ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300496; FRL–5719–8]

RIN 2070–AB78

Cyclanilide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the plant growth regulator, cyclanilide, in or on the food commodities cottonseed, cotton gin byproducts, milk, fat, meat, meat by-products, and kidney of cattle, goats, horses, hogs and sheep. Rhone-Poulenc Ag Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act of 1996 (Pub. L. 104-170) requesting the tolerances.

DATES: This regulation becomes effective May 23, 1997. Written objections and requests for hearings must be received on or before July 22, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300496], 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 docket control number and submitted to: Public Information and Records Integrity Branch, Information Resources and Services (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.

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 [OPP–300496]. 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: Cynthia Giles-Parker, Team Leader (22), Registration Division, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number and e-mail address: Room 227, CM#2, 1921 Jefferson Davis Highway, Arlington, VA (703–305–7740). e-mail: giles-parker.cynthia@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 23, 1996 (61 FR 67544)(FRL–5577–1), EPA issued a notice pursuant to section 408(d)of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), announcing the filing of a pesticide tolerance petition (PP 6F4643) by Rhone-Poulenc AG Company, P.O. Box 12014, Research Triangle Park, NC 27709 to EPA requesting that the Administrator amend 40 CFR part 180 by establishing tolerances for residues of the plant growth regulator, cyclanilide [1-(2,4-dichlorophenylaminocarbonyl)-cyclopropane carboxylic acid] determined as 2,4-dichloroaniline (calculated as cyclanilide) in or on the food commodities cottonseed at 0.60 parts per million (ppm); cotton gin byproducts at 25.0 ppm; milk at 0.04 ppm; fat of cattle, goats, horses, hogs and sheep at 0.10 ppm; meat of cattle, goats, horses, hogs and sheep at 0.02 ppm; meat by-products (except kidney) of cattle, goats, horses, hogs and sheep at 0.20 ppm; and kidney of cattle, goats, horses, hogs and sheep at 2.0 ppm. There were no comments received in response to the notice of filing.

I. Statutory Background

Section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq*., as amended by the Food Quality Protection Act of 1996, Pub. L. 104-170) authorizes the establishment of tolerances (maximum residue levels), exemptions from the requirement of a tolerance, modifications in tolerances, and revocation of tolerances for residues of pesticide chemicals in or on food commodities and processed foods. Without a tolerance or exemption, food containing pesticide residues is considered to be unsafe and therefore ''adulterated'' under section 402(a) of the FFDCA, and hence may not legally be moved in interstate commerce. For a pesticide to be sold and distributed, the pesticide must not only have appropriate tolerances under the FFDCA, but also must be registered under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 7 U.S.C. 136 *et seq*.).

Section 408 was substantially amended by the Food Quality Protection Act of 1996 (FQPA). Among other things, the FQPA amends the FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. New section 408(b)(2)(A)(i) 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 food, drinking water, and from pesticide use in gardens, lawns, or buildings (residential and other indoor uses) 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....''

II. Risk Assessment and Statutory Findings

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% 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 margin of exposure 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 margin of exposure (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''. These assessments are defined by the Agency as follows.

i. *Acute risk.* 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.

ii. *Short-term risk.* Short-term risk results from exposure to the pesticide for a period of 1 to 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 to 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.)

iii. *Intermediate-term risk.* 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.

iv. *Chronic 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 < 1 year old) was not regionally based.

III. 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 cyclanilide is discussed below.

1. *Acute toxicity.* The acute oral toxicity study resulted in a LD_{50} of 315 milligrams/kilogram (mg/kg) for males and 208 mg/kg for females. The acute dermal toxicity in rabbits resulted in an LD_{50} in either sex of greater than 2,000 mg/kg. The acute inhalation study in rats resulted in a LC_{50} greater than 2.64 mg/liter. In an acute oral neurotoxicity study in rats fed 0, 15, 50 and 150 mg/kg, the NOEL was 50 mg/kg and the LOEL was 150 mg/kg based on gait abnormalities, increased abdominal muscle tone, and slightly decreased motor activity test.

2. *Mutagenicity.* Cyclanilide was negative for mutagenic activity in the bacterial reverse mutation tests (duplicate tests), forward gene mutation (CHO/HGPRT) test and mouse micronucleus test (duplicate tests). Positive findings (clastogenicity) were seen in the *in vitro* chromosomal aberrations study with Chinese hamster ovary cells at high doses near the limit of cytotoxicity. Since cyclanilide caused liver toxicity in several studies, a confirmatory rat unscheduled DNA synthesis (UDS) test needs to be conducted with cyclanilide.

3. *Rat metabolism.* In the rat metabolism study radioactive cyclanilide was rapidly absorbed after oral administration. The principal route of elimination was by renal excretion of the parent compound and amino acid conjugates. Methylation was a minor metabolic pathway.

4. *Sub-chronic toxicity.* i. In a rat 90–day feeding study the No Observed Effect Level (NOEL) was 54.6 mg/kg/day for males and 62.4 mg/kg/day for females. The Lowest Observed Effect Level (LOEL) for males was 113.2 mg/kg/day and for females it was 121.4 mg/kg/day based on reductions in body weight, body weight gain, and food consumption, clinical signs, and increased liver weight in males and females.

ii. In a 90–day mouse feeding study the NOEL for males was 38 mg/kg/day and 43 mg/kg/day for females. The LOEL was 364 mg/kg/day for males and 416 mg/kg/day for females based on mortality, elevated alkaline phosphatase, increased absolute, relative liver weights, focal hepatocellular necrosis, and handling induced rigidity.

iii. In a 21–day rabbit dermal toxicity study the NOEL was equal or greater than 1,000 mg/kg/day. The LOEL was greater than 1,000 mg/kg/day.

iv. In a 90–day mammalian neurotoxicity study the NOEL for males was equal or greater than 78.6 mg/kg/day and for females was 4.0 mg/kg/day. The LOEL was greater than 78.6 mg/kg/day for males and was 35.8 mg/kg/day for females based on increased motor activity and decreased body weight.

5. *Chronic feeding toxicity and carcinogenicity.* i. In a 1–year feeding study in dogs fed diets containing 0, 40, 160, or 640 ppm (equivalent to 0, 1.5, 5.3, and 21.2 mg/kg/day for males and 0, 1.3, 5.2, and 21.5 mg/kg/day for females) the NOEL was 5.3 mg/kg/day for males and 5.2 mg/kg/day for females. The LOEL was 21.2 mg/kg/day for males and 21.5 mg/kg/day for females based on decreased body weight gain, elevated enzymes and gross and histopathological liver lesions.

ii. In a chronic feeding and carcinogenicity study in rats fed diets containing 0, 50, 150, 450, or 1,000 ppm (equivalent to 0, 2.0, 6.2, 18.9 and 43.1 mg/kg/day for males and 0, 2.6, 8.1, 25.5, and 58.6 mg/kg/day for females) the chronic NOEL was equal or greater than 43.1 mg/kg/day for males and was 8.1 mg/kg/day for females. The chronic LOEL was greater than 43.1 mg/kg/day for males and was 25.5 mg/kg/day for females based on decreased body weight gains and histopathological changes in liver. The study was negative for carcinogenicity.

iii. In a carcinogenicity study in mice fed diets containing 0, 50, 250, or 1,000 ppm (equivalent to 0, 8.4, 41.8, and 168 mg/kg/day for males and 0, 10.6, 52.4, and 206 mg/kg/day for females) the chronic NOEL was 41.8 mg/kg/day for males and was 52.4 mg/kg/day for females. The chronic LOEL was 168 mg/kg/day for males based on decreased weight gain and was 206 mg/kg/day for females based on decreased weight gain. The study was negative for carcinogenicity.

According to the new proposed guidelines for Carcinogen Risk Assessment (April, 1996), the appropriate descriptor for human carcinogenic potential of cyclanilide is ''Not Likely''. The appropriate subdescriptor is ''has been evaluated in at least two well conducted studies in two appropriate species without demonstrating carcinogenic effects''.

6. *Developmental toxicity.* i. In a developmental toxicity study in rats fed 0, 3, 10, and 30 mg/kg/day the maternal NOEL was 10 mg/kg/day and the maternal LOEL was 30 mg/kg/day based on decreased body weight gain and food consumption. The developmental NOEL was 30 mg/kg/day (Highest Dose Tested).

ii. In a developmental toxicity study in rabbits fed 0, 3, 10, and 30 mg/kg/day the maternal NOEL was 10 mg/kg/day and the maternal LOEL was 30 mg/kg/day based on wobbly gait, partial hindlimb paralysis and emaciation. The developmental NOEL was 30 mg/kg/day (Highest Dose Tested).

iii. In a 2 generation reproduction study in rats fed 0, 30, 300 or 1,000 ppm (equivalent to 0, 1.9, 19.0 or 64.1 mg/kg/day for P (Parental) Males; 0, 2.0. 20.2, or 70.4 mg/kg/day for F1 males; 0, 2.3, 21.8, or 84.5 mg/kg/day for P females; and 0, 2.4, 25.9, or 85.7 mg/kg/day for F1 females), the systemic NOEL was less than 2.0 mg/kg/day for males and less than 2.4 mg/kg/day for females. The systemic LOEL was 2.0 mg/kg/day for males based on reduced early post-weaning weight gains. The systemic NOEL for females was 2.4 mg/kg/day based on reduce early post-weaning body weight gains and increased renal mineralization. The reproduction NOEL is 2.3 mg/kg/day and the reproduction LOEL is 21.8 mg/kg/day based on decreased mean pup weight.

IV. Aggregate Exposures

1. *From food and feed uses.* The primary source for human exposure to cyclanilide will be from ingestion of both raw and processed agricultural commodities from cotton, milk, and meat. A DRES chronic exposure analysis was conducted using tolerance level residues and 100% crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups.

2. *From potable water.* As a worst case screen, upper bound estimates (acute/chronic) of the concentration of cyclanilide that might be found in surface water have been calculated with the generic expected environmental concentrations (GENEEC) screening model program. For cotton, based on the assumption of one application aerially at the maximum application rate 0.25 lb active ingredient/acre), GENEEC calculates the peak (acute)

concentration in runoff water adjacent to the application area to be 8.4 ppb and the chronic concentration to be 7.7 ppb.

3. *From non-dietary uses.* There are no non-food uses of cyclanilide registered under the Federal Insecticide, Fungicide and Rodenticide Act, as amended. No non-dietary exposures are expected for the general population.

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 cyclanilide 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, cyclanilide does not appear to produce a toxic metabolite produced by other substances. The Agency has determined that there are no metabolites of toxicological concern associated with cyclanilide. Cyclanilide appears to be the only know pesticide member of its class of chemistry and there are no reliable data to indicate that this chemical is structurally or toxicologically similar to existing chemical substances at this time. Therefore it appear unlikely that cyclanilide bears a common mechanism of activity with other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that cyclanilide has a common mechanism of toxicity with other substances.

V. Determination of Safety

A. Chronic Risk

The Reference Dose (RfD) for cyclanilide is 0.007 mg/kg/day. This value is based on the systemic LOEL of 30 ppm (2.0 mg/kg/day in males and 2.4 mg/kg/day in females) from the rat reproductive study. The NOEL was not achieved (less than 30 ppm the Lowest Dose Tested). Reduced body weights in young post-weaning F1 males and females and increased renal mineralization in adult F1 females were observed at this level. An Uncertainty Factor (UF) of 300 was applied to the LOEL based on an Uncertainty Factor of 100 to account for interspecies extrapolation and intraspecies variability and an additional Uncertainty Factor of 3 to account for the lack of a NOEL in the reproductive toxicity study.

The chronic analysis showed that exposure from the proposed new tolerances in or on cottonseed, cotton gin trash, milk, and meat for non-nursing infants (the subgroup with the highest exposure) would be 77% of the Reference Dose (RfD). The exposure for the general U.S. population would be 15% of the RfD. Based on the estimated exposures to cyclanilide from drinking water, the percentage of the RfD utilized for non-nursing infants (the subgroup with the highest exposure) would be 10% of the Reference Dose (RfD). The exposure for the general U.S. population would be 6% of the RfD. There is no established Maximum Concentration Level or Health Advisory Level for cyclanilide under the Safe Drinking Water Act. For the aggregate dietary exposures from food and drinking water, the percentage of the RfD utilized for non-nursing infants (the subgroup with the highest exposure) would be 91% of the Reference Dose (RfD). The exposure for the general U.S. population would be 21% of the RfD.

The analysis for cyclanilide is a worst case estimate of dietary exposure with all residues at tolerance levels and 100% of the commodities assumed to be treated with cyclanilide.

B. Acute Risk

An acute dietary analysis was conducted to determine the Margin of Exposure from how close the high end exposure comes to the lowest observed effect level of 150 mg/kg/day in the rat acute oral neurotoxicity study. Generally acute dietary margins of exposure greater than 100 tend to cause no dietary concern. The high end MOE for cyclanilide for all population subgroups was greater than 5,000 and is above the acceptable level and demonstrates no acute dietary concerns.

The Acute MOE for drinking water is estimated to be greater than 47,000 for all population subgroups. The acute dietary MOE greater than 100 indicates that there is not acute dietary risk concern from acute drinking water cyclanilide exposure.

The aggregate acute MOE for non-nursing infants (the subgroup with the highest exposure) would be greater than 8,000. The acute MOE for the general U.S. population would be greater than 11,000.

C. Conclusion

Based on these risk estimates EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to cyclanilide for consumers, including major identifiable subgroups and infants and children.

VI. Additional Safety Factor for Infants and Children

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 margin of exposure analysis or through using

uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In either case, EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the no observed effect level in the animal study appropriate to the particular risk assessment. This hundredfold uncertainty (safety) factor/margin of exposure (safety) is designed to account for combined inter- and intra-species variability. EPA believes that reliable data support using the standard hundredfold margin/factor not the additional tenfold margin/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 margin/factor.

