concludes that an additional uncertainty factor is not needed and that the RfD at 0.025 mg/kg/day is appropriate for assessing risk to infants and children.

Using the conservative exposure assumptions previously described (tolerance level residues), the percent RfD utilized by the aggregate exposure to residues of spinosad on apples, brassica leafy vegetables, cotton, and fruiting vegetables (except cucurbits) is 20.6 percent for children 1 to 6 years old, the most sensitive population subgroup. If average or anticipated residues are used in the dietary risk analysis, the use of spinosad on these crops will utilize 5.1 percent of the RfD for children 1 to 6 years old. Thus, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, DowElanco concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to spinosad residues on apples, brassica leafy vegetables, cotton, and fruiting vegetables (except cucurbits).

F. International Tolerances

There are no codex maximum residue levels established for residues of spinosad on apples, brassica leafy vegetables, cotton, fruiting vegetables (except cucurbits) or any other food or feed crop.

II. Administrative Matters

Interested persons are invited to submit comments on this notice of filing. Comments must bear a notation indicating the document control number, [PF–684]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address given above from 8:30 a.m. to 4 p.m., Monday through Friday, except legal holidays.

A record has been established for this notice under docket number [PF–684], including comments and data submitted electronically as described below. 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: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency Room 1132 , Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Electronic comments can be sent directly to EPA at:

opp=docket@epamail.epa.gov

Electronic comments must be submitted as ASCII file avoiding the use of special characters and any for 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 all comments 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.

List of Subjects

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

Dated: December 13, 1996.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 96–32528 Filed 12–23–96; 8:45 am]

BILLING CODE 6560–50–F

[PF–679; FRL–5576–6]

Monsanto; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Filing.

SUMMARY: This notice is a summary of the pesticide petitions which proposes to establish time-limited tolerances for residues of the herbicide glyphosate [*N*-phosphonomethyl)glycine] in or on the raw agricultural commodities (RACs) field corn grain at 1.0 parts per million (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 residues from treatment of field corn include residues from field corn varieties which have been genetically modified to be tolerant of glyphosate. Because additional time is needed for the petitioner to submit additional details on residue and processing data, the Agency is proposing to grant these tolerances with a 3–year expiration date. Monsanto Company requested these tolerances in petitions submitted to EPA pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA). A summary of the petition prepared by Monsanto is being included in this notice.

DATES: Comments, identified by the docket control numbers [PF–679] must be received on or before January 23, 1997.

ADDRESSES: By mail, submit written comments 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 comments to RM 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: 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.

Comments and data will also be accepted on disks in Word Perfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the Docket number [PF–679]. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment 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. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Robert J. Taylor, Product Manager (PM) 23, Registration Division, (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 241, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, 703–305–6027, e-mail: taylor.robert@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. section 346 a(d), EPA has received several pesticide petitions (PP 8F3672, PP 8F3673, PP 6E4645 and PP

5F4555) from Monsanto Company, 700 14th St., NW., Suite 1100, Washington, DC 20005. These petitions propose amending 40 CFR part 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 parts per million (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. PP 5F4555 specifically relates to field corn which has been genetically modified to be tolerant to glyphosate.

As required by section 408(d) of the FFDCA, as recently amended by the Food Quality Protection Act, Monsanto included in the petition a summary of the petition and authorization for the summary to be published in the Federal Register in a notice of receipt of the petition. The summary represents the views of Monsanto; EPA is in the process of evaluating the petition. As required by section 408(d)(3), EPA is including the summary as a part of this notice of filing. EPA has made minor edits to the summary for the purpose of clarity.

I. Monsanto Petition Summary

1. *Glyphosate uses*. Glyphosate is a postemergent, systemic herbicide with no residual soil activity. It is generally non-selective and provides broad spectrum control of many annual weeds, perennial weeds, woody brush and trees. Glyphosate is registered for a variety of agricultural uses, including preplant, preharvest, in-crop, fallow, reduced tillage, forestry and aquatic applications, as well as non-crop applications. When applied at lower rates, glyphosate also acts as a plant growth regulator. Glyphosate's primary mode of action is inhibition of the biosynthesis of aromatic amino acids in plants.

2. *Safety*. Monsanto Company has submitted numerous toxicology studies in support of glyphosate. According to Monsanto Company, the acute toxicity and irritation potential of glyphosate is low. There are large margins of safety for subchronic and chronic effects. Glyphosate does not produce reproductive effects and is not a teratogen, mutagen, carcinogen or a neurotoxin. Risk assessment calculations indicate the margin of safety for agricultural workers and the population in general far exceed the EPA required level of 100.

