List of Subjects in 40 CFR Part 180

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

Dated: April 3, 1998.

Stephen L. Johnson,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. By adding § 180.527, to read as follows:

§ 180.527 N-(4-fluorophenyl)-N-(1-methylethyl)-2-[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl]oxy]acetamide; tolerances for residues.

(a) *General.* (1) Time-limited tolerances are established for combined residues of the herbicide, *N*-(4-fluorophenyl)-*N*-(1-methylethyl)-2-[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl]oxy]acetamide and its metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration/Revocation Date
Corn, field, forage ..	0.05	4/30/03
Corn, field, grain	0.4	4/30/03
Corn, field, stover ...	0.4	4/30/03
Soybean seed	0.1	4/30/03

(2) Residues in these commodities not in excess of the established tolerance resulting from the use described in paragraph (a) of this section remaining after expiration of the time-limited tolerance will not be considered to be actionable if the herbicide is applied during the term of and in accordance with the provisions of the above regulation.

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

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

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 98–9549 Filed 4–7–98; 4:39 pm]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300643; FRL–5785–1]

RIN 2070–AB78

Cyprodinil; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyprodinil, 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine in or on the folowing commodities: almond hulls at 0.05 ppm; almond nutmeats at 0.02 ppm; apple pomace, wet at 0.15 ppm; grapes at 2.0 ppm; pome fruit at 0.1 ppm; raisins at 3.0 ppm and stone fruit at 2.0 ppm. Novartis Crop Protection, Inc. requested these tolerances under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170).

DATES: This regulation is effective April 10, 1998. Objections and requests for hearings must be received by EPA on or before June 9, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300643], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300643], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300643]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Mary L. Waller, Acting 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: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9354, e-mail: waller.mary@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 2, 1997 (64 FR 15690)(FRL–5593–9) EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of pesticide petitions (PP 6F4656 and 6H5746) for tolerances by Novartis Crop Protection, Inc. Greensboro, NC 27419 (formerly Ciba Crop Protection). This notice included a summary of the petitions prepared by Novartis Crop Protection, Inc., the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide cyprodinil, 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine in or on the following commodities: almond hulls at 0.05 ppm; almond nutmeats at 0.02 ppm; apple pomace, wet at 0.15 ppm; grapes at 2.0 ppm; pome fruit at 0.1 ppm; raisins at 3.0 ppm and stone fruit at 2.0 ppm.

Note that the scientific assessments relevant to establishing these tolerances for cyprodinil were conducted jointly between EPA and the Pest Management Regulatory Agency (PMRA) of Canada as a pilot project under the North American Free Trade Agreement (NAFTA) and the Canadian United States Trade Agreement (CUSTA). Cyprodinil qualified as the first candidate for such a pilot program due to its classification as a reduced risk pesticide.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is

''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue***.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This hundredfold MOE is based on the same rationale as the hundredfold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1–day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1–7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1–7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue

Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup, non-nursing infants, was not regionally based.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. Reviews of the submitted data were conducted under a joint review between Pest Management Regulatory Agency (PMRA), Canada and the EPA. EPA has sufficient data to assess the hazards of cyprodinil and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of cyprodinil in or on these commodities: almond hulls at 0.05 ppm; almond nutmeats at 0.02 ppm; apple pomace, wet at 0.15 ppm; grapes at 2.0 ppm; pome fruit at 0.1 ppm; raisins at 3.0 ppm and stone fruit at 2.0 ppm.

EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. 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 cyprodinil are discussed below.

1. *Acute toxicity.* The acute toxicity data of cyprodinil show that this chemical is not acutely toxic by the oral, inhalation and dermal routes of exposure. Technical cyprodinil, however, is a dermal sensitizer.

