EXHIBIT 284.523.—MEXICO—Continued

| State group | State name | State abbreviation | Package label (facing slip) Line 1 | Tag 116 3-letter exchange office code |
|---|---|---|---|---|
| | Remaining 82001 | SIN DIS | Mazatlan | MZT |
| 6 | Distrito Federal | DF | Mexico 506 DF (Mexico City) | MEX |
| 7 | Guerrero | GRO | 39301 Acapulco de Juarez GRO DIS | ACA |
| 8 | Baja Calif Norte | BCN | 22001 Tijuana BCN DIS | N/A |
| | Baja Calif Sur | BCS 23001 La Paz BCS DIS | N/A. | |
| | Chihuahua | CHIH | 32001 CD Juarez CHIH DIS | N/A |
| | Sonora | SON | 84001 Nogales SON DIS | N/A |

EXHIBIT 284.622 Labeling of IPA Mail to USPS Exchange Offices

| IPA Acceptance Office 3-Digit ZIP Code Prefix | U.S. Exchange Office and Routing Code for Line 1 |
|---|---|
| 004–005, 010–098, 100–199, 250–267 | AMC KENNEDY NY 003 |
| 200–249, 254, 268, 283–285, 400–418, 420–427, 476–477 | P&DC DULLES VA 201 |
| 270–282, 286–326, 344, 350–397, 399 | AMC ATLANTA GA 300 |
| 424, 430–459, 460–516, 520–528, 530–532, 534–535, 537–567, 570–588, 600–620, 622–631, 633–641, 644–658, 660–662, 664–681, 683–693, 739. | AMC O'HARE 606 |
| 700–708, 710–738, 740–799, 885 | ISC DALLAS TX 753 |
| 590–599, 821, 832–838, 970–986, 988–999 | AMC SEATTLE WA 980 |
| 850, 852–853, 855–857, 859–860, 863–865, 870–875, 877–884, 889–891, 900–908, 910–928, 930–936. | AMC LOS ANGELES CA 900 |
| 800–816, 820, 822–831, 840–847, 893–898, 937–966 | AMC SAN FRANCISCO CA 940 |
| 967–969 | P&DC HONOLULU 967 |

**Stanley F. Mires,**

*Chief Counsel, Legislative.*

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**BILLING CODE 7710–12–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[OPP–300794; FRL–6062–4]**

**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 almond nutmeats and hulls, and stone fruits (Crop Group 12, see 40 CFR 180.41). This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on almonds and stone fruits. This regulation establishes maximum permissible levels for residues of pyriproxyfen in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances for almond nut meats and hulls will expire and are revoked on April 30, 2002. The tolerance for stone fruits will expire and is revoked on August 31, 2000. This document will remove a second section (§ 180.534) published in the **Federal Register** on July 6, 1998 (63 FR 36366) which subsequently added pyriproxifen as a permanent tolerance on cotton seed and cotton gin byproducts.

**DATES:** This regulation is effective March 3, 1999. Objections and requests for hearings must be received by EPA on or before May 3, 1999.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number [OPP–300794], 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–300794], 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, Crystal Mall #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@epa.gov. Copies of electronic 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 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300794]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

**FOR FURTHER INFORMATION CONTACT:** For pyriproxyfen on almonds: Andrea Beard, (703)308-9356, beard.andrea@epa.gov; for pyriproxyfen on stone fruits: Andrew Ertman,

(703)308-9367, ertman.andrew@epa.gov; Office location (both): Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. Mailing address (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 sections 408 and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a and (l)(6), is establishing tolerances for residues of the insect growth regulator pyriproxyfen, in or on almond nutmeats and hulls at 0.02 and 2.0 parts per million (ppm), respectively, and in or on stone fruits at 0.1 ppm. The tolerances for almond nut meats and hulls will expire and are revoked on April 30, 2002. The tolerance for stone fruits will expire and is revoked on August 31, 2000. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

EPA published in the **Federal Register** on July 25, 1997 (62 FR 39962) (FRL–5731–9) a time-limited tolerance for residues of pyriproxifen in or on cotton seed and cotton gin byproducts (40 CFR 180.510). Subsequently, on July 6, 1998 (63 FR 36366) (FRL–5794–6), EPA issued a permanent tolerance for pyriproxyfen on cotton seed and cotton gin byproducts in response to a petition by Valent U.S.A. Corporation (40 CFR 180.534). Through oversight, tolerances have been established for residues of pyriproxyfen on cotton seed and cotton gin byproducts in two different sections of 40 CFR part 180. EPA is revising § 180.510 to add the permanent tolerance of § 180.534(a) and will remove § 180.534.

## I. Background and Statutory Findings

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 in this preamble and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL–5572–9).