The following mammalian toxicity studies have been conducted to support glyphosate:

A rat acute oral study with a combined LD_{50} of >5,000 mg/kg.

A rabbit acute dermal LD_{50} of > 5,000 mg/kg.

A primary eye irritation study in the rabbit which showed severe irritation for glyphosate acid. However, glyphosate is normally formulated as one of several salts and eye irritation studies on the salts showed essentially no irritation.

A primary dermal irritation study which showed essentially no irritation.

A primary dermal sensitization study which showed no sensitization.

A 90–day feeding study in rats fed dosage levels of 0, 1,000, 5,000 and 20,000 ppm with a no-observable-effect level (NOEL) of 20,000 ppm based on no effects even at the highest dose tested.

A 90–day feeding study in mice fed dosage levels of 0, 5,000, 10,000 and 50,000 with a NOEL of 10,000 ppm based on body weight effects at the high dose.

A 90–day feeding study in dogs given glyphosate, via capsule, at doses of 0, 200, 600 and 2000 mg/kg/day with a NOEL of 2000 mg/kg/day based on no effects even at the highest dose tested.

A 12–month oral study in dogs given glyphosate, via capsule, at doses of 0, 20, 100 and 500 mg/kg/day with a NOEL of 500 mg/kg/day based on no adverse effects at any dose level.

A 26–month chronic/feeding oncogenicity study with rats fed dosage levels of 0, 3, 10 and 31 mg/kg/day (males) and 0, 3, 11 and 34 mg/kg/day (females) with a systemic NOEL of 31 mg/kg/day (males) and 34 mg/kg/day (females) based on no carcinogenic or other adverse effects at any dose level.

A 24–month chronic/feeding oncogenicity study with rats fed dosage levels of 0, 89, 362 and 940 mg/kg/day (males) and 0, 113, 457 and 1,183 mg/kg/day (females) with a systemic NOEL of 362 mg/kg/day based on body weight effects in the female and eye effects in males. There was no carcinogenic response at any dose level.

A mouse oncogenicity study with mice fed dosage levels of 0, 150, 750 and 4,500 mg/kg/day with a NOEL of 750 mg/kg/day based on body weight effects and microscopic liver changes at the high dose. There was no carcinogenic effect at the highest dose tested of 4,500 mg/kg/day.

An oral developmental toxicity study with rats given doses of 0, 300, 1,000 and 3,500 mg/kg/day with a maternal NOEL of 1,000 mg/kg/day based on clinical signs of toxicity, body weight effects and mortality, and a fetal NOEL of 1,000 mg/kg/day based on reduced body weights and delayed sternebrae maturation at the highest dose tested of 3,500 mg/kg/day.

An oral developmental toxicity study with rabbits given doses of 0, 75, 175 and 350 mg/kg/day with a maternal of NOEL of 175 mg/kg/day based on clinical signs of toxicity and mortality, and a fetal NOEL of 350 mg/kg/day based on no developmental toxicity at any dose tested.

A three-generation reproduction study with rats fed dosage levels of 0, 3, 10 and 30 mg/kg/day with a NOEL for systemic and reproductive/developmental parameters of 30 mg/kg/day based on no adverse effects noted at any dose level.

A two-generation reproduction study with rats fed dosage levels of 0, 100, 500 and 1,500 mg/kg/day with a NOEL for systemic and developmental parameters of 500 mg/kg/day based on body weight effects, clinical signs of toxicity in adult animals and decreased pup bodyweights, and a reproductive NOEL of 1,500 mg/kg/day.

A number of mutagenicity studies were conducted and were all negative. These studies included: chromosomal aberration in vitro (no aberrations in Chinese hamster ovary cells were caused with or 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.

3. *Threshold effects— chronic effects.* The reference dose (RfD) for glyphosate based on maternal effects in a developmental study with rabbits (NOEL of 175 mg/kg bwt/day) and using a hundred-fold safety factor is calculated to be 2.0 mg/kg body weight/day.

Acute toxicity. Based on the available acute toxicity data, glyphosate does not pose any acute dietary risks.

4. *Non-threshold effects— carcinogenicity*. The Health Effects Division Carcinogenicity Peer Review Committee has classified glyphosate in Group E (evidence of noncarcinogenicity for humans), based upon lack of convincing carcinogenicity evidence in adequate studies in two animal species. There was no evidence of carcinogenicity in an 18–month feeding study in mice and a 2–year feeding study in rats at the dosage levels tested. The doses tested are adequate for identifying a cancer risk. Thus, a cancer risk assessment is not appropriate.

