Dated: November 26, 1997.

Felicia Marcus,

Regional Administrator.

Part 81, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 81—[AMENDED]

1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

2. In § 81.305 the table for California—Ozone, is amended by revising the entry for ''Santa Barbara-Santa Maria-Lompoc Area Santa Barbara County'' to read as follows:

§ 81.305 California.

* * * * *

CALIFORNIA-OZONE

Designated area	Designation		Classification	
	Date [1]	Type	Date [1]	Type
* * * *	*	*		*
Santa Barbara-Santa Maria-Lompoc Area Santa Barbara County	11/15/90	Nonattainment	1–9–98	Serious.
* * * *	*	*		*

[1] This date is November 15, 1990, unless otherwise noted.

[FR Doc. 97–32332 Filed 12–9–97; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300588; FRL–5758–2]

RIN 2070–AB78

Cyromazine; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for the combined residues of cyromazine and its metabolite melamine in or on lima beans and blackeye peas. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on lima beans and blackeye peas. This regulation establishes a maximum permissible level for residues of cyromazine in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on December 31, 1998.

DATES: This regulation is effective December 10, 1997. Objections and requests for hearings must be received by EPA on or before February 9, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300588], 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–300588], 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. 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 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–300588]. 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: Andrew Ertman, 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) 308–9367, e-mail: ertman.andrew@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for combined residues of the insecticide cyromazine and its metabolite melamine in or on lima beans at 5.0 part per million (ppm) and blackeye peas at 5.0 ppm. This tolerance will expire and is revoked on December 31, 998. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL–5572–9).

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....''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Cyromazine on Lima Beans and Blackeye Peas and FFDCA Tolerances

Insect pressure from the leafminer has increased over the past several years due to the rapid increase in the insect's resistance to currently registered insecticides and the resulting increase in insect populations. With the end of the California drought, over wintering has occurred in leafminer populations and mild weather has added to the resistance population with outbreaks increasing in the summer and carrying through the end of the harvest season. The applicant states that in 1996 some outbreaks were so severe that several fields (both lima bean and blackeye pea) were abandoned rather than harvested.

Current alternatives for use on blackeye peas have proven ineffective and there are few registered alternatives for control of leafminer in lima beans. EPA has authorized under FIFRA section 18 the use of cyromazine on lima beans and blackeye peas for control of leafminer in California. After having reviewed these submissions, EPA concurs that emergency conditions exist for this state.

As part of its assessment of these emergency exemptions, EPA assessed the potential risks presented by residues of cyromazine in or on lima beans and blackeye peas. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemptions in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on December 31, 1998, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on lima beans and blackeye peas after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions EPA has not made any decisions about whether cyromazine meets EPA's registration requirements for use on lima beans and blackeye peas or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of cyromazine by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than California to use this pesticide on these crops under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemptions for cyromazine, contact the Agency's Registration Division at the address provided above.

III. 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 ten 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 ten 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 100-fold MOE is based on the same rationale as the 100-fold 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 ground water 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 (children 1–6 years old) was not regionally based.

IV. 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 these actions, EPA has sufficient data to assess the hazards of cyromazine and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for the combined residues of cyromazine and its metabolite melamine on lima beans at 5.0 ppm and blackeye peas at 5.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance 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 cyromazine are discussed below.

1. *Acute toxicity.* An acute dietary risk endpoint was not identified and an acute dietary risk assessment is not required.

2. *Short—and intermediate—term toxicity.* For short-term

Margin of Exposure (MOE) calculations, the Agency used a systemic NOEL of 0.75 milligrams/kilogram/day (mg/kg/day) from a 6-month dog feeding study. At the lowest effect level (LEL) of 7.5 mg/kg/day, there were changes in hematological parameters.

3. *Chronic toxicity*. EPA has established the RfD for cyromazine at 0.0075 mg/kg/day. This RfD is based on a 6-month feeding study in the dog with a NOEL of 0.75 mg/kg/day and a LEL of 7.5 mg/kg/day based on pronounced effects on hematological parameters and an uncertainty factor of 100.

4. *Carcinogenicity*. Cyromazine has been classified as a Group

E (evidence of non-carcinogenicity for humans) chemical by the Agency's Cancer Peer Review (CPR) Committee.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40

CFR 180.414) for the combined residues of cyromazine, in or on a variety of raw agricultural commodities at levels ranging from 1.0 ppm in tomatoes to 10 ppm in leafy vegetables.