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

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

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

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

## II. Emergency Exemption for Pyriproxyfen on Almonds and Stone Fruits and FFDCA Tolerances

Almonds: The situation involving the discovery of Red Imported Fire Ant (RIFA) mounds in California almond orchards is urgent and non-routine, as this is a new pest which may become a serious economic pest as well as a public health pest in California, if its spread is not checked at this point. The Applicant states that a RIFA infestation could cause significant economic impacts to the affected growers, as well as other agricultural and non-agricultural interests for years to come. There are significant potential long-term losses, as well as the adverse impacts to other growers and entities, should RIFA infestations become established in the area

Stone Fruits: California has requested the use of pyriproxyfen due to the development of organophosphate-resistant San Jose scale populations. According to the Applicant, decades of organophosphate and carbamate insecticide usage, with no alternative modes of action have led to a build-up of these resistant populations. Individual orchards are now experiencing significant yield losses despite multiple insecticide applications. There are currently no insecticides registered for San Jose scale control in stone fruits which do not use acetyl-cholinesterase inhibition as their mode of action. Once a scale population takes over an orchard, it is difficult to bring it under control. Heavy infestations kill off branches and reduce yields. EPA has authorized under FIFRA section 18 the use of pyriproxyfen on almonds and stone fruits for control of Red Imported Fire Ants, and Resistant San Jose Scale, respectively in California. After having reviewed the submission, EPA concurs that emergency conditions exist for this state.

As part of its assessment of these emergency exemptions, EPA assessed the potential risks presented by residues of pyriproxyfen in or on almond nutmeats and hulls, and stone fruits. In doing so, EPA considered the 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 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 the tolerance for stone fruit will expire and is revoked on August 31, 2000, and the tolerances for almond commodities will expire and are revoked on April 30, 2002, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on almond nutmeats and hulls, or stone fruits after these dates will not be unlawful, provided the pesticide is

applied in a manner that was lawful under FIFRA, and the residues do not exceed levels that were 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 almonds and stone fruits or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerance serve as a basis for registration of pyriproxyfen by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than California to use this pesticide on these crops under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemptions for pyriproxyfen, contact the Agency's Registration Division at the address provided under the **ADDRESSES** section.

## III. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7) .

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 almond nutmeats and hulls, and stone fruits at 0.02, 2.0, and 0.1 ppm, respectively. 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 in this unit.

### *B. Toxicological Endpoint*

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 Reference Dose (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 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.

### *C. 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 tomatoes, pears, and citrus commodities, in association with use under emergency exemptions. Permanent tolerances were recently established for cotton commodities (July 6, 1998, 63 FR 36366). Risk assessments were conducted by EPA to assess dietary exposures and risks from pyriproxyfen as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. An acute dietary dose and endpoint was not identified in the database. The Agency concludes that there is a reasonable certainty of no harm from acute dietary exposure.

ii. *Chronic exposure and risk.* As stated above, tolerances for cotton commodities were recently established, and there are time-limited tolerances established in connection with use under emergency exemptions for citrus commodities, pears, and tomatoes. The chronic dietary (food only) risk assessment used tolerance level residues and assumed 100% crop treated. The Novigen Dietary Exposure Evaluation Model (DEEM) analysis was used and this analysis evaluates individual food consumption as reported by respondents in the USDA Continuing Surveys of Food Intake by Individuals conducted in 1989 through 1992. The model accumulates exposure to the chemical for each commodity and expresses risk as a function of dietary exposure. Resulting exposure values (at the 99th percentile) and percentage of the acute RfD are given below. Values for the 99th percentile are considered to be conservative as OPP policy dictates exposure estimates from as low as the 95th percentile may be utilized for risk estimates from DEEM runs. Thus, these results are viewed as conservative estimates, and refinement using anticipated residue values and percent crop treated information, would result in lower estimates of acute dietary exposure and risk. For chronic dietary (food only) risk estimates, the two most highly exposed subgroups, Children (1-6 years old) and Children (1-7 years old) had 1.9 and 1.2% of the RfD utilized, respectively. All other population subgroups had less than 1% of the RfD utilized, except for Non-hispanic other than black or white, which had 1.1% of the RfD utilized.

