will not be considered to be actionable if the herbicide is applied during the term of and in accordance with the provisions of paragraph (a) of this section.

Commodity	Parts per million	Expiration/ revocation date
Cottonseed	0.02	Sept. 30, 1999

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

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

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

[FR Doc. 97–27843 Filed 10–21–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180 and 186

[OPP–300563; FRL–5748–9]

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 the meat, fat, and meat byproducts of turkeys. 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 turkeys. This regulation establishes a maximum permissible level for residues of cyromazine and its metabolite melamine 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. These tolerances will expire and are revoked on October 1, 1998.

DATES: This regulation is effective October 22, 1997. Objections and requests for hearings must be received by EPA on or before December 22, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300563], 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–300563], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), 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 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–300563]. 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 tolerances for combined residues of the insecticide (larvicide) cyromazine and its metabolite melamine, in or on meat, fat, and meat byproducts of turkeys at 0.05 part per million (ppm). These tolerances will expire and are revoked on October 1, 1998. EPA will publish a document in the **Federal Register** to remove the revoked tolerances 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 tolerance 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 Turkeys and FFDCA Tolerances

The applicant has requested an emergency exemption for the use of cyromazine on turkeys to control flies. The applicant states that the flies are thought to carry spiking mortality, an acute form of Poult Enteritis Mortality Syndrome (PEMS). PEMS first appeared in Union County, North Carolina in 1991. Initially, the disease affected turkey flocks only in western North Carolina until it spread to eastern North Carolina and neighboring states in 1994. Since that time, it has devastated the relatively small turkey industry in Georgia, and has had significant impact on turkey production in North Carolina. Estimates are that the disease was responsible for about $55 million in losses to the turkey industry in 1996. Most of these losses were incurred by North Carolina.

Evidence suggests that house fly (*Musca domestica*) can transmit the PEMS disease agent(s). The applicant states that the alternative products available for use on house flies in poultry houses, tetrachlorvinphos, dichlorvos, and dimethoate, are applied as larvicides to the manure accumulated beneath cages or slatted floors. These products were developed for use under caged layers or in chicken houses with slatted floors; however, market turkeys are grown in open-floor environments, and the birds cannot be easily moved from areas needing treatment. One problem with this type of treatment of turkey houses is that rates for larvicidal use of these chemicals are generally the highest rates permitted by the label, creating a concern for the exposed birds. A second problem with these alternatives is that the residual control is 10 to 14 days at best, thus requiring at least two treatments over the course of a brooder house flock cycle. Additionally, it may not be possible to penetrate the breeding substrate with a low pressure sprayer as recommended, due to compaction of the litter. Finally, these alternatives are labeled as adulticides, leaving a question of possible resistance development by house flies to these chemicals. EPA has authorized under FIFRA section 18 the use of cyromazine on turkeys for control of flies in North Carolina. After having reviewed the submission, EPA concurs that emergency conditions exist for this state.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of cyromazine in or on the meat, fat, and meat byproducts of turkeys. 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 exemption 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 October 1, 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 meat, fat, and meat byproducts of turkeys 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 turkeys or whether permanent tolerances for this use 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 North Carolina to use this pesticide on this crop 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 exemption 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 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 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 3 sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

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

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

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroups (non-nursing infants <1 year old and 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 this action, 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 in or on meat, fat, and meat byproducts of turkeys at 0.05 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by 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 is using a systemic NOEL of 0.75 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 milligrams/kilogram/day (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.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.414) for the combined residues of cyromazine and its metabolite melamine, 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:

Chronic exposure and risk. In conducting this chronic dietary risk assessment, the Agency has made very conservative assumptions which result in an overestimate of human dietary exposure:

(1) 100% crop treated is assumed for all commodities with the exception of tomatoes, sweet peppers, celery, and lettuce, where percent crop treated is used.

(2) All commodities having cyromazine tolerances are assumed to contain cyromazine residues and those residues will be at the level of the established tolerance.

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	32
Nursing Infants	12
Non-Nursing Infants (<1 year old)	50
Children (1-6 years old)	50
Children (7-12 years old)	41

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 Level 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 tolerances 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 tolerances are granted.

3. *From non-dietary exposure.* Cyromazine is not currently 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. For the purposes of these tolerance actions, therefore, EPA has not assumed that cyromazine or its metabolite melamine have common mechanisms 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 above, and taking into account the completeness and reliability of the

toxicity data, EPA has concluded that aggregate exposure to cyromazine from food will utilize 32% 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. Since there are no residential uses, EPA concludes that there is a reasonable certainty that no harm will result from chronic aggregate exposure to cyromazine residues.

D. Aggregate Cancer Risk for U.S. Population

Cyromazine has been classified as a Group E (evidence of non-carcinogenicity for humans) chemical by the Agency.

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 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. Based on the above, EPA 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.

v. *Conclusion.* Aggregate exposure to cyromazine does not pose a risk to infants and children that exceeds the Agency's level of concern.

2. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to cyromazine from food ranges from 12% for non-nursing infants less than one year old, up to 50% 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 the published tolerance for chickens (HPLC with UV detector) is available in PAM II to enforce the tolerance expression. This method is adequate for turkeys.

C. Magnitude of Residues

Residues of Cyromazine and melamine are not expected to exceed 0.05 ppm in/on turkey meat, fat and meat byproducts as a result of this Section 18 use.

