Toxics Program, April 6, 1998, IBR approved for § 63.99(a)(5)(ii) of subpart E of this part.

Subpart E—Approval of State Programs and Delegation of Federal Authorities

3. Section 63.99 is amended by revising paragraph (a)(5)(ii) introductory text and adding paragraph (a)(5)(ii)(C), to read as follows:

§ 63.99 Delegated Federal authorities.

(a) * * *

(5) * * *

(ii) Affected sources must comply with the *California Regulatory Requirements Applicable to the Air Toxics Program*, April 6, 1998 (incorporated by reference as specified in § 63.14) as described below.

* * * * *

(C) The material incorporated in Chapter 3 of the *California Regulatory Requirements Applicable to the Air Toxics Program* (South Coast Air Quality Management District Rule 1421) pertains to the perchloroethylene dry cleaning source category in the South Coast Air Quality Management District, and has been approved under the procedures in § 63.93 to be implemented and enforced in place of Subpart M—National Perchloroethylene Air Emission Standards for Dry Cleaning Facilities, as it applies to area sources only, as defined in § 63.320(h).

(*1*) Authorities not delegated.

(*i*) South Coast Air Quality Management District is not delegated the Administrator's authority to implement and enforce Rule 1421 in lieu of those provisions of Subpart M which apply to major sources, as defined in § 63.320(g).

Dry cleaning facilities which are major sources remain subject to Subpart M.

(*ii*) South Coast Air Quality Management District is not delegated the Administrator's authority of § 63.325 to determine equivalency of emissions control technologies. Any source seeking permission to use an alternative means of emission limitation, under sections (c)(17), (d)(3)(A)(v), (d)(4)(B)(ii)(III), and (j) of Rule 1421, must also receive approval from the Administrator before using such alternative means of emission limitation for the purpose of complying with section 112.

[FR Doc. 98–12430 Filed 5–12–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300651; FRL–5788–2]

RIN 2070–AB78

Pyriproxyfen; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of pyriproxyfen in or on citrus fruit, juice, dried pulp, and oil; pears; and tomatoes. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on citrus, pears, and tomatoes. This regulation establishes maximum permissible levels for residues of pyriproxyfen in these food and feed commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The tolerances will expire and are revoked on July 31, 1999.

DATES: This regulation is effective May 13, 1998. Objections and requests for hearings must be received by EPA on or before July 13, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300651], 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–300651], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300651]. 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: Telephone numbers and e-mail addresses: *For pyriproxyfen on citrus*: Andrea Beard (703) 308-9356, e-mail: beard.andrea@epamail.epa.gov; *For pyriproxyfen on pears or tomatoes*: Virginia Dietrich (703) 308-9359, e-mail: dietrich.virginia@epamail.epa.gov. Office location (both): Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. By mail (both): Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the FFDCA, 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for residues of the pesticide pyriproxyfen, in or on citrus fruit at 0.3 parts per million (ppm), citrus juice and dried citrus pulp at 1.0 ppm, and citrus oil at 300 ppm; pears at 0.2 ppm; and tomatoes at 0.1 ppm. These tolerances will expire and are revoked on July 31, 1999. 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 FQPA (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the FFDCA, 21 U.S.C. 301 *et seq*., and the 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 Pyriproxyfen on Citrus and FFDCA Tolerances

Pyriproxyfen on Citrus: A request was received from California for use of pyriproxyfen on citrus to control red scale, which has developed resistance to available controls, in some localized citrus-producing areas of California, causing significant losses to the affected citrus producers.

Pyriproxyfen on Pears: A request was received from Oregon for the use of pyriproxyfen on pears for control of pear psylla, which has developed resistance to currently available controls, and is expected to cause significant economic loss if not adequately controlled.

Pyriproxyfen on Tomatoes: A request was received from Florida for the use of pyriproxyfen on tomatoes for control of whiteflies. A recently introduced strain or species of whitefly has caused extensive damage over the past several years to various vegetable crops in southern areas of the U.S., including tomatoes. This pest has demonstrated resistance to available materials and is expected to cause significant economic losses if not adequately controlled.

EPA has authorized under FIFRA section 18 the use of pyriproxyfen on citrus for control of red scale in California; on pears for control of pear psylla in Oregon; and, on tomatoes for control of whiteflies in Florida. After having reviewed the submissions, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of pyriproxyfen in or on citrus, pears, and tomatoes. 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 July 31, 1999, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on citrus commodities, pears and tomatoes after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these tolerances at the time of that application. 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 pyriproxyfen meets EPA's registration requirements for use on citrus, pears, or tomatoes, 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 pyriproxyfen 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, Oregon, and Florida 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 exemption for pyriproxyfen, 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 three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

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

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

B. Aggregate Exposure

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

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (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 pyriproxyfen and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for residues of pyriproxyfen on citrus fruit at 0.3 ppm, citrus juice and dried citrus pulp at 1.0 ppm, and citrus oil at 300 ppm; pears at 0.2 ppm; and tomatoes at 0.1 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the 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 pyriproxyfen are discussed below.

1. *Acute toxicity.* There are no acute dietary endpoints of concern for pyriproxyfen. No concern exists for acute dietary exposure to pyriproxyfen residues.

2. *Short - and intermediate - term toxicity.* There are no endpoints and no concern exists for short- or intermediate-term toxicity from pyriproxyfen.

3. *Chronic toxicity.* EPA has established the RfD for pyriproxyfen at 0.35 milligrams/kilogram/day (mg/kg/day). This RfD is based on 2-year and 90-day feeding studies in rats with a NOEL of 35.1 mg/kg/day and an uncertainty factor of 100, based on intra- and interspecies differences. At the LOEL of 141.28 mg/kg/day, there was a decrease in body weight gain in females.

4. *Carcinogenicity.* Pyriproxyfen has been classified in Group E of EPA's cancer classification system, indicating there is evidence of non-carcinogenicity for humans. Therefore, there is no concern for cancer risk from exposure to pyriproxyfen.

B. Exposures and Risks

1. *From food and feed uses.* Time-limited tolerances have been established (40 CFR 180.510) for the residues of pyriproxyfen, in or on cotton commodities, in association with the use under emergency exemptions. There are currently no registered food uses for pyriproxyfen, and thus no permanent tolerances established. Risk assessments were conducted by EPA to assess dietary exposures and risks from pyriproxyfen as follows:

Chronic exposure and risk. As stated above, there are time-limited tolerances for cotton commodities established in connection with use under emergency exemptions. This risk assessment took these into account, as well as these tolerances being established for citrus commodities, pears, and tomatoes. The chronic dietary (food only) risk assessment used tolerance level residues and assumed 100% crop treated. Therefore, the resulting exposure estimates should be viewed as conservative; further refinement using anticipated residues and/or percent of crop treated would result in lower dietary exposure estimates. For chronic dietary (food only) risk estimates, the two most highly exposed subgroups, Non-Nursing Infants (<1 Year Old) and Children (1-6 Years Old) had 1.54 and 1.84% of the RfD utilized, respectively. All other population subgroups had less than 1% of the RfD utilized.

2. *From drinking water.* A Tier II drinking water assessment of pyriproxyfen was conducted, using computer models which simulate the fate in a surface water body. The estimated environmental concentrations (EECs) are generated for high exposure agricultural scenarios and represent one in ten years EECs in a stagnant pond with no outlet that receives pesticide loading from an adjacent 100% cropped, 100% treated field. As such, these computer generated EECs represent conservative screening levels for ponds and lakes and are used only for screening. The EECs for surface water ranged from a peak of 0.677 ppb, to a 60-days average of 0.142 ppb, to a 1-year average of 0.103 ppb. These estimates are based on 2 applications at a rate of 0.11 lb. active ingredient per acre. For ground water, a computer model was used which resulted in estimated 60-day average concentrations of pyriproxyfen of 0.006 ppb.

Chronic exposure and risk. A human health drinking water level of concern (DWLOC) is the concentration in drinking water that would be acceptable as an upper limit in light of total aggregate exposure to that chemical from food, water and non-occupational (residential) sources. The DWLOC for chronic risk is the concentration in drinking water as a part of the aggregate chronic exposure, that occupies no more than 100% of the RfD. In conducting these calculations, default body weights are used of 70 kg (adult male), 60 kg (adult female) and 10 kg (child); default consumption values of water are used of 2 liters per day for adults and 1 liter per day for children. Using these assumptions and the levels provided by the computer models, given above, the resultant percentage of the RfD utilized for both children and adults was calculated to be 0.35%. Therefore, taking into account present uses, including this use on citrus under section 18, EPA concludes that there is reasonable certainty of no harm if these tolerances are established.

3. *From non-dietary exposure.* Pyriproxyfen is currently registered for use on the following residential non-food sites: Products for flea and tick control, including foggers, aerosol sprays, emulsifiable concentrates, and impregnated material (pet collars).

Chronic exposure and risk. Long-term exposure to pyriproxyfen in residential use products is not expected. Consumer use of these products typically results in short-term intermittent exposures. Hence, a chronic residential exposure assessment is not required.

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

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

EPA does not have, at this time, available data to determine whether pyriproxyfen 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, pyriproxyfen 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 pyriproxyfen has a common mechanism of toxicity with other substances.

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

1. *Acute risk.* There are no acute dietary endpoints of concern for pyriproxyfen. No concern exists for acute dietary exposure to pyriproxyfen residues.

2. *Chronic risk.* Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to pyriproxyfen from food and drinking water will utilize 0.67 and 0.35% of the RfD, respectively, for the U.S. population (total of 1.02% RfD utilized). The major identifiable subgroup with the highest aggregate exposure is Children (1-6 Years Old), with 1.84 and 0.35% of the RfD utilized by food and drinking water, respectively, for a total of 2.19% of the RfD utilized. This is discussed further below. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to pyriproxyfen residues.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. There are no endpoints and no concern exists for short- or intermediate-term toxicity from pyriproxyfen.

D. Aggregate Cancer Risk for U.S. Population

Pyriproxyfen has been classified in Group E of EPA's cancer classification system, indicating there is evidence of non-carcinogenicity for humans. Therefore, there is no concern for cancer risk from exposure to pyriproxyfen.

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 pyriproxyfen, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard 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.* In the developmental study in rats, the maternal (systemic) NOEL was 100 mg/kg/day, based on decreased bodyweight, body weight gain, food consumption, and increased water consumption at the LOEL of 300 mg/kg/day. The developmental (fetal) NOEL was 300 mg/kg/day, based on increased skeletal variations and unspecified visceral variations at the LOEL of 1,000 mg/kg/day

In the developmental toxicity study in rabbits, the maternal (systemic) NOEL was 100 mg/kg/day, based on abortions, soft stools, emaciation, decreased activity, and bradypnea at the LOEL of 300 mg/kg/day. The developmental (pup) NOEL was 300 mg/kg/day, based on decreased viable litters available for examination at the LOEL of 1,000 mg/kg/day.

iii. *Reproductive toxicity study.* In the 2-generation reproductive toxicity study in rats, the maternal (systemic) NOEL was 87/96 mg/kg/day for Males/Females, based on decreased body weights, body weight gains, and increased liver weight associated with histopathological findings in the liver at the LOEL of 453/498 mg/kg/day for M/F. The developmental (pup) NOEL was 87/96 mg/kg/day, based on decreased body weight on lactation days 14 and 21 at the LOEL of 453/498 mg/kg/day. The reproductive NOEL was 453/498 mg/kg/day for M/F (the highest dose tested).

iv. *Pre- and post-natal sensitivity.* In both rats and rabbits, developmental studies demonstrated that the developmental findings occurred at dose levels at which maternal toxicity was also present, demonstrating no special pre-natal sensitivity for developing fetuses. In the post-natal evaluation to infants and children, as shown in the results of the rat reproduction study, the NOEL and LOEL for both parental systemic toxicity and pup toxicity occurred at the same dose levels, demonstrating no special post-natal sensitivity for infants and children.

v. *Conclusion.* Given the fact that there is a complete toxicity data base for pyriproxyfen, and no special pre- or post- natal sensitivities are indicated for infants and children, an additional 10-fold safety factor is not warranted. EPA concludes that there is reasonable certainty of safety for infants and children exposed to dietary residues of pyriproxyfen.

2. *Acute risk.* There are no acute dietary endpoints of concern for pyriproxyfen. No concern exists for acute dietary exposure to pyriproxyfen residues.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to pyriproxyfen from food will utilize 1.84% of the RfD for Children 1-6 years old, the most highly exposed subgroup of infants and children. 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. The risk from drinking water is conservatively estimated to utilize 0.35% of the RfD for infants and children, as discussed above. Despite the potential for exposure to pyriproxyfen 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 pyriproxyfen residues.