5. *Aggregate exposure*. For purposes of assessing the potential dietary exposure, Monsanto has estimated

aggregate exposure based on the tolerances for glyphosate on field corn grain at 1.0 ppm, field corn forage at 1.0 ppm, field corn fodder at 100 ppm, corn aspirated grain fractions at 200 pm, grain sorghum at 15 ppm, grain sorghum fodder at 40 ppm and oats at 20 ppm. Corn forage and fodder, sorghum fodder and aspirated grain fractions are fed to animals; thus exposure of humans to residues in these commodities might result if such residues are transferred to meat, milk, poultry, or eggs. However, based on the results of animal metabolism studies and the amount of glyphosate residues expected in animal feeds, Monsanto has concluded that there is no reasonable expectation that residues of glyphosate will exceed existing tolerances in meat, milk, poultry or eggs. In conducting this exposure assessment, Monsanto has made very conservative assumptions — 100 percent of these crops will contain glyphosate residues and those residues would be at the level of the tolerance — which result in an overestimate of human exposure. Thus, in making a safety determination for these tolerances, Monsanto is taking into account this conservative exposure assessment. Other potential sources of exposure of the general population to residues of pesticides are residues in drinking water and exposure from non-occupational sources. A Maximum Concentration Level (MCL) has been established for residues of glyphosate in drinking water at 0.7 mg/l since glyphosate is approved for direct application to water. The MCL represents the level at which no known or anticipated adverse health effects occur, allowing for an adequate margin of safety, and is based on the reference dose (RfD). Non-occupational exposure to glyphosate is expected based on the currently-registered uses; however, due to the low acute toxicity and lack of other toxicological concerns, the risk posed by non-occupational exposure to glyphosate is minimal. Monsanto believes that EPA consideration of a common mechanism of toxicity is not appropriate at this time since Monsanto believes that EPA does not have information to indicate that toxic effects produced by glyphosate would be cumulative with those of any other chemical compound.

6. *Determination of safety for U.S. population*. RfD: The theoretical maximum residue contribution (TMRC) for existing, published tolerances for glyphosate is 0.021460 mg/kg bwt/day or 1.0 percent of the RfD for the overall U.S. population. Using the conservative exposure assumptions described above, the proposed new tolerances on corn, sorghum and oat commodities will contribute 0.0023 mg/kg/day to the TMRC. This aggregate exposure will utilize an additional 0.12 percent of the RfD for the overall U.S. population. EPA generally has no concern for exposures below 100 percent of the RfD. Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, Monsanto concludes that there is a reasonable certainty that no harm will result from aggregate exposure to residues of glyphosate, including all anticipated dietary exposure and all other non-occupational exposures.

7. *Determination of safety for infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of glyphosate, data were considered from developmental toxicity studies in the rat and rabbit and multi-generation reproduction studies in rats.

No birth defects were observed in the offspring of rats given glyphosate by gavage at dose levels of 0, 300, 1,000, and 3,500 mg/kg/day on days 6 through 19 of gestation. The NOEL for this study was 1,000 mg/kg/day based on maternal and developmental toxicity observed at the highest dose tested, 3,500 mg/kg/day. The high-dose in this study was 3.5 times higher than the limit dose that is currently required by the guidelines.

No birth defects were observed in the offspring of rabbits given glyphosate by gavage at dose levels of 0, 75, 175, and 350 mg/kg/day on days 6 through 27 of gestation. The NOEL for this study is considered to be 175 mg/kg/day based on maternal toxicity at the high-dose of 350 mg/kg/day. Because no developmental toxicity was observed at any dose level, the developmental NOEL is considered to be 350 mg/kg/day.

Male and female rats were fed glyphosate at dose levels of 0, 3, 10, and 30 mg/kg/day every day throughout the production of three successive generations. No adverse treatment-related effects on reproduction were observed. Because no toxicity was noted even at the highest dose tested, a second reproduction study at higher dose levels was performed and is described below.

Male and female rats were fed glyphosate at dose levels of 0, 100, 500, and 1,500 mg/kg/day every day throughout the production of two successive generations. Reduced body weights and soft stools occurred at 1,500 mg/kg/day (3 percent of the diet); therefore, the systemic NOEL is considered to be 500 mg/kg/day. Glyphosate did not affect the ability of rats to mate, conceive, carry or deliver normal offspring at any dose level.

The results of these studies indicate that glyphosate does not produce birth defects and is not a reproductive toxin.