An additional Uncertainty Factor of 10 was not used for cyclanilide because (1) the experimental data provided no indication of increased sensitivity of fetal animals to in utero exposure to cyclanilide or of neonates to pre-weaning exposure to cyclanilide; (2) the endpoint upon which the RfD was set, decreased body weight gain in young post-weaning rats, was observed in young, growing animals and therefore already considered the increased sensitivity of young animals in the determination for the LOEL; and (3) treatment related effects seen in other animals did not indicate potential pre or post-natal effects of concern to infants or small children. An additional safety factor of 3 was incorporated to account for the fact that a NOEL was not determined in the study used to establish the RfD.

VII. Other Considerations

1. *Endocrine effects.* No evidence of endocrine effects on the systems of mammals was reported in the toxicology studies described above. There was no observed pathology of the endocrine organs in these studies. There is no evidence at this time that cyclanilide causes endocrine effects.

2. *Metabolism in plants and animals.* The metabolism of cyclanilide in plants and animals is adequately understood for purposes of these tolerances. There are no Codex Alimentarius Commission (Codex) Maximum Residue Levels (MRLs) for cyclanilide. An adequate analytical method, gas chromatography with electron-capture detection, is available for enforcement purposes. Because of the long lead time from establishing these tolerances to publication of the enforcement methodology in the Pesticide Analytical Manual, Vol. II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, Public Information Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Room 1130A, CM#2, 1921 Jefferson Davis Highway, Arlington, VA (703–305–5937).

VIII. Summary of Findings

The analysis for cyclanilide for all population subgroups examined by EPA shows the proposed uses on cotton will not cause exposure at which the Agency believes there is an appreciable risk.

Based on the information cited above, the Agency has determined that the establishment of the tolerances by amending 40 CFR part 180 will be safe; therefore, the tolerances are established as set forth below.

IX. 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 (1)(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 governs 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 July 22, 1997, 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 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 a 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). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. 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.

X. Public Docket

A record has been established for this rulemaking under the docket number [OPP–300496] (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 1132 Public Information and Records Integrity Branch, Information Resources and Services 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 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 rule-making 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.

XI. Regulatory Assessment Requirements

This final rule establishes a tolerance under section 408 of the FFDCA and is in response to a petition received by the Agency requesting the establishment of such a tolerance. 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). In addition, 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, because tolerances that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rwule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Prior to the recent amendments to the FFDCA, however, EPA had treated such actions as subject to the RFA. The amendments to the FFDCA clarify that no proposed rule is required for such regulatory actions, which makes the RFA inapplicable to these actions. 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 (46 FR 24950, May 4, 1981). In accordance with Small Business Administration (SBA) policy, this determination will be provided to the Chief Counsel for Advocacy of the SBA upon request.

XII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted 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 General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Recording and recordkeeping requirements.

Dated: May 16, 1997.

Stephen L. Johnson,

Acting Director, 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. By adding § 180.506 to read as follows:

§ 180.506 Cyclanilide; tolerances for residues.

(a) *General.* Tolerances are established for residues of the plant growth regulator, cyclanilide, [1-(2,4-dichlorophenylaminocarbonyl)-cyclopropane carboxylic acid] determined as 2,4-dichloroaniline (calculated as cyclanilide) in or on the following food commodities and processed feed:

Commodity	Parts Per Million
Cattle, fat	0.10
Cattle, meat	0.20
Cattle, mbyp (except kidney)	0.2
Cattle, kidney	2.0
Cottonseed	0.60
Cotton gin byproducts	25.0
Goats, fat	0.10
Goats, meat	0.20
Goats, mbyp (except kidney)	0.20
Goats, kidney	2.0
Horses, fat	0.10
Horses, meat	0.20
Horses, mbyp (except kidney)	0.20
Horses, kidney	2.0
Hogs, fat	0.10
Hogs, meat	0.20
Hogs, mbyp (except kidney)	0.20
Hogs, kidney	2.0
Milk	0.04
Sheep, fat	0.10
Sheep, meat	0.20
Sheep, mbyp (except kidney)	0.20
Sheep, kidney	2.0

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

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

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

[FR Doc. 97–13645 Filed 5–22–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300493; FRL–5718–5]

RIN 2070–AB78

Pendimethalin; Pesticide Tolerance for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of the herbicide pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite (CL 202, 347) in or on fresh mint hay and mint oil in connection with EPA's granting an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on mint in Idaho, Oregon, South Dakota and Washington. These tolerances will expire and are revoked on May 31, 1998.

DATES: This regulation becomes effective May 23, 1997. Objections and requests for hearings must be received by EPA on or before July 22, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300493], 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–300493], must be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division, (7506C), Office of Pesticide Programs, Environmental