the teleconference to be mailed to the Council or its appropriate subcommittee participants shortly after the teleconference. Written comments may be provided up until the time of the meeting.

Dated: February 24, 1997.
Donald G. Barnes,
Staff Director, Science Advisory Board.
[FR Doc. 97–5309 Filed 3–4–97; 8:45 am]
BILLING CODE 6560–50–P

[PF-705; FRL-5585-6]

Bayer Corporation; 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 tolerance for residues of tebuconazole in or on grapes. This notice contains a summary of the petition that was prepared by the petitioner, Bayer Corporation. **DATES:** Comments, identified by the docket control number PF-705 must be received on or before April 4, 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, Crystal Mall #2, 1921 Jefferson Davis Highway., Arlington, VA 22202.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: oppdocket@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 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number PF-705. 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

Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). No CBI should 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: Connie B. Welch, Product Manager (PM) 21, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 227, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305–6226; e-mail:

welch.connie@epamail.epa.gov. SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition (PP) 6F4669 from Bayer Corp., P.O. Box 4913, 8400 Hawthorne Road, Kansas City, MO 64120-0013, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, to amend 40 CFR 180.474 by establishing tolerances for residues of the fungicide tebuconazole in or on the agricultural commodity grapes at 5.0 ppm. The proposed analytical method for determining residues uses gas-liquid chromatography coupled with a thermionic detector. EPA has determined that the 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 or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

As required by section 408(d) of the FFDCA, as recently amended by the Food Quality Protection Act, (Pub. L. 104–170), Bayer 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 Bayer; 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 may have made minor edits to the summary for the purpose of clarity.

I. Petition Summary

A. Residue Chemistry

1. *Nature of residue*. Bayer believes the nature of the residue in plants and animals is adequately understood. The

- residue of concern is the parent compound only, as specified in 40 CFR 180.474.
- 2. Analytical method. An enforcement method for plant commodities has been validated on various commodities. It has undergone successful EPA validation and has been submitted for inclusion in PAM II. The method should be adequate for grapes. The animal method has also been approved as an adequate enforcement method and will be submitted to FDA for inclusion in PAM II.
- 3. Magnitude of residue. Fifteen separate residue trials have been conducted and submitted to the EPA with tebuconazole on grapes. The EPA has determined that these data show that residues of tebuconazole, α -[2-(4 -Chlorophenyl)ethyl]- α -(1,1 dimethylethyl)-*H*-1,2,4-triazole-1ethanol, are not expected to exceed 5 ppm in grapes as a result of the proposed use. Processing data show that residue of tebuconazole do not concentrate in grape juice and that a tolerance is not required in or on raisins. In addition, since grapes are not normally rotated, the nature of residue in rotational crops is not of concern.

B. Toxicological Profile

The following mammalian toxicity studies have been conducted to support the tolerances of tebuconazole:

- 1. Acute toxicity. i. Rat acute oral study with an LD_{50} of >5,000 milligrams/kilogram (mg)/(kg) (male) and 3,933 mg/kg (female).
- ii. Rabbit acute dermal of LD_{50} of >5,000 mg/kg.
- iii. Rat acute inhalation of LC₅₀ of >0.371 mg/liter(l).
- iv. Primary eye irritation study in the rabbit which showed mild irritation reversible by day 7.
- v. Primary dermal irritation study which showed no skin irritation.
- vi. Primary dermal sensitization study which showed no sensitization.
- 2. Genotoxicity. i. An Ames mutagenesis study in Salmonella showed no mutagenicity with or without metabolic activation.
- ii. A micronucleus mutagenesis assay study in mice showed no genotoxicity.
- iii. A sister chromatid exchange mutagenesis study using CHO cells was negative at dose levels 4 to 30 micrograms/milliliter (μ g/mL) without activation or 15 to 120 μ g/mL with activation.
- iv. An unscheduled DNA synthesis (UDS) study was negative for UDS in rat hepatocytes.
- 3. Reproductive and developmental toxicity. i. A rat oral developmental toxicity study with a maternal no

observed effect level (NOEL) of 30 milligrams per kilogram of body weight per day (mg/kg bw/day) and an lowest effect level (LEL) of 60 mg/kg bw/day based on elevation of absolute and relative liver weights. For developmental toxicity, a NOEL of 30 mg/kg bw/day and an LEL of 60 mg/kg bw/day was determined, based on delayed ossification of thoracic, cervical and sacral vertebrae, sternum, fore and hind limbs and increase in supernumerary ribs.

ii. A rabbit oral developmental toxicity study with a maternal NOEL of 30 mg/kg bw/day and an LEL of 100 mg/kg bw/day based on depression of body weight gains and food consumption.

iii. A developmental NOEL of 30 mg/kg bw/day and an LEL of 100 mg/kg bw/day were based on increased post-implantation losses, from both early and late resorptions and frank malformations in eight fetuses of five litters.

iv. A mouse oral developmental toxicity study with a maternal NOEL of 10 mg/kg bw/day and an LEL of 20 mg/kg bw/day based on a supplementary study indicating reduction in hematocrit and histological changes in liver.

v. A developmental NOEL of 10 mg/kg bw/day and an LEL of 30 mg/kg bw/day based on dose-dependent increases in runts/dam at 30 and 100 mg/kg bw/day

vi. A mouse dermal developmental toxicity study with a maternal NOEL of 30 mg/kg bw/day and an LEL of 60 mg/kg bw/day based on a supplementary study indicating increased liver microsomal enzymes and histological changes in liver.

vii. The NOEL for developmental toxicity in the dermal study in the mouse is 1,000 mg/kg bw/day, the highest dose tested (HDT).

viii. A 2-generation rat reproduction study with a dietary maternal NOEL of 15 mg/kg bw/day (300 ppm) and an LEL of 50 mg/kg bw/day (1,000 ppm) based on depressed body weights, increased spleen hemosiderosis, and decreased liver and kidney weights.

ix. A reproductive NOEL of 15 mg/kg bw/day (300 ppm) and an LEL of 50 mg/kg bw/day (1,000 ppm) were based on neonatal birth weight depression.

4. Subchronic toxicity. i. A 28-day feeding study in the rat with a NOEL of 30 mg/kg/day and a LEL of 100 mg/kg/day based on changes in hematology and clinical chemistry parameters.

ii. A 90–day rat feeding study with a NOEL of 34.8 mg/kg bw/day (400 ppm) and an LEL of 171.7 mg/kg bw/day (1,600 ppm) in males, based on decreased body weight gains and histological changes in the adrenals. For

females, the NOEL was 10.8 mg/kg bw/day (100 ppm) and the LEL was 46.5 mg/kg bw/day (400 ppm) based on decreased body weights, decreased body weight gains, and histological changes in the adrenals.

iii. A 90-day dog-feeding study with a NOEL of 200 ppm (73.7 mg/kg bw/day in males and 73.4 mg/kg bw/day in females) and an LEL of 1,000 ppm (368.3 mg/kg bw/day in males and 351.8 mg/kg bw/day in females). The LEL was based on decreases in mean body weights, body weight gains, and food consumption, and an increase in liver *N*-demethylase activity.

5. Chronic toxicity. i. A 2-year rat chronic feeding study defined a NOEL of 7.4 mg/kg bw/day (100 ppm) and an LEL of 22.8 mg/kg bw/day (300 ppm) based on body weight depression, decreased hemoglobin, hematocrit, MCV and MCHC, and increased liver microsomal enzymes in females. Tebuconazole was not oncogenic at the dose levels tested (0, 100, 300, and 1,000 ppm).

ii. A 1-year dog feeding study with a NOEL of 1 mg/kg bw/day (40 ppm) and an LEL of 5 mg/kg bw/day (200 ppm), based on lenticular and corneal opacity and hepatic toxicity in either sex (the current Reference Dose was determined based on this study). A subsequent 1-year dog feeding study, using lower doses to further define the NOEL for tebuconazole, defines a systemic LOEL of 150 ppm (based on adrenal effects in both sexes) and a systemic NOEL of 100 ppm

iii. A mouse oncogenicity study at dietary levels of 0, 20, 60, and 80 ppm for 21 months did not reveal any oncogenic effect for tebuconazole at any dose tested. Because the maximumtolerated-dose (MTD) was not reached in this study, the study was classified as supplementary. A follow-up mouse study at higher doses (0, 500, and 1,500 ppm in the diet), with an MTD at 500 ppm, revealed statistically significant incidences of hepatocellular adenomas and carcinomas in males and carcinomas in females. The initial and follow-up studies, together with supplementary data were classified as core minimum.

6. Animal metabolism. A general rat metabolism study at dietary levels of 2 and 20 mg/kg showed rapid elimination from the rat in 3 days (some 99 percent excreted by the feces and urine and 0.0304 percent in expired air). Increased concentrations of radioactivity from the active ingredient and metabolites were found only in the liver. The bones and the brain were among the tissues showing the least amount of radioactivity.

7. Metabolite toxicity. The residue of concern in plants is the parent compound, tebuconazole, only. For animal commodities, the EPA has determined that the tolerance expression should include the HWG 2061 metabolite, α -[2-(4 -Chlorophenyl)ethyl]- α -[(2-hydroxy-1,1dimethyl)ethyl]-1H-1,2,4-triazole-1ethanol. An acute oral toxicity study has been submitted to the EPA on this metabolite. This study shows an oral LD_{50} of >5,000 for female rats. This value indicates that the HWG 2061 metabolite is relatively innocuous and less acutely toxic than tebuconazole.

8. Endocrine effects. No special studies investigating potential estrogenic or endocrine effects of tebuconazole have been conducted. However, the standard battery of required studies has been completed. These studies 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. These studies are generally considered to be sufficient to detect any endocrine effects but no such effects were noted in any of the studies with either tebuconazole or its metabolites.

9. Carcinogenicity. EPA's Carcinogenicity Peer Review Committee (CPRC) has classified tebuconazole as a Group C carcinogen (possible human carcinogen). This classification is based on the Agency's "Guidelines for Carcinogen Risk Assessment" published in the Federal Register of September 24, 1986 (51 FR 33992). The Agency has chosen to use the reference dose calculations to estimate human dietary risk from tebuconazole residues. The decision supporting classification of tebuconazole as a possible human carcinogen (Group C) was primarily based on the statistically significant increase in the incidence of hepatocellular adenomas, carcinomas, and combined adenomas/carcinomas in both sexes of NMRI mice both by positive trend and pairwise comparison at the HDT.

C. Aggregate Exposure

1. Dietary (food) exposure. For purposes of assessing the potential dietary exposure from food under the proposed tolerances, Bayer has estimated exposure based on the Theoretical Maximum Residue Contribution (TMRC) derived from the previously established tolerances for tebuconazole on cherries, peaches, bananas, barley, oats, wheat, and peanuts as well as the proposed tolerances for tebuconazole on grapes at 5.0 ppm. The TMRC is obtained by

using a model which multiplies the tolerance level residue for each commodity by consumption data which estimate the amount of each commodity and products derived from the commodities that are eaten by the U.S. population and various population subgroups. In conducting this exposure assessment, very conservative assumptions - 100 percent of all commodities will contain tebuconazole residues, and those residues would be at the level of the tolerance — which result in a large overestimate of human exposure. Thus, in making a safety determination for these tolerances, Bayer took into account this very conservative exposure assessment.

2. Dietary (drinking water) exposure. There is no Maximum Contaminant Level established for residues of tebuconazole. Bayer was advised by the EPA's Environmental Fate and Ground Water Branch's (EFGWB) May 26, 1993 memorandum for our application for use on bananas and peanuts that all environmental fate data requirements for tebuconazole were satisfied. The EFGWB had determined that tebuconazole is resistant to most degradative processes in the environment, including hydrolysis, photolysis in water and aerobic and anaerobic metabolism. Only minor degradation occurred in soil photolysis studies. The photolytic half-life of tebuconazole is 19 days. Laboratory and field studies have shown that the mobility of tebuconazole in soil is minimal. Therefore, tebuconazole bears no apparent risk to ground water under most circumstances.

3. Non-dietary exposure. Although current registrations and the proposed use on grapes are limited to commercial crop production, Bayer has submitted an application to register tebuconazole on turf. Bayer has conducted an exposure study designed to measure the upper bound acute exposure potential of adults and children from contact with tebuconazole treated turf. The population considered to have the greatest potential exposure from contact with pesticide treated turf soon after pesticides are applied are young children. Margins of exposure of 1,518 to 8,561 for 10-year-old children and 1,364 to 7,527 for 5-year-old children were estimated by comparing dermal exposure doses to the tebuconazole noobservable effect level of 1,000 mg/kg/ day established in a subacute dermal toxicity study in rabbits. The estimated safe residue levels for tebuconazole on treated turf for 10-year-old children ranged from 4.8 to 27.3 micrograms per square centimeter (µg/cm²) and for 5year-old children from 4.4 to 24.0 μg/

cm². This compares with the average tebuconazole transferable residue level of $0.319~\mu g/cm^2$ present immediately after the sprays have dried. These data indicate that children can safely contact tebuconazole-treated turf as soon after application as the spray has dried.

D. Cumulative Effects

At this time, the EPA has not made a determination that tebuconazole and other substances that may have a common mechanism of toxicity would have cumulative effects. Therefore, for this tolerance, only the potential risks of tebuconazole in its aggregate exposure are considered.

E. Safety Determination

1. U.S. population. Based on a complete and reliable toxicity database, the EPA has adopted an RfD value of 0.03 mg/kg/day. This RfD is based on a 1-year dog study with a NOEL of 2.96 mg/kg/day and an uncertainty factor of 100. Using the conservative exposure assumptions described above, Bayer has determined that aggregate dietary exposure to tebuconazole from the previously established and the proposed tolerances will utilize 7.1 percent of the RfD for the U.S. population (48 states) and 29.5 percent of the RfD for the most highly exposed population subgroup (children 1 to 6 years old). There is generally no concern for exposures below 100 percent of the RfD because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. Therefore, there is a reasonable certainty that no harm will result from aggregate exposure to tebuconazole.

2. Infants and children. In assessing the potential for additional sensitivity of infants and children to residues of tebuconazole, the data from developmental studies in both the rat and rabbit and a 2-generation reproduction study in the rat should be considered. The developmental toxicity studies evaluate any potential adverse effects on the developing animal resulting from pesticide exposure of the mother during prenatal development. The reproduction study evaluates any effects from exposure to the pesticide on the reproductive capability of mating animals through two generations, as well as any observed systemic toxicity.

A developmental toxicity study in the rat, a developmental toxicity study in the rabbit, two developmental studies in the mouse and a 2–generation rat reproduction study have been conducted with tebuconazole. Maternal and developmental toxicity NOELs of 30 mg/kg/day were determined in the rat

and rabbit studies. An oral mouse developmental toxicity study had maternal and developmental toxicity NOELs of 10 mg/kg/day while the mouse dermal developmental study had a maternal NOEL of 30 mg/kg/day and a developmental toxicity NOEL of 1,000 mg/kg/day. The parental and reproductive NOELs in the 2-generation rat reproduction study were determined to be 15 mg/kg/day (300 ppm). In all cases, the reproductive and developmental NOELs were greater than or equal to the parental NOELs. Bayer concludes that this indicates that tebuconazole does not pose any increased risk to infants or children.

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 pre-and post-natal effects and the completeness of the toxicity database. Based on current toxicological data requirements, the toxicology database for tebuconazole relative to pre-and post-natal effects is complete. Further for tebuconazole, the NOEL of 2.96 mg/kg/bw from the 1-year dog study, which was used to calculate the RfD, is already lower than the NOELs from the developmental studies in rats (30 mg/kg bw/day) and rabbits (30 mg/kg bw/day) by a factor of 10 times. Since a 100-fold uncertainty factor is already used to calculate the RfD, Bayer surmises that an additional uncertainty factor is not warranted and that the RfD at 0.03 mg/kg/bw/day is appropriate for assessing aggregate risk to infants and children.

Using the conservative exposure assumptions, Bayer has determined from a chronic dietary analysis that the percent of the RfD utilized by aggregate exposure to residues of tebuconazole ranges from 9.2 percent for children 7 to 12 years old up to 29.5 percent for children 1 to 6 years old. EPA generally has no concern for exposure below 100 percent of the RfD. Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, Bayer concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the residues of tebuconazole, including all anticipated dietary exposure and all other non-occupational exposures.

F. International Issues

No Codex Maximum Residue Level (MRL) have been established for residues of tebuconazole on any crops at this time. A Codex MRL of 2.0 ppm for residues of tebuconazole on grapes has been proposed. There are no established tolerances for tebuconazole in or on grapes in Canada and Mexico.

G. Mode of Action

Tebuconazole, the active ingredient of Folicur 3.6 F is a sterol demethylation inhibitor (DMI) fungicide. It is systemic and shows activity against powdery mildew and black rot infecting grapes. Tebuconazole provides protective activity by preventing completion of the infection process by direct inhibition of sterol synthesis. It is rapidly absorbed by plants and translocated systemically in the young growing tissues.

II. Public Record

EPA invites interested persons to submit comments on this notice of filing. Comments must bear a notification indicating the docket control number PF–705.

A record has been established for this notice docket under docket control number PF-705 (including any 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 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 an ASCII file avoiding the use of special characters and any form of encryption. The official record for this notice of filing, 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. Dated: February 19, 1997.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97-5200 Filed 3-4-97; 8:45 am] BILLING CODE 6560-50-F

[PF-579A; FRL-5587-1]

Novartis; Pesticide Petition Withdrawal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of withdrawal of pesticide petition.

SUMMARY: EPA is withdrawing a pesticide petition from Novartis (formerly known as Ciba-Geigy Corporation) for the combined residues of the insecticide cyromazine, (*N* cyclopropyl-1,3,5-triazine-2,4,6-triamine plus its major metabolite, melamine, 1,3,5-triazine-2,4-6-triamine) for use in or on certain commodites.

FOR FURTHER INFORMATION CONTACT:
George T. LaRocca, Product Manager
(PM) 13, Registration Division, (7505C),
Office of Pesticide Programs,
Environmental Protection Agency, 401
M. St., SW., Washington, DC 20460.
Office location, telephone number and
e-mail address: Rm. 200, CM#2, 1921
Jefferson Davis Highway, Arlington, VA;
703–305–6100; e-mail:
larocca.george@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA in a notice issued in the Federal Register of August 18, 1993 (58 FR 43892), announced that Novartis, P.O. Box 18300, Greensboro, NC 27419, had filed a pesticide petition (PP) 6F3422 proposing to amend 40 CFR part 180.414 to establish tolerances for the combined residues of the insecticide cyromazine, (N cyclopropyl-1,3,5triazine-2,4,6-triamine plus its major metabolite, melamine, 1,3,5-triazine-2,4-6-triamine) for use in or on cabbage, sweet potatoes, sugar beets (roots and tops), and sorghum (grain, forage and fodder). The tolerances were to cover residues resulting from the planting of these crops as rotational crops following the harvest of cyromazine treated crops. On August 26, 1996 Novartis notified EPA that it requests that the petition be withdrawn without prejudice to future filing. The Agency has withdrawn the subject pesticide petition.

List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural Commodities, Pesticides and pests, Reporting and recordkeeping requirements. Dated: February 17, 1997.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97–4884 Filed 3–4–97; 8:45 am] BILLING CODE 6560-50-F

[PF-700; FRL-5586-1]

Rhone-Poulenc Ag Company; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection

Agency (EPA).

ACTION: Notice of filing.

Arlington, VA 22202.

SUMMARY: This notice announces the filing of a pesticide petition proposing to establish tolerances for residues of thiodicarb and its metabolite in or on leafy vegetables, broccoli, cabbage and cauliflower. The notice includes a summary of the petition prepared by the petitioner, Rhone-Poulenc Ag Company. DATES: Comments, identified by the docket control number [PF-700], must be received on or before, April 4, 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, Crystal Mall #2, 1921 Jefferson Davis Highway,

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: oppdocket@epamail.epa.gov. Electronic comments must be submitted either as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be acceped 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 control number [PF-700]. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below this document.

Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. No CBI should be submitted through email. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record.