D. International Residue Limits

There is a CODEX MRL for residues of cyromazine *per se* on poultry meat at 0.05 ppm.

E. Rotational Crop Restrictions

While there are no crop rotation restrictions on the label of this feed through product, manure from treated animals may be used as a soil fertilizer supplement. There are restrictions on the amount of manure that may be used per acre and manure is not to be used on small grains.

VI. Conclusion

Therefore, tolerances are established for combined residues of cyromazine and its metabolite melamine in or on meat, fat and meat byproducts of turkeys at 0.05 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 December 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 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–300563] (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 (7506C), 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 the 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

40 CFR Part 180

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

40 CFR Part 186

Environmental protection, Animal feeds, Pesticides and pests.

Dated: October 6, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. In part 180:

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

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

b. In § 180.414:

i. By adding paragraph (a)(4).

ii. In paragraph (b), by alphabetically adding the following commodities to the table.

The addition and amendment to § 180.414 read as follows:

§ 180.414 Cyromazine; tolerances for residues.

(a) * * *

(4) The additive cyromazine (*N*-cyclopropyl-1,3,5-triazine-2,4,6-triamine) may be safely used in

accordance with the following prescribed conditions:

(i) It is used as a feed additive only in the feed for chicken layer hens and chicken breeder hens at the rate of not more than 0.01 pound of cyromazine per ton of poultry feed.

(ii) It is used for control of flies in manure of treated chicken layer hens and chicken breeder hens.

(iii) Feeding of cyromazine-treated feed must stop at least 3 days (72 hours) before slaughter. If the feed is formulated by any person other than the end user, the formulator must inform the end user, in writing, of the 3-day (72 hours) preslaughter interval.

(iv) To ensure safe use of the additive, the labeling of the pesticide formulation containing the feed additive shall conform to the labeling which is registered by the U.S. Environmental Protection Agency, and the additive shall be used in accordance with this registered labeling.

(v) Residues of cyromazine are not to exceed 5.0 parts per million (ppm) in poultry feed.

(b) * * *

Commodity	Parts per million	Expiration/revocation date
* * *	* *	* *
Turkey, fat	0.05	10/1/98
Turkey, mbyp	0.05	10/1/98
Turkey, meat	0.05	10/1/98

* * * * *

PART 186—[AMENDED]

2. In part 186:

a. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C. 342, 348, and 701.

§ 186.1400 [Removed]

b. Section 186.1400 is removed.

[FR Doc. 97–27844 Filed 10–21–97; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR PART 68

[CC Docket Nos. 96–128 and 91–35; DA 97–1793]

Pay Telephone Equipment Grandfathering

AGENCY: Federal Communications Commission.

ACTION: Final rules; correction.

SUMMARY: The Federal Communications Commission issues a correction to the previously published final rule in 62 FR 47371, September 9, 1997, concerning the connection of terminal equipment to the telephone network. The rule allows certain terminal equipment presently connected to central-office-implemented payphones to remain connected without registration. This correction is issued to clarify that the rule applies to the ''central-office-implemented telephone line'' rather than the ''central-office-implemented telephone.'' The correction is intended clarify the distinction between terminal equipment and a central-office-implemented telephone line.

EFFECTIVE DATE: October 5, 1997.

FOR FURTHER INFORMATION CONTACT:

Technical Information: William Von Alven, 202–418–2342.

Legal Information: Alan Thomas, 202–418–2338.

SUPPLEMENTARY INFORMATION: Section 68.2(l) (1) and (2) are corrected. 68.2(1) is corrected by inserting the word ''line'' after the phrase ''central-office-implemented telephone'' in the first sentence. Section 68.2(l)(2) is corrected by inserting the word ''line'' after the phrase ''central-office-implemented telephone'' in the first and second sentences.

List of Subjects in 47 CFR Part 68

Communications common carriers, Communications equipment, Reporting and recordkeeping requirements.

Federal Communications Commission.

LaVera F. Marshall,

Acting Secretary.

Correction

For the reasons discussed in Supplementary Information make the following corrections.

§ 68.2 [Corrected]

1. On page 47371, in the third column, in § 68.2, in paragraph (l)(1), in lines 3 and 4, the phrase ''central-office-implemented telephone'' is corrected to read ''central-office-implemented telephone line.''

2. On page 47371, in the third column, in § 68.2, in paragraph (l)(2), in lines 4 and 5 and lines 8 and 9, the phrase ''central-office-implemented telephone'' is corrected to read ''central-office-implemented telephone line.''

[FR Doc. 97–27635 Filed 10–17–97; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 97–148; RM–9088]

Radio Broadcasting Services; New London, IA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Sound In Spirit Broadcasting, Inc., allots Channel 247A at New London, Iowa, as the community's first local aural transmission service. Channel 247A can be allotted to New London in compliance with the Commission's minimum distance separation requirements with a site restriction of 2.7 kilometers (1.7 miles) west in order to avoid a short-spacing conflict with the licensed operation of Station WFYR-FM, Channel 247B1, Elmwood, Illinois. The coordinates for Channel 247A at New London are 40–55–30 NL and 91–25–40 WL. With this action, this proceeding is terminated.

DATES: Effective: November 24, 1997. The window period for filing applications for Channel 247A at New London, Iowa, will open on November 24, 1997, and close on December 26, 1997.

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 97–148, adopted September 24, 1997, and released October 10, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC