June 10, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the document control number, [OPP], should be submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [OPP]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Stephen Schaible, Registration Division (7505W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA 22202. (703) 308–8337, e-mail: schaible.stephen@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for residues of the fungicide myclobutanil [alpha-butyl-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile] and its metabolite alpha-(3-hydroxybutyl)-alpha-(4-chlorophenol)-1H-1,2,4-triazole-1-propanenitrile (free and bound), hereafter referred to as myclobutanil, in or on strawberries at 0.5 part per million (ppm). This tolerance will expire and be revoked on March 31, 1998.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 CFR 58135, November 13, 1996)(FRL–5572–9).

New section 408(b)(2)(A)(i) 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, 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....''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions