

requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

A record has been established for this rulemaking under docket number, [PP 9F3818/R2153] (including objections and hearing requests 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 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Written objections and hearing requests, identified by the document control number, [PP 9F3818/R2153], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, DC 20460.

A copy of electronic objections and hearing requests can be sent directly to EPA at:

opp-docket@epamail.epa.gov.

A copy of electronic objections and hearing requests may be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any 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 objections and hearing requests submitted directly in writing. The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory

action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines "significant" as those actions likely to lead to a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

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

Dated: July 28, 1995.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 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. In § 180.474, by revising the table therein, to read as follows:

§ 180.474 Tebuconazole (alpha-[2-(4-chlorophenyl)-ethyl]-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol); tolerances for residues.

* * * * *

Commodity	Parts per million
Bananas	0.05
Barley, forage	0.10
Barley, grain	0.05
Barley, hay	0.10
Barley, straw	0.10
Oat, forage	0.10
Oat, grain	0.05
Oat, hay	0.10
Oat, straw	0.10
Peanuts	0.1
Peanut, hulls	4.0
Wheat, forage	0.10
Wheat, grain	0.05
Wheat, hay	0.10
Wheat, straw	0.10

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40 CFR Part 180

[PP 0F3876/R2155; FRL-4967-8]

RIN 2070-AB78

Myclobutanil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes tolerances for the combined residues of the fungicide myclobutanil and a metabolite in or on the raw agricultural commodities almond nutmeat at 0.1 part per million (ppm) and almond hulls at 2.0 ppm, and increases the tolerances established for milk to 0.2 ppm and meat to 0.1 ppm, meat byproducts (except liver) to 0.2 ppm and liver to 1.0 ppm for cattle, goats, hogs, horses, and sheep. Rohm & Haas Co. requested in a petition submitted pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA) the regulation to establish a maximum permissible level for residues of myclobutanil on almond nuts and almond hulls. EPA initiated the increased tolerances for milk, meat, meat byproducts, and liver based on the additional residues in or on almond nuts and almond hulls.

EFFECTIVE DATE: This regulation became effective on July 27, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 0F3876/R2155], may be submitted to: Hearing

Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections 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 should be identified by the document control number and submitted to: Public Response and Program Resource Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of the objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

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 in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number, [PP 0F3876/R2155]. 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. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: 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 and telephone number: Rm. 227, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6900; e-mail: welch.connie@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the **Federal Register** of January 16, 1991 (56 FR 1631), which announced that the Rohm & Haas Co., Independence Mall West, Philadelphia, PA 19105, had submitted pesticide petition (PP) 0F3876 to EPA requesting that the Administrator, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), establish tolerances for the

combined residues of the fungicide myclobutanil, [*alpha*-butyl-*alpha*-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile], and both the free and bound forms of its metabolite, *alpha*-(3-hydroxybutyl)-*alpha*-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile, in or on the raw agricultural commodities almond nuts at 0.1 ppm and almond hulls at 2.0 ppm.

There were no comments received in response to the notice of filing of the petition.

The data submitted in support of the petition and other relevant material have been evaluated. The pesticide is considered useful for the purpose for which the tolerances are sought. The toxicological data considered in support of the tolerances include the following:

1. A 1-year dog feeding study using doses of 0, 10, 100, 400, and 1,600 ppm (equivalent to doses of 0, 0.34, 3.09, 14.28, and 54.22 milligrams/kilogram (mg/kg) body weight (bwt)/day in males and 0, 0.40, 3.83, 15.68, and 58.20 mg/kg bwt/day in females). The no-observed-effect (NOEL) is 100 ppm (3.09 mg/kg/day for males and 3.83 mg/kg/day for females) based upon hepatocellular hypertrophy, increases in liver weights, "ballooned" hepatocytes, and increases in alkaline phosphatase, SGPT and GGT, and possible slight hematological effects. The lowest-observed-effect level (LOEL) is 400 ppm (14.28 mg/kg/day for males and 15.68 mg/kg/day for females).

2. A 2-year chronic feeding/carcinogenicity study in rats using dietary concentrations of 0, 50, 200, and 800 ppm (equivalent to doses of 0, 2.49, 9.84 and 39.21 mg/kg bwt/day in males and 0, 3.23, 12.86, and 52.34 mg/kg bwt/day in females). The NOEL for chronic effects other than carcinogenicity is 2.49 mg/kg/day, and the LOEL is 9.84 mg/kg/day based on testicular atrophy in males. No other significant effects were observed in either sex at the stated dose levels over a 2-year period. In addition, no carcinogenic effects were observed in either sex at any of the dose levels tested. Based on the toxicological findings, the maximum tolerated dose (MTD) selected for testing (based on the 90-day feeding study) was not high enough to fully characterize the compound's carcinogenic potential.

The study was repeated at dose levels of 0 and 2,500 ppm (125 mg/kg/day) in the diet, which approaches the MTD, in order to characterize the carcinogenic potential. At 2,500 ppm, the observed effects included: decreases in absolute and relative testes weights, increases in the incidences of centrilobular to midzonal hepatocellular enlargement and vacuolation in the liver of both

sexes, increases in bilateral aspermatogenesis in the testes, increases in the incidence of hypospermia and cellular debris in the epididymides, and increased incidence of arteritis/periarteritis in the testes. In this study, a NOEL could not be established because there were effects at the only dose level tested. Myclobutanil was not oncogenic when tested under the conditions of the study.

3. A 2-year carcinogenicity study in mice using dietary concentrations of 0, 20, 100, and 500 ppm (equivalent to 0, 2.7, 13.7, and 70.2 mg/kg/day in males and 0, 3.2, 16.5 and, 85.2 mg/kg/day in females). The NOEL for chronic effects other than carcinogenicity was 20 ppm (2.7 mg/kg/day in males and 3.2 mg/kg/day in females). The LOEL was 100 ppm (13.7 mg/kg/day in males and 16.5 mg/kg/day in females) based on a slight increase in liver mixed-function oxidase (MFO). Microscopic changes in the liver were evident in both sexes at 500 ppm (70.2 mg/kg/day in males and 85.2 mg/kg/day in females). There were no carcinogenic effects in either sex at any dose level tested. The highest selected dose was satisfactory for evaluating carcinogenic potential in male mice, but was lower than the MTD in females.

The above study was reevaluated since the increase in the MFO at 3 months in females was not considered to be significant enough to establish a LOEL. The LOEL was raised to 500 ppm (70.2 mg/kg/day for males and 85.2 mg/kg/day for females) based on increases in MFO in both sexes, increases in SGPT values in females and in absolute and relative liver weights in both sexes at 3 months, increased incidences and severity of centrilobular hepatocytic hypertrophy, Kupffer cell pigmentation, periportal punctate vacuolation and individual hepatocellular necrosis in males, and increased incidences of focal hepatocellular alteration and multifocal hepatocellular vacuolation in both sexes. The NOEL has been raised to 100 ppm (13.7 mg/kg/day for males and 16.5 mg/kg/day for females).

An 18-month study was conducted with female mice using a dose level of 2,000 ppm, which approaches the MTD, to evaluate the carcinogenic potential in female mice. In this study, a NOEL could not be established because there were effects at the only dose level tested. These effects included: decreases in body weight and body weight gain, increases in liver weights, hepatocellular hypertrophy, hepatocellular vacuolation, necrosis of single hypertrophied hepatocytes, yellow-brown pigment in the Kupffer cells and cytoplasmic eosinophilia and hypertrophy of the cells of the zona

fasciculata area of the adrenal cortex. Myclobutanil was not oncogenic when tested under the conditions of the study.

4. A rabbit developmental toxicity study at dosages of 0, 20, 60, and 200 mg/kg/day administered by oral gavage. The LOEL for maternal toxicity was 200 mg/kg/day, and the maternal toxicity NOEL was 60 mg/kg/day based on reduced body weight and body weight gain during the dosing period, clinical signs of toxicity, and possibly abortions. THE LOEL for developmental toxicity is 200 mg/kg/day and NOEL for developmental toxicity is 60 mg/kg/day based on increases in resorptions, decreases in litter size, and a decrease in the viability index.

5. A developmental toxicity study on rats treated with dosages of 0, 31.26, 93.77, 312.58 and 468.87 mg/kg/day. The maternal toxicity LOEL was 312.6 mg/kg/day and maternal toxicity NOEL was 93.8 mg/kg/day based on clinical signs of toxicity. The developmental toxicity LOEL was 312.6 mg/kg/day and the developmental toxicity NOEL was 93.8 mg/kg/day based on increased incidences of 14th rudimentary and 7th cervical ribs.

6. A two-generation rat reproduction study with dosage rates of 0, 50, 200, and 1,000 ppm (equivalent to 0, 2.5, 10 and 50 mg/kg/day). The parental (systemic) toxicity LOEL was 200 ppm (10 mg/kg/day) and the parental (systemic) toxicity NOEL was 50 ppm (2.5 mg/kg/day) based on hepatocellular hypertrophy and increases in liver weights. The reproductive toxicity LOEL was 1,000 ppm (50 mg/kg/day) and reproductive toxicity NOEL was 200 ppm (10 mg/kg/day) based on an increased incidence in the number of stillborns and atrophy of the testes and prostate. The developmental toxicity LOEL was 1,000 ppm (50 mg/kg/day) and the developmental toxicity NOEL was 200 ppm (10 mg/kg/day) based on a decrease in pup body weight gain during lactation.

7. A reverse mutation assay (Ames), point mutation in CHO/HGPRT cells, in vitro and in vivo (mouse) cytogenetic assays, unscheduled DNA synthesis and a dominant-lethal study in rats, all of which were negative for mutagenic effects.

The Reference Dose (RfD) based on the 2-year rat chronic feeding study (NOEL of 2.49 mg/kg bwt/day) and using a hundredfold uncertainty factor, is calculated to be 0.025 mg/kg bwt/day. The theoretical maximum residue contribution (TMRC) from previously established tolerances and tolerances established here is 0.004153 mg/kg bwt/day for the general population and utilizes 16% of the RfD. The percentage

of the RfD for the most highly exposed subgroup, nonnursing infants (less than 1 year old), is 98%. The TMRC was calculated based on the assumption that myclobutanil occurs at the maximum legal limit in all of the dietary commodities for which tolerances are proposed. Even with this probable large overestimate of exposure/risk, the TMRC is below the RfD for the population as a whole and for each of the 22 subgroups considered. Dietary risk from exposure to myclobutanil on almond nuts and hulls, including increases in the meat and milk tolerances because almond hulls are a feed item, contributes 7% of the RfD for the U.S. population and 40% of the RfD for the nonnursing infants less than 1-year old. Considering that the risk estimates are based on tolerance levels, the actual risk is probably lower.

The nature of the residues is adequately understood and adequate analytical methods, gas liquid chromatography using nitrogen/phosphorus and electron-capture detectors, are available for enforcement. Prior to its publication in the Pesticide Analytical Manual, Vol. II, the enforcement methodology is being made available in the interim to anyone who is interested in pesticide enforcement when requested from: Calvin Furlow, Public Response and Program Resource Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1130A, CM #2, 1921 Jefferson Davis Hwy, Arlington, VA 22202, (703)-305-5937.

There are currently no actions pending against the continued registration of this chemical. The pesticide is considered useful for the purpose for which the tolerances are sought. Based on the information and data considered, the Agency has determined that the tolerances established by amending 40 CFR part 180 will protect the public health. Therefore, the tolerances are established as set forth below. By way of public reminder, this notice also reiterates the registrant's responsibility under section 6(a)(2) of FIFRA, to submit additional factual information regarding adverse effects on the environment and to human health by these pesticides.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register**, file written objections to the 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 issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (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(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

A record has been established for this rulemaking under docket number [PP 0F3876/R2155] (including any objections and hearing requests 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 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 1132 of the Public Response and Program Resource Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Written objections and hearing requests, identified by the document control number [PP 0F3876/R2155], may be submitted to the Hearing Clerk (1900), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, DC 20460.

A copy of electronic objections and hearing requests filed with the Hearing Clerk can be sent directly to EPA at: opp-docket@epamail.epa.gov. A copy of electronic objections and hearing requests filed with the Hearing Clerk 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 objection 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 objections and hearing requests submitted directly in writing. The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines "significant" as those actions likely to lead to a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

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

Dated: July 27, 1995.

Stephen L. Johnson,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 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. In § 180.443, by amending paragraphs (a), (b), and (c) by revising the tables therein, to read as follows:

§ 180.443 Myclobutanil; tolerances for residues,

(a) * * *

Commodity	Parts per million
Almond hulls	2.0
Almond nutmeat	0.1
Apples	0.5
Cherries (sweet and sour)	5.0
Cotton seed	0.02
Grapes	1.0
Stone fruits (except cherries) ...	2.0

(b) * * *

Commodity	Parts per million
Milk	0.2

(c) * * *

Commodity	Parts per million
Cattle, fat	0.05
Cattle, liver	1.0
Cattle, meat	0.1
Cattle, mby (except liver)	0.2
Eggs	0.02
Goats, fat	0.05
Goats, liver	1.0
Goats, meat	0.1
Goats, mby (except liver)	0.2
Hogs, fat	0.05
Hogs, liver	1.0
Hogs, meat	0.1
Hogs, mby (except liver)	0.2
Horses, fat	0.05
Horses, liver	1.0
Horses, meat	0.1
Horses, mby (except liver)	0.2
Poultry, fat	0.02
Poultry, meat	0.02
Poultry, mby	0.02
Sheep, fat	0.05
Sheep, liver	1.0
Sheep, meat	0.1
Sheep, mby (except liver)	0.2

[FR Doc. 95-19530 Filed 8-8-95; 8:45 am]
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40 CFR Parts 180 and 185

[OPP-300391A; FRL-4967-5]

RIN 2070-AB78

Clethodim; Pesticide Tolerance and Food Additive Regulation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is establishing an import tolerance and a food additive regulation, respectively, for residues of the herbicide clethodim ((E)-(±)-2-[1-[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one) and its metabolites containing the 2-cyclohexen-1-one moiety in or on the raw agricultural commodity potatoes and the food additive commodities potato flakes and granules. EPA is issuing this rule on its own initiative pursuant to a project to harmonize certain tolerances and food additive regulations with those established by the Canadian government.

EFFECTIVE DATE: This regulation becomes effective August 9, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [OPP-300391A], may 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 should be identified by the document control number and submitted 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 copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: oppdocket@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 in 5.1 file