2. *Subchronic toxicity.* i. In a range-finding subchronic toxicity study, cyprodinil was administered in the diet to rats at 0, 100, 600, 3,000 or 15,,000 ppm (males - 0, 10.3, 64.8, 316 or 1460 milligrams/kilogram/day (mg/kg/day); females - 0, 10.1, 62.2, 299 or 1390 mg/kg/day) for 28 days. In this study, the LOEL is 3,000 ppm (316 and 299 mg/kg/day for males and females respectively) based on lower bodyweight gains, microcytosis, increased cholesterol and phospholipid levels and hepatocyte hypertrophy. The NOEL is 600 ppm (64.8 and 62.2 mg/kg/day for males and females respectively).

ii. In a subchronic toxicity study, cyprodinil was administered to rats by gavage at dose levels of 0, 10, 100, or 1,000 mg/kg/day for 28 days. In this study, the LOEL is 100 milligrams/kilogram body weight/day (mg/kg bwt/day) for rats, based on increased liver weights and abnormalities in liver morphology. The NOEL is 10 mg/kg bwt/day.

iii. In a subchronic toxicity study, cyprodinil was administered in the diet to rats at dose levels of 0 or 12,000 ppm (0 or 810 mg/kg/day, respectively, for males; 0 or 803 mg/kg/day, respectively, for females), and to rats at dose levels of 50, 300, or 2,000 ppm (3.14, 19.0, or 134 mg/kg/day, respectively, for males; 3.24, 19.3, or 137 mg/kg/day for females) for 90 days. In this study, the LOEL is 300 ppm (19 mg/kg bwt/day) for rats, based on increased chronic tubular kidney lesions in males. The NOEL is 50 ppm (3.14 mg/kg/day).

iv. A 3–month range-finding study was carried out in mice where animals were fed diets containing 0, 500, 2,000 or 6,000 ppm (actual doses: males - 0, 73.3, 257 or 849 mg/kg/day; females - 0, 103, 349 or 1,121 mg/kg/day) of cyprodinil. In this study, the LOEL is 2,000 ppm based on histopathological changes in the liver. The NOEL is 500 ppm (males - 73.3; females - 103 mg/kg/day).

v. A 3–month study was carried out in Beagle dogs where animals were fed diets containing 0, 200, 1,500, 7,000 or 20,000 ppm (actual doses: males - 0, 6.07, 45.87, 210.33 or 559.66 mg/kg/day; females - 0, 6.79, 52.75, 231.93 or 580.95 mg/kg/day) of cyprodinil. In this study, the LOEL is 20,000 ppm (males - 560, females - 581 mg/kg/day) based on lower bodyweight gains and decreased food consumption in both sexes. The NOEL is 7,000 ppm (males - 210, females - 232 mg/kg/day).

vi. Groups of rats received repeated dermal applications of cyprodinil at doses of 0, 5, 25, 125 or 1,000 mg/kg/day, 6 hours/day, 5 days /week over a 28-day period. Hunched posture was observed in females at 125 mg/kg/day. In this study, the LOEL is 25 mg/kg/day for female rats and 1,000 mg/kg/day for male rats, based on alterations in clinical signs (piloerection). The NOEL is 5 mg/kg/day for females and 125 mg/kg/day for males.

3. *Chronic toxicity.* i. A 24–month chronic toxicity/carcinogenicity study was carried out in rats where animals (50 rats/sex/dose - carcinogenicity portion, plus 20/sex/dose laboratory investigations) were fed diets containing 0, 5, 75, 1,000 or 2,000 ppm cyprodinil (actual doses: males - 0, 0.177, 2.7, 35.6 or 73.6 mg/kg/day; females - 0, 0.204, 3.22, 41.2 or 87.1 mg/kg/day). An additional 10/sex/dose were fed test diets for 12 months (interim sacrifice). In this study the LOEL is 1,000 ppm (35.6 mg/kg/day) based on the degenerative liver lesions (spongiosis hepatis) in males. The NOEL for chronic toxicity is set at 75 ppm (2.7 mg/kg/day).

ii. In a chronic toxicity study, cyprodinil was administered to five Beagle dogs/sex/dose in the diet at dose levels of 25, 50, or 100 ppm for females (0.7, 1.6, or 3.1 mg/kg/day, respectively) and 50, 100, or 200 ppm for males (1.8, 3.0, or 5.7 mg/kg/day, respectively) for 52 weeks. An additional 1–year study was carried out in Beagle dogs where animals (4/sex/dose) were fed diets containing 0, 25, 250, 2,500 or 15,000 ppm (actual doses: males - 0, 0.72, 6.87, 65.63 or 449.25; females - 0, 0.76, 6.80, 67.99 or 446.37 mg/kg/day) cyprodinil. In this study, the LOEL is 15,000 ppm (males - 449.25, females 446.37 mg/kg/day) based on lower bodyweight gains and decreased food consumption and food efficiency. The NOEL is 2,500 ppm (males - 65.63, females - 67.99 mg/kg/day).

4. *Carcinogenicity*. i. For the discussion of the rat study, see Unit II.A.3.i. of this preamble. This study was tested to adequate levels based on signs of toxicity in males at 2,000 ppm and females at 5,000 ppm. There was no indication of carcinogenic potential at any dose level.

ii. An 18–month carcinogenicity study was carried out in mice where animals (50 mice/sex/dose - carcinogenicity portion, plus 10/sex/dose - hematology) were fed diets containing 0, 10, 150, 2,000 or 5,000 ppm (actual doses: males - 0, 1.15, 16.1, 212.4 or 630; females - 0, 1.08, 14.7, 196.3 or 558.1 mg/kg/day) of cyprodinil. In this study the LOEL is 2,000 ppm (males - 212.4 mg/kg/day) based on a dose-related increase in the incidence of focal and multifocal hyperplasia of the exocrine pancreas in males. The NOEL is 150 ppm (males - 16.1 mg/kg/day). This study was tested to adequate levels based on signs of toxicity in males at 2,000 ppm and females at 5,000 ppm. There was no indication of carcinogenic potential at any dose level.

5. *Developmental toxicity*. i. In a developmental toxicity study, cyprodinil was administered in 3% aqueous corn starch suspension by oral gavage to 20–23 female rats per dose of 0, 20, 200 or 1,000 mg/kg/day or gestation days 6–15. The LOEL for maternal toxicity is 1,000 mg/kg/day based on lower bodyweight/bodyweight gain and reduced food consumption. The NOEL for maternal toxicity was 200 mg/kg/day. The LOEL for developmental toxicity is 1,000 mg/kg/day based on lower mean fetal weights and an increased incidence of delayed ossification. The NOEL for developmental toxicity is 200 mg/kg/day.

ii. In a developmental toxicity study, cyprodinil was administered in 3% aqueous corn starch suspension to 19 inseminated female rabbits, dosed by gavage at dose levels of 0, 5, 30, 150, or 400 mg/kg/day from days 7 through 19 of gestation. In this study, the maternal LOEL is 400 mg/kg/day, based on decreased body weight gain. The maternal NOEL is 150 mg/kg/day. The fetal developmental LOEL is 400 mg/kg/day based on a slight increase of litters showing extra (13th) ribs. The fetal developmental NOEL is 150 mg/kg/day.

6. *Reproductive toxicity*. A two-generation reproduction study was carried out in rats, with one litter per generation. Animals (30 rats/sex/dose) received cyprodinil in the diet at doses of 0, 10, 100, 1,000 or 4,000 ppm (actual intake males - 0, 0.7, 6.7, 68 or 273; females - 0, 0.8, 8.2, 81 or 326 mg/kg/day) for a 10 week pre-mating period. In this study, the LOEL for maternal systemic toxicity is 4,000 (about 326 mg/kg/day) based on lower body weights in the F_0 females during the pre-mating period. The NOEL for maternal systemic toxicity is 1,000 ppm (about 81 mg/kg/day). The LOEL for reproductive/developmental toxicity is 4,000 ppm (about 326 mg/kg/day) based on decreased pup weights (F_1 and F_2). The NOEL for reproductive toxicity is 1,000 ppm (about 81 mg/kg/day).

7. *Neurotoxicity*. Neurotoxicity studies were not required for this chemical.

8. *Mutagenicity*. Mutagenicity studies with cyprodinil included gene mutation assays in bacterial and mammalian cells, a mouse micronucleus assay and *in vivo* unscheduled DNA synthesis (UDS) assays. The results were negative for mutagenicity in all studies.

9. *Metabolism*. In a metabolism study, single oral doses (0.5 or 100 mg/kg bwt) of phenyl or pyrimidyl-radiolabelled cyprodinil were administered to rats, with one low-dose group receiving unlabeled cyprodinil for 2 weeks prior to treatment with radiolabelled compound. Absorption was very rapid (t_{cmax}= 0.3 hours) with rapid clearance ($t_{cmax/2}$=1.2 hours). A minimum of 75% of the administered dose was absorbed. A biphasic first order kinetics was observed for radioactivity depletion, with a duration of 0.3–1.2 hours for the first phase, and 27–65 hours for the second phase. Excretion was rapid and almost complete, with urine as the principle route of excretion (48–68%), and > 90% of the administered dose detected in the urine and feces within 48 hours. Tissue residues declined rapidly, with the highest concentrations (≧ 1.8 ppm) found in kidneys, liver, lungs, spleen, thyroid, whole blood, and carcass. The urine, fecal, and bile metabolite patterns were complex, with 8 and 9 defined metabolite fractions, respectively. Unchanged parent compound was detected in feces extract only. Excretion, distribution and metabolite profiles were essentially independent of dose level, pretreatment, and type of label, although there were some sex-dependent qualitative differences in two urinary metabolite fractions.

Excreta (Group D1 and D2) and bile (Group G1) from radiolabelled cyprodinil-treated rats were used to characterize, isolate and identify metabolites of cyprodinil. Eleven metabolites were isolated from urine, feces and bile, and the metabolic pathways in the rat were proposed. All urinary and biliary metabolites (with the exception of 7U) were conjugated with glucuronic acid or sulfonated, and excreted. Cyprodinil was almost completely metabolized by hydroxylation of the phenyl ring (position 4) or pyrimidine ring (position 5), followed by conjugation. An alternative pathway involved oxidation of the phenyl ring followed by glucuronic acid conjugation. A quantitative sex difference was observed with respect to sulfonation of the major metabolite that formed 6U. The monosulfate metabolite (1U) was predominant in females, whereas equal amounts of mono- and disulfate (6U) conjugates were noted in males. Most of the significant metabolites in feces were exocons of biliary metabolites (2U, 3U, 1G). These were assumed to be deconjugated in the intestines, partially reabsorbed into the general circulation, conjugated again, and eliminated renally. The major metabolic pathways of cyprodinil were not significantly influenced by the dose, treatment regimen, or sex of the animal.

B. Toxicological Endpoints

1. *Acute toxicity*. No effects that could be attributed to a single exposure (dose) were observed in oral toxicity studies including the developmental toxicity studies in rats and rabbits. Therefore, a dose and endpoint were not identified for acute dietary risk assessment.

2. *Short- and intermediate-term toxicity*. The dose of 25 mg/kg/day was selected as the toxicological endpoint for short- and intermediate-term risk calculations based on the repeated dose study in rats resulting in hunched postures in female rats at 125 mg/kg/day.

3. *Chronic toxicity*. EPA has established the RfD for cyprodinil at 0.03 mg/kg/day. This RfD is based on a chronic rat study with a NOEL of 2.7 mg/kg/day and an Uncertainty Factor of 100. Effects seen at the LOEL, 35.6 mg/kg/day, were histopathological alternations in the liver (spongiosis hepatis) in males.

4. *Carcinogenicity*. Based on the lack of evidence of carcinogenicity in mice and rats at doses that were judged to be adequate to assess the carcinogenic potential, cyprodinil was classified as ''not likely'' human carcinogen according to EPA Proposed Guidelines for Carcinogen Risk Assessment (April 10, 1996).

C. Exposures and Risks

1. *From food and feed uses*. Currently, there are no established tolerances (40 CFR part 180) for the residue of cyprodinil, in or on any raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary

exposures and risks from cyprodinil as follows:

i. *Acute exposure and risk*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. No effects that could be attributed to a single exposure (dose) were observed in oral toxicity studies including the developmental toxicity studies in rats and rabbits. Therefore, a dose and endpoint were not identified for acute dietary risk assessment.

ii. *Chronic exposure and risk*. Chronic dietary (food only) exposure estimates were calculated by using the proposed tolerance levels for all pome fruit, stone fruit, almond and grape commodities. The required tolerances result in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to the following percent of the RfD: (only values greater than those for the U.S. population are listed below)

Subgroups	Percent of RFD
U.S. population (48 states)	5.8
Non-Hispanic White	6.2
Nursing Infants (< 1 year old) ...	14.0
Non-Nursing Infants (< 1 year old)	27.0
Females (13+ years, nursing) ..	6.5
Children (1–6 years old)	15.0
Children (7–12 years old)	7.5

EPA does not consider the chronic dietary risk to exceed the level of concern.

2. *From drinking water*—i. *acute exposure and risk*. No acute endpoint was identified, therefore no drinking water risk assessment is presented.

ii. *Chronic exposure and risk*. The drinking water levels of concern (DWLOC) are 990 parts per billion (ppb) for U.S. population and 200 ppb for non-nursing infants. The estimated maximum concentration in surface water is 16 ppb. The estimated average concentration in surface water is expected to be less than 16 ppb. Chronic concentrations in groundwater are not expected to be higher than the acute concentrations. The maximum estimated concentrations of cyprodinil in surface water are less than OPP's levels of concern for cyprodinil in drinking water as a contribution to acute aggregate exposure. Also, the estimated average concentrations in groundwater are less than OPP's levels of concern for cyprodinil in drinking water as a contributor to chronic aggregate exposure. Therefore, taking into account the proposed uses in this action, EPA concludes with reasonable certainty that residues of cyprodinil in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk.

EPA bases this determination on a comparison of estimated concentrations of cyprodinil in surface water and groundwaters to back-calculated ''levels of concern'' for cyprodinil in drinking water. These levels of concern in drinking water were determined after EPA has considered all other non-occupational exposures for which it has reliable data, including all uses considered in this action. The estimates of cyprodinil in surface water are derived from water quality models that use conservative assumptions (health-protective) regarding the pesticide transport from the point of application to surface and ground water.

3. *From non-dietary exposure*. Cyprodinil is not currently registered for use on residential non-food sites. Therefore residential risk assessments are not required.

4. *Cumulative exposure to substances with common mechanism of toxicity*. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

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

EPA does not have, at this time, available data to determine whether cyprodinil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, cyprodinil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that cyprodinil has a common mechanism of toxicity with other substances.

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk*. There was no acute dietary endpoint identified, since cyprodinil does not pose acute dietary risk.

2. *Chronic risk*. Using the Theoretical Maximum Residue Contribution (TMRC) exposure assumptions described above, EPA has concluded that aggregate exposure to cyprodinil from food will utilize 5.8% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants (< 1 year old) discussed below. EPA generally has no concern for exposures 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 risks to human health. Despite the potential for exposure to cyprodinil in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from

aggregate exposure to cyprodinil residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*— i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of cyprodinil, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intra-species variability)) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* In a prenatal developmental toxicity study, rats received oral administration of cyprodinil in 3.0% aqueous corn starch suspension at dose levels of 0, 20, 200 or 1,000 mg/kg/day during gestation days 6 through 15. For maternal toxicity, the NOEL was 200 mg/kg/day, and the LOEL was 1,000 mg/kg/day based on decreased body weight, decreased body weight gain, and decreased food consumption. For developmental toxicity, the NOEL was 200 mg/kg/day, and the LOEL was 1,000 mg/kg/day based on increased incidence of skeletal variations (primarily absent or reduced ossification of the metacarpals) and on decreased mean fetal weight.

In a prenatal developmental toxicity study, New Zealand White rabbits (19/group) received oral administration of cyprodinil in 3.0% corn starch suspension (4 ml/kg) at dose levels of 0, 5, 30, 150 or 400 mg/kg/day during gestation days 7 through 19. For maternal toxicity, the NOEL was 150 mg/kg/day and the LOEL was 400 mg/kg/day based on decreased body weight gain during the treatment period. For developmental toxicity, the NOEL was 150 mg/kg/day and the LOEL was 400 mg/kg/day, based on an increased incidence of 13th rib.

iii. *Reproductive toxicity study*. In a two-generation reproduction study, rats (30/sex/group) were fed diets containing cyprodinil at does levels of 0, 10, 100, 1,000 or 4,000 ppm (0.7, 6.7, 68 or 273 mg/kg/day in males and 0.8, 8.2, 81 or 326 mg/kg/day in females) For parental systemic toxicity, the NOEL was 1,000 ppm (81 mg/kg/day) and the LOEL was 4,000 ppm (326 mg/kg/day) based on decreased parental female premating body weight gain. In addition, significant increases in liver and kidney weight at 4,000 ppm were judged to be non-adverse due to lack of corroborative histopathological lesions. However, in light of the fact that the chronic study demonstrates liver toxicity, the EPA believes that these organ weight changes should be considered as supportive evidence of toxicity at the LOEL of 4,000 ppm. Organ weight changes at 1,000 ppm were not considered sufficient in magnitude to allow revision of the NOEL and LOEL for parental systemic toxicity. For offspring toxicity, the NOEL was 1,000 ppm (81 mg/kg/day) and the LOEL was 4,000 ppm (326 mg/kg/day), based on decreased F_1 and F_2 pup body weight during lactation and continuing into adulthood for F_1 rats.

iv. *Pre- and post-natal sensitivity*. The pre- and post-natal toxicology database is complete with respect to current toxicological data requirements. Based on the developmental and reproductive toxicity studies discussed above, there does not appear to be an extra sensitivity to pre- and post- natal effects.

v. *Conclusion*. EPA concludes that reliable data support use of the hundredfold uncertainty factor and that an additional tenfold factor is not needed to ensure the safety of infants and children from dietary exposure.

2. *Chronic risk*. Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to cyprodinil from food will utilize 14% of the RfD for nursing infants (< 1 year old), 27% of the RfD for non-nursing infants (< 1 year old), 15% of the RfD for children 1 to 6 years old and 7.5% of the RfD for children 7 to 12 years old. EPA generally has no concern for exposures 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 risks to human health. Despite the potential for exposure to cyprodinil in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to cyprodinil residues.

III. Other Considerations

A. Metabolism in Plants and Animals

1. *Nature of residue — plants.* The nature of the residue in plants is understood. Acceptable metabolism studies using ^{14}C-labeled cyprodinil have been performed in stone fruit (peaches), pome fruit (apples), wheat, tomatoes, and potatoes. Cyprodinil is metabolized primarily by hydroxylation followed by sugar conjugation. Cleavage of the amino bridge, opening of the pyrimidine ring, opening of the cyclopropyl ring and formation of thiolactic acid conjugates are also minor pathways. Incorporation into starch was also observed in potato tubers and wheat grain.

EPA has determined that there are no cyprodinil metabolites of toxicological or regulatory concern in plants.

2. *Nature of residue— animals*— i. *Ruminants.* The nature of the residue in ruminants is understood. An acceptable metabolism study using ^{14}C phenyl-labeled cyprodinil has been performed in goats. Based on the structures characterized, the metabolism of cyprodinil proceeded predominantly via hydroxylation followed by conjugation with sulfuric and glucuronic acid. A breakdown of the pyrimidine ring was seen only in the liver and resulted in metabolite L1. Cleavage of the amino bridge between the phenyl and the pyrimidine ring was only a minor reaction as indicated by the small amounts of CGA 249287 found in the liver and kidneys of goats dosed with ^{14}C-pyrimidine cyprodinil.

For compounds with multiple rings, it is generally required that acceptable metabolism studies be performed with each ring labeled. However, as the acceptable metabolism study using ^{14}C-phenyl-labeled cyprodinil indicated that ring cleavage is a minor pathway and the available data from a supplementary ruminant metabolism study using ^{14}C-pyrimidine-labeled cyprodinil support this conclusion, further ruminant

metabolism studies for cyprodinil will not be required.

EPA has determined that there are no cyprodinil metabolites of toxicological or regulatory concern in animals based on the dietary burden associated with the proposed uses.

ii. *Poultry.* There are no poultry feed items associated with the proposed uses. Therefore data on the nature of the residue in poultry is not required for this petition.

B. Analytical Enforcement Methodology

An adequate enforcement methodology, AG–631B, is available to enforce the tolerance on stone fruits, pome fruits, almond hulls, almond nutmeats and grapes. Quantitation is by high performance liquid chromatography with column switching. Information about the analytical method is available to the public from: Calvin Furlow, Information Resources and Services Division, Public Information and Records Integrity Branch, 7502C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, office location and telephone number: Room 101FF, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202 (703–305–5229).