Reference Dose (RfD). The TMRC for existing, published tolerances for glyphosate ranges from 0.015561 for nursing infants to 0.049134 for non-nursing infants (0.8 to 2.5 percent of the RfD). Using the conservative exposure assumptions described above, the proposed new tolerances on corn, sorghum and oat commodities will contribute 0.0158 mg/kg/day to the TMRC for non-nursing infants. For non-nursing infants, the proposed new tolerances and previously established tolerances will utilize a total of 3.2 percent of the RfD. EPA generally has no concern for exposures below 100 percent of the RfD. Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, Monsanto concludes that there is a reasonable certainty that no harm will result from aggregate exposure to residues of glyphosate, including all anticipated dietary exposure and all other non-occupational exposures.

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

9. *Chemical residue*. The nature of the residue in plants and animals is adequately understood. The residue to be regulated is the parent glyphosate. The submitted residue data adequately support the proposed tolerances on field corn grain (1.0 ppm), field corn forage (1.0 ppm), field corn stover (100 ppm), aspirated grain fractions (200 ppm), grain sorghum (15 ppm), grain sorghum

fodder (40 ppm) and oats (20 ppm). Residues from genetically-modified glyphosate tolerant field corn varieties did not exceed those from unmodified varieties and there were no residues of metabolites which would be of toxicological concern. Codex maximum residue levels (MRLs) have been established for residues of glyphosate on oats at 20 ppm and on corn grain and grain sorghum at 0.1 ppm. The Codex MRLS on corn and sorghum were established based on preplant/ preemergent uses of glyphosate, and are identical to the exixting tolerances for these crops under the same use conditions in the United States. The increased tolerances now being proposed on corn and sorghum are based on the new preharvest uses of glyphosate to these crops in the United States. Monsanto will be submitting a petition to request that the Codex MRLs on these crops be increased; however the Codex Commission does not generally begin the data review until the new use has been approved by a member company. Any secondary residues occurring in milk, eggs, meat, fat, liver and kidney of cattle, goats, horses, hogs, poultry and sheep are covered by existing tolerances. There is a practical analytical method for detecting and measuring levels of glyphosate in or on food with a limits of detection (0.05 ppm) that allows monitoring of food with residues at or above the levels set in these tolerances. EPA has provided information on this method to FDA. This method is available to anyone who is interested in pesticide residue enforcement from the Field Operations Division, Office of Pesticide Programs.

10. *Environmental fate.* Glyphosate adsorbs strongly to soil and is not expected to move vertically below the 6–inch soil layer; residues are expected to be immobile in soil. Glyphosate is readily degraded by soil microbes to AMPA, which is degraded to carbon dioxide. Glyphosate and AMPA are not likely to move to ground water due to their strong adsorptive characteristics. However, due to its aquatic use patterns and through erosion, glyphosate does have the potential to enter surface waters, where it will adsorb to sediment and undergo microbial degradation.

Glyphosate is no more than slightly toxic to birds and is practically non-toxic to fish, aquatic invertebrates and honeybees.

II. Administrative Matters

EPA invites interested persons to submit comments on this notice of filing. Comments must bear a notification indicating the docket number [PF–679]. All written comments filed in response to this petition will be availble , in the Public Response and Program Resources Branch, at the address given above from 8:30 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

A record has been established for this notice under docket numbers [PF–679] (including comments and data submitted electronically as described below). 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 4:30 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 can be sent directly to EPA at:

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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 all comments 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.

List of Subjects

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

Dated: December 16, 1996.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 96–32531 Filed 12–20–96; 10:00 am]

BILLING CODE 6560–50–F

[PF–681; FRL–5576–8]

Rhone-Poulenc Ag Company; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: This notice announces the filing of a pesticide petition proposing the establishment of a regulation for residues of the herbicide bromoxynil (3,5-dibromo-4 hydroxybenzonitrile), resulting from the application of its octanoic and heptanoic acid esters. The proposal would extend the time-limited tolerance in or on the raw agricultural commodity (RAC) cottonseed (transgenic BXN varieties only) at 0.04 part per million. This notice includes a summary of the petition that was prepared by the petitioner, Rhone-Poulenc Ag Company.

DATES: Comments, identified by the docket number [PF–681], must be received on or before, January 23, 1997.

ADDRESSES: By mail, submit written comments 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 comments to Rm. 1132, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: 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. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PF–681]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

Information submitted as comments concerning this document may be claimed confidential by marking any part of all of that information as Confidential Business Information (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA