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:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as 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 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

without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Robert Taylor Product Manager (PM 25) Rm., 241, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 703–305–6224, e-mail: Taylor.Robert@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition (PP) 3F4233 from Rhone-Poulenc Ag Company, PO Box 12014 T.W. Alexander Drive, Research Triangle Park, North Carolina 27709 porposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. section 346a(d), to amend CFR part 180 by establishing a tolerance for residues of the herbicide bromoxynil (3,5-dibrom-4-hydroxybenxonitrile), resulting from the application of its octanoic and heptanoic acid esters in or on the raw agricultural commodity cottonseed at 0.04 ppm. The proposed analytical method is a revised version of Method 1 in the Pesticide Analytical Manual (PAM), Vol II.

As required by section 408(d) of the FFDCA, as recently amended by the Food Quality Protection Act, Rhone-Poulenc 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 Rhone-Poulenc; 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.

EPA invites interested persons to submit comments on this notice of filing. Comments must bear a notification indicating the document control number [PF–681]. 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 p.m., Monday through Fridy, except legal holidays.

A record has been established for this notice under docket numbers [PF–681] (including com ents 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 Rm. 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:
opp-docket@epamail.epa.gov

Electronic comments must be submitted as 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 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.

I. Petition Summary

There is an extensive data base supporting the registration of Bromoxynil and its esters. This data base is current as the majority of the studies have been submitted and accepted under the reregistration process mandated by FIFRA 88. The Reregistration Eligibility Document (RED) for Bromoxynil has been scheduled by the Agency for early in fiscal year 1997. Included in this data submitted were studies which showed the nature and magnitude of Bromoxynil residue in ruminants and poultry. Based on these studies the Agency has determined that the nature of the residue in ruminants and poultry are understood and that any secondary residues from this tolerance occurring in the fat, meat, and meat byproducts of cattle, goats, horses, poultry, and sheep will be covered by existing tolerances.

The nature of the residue in Transgenic Cotton is considered to be adequately understood. The primary Bromoxynil metabolite is 3,5-dibrom-4-hydroxybenzoic acid (DBHA). DBHA is only a major metabolite in/on transgenic cotton treated with Bromoxynil. For the purposes of extending the time-limited tolerance, only the parent compound should be regulated as in 40 CFR 180.324. This interim decision is based on several factors. There will be very minimal risk from total residues of the parent compound and the DBHA metabolite in cotton seed contributing only about 1/1000th of the total dietary exposure from all registered uses of Bromoxynil. The registration of Bromoxynil on Transgenic Cotton in 1997 will be limited to 400,000 acres. This represents less than 3% of the total cotton acres anticipated to be planted in 1997. The only other potential source of dietary exposure from this use would be from cattle fed cotton gin trash. Any potental dietary risk from this source would be even less than the risk from cottonseed. This is based on again less than 3% of the cotton acres being treated with Bromoxynil. It is also based on the fact that the majority of the cotton gin trash is disked back into the fields and not fed to cattle. Even when the cotton gin trash is fed to cattle it represents only a maximum of 30% of the diet.

Adequate methodology is available for enforcement purposes, based upon methods for the parent compound. The method involves sample reflux in methanolic KOH, partitioning with ether/hexane and analysis by GC. The limit of detection (LOD) for this method is 0.02 ppm. The method is a modified version of Method I in the Pesticide Analytical Manual (PAM), Vol. II.

A. Toxicological Profile

The following mammalian toxicity studies have been conducted to support the tolerance of bromoxynil:

1. *Acute Toxicity--Bromoxynil Phenol Technical.* A complete battery of acute toxicity studies for Bromoxynil Phenol were completed. The acute oral toxicity study resulted in a LD^{50} of 81 mg/kg (males) and a LD^{50} of 93 mg/kg (females). The acute dermal toxicity study in rabbits resulted in a LD^{50} of >2000 mg/kg for both males and females. The acute inhalation study in rats resulted in a LC^{50} of 0.269 mg/L for males and 0.150 for females. The primary eye irritation study showed corneal opacity resolved within 3 days, iritis resolved within 4 days and conjuctival irritation which persisted for 10 days. There was no irritation in the Primary dermal irritation study and the dermal sensitization study in guinea pigs was negative. Based on the results of these studies Bromoxynil Phenol is placed in toxicity Category II.

2. *Acute Toxicity--Bromoxynil Octanoate Technical.* A complete battery of acute toxicity studies for Bromoxynil Octanoate technical were completed. The acute oral toxicity study resulted in a LD^{50} of 400 mg/kg (males) and a LD 50 of 238 mg/kg (females). The acute dermal toxicity study in rabbits resulted in a LD^{50} of 2000 mg/kg for males with abraded skin, 1310 mg/kg for females with intact skin and 1660 mg/kg for females with abraded skin. The

acute inhalation study in rats resulted in a LC^{50} of 0.81 mg/L for males and 0.72 mg/L for females. The primary eye irritation study showed corneal opacity and irritation lasting for 24–72 hours. It had cleared by 96 hours. The primary dermal irritation study showed erythema for 72 hours and no edema. The dermal sensitization study in guinea pigs showed compound to be a positive contact sensitizer in modified Draize test. Based on the results of these studies Bromoxynil Octanoate is placed in toxicity category II.

3. *Acute Toxicity--Bromoxynil Heptanoate Technical*. A complete battery of acute toxicity studies for Bromoxynil Heptanoate were completed. The acute toxicity study resulted in a LD^{50} of 362 mg/kg (males) and a LD^{50} of 292 mg/kg (females). The acute dermal toxicity study in rabbits resulted in a LD^{50} of >2020 mg/kg. The acute inhalation study in rats resulted in a LC^{50} of 1.975 mg/L for males and 1.479 mg/L for females. Based on the results of these studies Bromoxynil Heptanoate is placed in toxicity Category II.

Conclusion: Based on the acute toxicity data cited above and a margin of safety between the most conservative acute oral toxicity value and the oral RfD of 0.015 mg/kg/day of >9000, Rhone-Poulenc it is concludeds that neither Bromoxynil nor its octanoic or heptanoic acide esters pose any acute dietary risks.

B. Mutagenicity

1. *Mutagenicity--Bromoxynil Phenol Technical*. Mutagenicity studies completed included an unscheduled DNA synthesis study-rat primary hepatocytes (negative); in vitro transformation assay--mouse cells (negative); sister chromosomal exchange study--CHO cells (negative); forward mutation study--mouse lymphoma cells (negative without activation and positive with activation); DNA repair test--E. Coli (positive); in vitro chromosomal aberration (negative without activation and positive with activation); two separate micronucleus assays (both negative); forward mutation-- CHO cells (negative); and an Ames Study--Salmonella typhimurium (negative with and without activation).

2. *Mutagenicity--Bromoxynil Octanoate Technical*. Mutagenicity studies completed included an Ames Study--Salmonella typhimurin (negative with and without activation); micronucleus assay (negative); and an unscheduled DNA synthesis--rat primary hepatocytes (negative).

Conclusion. Based on the data cited above Rhone-Poulenc concludes neither Bromoxynil nor its octanoic or heptanoic acid esters are considered to be mutagenic.

C. Rat Metabolism

1. *Rat Metabolism--Bromoxynil Heptanoate Technical*. Similar results were obtained when a single low dose (2 mg/kg), a single high dose (20 mg/kg) and a low dose (2 mg/kg) administered for 14 consecutive days were fed to rats. Bromoxynil Heptanoate is rapidly absorbed and widely distributed in most tissues. The highest concentrations were found in the blood, plasma, liver, kidney and thyroid. Higher tissue concentrations were found in females than in males while excretion was more rapid in males. Most of the radioactivity was excreted in the urine. Most of this was in the form of Bromoxynil Phenol. Both Bromoxynil Phenol and Bromoxynil Heptanoate were present in the feces. There was no significant retention in tissues after 7 days. Bromoxynil Heptanoate was essentially metabolized to Bromoxynil Phenol via ester hydrolysis.

2. *Rat Metabolism--Bromoxynil Octanoate Technical*. The study demonstrated that 2 mg/kg of radiolabeled Bromoxynil Octanoate was rapidly absorbed, distributed, and excreted in rats following repeated oral administration. A sex-related difference was seen in the excretion of Bromoxynil Octanoate. The urine was the major route of excretion, representing 80.24% of the administered dose in males and 67.91% in females at 7 days post-dosing. The urinary excretion rate was also higher in males than in females. The feces accounted for 7 - 10% of the administered dose at 7 days post-dosing. A sex-related difference was also noted in tissue bioaccumulation of Bromoxynil Octanoate with 1.482% of the dose in males and 8.036% in females. Tissue distribution was similar for both sexes with the highest radioactivity recovered in the liver and kidney. Bromoxynil Octanoate was essentially metabolized to Bromoxynil Phenol via ester hydrolysis.

D. Chronic Effect:

A 1 year oral dog study was run with dogs administered Bromoxynil Phenol at dose levels of 0, 0.1, 0.3, 1.5, and 7.5 mg/kg/day in capsules. The NOEL/LEL is 1.5 mg/kg/day for both females and males based on decreased body weight gain, decreased RBC count, decreased hemoglobin, decreased PCV, increased liver weights.