Because no tolerances for animal commodities are required, no analytical methods for animal commodities were required.

C. Magnitude of Residues

The residues of cyprodinil resulting from the proposed uses will not exceed almond hulls at 0.05 ppm; almond nutmeats at 0.02 ppm; apple pomace, wet at 0.15 ppm; grapes at 2.0 ppm; pome fruit at 0.1 ppm; raisins at 3.0 ppm and stone fruit at 2.0 ppm. .

D. International Residue Limits

There are no Codex or Mexican residue limits established for cyprodinil. As part of the joint review, Canada will be setting equivalent tolerances for pome fruits and stone fruits and equivalent import tolerances for almonds and grapes. Therefore no compatibility problems exist for the proposed tolerances.

E. Rotational Crop Restrictions

Stone fruit, pome fruit, almonds and grapes are not rotated, therefore rotational crop restrictions do not apply to this petition.

IV. Conclusion

Therefore, the following tolerances are established for residues of cyprodinil: almond hulls at 0.05 ppm; almond nutmeats at 0.02 ppm; apple pomace, wet at 0.15 ppm; grapes at 2.0 ppm; pome fruit at 0.1 ppm; raisins at 3.0 ppm and stone fruit at 2.0 ppm.

V. Objections and Hearing Requests

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

Any person may, by June 9, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any 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. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300643] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

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

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

VII. Regulatory Assessment Requirements

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior

consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances set in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: April 6, 1998.

Stephen L. Johnson,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. By adding § 180.532 to subpart C to read as follows:

§ 180.532 Cyprodinil, tolerances for residues.

(a) *General* . Tolerances are established for residues of the fungicide cyprodinil, 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine in or on the following food commodities:

Commodity	Parts per million
Almond hulls	0.05
Almond nutmeats	0.02
Apple pomace, wet	0.15
Grapes	2.0
Pome fruit	0.1
Raisins	3.0
Stone fruit	2.0

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

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

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 98–9679 Filed 4–9–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 258

[FRL–5994–7]

RIN 2050–AD77

Financial Assurance Mechanisms for Corporate Owners and Operators of Municipal Solid Waste Landfill Facilities

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency is amending the financial assurance regulations under the Resource Conservation and Recovery Act (RCRA) for owners and operators of municipal solid waste landfills. Today's rule increases the flexibility available to owners and operators by adding two mechanisms to those currently available: a financial test for use by private owners and operators, and a corporate guarantee that allows companies to guarantee the costs for another owner or operator.

EFFECTIVE DATE: This regulation is effective April 10, 1998. This rule provides regulatory relief by establishing additional, less costly mechanisms for owners and operators to comply with existing financial assurance requirements.

ADDRESSES: Supporting materials are available for viewing in the RCRA Information Center (RIC), located at Crystal Gateway I, First Floor, 1235 Jefferson Davis Highway, Arlington, VA. The Docket Identification Number is F–98–FTMF–FFFFF. The RIC is open from 9 a.m. to 4 p.m., Monday through Friday, excluding federal holidays. To review docket materials during these hours, it is recommended that the public make an appointment by calling 703 603–9230. The public may copy a maximum of 100 pages from any regulatory docket at no charge. Additional copies cost $0.15/page. The docket index and some supporting materials are available electronically. See the **SUPPLEMENTARY INFORMATION** section for information on accessing them.

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA Hotline at 800 424–9346 or TDD 800 553–7672 (hearing impaired). In the Washington, DC, metropolitan area, call the RCRA Hotline at 703 412–9810 or TDD 703 412–3323. You may also contact Dale Ruhter at 703 308–8192, or by electronic mail at ruhter.dale@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

Regulated entities

Entities potentially regulated by this action are private owners or operators of municipal solid waste landfills. Regulated categories and entities include:

Category	Examples of regulated entities
Industry	Privately owned municipal solid waste landfill facilities. Privately operated municipal solid waste landfill facilities.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your company is regulated by this action, you should carefully examine the