4. *Short- or intermediate-term risk.* There are no endpoints and no concern exists for short- or intermediate-term toxicity from pyriproxyfen.

V. Other Considerations

A. Metabolism In Plants and Animals

For the purposes of these uses under section 18, the nature of the residue in plants is adequately understood, and the residue to be regulated is parent pyriproxyfen *per se* [4-phenoxyphenyl (RS)-2-(2-pyridyloxy)propyl ether]. There are no detectable residues expected in animal commodities as a result of these uses.

B. Analytical Enforcement Methodology

Adequate analytical methodology is available to enforce the tolerance expression, in residue analytical method RM-33P-2 using gas chromatography with a nitrogen-phosphorus detector. This has been validated by EPA and is available from the Registrant of pyriproxyfen, Valent U.S.A. Corporation, Dublin, California.

C. Magnitude of Residues

Residues of pyriproxyfen are not expected to exceed 0.3 ppm in/on citrus fruit, 1.0 ppm in citrus juice and dried citrus pulp, and 300 ppm in citrus oil; 0.2 ppm in/on pears; and 0.1 ppm in/on tomatoes; no detectable residues are expected to occur in animal commodities, as a result of these emergency exemption uses.

D. International Residue Limits

There are no Canadian, Mexican, or Codex maximum residue limits (MRLs) for residues of pyriproxyfen in/on citrus, pears, or tomatoes.

E. Rotational Crop Restrictions

There are no applicable rotational crop restrictions for these emergency exemption uses.

VI. Conclusion

Therefore, the tolerances are established for residues of pyriproxyfen in/on citrus fruit at 0.3 ppm, citrus juice and dried citrus pulp at 1.0 ppm, and citrus oil at 300 ppm; 0.2 ppm in/on pears; and 0.1 ppm in/on tomatoes.

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 July 13, 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–300651] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis 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 time-limited tolerances under FFDCA section 408(d) in response to petitions submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established under FFDCA section 408 (l)(6), such as the time-limited 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: April 27, 1998.

James Jones,

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 § 180.510, in paragraph (b) by alphabetically adding the following commodities to the table to read as follows:

§ 180.510 Pyriproxyfen; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/revocation date
Citrus fruit	0.3	7/31/99
Citrus juice	1.0	7/31/99
Citrus oil	300	7/31/99
Citrus pulp, dried	1.0	7/31/99
* *		*
* *		*
*		
Pears	0.2	7/31/99
Tomatoes	0.1	7/31/99

* * * * *

[FR Doc. 98–12426 Filed 5–12–98; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300636A; FRL–5787–6]

RIN 2070–AB78

N-(4-fluorophenyl)-N-(1-methylethyl)-2-[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl]oxy]acetamide; Time-Limited Pesticide Tolerance, Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: EPA is correcting the time-limited tolerance levels for the combined residues of the herbicide *N*-(4-fluorophenyl)-*N*-(1-methylethyl)-2-[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl]oxy]acetamide and its metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety in or on corn, field, grain; corn, field, forage; corn, field, stover, and soybean seed.

DATES: This correction is effective on April 10, 1998.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Tompkins, 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) 305–5697, e-mail: tompkins.jim@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 10, 1998 (63 FR 17692)(5782–9), EPA issued a regulation establishing time-limited pesticide tolerances under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) for residues of *N*-(4-fluorophenyl)-*N*-(1-methylethyl)-2-[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl]oxy]acetamide on ''corn, field, forage,'' and ''corn, field, grain'' corn, field, stover, and soybean seed (40 CFR 180.527). Inadvertently, the tolerance levels for corn, field, grain and corn, field, forage were transposed. This document corrects the tolerance levels by correcting § 180.527.

I. Regulatory Assessment Requirements

This final rule does not impose any requirements. It only implements a technical correction to the Code of Federal Regulations (CFR). As such, this action does not require review by the Office of Management and Budget (OMB) under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993), the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). For the same reason, it does not require any action under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4), Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994). In addition, since this type of action does not require any proposal, no action is needed under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.).

II. 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.