ENVIRONMENTAL PROTECTION AGENCY

[PF–1034; FRL–6794–2]

Notice of Filing a Pesticide Petition to Establish a Tolerance fora Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–1034, must be received on or before September 10, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1034 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5697; e-mail address: *tompkins.jim@;epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number PF–1034. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1034 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: *opp-docket@epa.gov,* or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–1034. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT.**

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 25, 2001

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues of an explanation of why no such method is needed.

DuPont Agricultural Products

PP 4F4391

EPA has received a pesticide petition (PP 4F4391) from DuPont Agricultural Products,Wilmington, DE proposing, pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180. This regulation extends the time-limited tolerance for residues of the herbicide pyrithiobac sodium salt (sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate) in or on the raw agricultural commodity cottonseed at 0.02 parts per million (ppm). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

Background and Statutory Findings

In the **Federal Register** of October 22, 1997 (62 FR 54778) (FRL–5746–6), and the **Federal Register** of October 20, 1999 (64 FR 56464) (FRL–6386–5), EPA twice extended the time-limited tolerance pursuant to FFDCA for residues of the herbicide pyrithiobac sodium salt (sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate) in or on the raw agricultural commodity cottonseed at 0.02 ppm. The tolerance was issued and renewed as a time-limited tolerance because EPA required additional residue data on the commodity of cotton gin byproducts. At this time EPA has not fully evaluated the sufficiency of the submitted data supporting this petition. The petitioner proposes to again renew the time-limited tolerance for an additional 3–year period and continue to retain the pesticide labeling previously accepted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, which bears a restriction against feeding cotton gin byproducts from treated fields to livestock. DuPont has requested this tolerance extension pursuant to section 408(d) of the FFDCA, as amended, 21 U.S.C. 346a(d), by the Food Quality Protection Act of 1996 (Public Law 104–170, 110 Stat. 1489). The request addresses the requirements of the new FFDCA section 408(d)(2). The time-limited tolerance would expire on September 30, 2001. An adequately validated analytical method is available for enforcement purposes. Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, DuPont has submitted the following summary of information, data and arguments in support of its pesticide petition. This summary was proposed by DuPont and EPA has not yet fully evaluated the additional data supporting this petition. EPA edited the document to clarify the conclusions and arguments presented by DuPont and to remove certain extraneous material.

A. Residue Chemistry

1. *Plant metabolism*. The qualitative nature of the residues of pyrithiobac sodium in cotton is adequately understood for the purposes of this tolerance. Metabolism studies with pyrithiobac sodium indicate the major metabolic pathway being o-dealkylation of the parent compound resulting in o-desmethyl pyrithiobac sodium (O-DPS). O-DPS, both free and conjugated, was the major metabolite identified in cotton foliage. The results of a confined crop rotation study with pyrithiobac sodium revealed the presence of a metabolite 2-chloro-6-sulfobenzoic acid (CSBA) not seen in the cotton metabolism study. This metabolite appeared to originate from soil metabolism of pyrithiobac sodium. Since preemergence applications of pyrithiobac sodium are allowed, crop residues of CSBA were considered a possibility. In consideration of PP 4F4391 CBTS, in consultation with the HED Metabolism Committee has previously concluded that for the proposed use on cotton, none of the pyrithiobac sodium metabolites including O-DPS and CSBA warrant inclusion in the tolerance regulation, and that the only residue of concern is the parent, pyrithiobac sodium.

2. *Analytical method*. There is a adequately validated practical analytical method available using HPLC-UV with column switching, to measure levels of pyrithiobac sodium in or on cotton with a limit of quantitation that allows monitoring of cottonseed at or above tolerance levels. EPA has provided information on this method to FDA for future publication in PAM II.

3. *Magnitude of residues*. Crop field trial residue data from a 60–day PHI study shows that the established pyrithiobac sodium time-limited tolerance on cottonseed of 0.02 ppm will not be exceeded when Staple* is used as directed. An adequate cottonseed processing study shows that pyrithiobac sodium does not concentrate in cottonseed processed commodities; thus no tolerances on these commodities are required.

B. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as

the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by pyrithiobac sodium are discussed in this unit.

1. *Acute toxicity*. Pyrithiobac sodium technical has been placed in EPA Toxicity Category II for acute eye irritation based on the test article inducing irritation in the form of corneal opacity, iritis and conjunctival redness, and discharge in the eyes of rabbits after receiving ocular doses of 36 mg (0.1 mL). Signs of irritation were clear within 14 days of treatment. Pyrithiobac sodium has been placed in Toxicity Category III for acute dermal toxicity based on the test article being nonlethal and nonirritating at the limit dose of 2,000 milligrams/kilogram (mg/kg) (highest dose tested). Pyrithiobac sodium has been placed in Toxicity Category III for acute oral toxicity based on acute oral LD_{50s} of 3,200 and 3,300 mg/kg for male and female rats, respectively. Pyrithiobac sodium has been placed in Category IV for the remaining acute toxicity tests based on the following: A rat acute inhalation study with an LC_{50} 6.9 mg/L; and a primary dermal irritation test that did not induce a dermal irritation response. A dermal sensitization test with pyrithiobac sodium technical in guinea pigs demonstrated no significant effects. EPA has concluded that no endpoint exists to suggest any evidence of significant toxicity from acute, short-termor intermediate term exposures from the use of pyrithiobac sodium on cotton.

2. *Genotoxicity*. Pyrithiobac sodium technical was negative (non-mutagenic and non-genotoxic) in the following tests: Ames microbial mutation assay; the hypoxanthine-guanine phosphoribosyl transferase gene mutation assay using Chinese hamster ovary cells; induction of unscheduled DNA synthesis (UDS) in primary rat hepatocytes; and induction of micronuclei in the bone marrow cells of mice. Pyrithiobac sodium was positive in an*in vitro* assay for chromosome aberrations in human lymphocytes. Based on the weight of these data, pyrithiobac sodium is neither genotoxic nor mutagenic.

3. *Reproductive and developmental toxicity.*A two-generation reproduction study with rats treated in the diet with pyrithiobac sodium demonstrated a maternal no observed adverse effect level (NOAEL) of 1,500 ppm (103 mg/kg/day) and a maternal lowest observed adverse effect level (LOAEL) of 7,500 ppm (508 mg/kg/day), based on decreased body weight/gain and food efficacy. The reproductive and offspring NOAEL of 7,500 ppm (508 mg/kg/day) and LOAEL of 20,000 ppm (1,551 mg/kg/day) were also demonstrated based on decreased offspring body weight. Pyrithiobac sodium was not teratogenic when administered to rats or rabbits. A developmental toxicity study with pyrithiobac sodium in rats demonstrated a maternal NOAEL of 200 mg/kg and a maternal LOAEL of 600 mg/kg due to increased incidence of peritoneal staining. A developmental NOAEL of 600 mg/kg and LOAEL of 1,800 mg/kg were demonstrated based on an increased incidence of skeletal variations. A developmental toxicity study with pyrithiobac sodium in rabbits demonstrated maternal and developmental NOAELs of 300 mg/kg and a maternal LOAEL of 1,000 mg/kg based on mortality, decreased body weight gain and feed consumption, increased incidence of clinical signs, and an increase in early resorptions. A developmental LOAEL of 1,000 mg/kg was based on decreased fetal body weight gain.

4. *Subchronic toxicity*. In a 90–day feeding study in rats conducted with pyrithiobac sodium at dietary levels of 0, 10, 50, 500, 7,000 and 20,000 ppm, the NOAEL was 500 ppm (31.8 and 40.5 mg/kg/day, M/F) and the LOAEL was 7,000 ppm (466 and 588 mg/kg/day, M/F) based on decreased body weight gains and increased rate of hepatic B-oxidation in males. In a 90–day feeding study in mice conducted with pyrithiobac sodium at dietary levels of 0, 10, 50, 500, 1,500 and 7,000 ppm, the NOAEL was 500 ppm (83.1 and 112 mg/kg/day, M/F) and the LOEL was 1,500 ppm (263 and 384 mg/kg/day, M/F) based on increased liver weight and increased incidence of hepatocellular hypertrophy in males and decreased neutrophil count in females. In a 90–day feeding study in dogs conducted with pyrithiobac sodium at dietary levels of 0, 50, 5,000, or 20,000 ppm, the NOAEL was 5,000 ppm (165 mg/kg/day) and the LOAEL was 20,000 ppm (626 mg/kg/day) based on decreased red blood cell count, hemoglobin, and hematocrit in females and increased liver weight in both sexes. In a 21–day dermal study with rats conducted with pyrithiobac sodium at exposure levels of 0, 50, 500, or 1,200 mg/kg/day, the dermal irritation NOAEL was 500 mg/kg/day and the dermal irritation LOAEL was 1,200 mg/kg/day. There were no systemic effects observed at this high dose; therefore, the systemic NOAEL is considered to be 1,200 mg/kg/day.

5. *Chronic toxicity*. A 1–year feeding study in dogs conducted with pyrithiobac sodium resulted in a NOAEL of 5,000 ppm (143 and 166 mg/kg/day, M/F) and a LOAEL of 20,000 ppm (580 and 647 mg/kg/day, M/F) based on decreases in body weight gain and increased liver weight. A 78–week dietary oncogenicity study conducted in mice resulted in a systemic NOAEL is 1,500 ppm (217 and 319 mg/kg/day, M/F); the LOAEL is 5,000 ppm (745 and 1,101 mg/kg/day, M/F), based on decreased body weight gain and glomerulonephropathy (murine) in both sexes and treatment related increase in the incidence of foci/focus of hepatocellular alteration in males. There was evidence of carcinogenicity based on significant differences in the pair-wise comparisons of hepatocellular adenomas or adenomas plus carcinomas in the 150 and 1,500 ppm males (but not at the high dose of 5,000 ppm). A 2–year dietary study in rats resulted in systemic NOAELs of 1,500 ppm (58.7 mg/kg/day) for males and 5,000 ppm (278 mg/kg/day) for females. The LOAEL was 5,000 ppm (200 and 918 mg/kg/day, M/F). The LOAEL was based on the following: Increased incidence of eye lesions and mild changes in hematology and urinalysis, and clinical signs indicative of urinary tract dysfunction (both sexes); decreased body weight, body weight gain and food efficiency and an increased incidence of inflammatory and degenerative microscopic lesions in the kidney (females); and increased incidence of focal cystic degeneration in the liver and increased rate of hepatic peroxisome beta-oxidation (males). There was evidence of oncogenicity based on an increasing trend for kidney tubular combined adenoma/carcinoma in male rats and an increasing trend for kidney tubular adenomas in female rats. Although the incidences were low, they were statistically significant. The highest dose level tested in male rats (5,000 ppm) was considered adequate for assessment of oncogenic potential, that in female rats (15,000 ppm) exceeded the Maximum Tolerated Dose (MTD).

6. *Animal metabolism*. Disposition and metabolism of pyrithiobac sodium were tested in male and female rats using two radiolabeled forms of pyrithiobac sodium, both orally and intravenously. Essentially all of the dose was excreted in the urine and feces, with greater than 90% being excreted within 48 hours. The major compound eliminated in urine and feces was O-DPS (desmethyl metabolite), formed by

demethylation of the pyrimidine ring. There was evidence that conjugation with glucuronic acid and 5-hydroxylation of the pyrimidine ring of pyrithiobac sodium were additional minor routes of metabolism in the rat.

7. *Metabolite toxicology*. At this time, there is no evidence that the metabolites of pyrithiobac sodium as identified in either the plant metabolism, confined crop rotation, or animal metabolism studies are of toxicological concern.

8. *Endocrine disruption*. No special studies investigating potential estrogenic or other endocrine effects of pyrithiobac sodium have been conducted. However, the standard battery of required toxicology studies has been completed and found acceptable. These include an evaluation of the potential effects on reproduction and development, and an evaluation of the pathology of the endocrine organs following repeated or long-term exposure to doses that far exceed likely human exposures. Based on these studies there is no evidence to suggest that pyrithiobac sodium has an adverse effect on the endocrine system.

C. Aggregate Exposure

1. *Dietary exposure*— i. *Food*. For purposes of assessing the potential dietary exposure under this tolerance, an estimate of aggregate exposure is made using the time-limited tolerance on cottonseed at 0.02 ppm. The potential exposure is obtained by multiplying the tolerance level residues by the consumption data which estimates the amount of cottonseed products translated as cottonseed meal and cottonseed oil eaten by various population subgroups. Cottonseed is fed to animals, thus exposure of humans to residues of cottonseed might result if such residues are transferred to meat, milk, poultry, or eggs. However, in consideration of PP 4F4391 CBTS has previously concluded that secondary residues in meat, milk, poultry and eggs are not expected from the use of cottonseed (undelinted) as an animal feed. There are no other established tolerances or registered uses for pyrithiobac sodium in the United States. Based on a NOAEL of 58.7 mg/kg/day, from the chronic rat toxicity study and a 100-fold safety factor, the reference dose (RfD) is 0.58 mg/kg/day. Assuming residues at tolerance levels and that 100% of the crop is being treated, a theoretical maximum residue contribution (TMRC) of 0.000001 mg/kg/day is calculated. With the above assumptions (which lead to a conservative assessment of risk), dietary (food) exposure to pyrithiobac sodium will utilize significantly less than 1% of the RfD for the overall U.S. population. For the most highly exposed subgroup (children aged 1 to 6 years), the TMRC is 0.000001 mg/kg/day, which is still less than 1% of the RfD. Pyrithiobac sodium is classified as a group C carcinogen (possible human carcinogen with limited evidence of carcinogenicity in animals). The unit risk, Q1* $(mg/kg/day)^{-1}$, is 1.05 $x10^{-3}$ $(mg/kg/day)^{-1}$ in human equivalents based on kidney tumors in male rats and mice. Based on this upper bound potency factor (Q1*), a 70–year lifespan, and the assumption that 100% of the crop is treated with pyrithiobac sodium, the upper-bound limit of a dietary carcinogenic risk is calculated in the range of 1 incidence in a billion (1.0×10^{-9}).

ii. *Drinking water*. Other potential dietary sources of exposure of the general population to pesticides are residues in drinking water. There is no maximum contaminant level established for residues of pyrithiobac sodium. Based on maximum exposure estimates developed using screening models, the exposure based on drinking water is less than 0.1% of the RfD. In addition, the Environmental Fate and Effects Division (EFED) of EPA has previously concluded after preliminary evaluation of the results of a prospective ground water monitoring study conducted at a highly vulnerable site that pyrithiobac sodium may not be stable enough to leach to ground water at most use sites, even in sandy soils. Based on the results of environmental fate studies and the conditions of use, the potential for drinking water to contribute to the dietary exposure of pyrithiobac sodium is minimal.

2. *Non-dietary exposure*. Pyrithiobac sodium is not currently registered for any use which could result in non-occupational, non-dietary exposure to the general population.

D. Cumulative Effects

Pyrithiobac sodium is based on a new chemical class; there are no known registered herbicides with similar structure. Therefore, EPA should consider only the potential risks of pyrithiobac sodium in its exposure assessment. The herbicidal activity of pyrithiobac sodium is due to the inhibition of acetolactate synthase (ALS), an enzyme only found in plants. ALS is part of the biosynthetic pathway leading to the formation of branched chain amino acids. Animals lack ALS and this biosynthetic pathway. This lack of ALS contributes to the low toxicity of pyrithiobac sodium in animals. There is no evidence to indicate of suggest that pyrithiobac sodium has any toxic effects on mammals that would be cumulative with those of any other chemical.

E. Safety Determination

1. *U.S. population*. EPA has concluded that no endpoint exists to suggest any evidence of significant toxicity from acute, short-term or immediate-term exposure form the use of pyrithiobac sodium on cotton. Based on a complete and reliable toxicity data base, the EPA has adopted an reference dose (RfD) value of 0.58 mg/kg/day using the NOAEL of 58.7 mg/kg/day, from the 2–year chronic toxicity study in rats and a 100-fold safety factor. Using crop tolerance levels and assuming 100% of the crop being treated a Theoretical Maximum Residue Contribution (TMRC) was calculated for the overall U.S. population and 22 population subgroups. This analysis concluded that aggregate exposure to pyrithiobac sodium will utilize significantly less that 1% of the RfD for either the entire U.S. population or any subgroup population. The TMRC for the most highly exposed subgroup identified as children aged 1 thru 6 years was 0.000001 mg/kg/day. EPA generally has no concern for exposure below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risk to human health. The unit risk, Q1* $(mg/kg/day)^{-1}$, of pyrithiobac sodium is 1.05 $x\ 10^{-3}$ $(mg/kg/day)^{-1}$ in human equivalents based on male kidney tumors. Based on this upper bound potency factor (Q1*) and assuming a 70–year lifetime exposure, an upper-bound limit of a dietary carcinogenic risk is calculated in the range of 1 incidence in a billion (1.0×10^{-9}). This indicates a negligible cancer risk. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure of the U.S. population to pyrithiobac sodium residues.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of pyrithiobac sodium, data from the previously discussed developmental and reproduction toxicity studies were considered. Developmental studies are designed to evaluate adverse effects on developing organism resulting from pesticide exposure during prenatal development. Reproduction studies provide information relating to reproductive and other effects on adults and offspring from prenatal and postnatal exposure to the pesticide. Based on the weight of these data, pyrithiobac sodium was not a

reproductive toxicant. Maternal and developmental effects (NOAELs, LOAELs) were comparable indicating no increase in susceptibility of developing organisms. FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base. Based on current toxicological data requirements, the data base for pyrithiobac sodium relative to prenatal and postnatal effects for children is complete. Since the data indicate that infants and children are not more sensitive to exposure, the standard 100-fold safety factor was used. The NOAEL of 58.7 mg/kg/day from the 2–year rat study with pyrithiobac sodium, which was used to calculate the RfD, is lower than any of the NOAELs defined in the developmental and reproductive toxicity studies with pyrithiobac sodium. As stated above, aggregate exposure assessments utilized significantly less than 1% of the RfD for either the entire U.S. population or any of 22 population subgroups including infants and children. Therefore, it may be concluded that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to pyrithiobac sodium residues.

F. International Tolerances

There are no established Codex MRLs for pyrithiobac sodium on cottonseed. An established Mexican tolerance for pyrithiobac sodium on cottonseed is identical to the U.S. tolerance. Compatibility of tolerance levels is not a issue at this time.

[FR Doc. 01–20133 Filed 8–9–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7029–8]

Notice of Availability: Final Guidance: Coordinating CSO Long-Term Planning With Water Quality Standards Reviews

AGENCY: Environmental Protection Agency (EPA).

ACTION: Availability of final guidance.

SUMMARY: This notice announces that the U.S. Environmental Protection Agency (EPA) is publishing the final Guidance: Coordinating CSO Long-Term Planning with Water Quality Standards Reviews. The guidance addresses questions raised since the publication of the CSO Control Policy in 1994 on coordinating the long-term control plan (LTCP) development process with the water quality standards review. As outlined in the guidance, EPA will continue to implement the CSO Control Policy through its existing statutory and regulatory authorities. The guidance cannot impose legally binding requirements on EPA, States, Tribes, or the regulated community. It cannot substitute for Clean Water Act (CWA) requirements, EPA's regulations, or the obligations imposed by consent decrees or enforcement orders.

ADDRESSES: Interested persons may obtain a copy of the guidance from the EPA's NPDES website at *www.epa.gov/npdes* or by contacting the Office of Water Resources Center at 202–260–7786 (e-mail: *center.water-resource@epa.gov*) or at U.S. Environmental Protection Agency, RC–4100, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Please request Guidance: Coordinating CSO Long-Term Planning with Water Quality Standards Reviews (EPA Number EPA–833–R–01–002; July 2001).

FOR FURTHER INFORMATION CONTACT: Timothy Dwyer, U.S. Environmental Protection Agency, ICC Building (MC 4203M), 1200 Pennsylvania Avenue, NW., Washington, DC, 20460. E-mail address: dwyer.tim@epa.gov. Telephone: 202–564–0717.

SUPPLEMENTARY INFORMATION: EPA issued the Combined Sewer Overflow (CSO) Control Policy in April 1994 (59 FR 18688). To date, EPA has released seven guidance documents and worked with stakeholders to foster implementation of the Policy. The CSO Control Policy calls for the development of a long-term control plan (LTCP), which includes measures that provide for compliance with the Clean Water Act including attainment of water quality standards. The CSO Control Policy provides that the LTCP should be coordinated with the review and revision, as appropriate, of water quality standards and implementation procedures on CSO-impacted receiving waters. This process is intended to ensure that the long-term controls will be sufficient to meet water quality standards (59 FR 18694).

As part of EPA's FY 1999 Appropriation, Congress directed EPA to develop guidance on the conduct of water quality standards and designated use reviews for CSO-receiving waters, and urged EPA to provide technical and financial assistance to States and EPA Regions to conduct these reviews. Further, in December 2000, amendments to the Clean Water Act at section 402(q) required EPA to issue final guidance on this subject by July 31, 2001.

The objective of this guidance is to lay a strong foundation for coordinating CSO long-term control planning with water quality standards reviews. Reaching early agreement among interested parties on the data to be collected and the analyses to be conducted to support the long-term control plan development and water quality standards reviews can facilitate the review of water quality standards and the reconciliation of water quality standards with a well-designed and operated CSO control program.

The guidance describes the process for coordinating LTCP development and implementation with the water quality standards review. This process is the centerpiece of EPA's commitment to assure that both communities with combined sewer systems and States participate in implementing the water quality-based provisions in the CSO Control Policy. The CSO Control Policy anticipates the ''review and revision, as appropriate, of water quality standards and their implementation procedures when developing CSO control plans to reflect site-specific impacts of CSOs.'' Although this coordination is an intensive iterative process, it provides greater assurance that CSO communities will implement CSO control programs to help attain appropriate water quality standards.

This guidance was published as a draft in January 2001 and titled, Draft Guidance on Implementing the Water Quality-Based Provisions in the Combined Sewer Overflow Control Policy (66 FR 364; January 3, 2001). EPA received comments from 27 interested parties. EPA reviewed the comments and made appropriate changes to the draft guidance in response to the submitted comments.

Dated: August 3, 2001.

Diane Regas,

Acting Assistant Administrator for Water.

[FR Doc. 01–20126 Filed 8–9–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7028–3]

Proposed Cercla Administrative Cashout Settlement; City of New Bedford, Massachusetts, New Bedford Industrial Park Superfund Site

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed settlement; request for public comment.