Conclusion: The chronic dog study was determined by the EPA to be the most appropriate study for setting the RfD of 0.015 mg/kg/day (includes a 100 fold safety factor). Based on the chronic toxicity data cited above Rhone-Poulenc concludes that neither Bromoxynil nor its octanoic or heptanoic acid esters pose any chronic dietary risks.

E. Carcinogenicity

Several feeding/carcinogenicity studies were conducted with Bromoxynil Phenol. These studies are summarized below.

1. A 2 year combined feeding/carcinogenicity study was conducted with rats administered (oral) dosages of 0, 60, 190, or 600 ppm (0, 2.6, 8.2, or 28 mg/kg/day in males; 0, 3.3, 11.0, or 41 mg/kg/day in females) Bromoxynil Phenol in the diet. In males the no-observed-effect-level (NOEL) for systemic toxicity is 2.6 mg/kg/day, and the Lowest-effect-level (LEL) is 8.2 mg/kg/day. In females, the NOEL is 3.3 mg/kg/day, and the LEL is 11.0 mg/kg/day. This study did not demonstrate any increase in tumor incidences in either male or female rats.

2. A 2 year combined feeding/carcinogenicity study was conducted with rats administered Bromoxynil Phenol in the diet at dose levels of 0, 10, 30, or 100 ppm (0, 0.5, 1.5, or 5 mg/kg/day). In both males and females, the NOEL and LOEL for systemic toxicity was 5 mg/kg/day and >5 mg/kg/day, respectively. At the highest dose tested, increased liver weights were observed at 12 months, but not at 24 months. This study was considered negative for carcinogenicity.

3. An 18 month carcinogenicity study was conducted with mice administered Bromoxynil Phenol at dose levels of 0, 10, 30, or 100 ppm (0, 1.3, 3.9, or 13 mg/kg/day) in the diet. For males, dose related increases in hyperplastic nodules and liver adenomas/carcinomas were observed which were statistically significant at the 13 mg/kg/day level. Increased relative liver weights were also observed. In females, increased absolute liver weights and relative liver and kidney weights were observed. The study was considered negative for carcinogenicity for females.

4. An 18 month carcinogenicity study was conducted with mice administered Bromoxynil Phenol at dose levels of 0, 20, 75, or 300 ppm (0, 3.1, 12 or 46 mg/kg/day in males and 0, 3.7, 14, or 53 mg/kg/day in females). Mice given 300 ppm had significantly increased absolute and relative liver weights. Histopathology of the liver revealed increased hepatocellular hypertrophy, hepatocellular degeneration, necrosis of individual hepatocytes, and pigment accumulation in hepatocytes and Kupffer cells. Male

mice had statistically significant increased numbers of hepatocellur adenomas and carcinomas at 20 ppm, but not 75 ppm. In contrast, no significant increase in tumor incidence was observed for female mice by pair-wise analysis. The trend test was significant for adenomas or carcinomas in females, only at $p<0.05$, not $p<0.01$ as would be appropriate for this type of tumor. The trend is due entirely to the high dose group and therefore is of questionable validity.

Conclusion. Bromoxynil is a weak, single sex, single species, non-metastic, single target organ carcinogen, inducing hepatocellular tumors in male mice exposed to 300 ppm for 18 months. These tumors and associated histopathological findings are consistent with secondary mechanisms such as peroxisome proliferation, a mechanism known to have marked species differences and questionable relevance for humans. The data are not suitable for quantitative risk assessment. A threshold safety factor approach is more appropriate and is commonly used for single sex, single species carcinogens such as Bromoxynil that are thought to work through secondary mechanisms. Based on these data, Rhone-Poulenc concludes Bromoxynil is not expected to pose any increased dietary risks.

F. Teratology

1. *Bromoxynil Phenol Technical*. Several teratology studies were conducted with Bromoxynil Phenol Technical. These are summarized below:

a. A teratology study was conducted with rats administered (orally) Bromoxynil Phenol at dose levels of 0, 4, 12.5, or 40 mg/kg/day. The maternal NOEL and LEL are 12.5 and 40 mg/kg/day respectively. The developmental NOEL and LEL are 4.0 and 12.5 mg/kg/day, respectively. Maternal body weights and food consumption were reduced in the high dose group. Fetal effects observed were reduced body weight, with associtaed decreases in ossification. An increase in 14th ribs, was observed in the mid and high dose levels.

b. A teratology study was conducted with rats administered (orally) Bromoxynil Phenol at dose levels of 0, 5, 15, or 35 mg/kg/day. The maternal NOEL and LEL are 5.0 and 15 mg/kg/day, respectively. The fetotoxicity and developmental NOEL and LEL are less than 5 and 5 mg/kg/day, respectively. Significant maternal mortality and decreased body weight gain were associated with the high dose, indicating that the MTD was exceeded. Decreases in maternal body weight gain were also observed in the mid and low dose levels. At the mid-dose level a statistically significant increase in the number of fetuses with supernumerary ribs, a common fetal variant was observed.

c. A teratology study was conducted with rats administered (orally) Bromoxynil Phenol at dose levels of 0, 1.7, 5, or 15 mg/kg/day. The maternal NOEL and LEL sre 5 and 15 mg/kg/day, respectively. The developmental NOEL and LEL are 5 and 15 mg/kg/day, respectively. This study was classified as unacceptable, primarily due to reporting deficiendies.

d. A teratology study was conducted with rabbits administered (orally) Bromoxynil Phenol at dose levels of 0, 15, 30, or 60 mg/kg/day. The maternal NOEL and LEL are 15 and 30 mg/kg/day, respectively. The developmental NOEL and LEL are less than 15 and 15 mg/kg/day, respectively. Significant body weight gain decrements were reported at the two highest dose levels along with observed decreases in food sonsumption. The severe maternal toxicity among high dose dams was associated with fetoxicity and teratogenicity. A slight, nonsignificant increase in supernumerary ribs was reported at the mid and low dose levels.

e. A teratology study was conducted with mice administered (orally) Bromoxynil Phenol at dose levels of 0, 11, 32, or 96 mg/kg/day. Maternal mortality was observed at 32 and 96 mg/kg/day. Fetal body weight was decreased at the top dose level, associated with a decrease in caudal vertebral ossification and an increase in supernumerary ribs. The maternal NOEL and LEL are 11 and 32 mg/kg/day respectivel. The developmental NOEL and LEL are 32 and 96 mg/kg/day, respectively.

2. *Bromoxynil Octanoate Technical*. A teratology study was conducted with Bromoxynil Octanaote administered (orally) to rats at dose levels of 0, 2.4, 7.3 or 21.8 mg/kg/day. This is equivalent to 0, 1.7, 5, or 15 mg/kg/day Bromoxynil Phenol. Transient decreases in maternal body weight were observed at the highest dose level. Fetal body weight was also decreased and the incidence of supernumerary ribs was increased at this dose level. The maternal NOEL and LEL are 5 and 15 mg/kg/day, respectively. The developmental NOEL and LEL are also 5 and 15 mg/kg/day, respectively.

Conclusion. Based on all the studies cited above Rhone-Poulenc concludes that neither Bromoxynil nor Bromoxynil Octanoate are teratogens at doses that are not maternally toxic.

G. Reproductive Effects

1. Two reproduction studies were conducted with Bromoxynil Phenol. These are summarized below:

a. A reproduction study was conducted with rats administered (orally) Bromoxynil Phenol at dose levels of 0. 0.8, 4, or 21 mg/kg/day in the diet. The systemic adult rat NOEL is 4 mg/kg/day and the LEL is 21 mg/kg/day. The reproductive NOEL is 21 mg/kg/day, and the LEL is greater than 21 mg/kg/day. The postnatal developmental NOEL is 4 mg/kg/day, and the LEL is 21 mg/kg/day. Body weight gain decrements were reported. However, no adverse effects on fertility, fecundity, reproductive performance or pre and postnatal development were observed.

b. A reproduction study was conducted with rats administered (orally) Bromoxynil Phenol at dose levels of 0, 1.5, 5, or 15 mg/kg/day in the diet. The systemic rat NOEL is 1.5 mg/kg/day, and the LEL is is 5 mg/kg/day. The reproductive NOEL is 15 mg/kg/day, and the LEL is greater than 15 mg/kg/day. The offspring developmental NOEL is 5 mg/kg/day and the LEL is 15 mg/kg/day. Body weight gain decrements were reported. However, no adverse effects on fertility, fecundity, reproductive performance or pre and postnatal development were observed.

Conclusion. Based on the studies cited above Rhone-Poulenc concludes Bromoxynil is not considered a reproductive toxicant and shows no evidence of endocrine effects.

2. *Aggregate Exposure*. The Food Quality Protection Act of 1996 list three other potential sources of exposure to the general population that must be addressed. These are pesticides in drinking water, exposure from non-occupational sources, and the potential cumulative effect of pesticides with similar toxicological modes of action. Based on available studies which show a short half-life of Bromoxynil in the environment (average half-life of 3–7 days under actual field conditions), Rhone-Poulenc does not anticipate residues of Bromoxynil in drinking water. There is no established Maximum Concentration Level or Health Advisory Level for Bromoxynil under the Safe Drinking Water Act.

The potential for non-occupational exposure to the general public is also insignificant. There are no residential lawn or garden uses for Bromoxynil products where the general population may be exposed via inhalation or dermal routes. Bromoxynil is registered for use on grass grown for seed or sod

production and for non-residential turfgrass. These uses are very minor and applied at only 0.5 lbs per acre. These uses will therefore not significantly add to the aggregate exposure.

Rhone-Poulenc concludes that consideration of a common mechanism of toxicity is not appropriate at this time since there is no reliable data to indicate that the toxic effects caused by Bromoxynil would be cumulative with those of any other compound. Based on this point, Rhone-Poulenc has considered only the potential risks of Bromoxynil in its exposure assessment.

C. Safety Determination

1. *DRES-U.S. Population, Infants, Children (1–6 years old)*

a. *General U.S. population*. Using the stated EPA RfD for bromoxynil of 0.015 mg/kg/day and the conservative assumptions stated above, and based on the completeness of the toxicology database, it has been determined that aggregate exposure to Bromoxynil will use 2.4% of the RfD for the US population. This is assuming that 100% of the acres for each crop for which a tolerance has been established (including transgenic cotton) was treated and the residue found was at the tolerance level. If one assumes market share values this number is decreased to 1.4%.

b. *Infants and children (1–6 years old)*. The Food Quality Protection Act of 1996 provides that an additional safety factor for infants and children may be applied in the case of threshold effects. The NOEL/LEL of 1.5 mg/kg/day in the chronic dog study, on which the RfD is based, is already lower than the NOELs from the developmental and reproductive toxicity studies. Rhone-Poulenc concludes that an adequate margin of safety is therefore provided by the currents RfD. Using the stated EPA RfD for Bromoxynil of 0.015 mg/kg/day and the conservative assumptions stated above, it has been determined that aggregate exposure to Bromoxynil will use 2.3% for infants and 4.9% for children under 6 years old. This is assuming that 100% of the acres for each crop for which a tolerance has been established (including transgenic cotton) was treated and the residue found was at the tolerance level. If one assumes market share values these values are decreased to 1.8% for infants and 2.8% for children under 6 years old.

c. *Additional Comments on Safety to Infants and Children*. In assessing the potential for additional sensitivity of infants and children to residues of Bromoxynil, the available teratology and reproductive toxicity studies and the potential for endocrine modulation by Bromoxynil were considered. Developmental toxicity studies in three species indicates that Bromoxynil is not a teratogen at doses that are not maternally toxic. Two multi-generation rodent reproduction studies demonstrated that there were no adverse effects on reproductive performance, fertility, fecundity, pup survival, or pup development. Maternal and developmental NOELs and LOELs were comparable indicating no increase susceptibility of developing organisms. No evidence of endocrine effects were noted in any study. Rhone-Poulence concludesIt is therefore concluded that Bromoxynil poses no additional risk for infants and children and no additional uncertainty factor is warrented.

d. *Environmental Fate*. Extensive laboratory and field studies indicate that bromoxynil has little tendency to move within or persist in soil or water under field conditions. Once in contact with soil, bromoxynil rapidly degrades. An average half-life of 3–7 days for bromoxynil has been demonstrated under field conditions. The soil breakdown process begins almost immediately and involves hydrolysis, dehalogenation, as well as other complex metabolic pathways carried out by soil bacteria and other microorganisms.

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–681]. 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.

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List of Subjects

Environmental Protection, Administrative practice and procedure, Agricultural commodities, Pesticide and pest, Reporting and recordkeeping requirements.

Dated: December 13, 1996.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 96–32530 Filed 12–23–96; 8:45 am]

BILLING CODE 6560–50–F

[FRL–5669–6]

Notice of Proposed Administrative Settlement Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as Amended by the Superfund Amendments and Reauthorization Act; Sussex County Landfill No. 5 Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Request for public comment.

SUMMARY: In accordance with Section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA), 42 U.S.C. 9622(i), notice is hereby given of a proposed administrative cost recovery settlement concerning the Sussex County Landfill No. 5 Superfund Site, Laurel, Sussex County, Delaware (Proposed Settlement).

The Proposed Settlement with Sussex County, Delaware (Settling Party) has been approved by the Attorney General, or her designee, of the United States Department of Justice. The Proposed Settlement was signed by the Regional Administrator of the U.S. Environmental Protection Agency (EPA), Region III, on December 13, 1996, pursuant to Section 122(h) of CERCLA,