Currently there are tolerances for residues of cyromazine and its metabolite melamine on the meat fat and meat by-products of chickens from the use of cyromazine as a feed-through. Risk assessments were conducted by EPA to assess dietary exposures and risks from cyromazine 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. An acute dietary risk endpoint was not identified and an acute risk assessment is not required.

ii. *Chronic exposure and risk.* In conducting this chronic dietary risk assessment, EPA has made very conservative assumptions including 100% of crop treated for lima bean and blackeyed pea and most other commodities having cyromazine tolerances. The Agency used percent crop treated on such crops as tomatoes, peppers and lettuce and assumed all crops will contain cyromazine residues and those residues would be at the level of the tolerance. This will result in an overestimate of human dietary exposure. Thus, in making a safety determination for this tolerance, EPA is taking into account this conservative exposure assessment.

The existing cyromazine tolerances (published, pending, and including the necessary section 18 tolerance(s)) result in an Anticipated Residue Contribution (ARC) that is equivalent to the following percentages of the RfD:

Subgroup	Percent
U.S. population (48 States)	34
Nursing infants (<1 year old)	12
Non-nursing infants (<1 year old)	53
Children (1–6 years old)	54
Children (7–12 years old)	44

The subgroups listed above are: (1) the U.S. population (48 states); (2) those for infants and children; and, (3) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 states).

2. *From drinking water.* Based on information available to the

Agency, cyromazine is persistent and relatively mobile. There are no established Maximum Contaminant Levels for residues of cyromazine in drinking water. No health advisory levels for cyromazine in drinking water have been established.

Chronic exposure and risk. Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water-related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for exposure from contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause cyromazine to exceed the RfD if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with cyromazine in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

3. *From non-dietary exposure.* Cyromazine is not registered for use on residential non-food sites.

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 cyromazine 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, cyromazine 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 cyromazine has a common mechanism of toxicity with other substances.

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

Chronic risk. Using the conservative ARC exposure assumptions described in Unit IV.B.1.ii. of this preamble, and taking into account the completeness and reliability of the toxicity data, EPA has calculated that dietary exposure to cyromazine from food will utilize 34% of the RfD for the U.S. population. The Agency 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 cyromazine in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD. Under current Agency guidelines, the registered non-dietary uses of cyromazine do not constitute a chronic exposure scenario. The Agency concludes that there is a reasonable certainty that no harm will result from chronic aggregate exposure to cyromazine residues.

D. Endocrine Disrupter Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect....'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program.

Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

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 cyromazine, 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 pesticide exposure during prenatal development to one or both parents. 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 MOE and 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.* From the rat developmental study, the maternal (systemic) NOEL was 100 mg/kg/day, based on increased incidence of clinical signs and decreased body weight at the lowest observed effect level (LOEL) of 300 mg/kg/day. The developmental (pup) NOEL was 300 mg/kg/day, based on increased incidence of skeletal variations at the LOEL of 600 mg/kg/day.

From the rabbit developmental study, the maternal (systemic) NOEL was 10 mg/kg/day, based on decreased weight gain and food consumption at the LOEL of 30 mg/kg/day. The developmental (pup) NOEL was 60 mg/kg/day, the highest dose tested (HDT).

iii. *Reproductive toxicity study.* From the rat reproduction study, the maternal (systemic) NOEL was 50 mg/kg/day, based on body weight loss at the LOEL of 150 mg/kg/day. The reproductive/developmental (pup) NOEL was 50 mg/kg/day, based on decreased pup growth, decreased number of pups per litter, and increased fetotoxicity at the LEL of 150 mg/kg/day.

iv. *Pre-and post-natal sensitivity.* The toxicological data base for evaluating pre-and post-natal toxicity for cyromazine is complete with respect to current data requirements. There are no pre-or post-natal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies and the 2-generation rat reproductive toxicity study.

v. *Conclusion.* The Agency concludes that reliable data support use of the standard 100-fold margin of exposure/uncertainty factor and that an additional margin/factor is not needed to protect infants and children.

2. *Chronic risk.* Using the conservative exposure assumptions described in Unit IV.B.1.ii. of this preamble, EPA has concluded that the percentage of the RfD that will be utilized by dietary (food) exposure to residues of cyromazine ranges from 53% for non-nursing infants less than one year old, up to 54% for children 1–6 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 cyromazine 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 cyromazine residues.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants and animals is adequately understood.

The residue of concern is parent cyromazine and the metabolite melamine as specified in 40 CFR 180.414.

B. Analytical Enforcement Methodology

Adequate enforcement methodology for crops (HPLC with UV detector) is available in PAM II to enforce the tolerance expression.

C. Magnitude of Residues

Residues of cyromazine and its metabolite melamine are not expected to exceed 5.0 ppm in/on either lima beans or blackeyed peas as a result of this section 18 use. Secondary residues in animal commodities are not expected to exceed existing tolerances as a result of this section 18 use.

D. International Residue Limits

There are no CODEX, Canadian, or Mexican MRL's for cyromazine on lima beans or blackeyed peas.

E. Rotational Crop Restrictions

Crops with permitted uses on the federal label may be planted as rotational crops, additionally sweet corn and radishes may be planted as rotational crops 3 months after the last application to beans.

VI. Conclusion

Therefore, the tolerance is established for combined residues of cyromazine in lima beans at 5.0 ppm and blackeye peas at 5.0 ppm.

VII. 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 February 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 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.

VIII. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300588] (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 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 Hwy., 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.

IX. Regulatory Assessment Requirements

This final rule establishes tolerances under FFDCA section 408(l)(6). 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 under FFDCA section 408 (l)(6), such as the tolerances 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.

X. 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

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

Dated: November 25, 1997.

Peter Caulkins,

Acting Director, Registration Division, 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. In § 180.414, in paragraph (b) by alphabetically adding the following commodities to the table to read as follows:

§ 180.414 Cyromazine; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/revocation date
Beans, lima	5.0	12/31/98
* *	* *	* * *
Peas, blackeyed	5.0	12/31/98
* *	* *	* * *

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[FR Doc. 97–32039 Filed 12–9–97; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[CC Docket No. 96–45, CC 97–21; FCC 97–400]

Universal Service Support Mechanisms

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission authorized the Administrator of the universal service support mechanisms to require payment of quarterly contributions to universal service in equal monthly installments. Allowing monthly payments will reduce the cash flow impact on contributors because their payments will be smaller. It also will better enable contributors to offset their contributions by payments from the support mechanisms. It will not jeopardize the sufficiency of the support mechanisms.

EFFECTIVE DATE: January 9, 1998.

FOR FURTHER INFORMATION CONTACT: Diane Law, (202) 418–7400.

SUPPLEMENTARY INFORMATION:

SECOND ORDER ON RECONSIDERATION in CC Docket No. 97–21

I. Background

1. In the *Universal Service Order,* the Commission created new federal universal service support mechanisms and concluded that all telecommunications carriers that provide interstate telecommunications services, other providers of interstate telecommunications, and payphone service providers will contribute to universal service. (*See* Federal-State Joint Board on Universal Service, *Report and Order,* CC Docket No. 96–45, FCC 97–157, 62 FR 32862 (June 17, 1997)). In the *NECA Report and Order,* the Commission instructed the National Exchange Carrier Association (NECA) to create an independent subsidiary, the Universal Service Administrative Company (USAC or Administrator), to administer temporarily portions of the universal service support mechanisms. (*See* Changes to the Board of Directors of the National Exchange Carriers Association, Inc., Federal-State Joint Board on Universal Service, *Report and Order and Second Order on Reconsideration,* CC Docket No. 97–21, CC Docket No. 96–45, FCC 97–253, 62 FR 41294 (August 1, 1997)). The Commission also instructed the Administrator to bill contributors and collect contributions to the federal universal service support mechanisms on a quarterly basis.

2. USAC requests that it be authorized to collect universal service contributions on a monthly, as opposed to a quarterly, basis. USAC states that collecting contributions on a quarterly basis may create significant cash flow problems for contributors. USAC explains that, because of the delay between funds collection and funds distribution, monthly billing will not increase the likelihood that the Administrator will be required to borrow money to fund early requests for discounts by eligible schools and libraries. In addition, USAC notes that collecting contributions on a monthly basis will generate some interest income, albeit less than would be collected on a quarterly basis, that can be applied to meet program demands. NECA supports USAC's request.

II. Discussion

3. Based on the Administrator's request, we reconsider, on our own motion, our requirement that the Administrator collect contributions on a quarterly basis. Allowing monthly payments would reduce the cash flow impact on contributors because their payments would be smaller. It also would better enable contributors to offset their contributions by payments from the support mechanisms. We conclude that permitting monthly as opposed to quarterly contributions will not jeopardize the sufficiency of the support mechanisms. The Commission reduced the estimated total contribution base by two percent when calculating the universal service contribution factors to take account of the possibility that contributions to the support mechanisms may fall short of estimated levels due to, for example, uncollectibles or higher-than-foreseen demand. In addition, since March 20, 1998 appears to be the earliest date on which the Administrator could be required to make distributions under the schools, libraries, and rural health care programs,[1] we anticipate that, under our

[1] We calculate that March 20, 1998 reflects the earliest date on which the Administrator will distribute funds under these programs, by starting with November 24, 1997 and adding to it a 75-day