2. *From drinking water.* 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 part per billion (ppb), to a 60-day 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.

i. *Acute exposure and risk.* An acute dietary dose and endpoint was not identified in the database. The Agency concludes that there is a reasonable certainty of no harm from acute exposure through drinking water.

ii. *Chronic exposure and risk.* A human health drinking water level of comparison (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 2L per day for adults and 1L per day for children. Using these assumptions and the levels provided by the computer models, given above, the DWLOCs were calculated to be 12,168 and 3,436 ppb, for the Overall U.S. population, and Children (1-6 Yrs. old), respectively. Since these levels are very significantly higher than the EECs calculated above, 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).

i. *Acute exposure and risk.* An acute endpoint was not identified in the database. The Agency concludes that there is a reasonable certainty of no harm from acute residential non-food exposure.

ii. *Chronic exposure and risk.* With the exception of the pet collar use, consumer use of these residential-use products typically results in short-term, intermittent exposures. Hence, chronic residential exposure and risk assessments were conducted to estimate the potential risks from pet collar uses only. The estimated chronic term Margins of Exposure (MOEs) was 230,000 for children, and 430,000 for adults, which indicates that potential risks from pet collar uses do not exceed levels of concern. (An MOE of 100 or more is generally considered to be of no concern.)

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

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.''

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. For more information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

*D. Aggregate Risks and Determination of Safety for U.S. Population*

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

2. *Chronic risk.* Using the TMRC exposure assumptions described in this unit, EPA has concluded that aggregate exposure to pyriproxyfen from food will utilize 0.7%, respectively of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is Children (1 - 6 years old with 1.9% of the RfD utilized by food. 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. 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.

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.

4. *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.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to pyriproxyfen residues.

*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 2-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 margin of exposure (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 1000 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 1000 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 in this unit, EPA has concluded that aggregate exposure to pyriproxyfen from food will utilize 1.9% of the RfD for the most highly exposed infant and children population subgroup, 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. 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.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to pyriproxyfen residues.

## IV. 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 may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5229.

### *C. Magnitude of Residues*

Residues of pyriproxyfen are not expected to exceed 0.02 ppm in/on almond nutmeat, 2.0 ppm in/on almond hulls, and 0.1 ppm in/on stone fruits; 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 almond nutmeats or hulls, or stone fruits.

### *E. Rotational Crop Restrictions*

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

## V. Conclusion

Therefore, the tolerances are established for residues of pyriproxyfen in almond nutmeats and hulls at 0.02 and 2.0 ppm, respectively, and on stone fruits at 0.1 ppm.

## VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation 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 May 3, 1999, 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 under the ''ADDRESSES'' section (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). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection. For additional information regarding tolerance objection fee waivers, contact James 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: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection

Agency, 401 M St., SW., Washington, DC 20460.

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.

## VII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300794] (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.

Objections and hearing requests may be sent by e-mail directly to EPA at: opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit 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 record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

## VIII. Regulatory Assessment Requirements

### *A. Certain Acts and Executive Orders*

This final rule establishes a tolerance under section 408 of the FFDCA. 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 tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(l)(6), such as the tolerance 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 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.

### *B. Executive Order 12875*

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

### *C. Executive Order 13084*

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on

matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

### IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the United States prior to publication of the rule in the **Federal Register**. This rule 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: February 11, 1999.

**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. Section 180.510 is revised to read as follows:

### § 180.510 Pyriproxyfen; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the insecticide pyriproxyfen in or on the following agricultural commodities:

| Commodity | Parts per million |
|---|---|
| Cotton, gin byproducts | 2.0 |
| Cottonseed | 0.05 |

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the residues of the insect growth regulator pyriproxyfen, in connection with the use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire on the dates specified in the following table.

| Commodity | Parts per million | Expiration/revocation date |
|---|---|---|
| Almond hulls | 2.0 | 4/30/02 |
| Almond nutmeats | 0.02 | 4/30/02 |
| 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 |
| Stone fruits (Crop Group 12). | 0.1 | 8/31/00 |
| Tomatoes | 0.1 | 7/31/99 |

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

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

### § 180.534 [Removed]

3. Section 180.534 is removed.

[FR Doc. 99–4832 Filed 3–2–99; 8:45 am]

BILLING CODE 6560–50–F

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[OPP–300767A; FRL–6049–2]**

## Dicamba (3,6-dichloro-o-anisic acid); Pesticide Tolerance, Technical Correction

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule, correction.

**SUMMARY:** This document makes a technical correction to the dicamba pesticide tolerance regulations that established, revised and revoked tolerances for use of the combined residues of dicamba on various raw agricultural commodities.

**DATES:** This technical correction is effective on March 3, 1999.

**FOR FURTHER INFORMATION CONTACT:** By mail: Joanne I. Miller, 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) 305–6224, e-mail: miller.joanne@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:**

### I. Background

In the **Federal Register** of November 20, 1998 (63 FR 64481)(FRL–6043–9), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of pesticide petitions (PP 6F4604, 4F3041 and FAP 4H5428) for tolerances by BASF Corporation. This notice included a summary of the petitions prepared by BASF. There were no comments received in response to the notice of filing.

In the **Federal Register** of January 6, 1999 (64 FR 759)(FRL–6049–2) EPA issued a rule amending 40 CFR 180.227 by establishing, revising and revoking tolerances for combined residues of the herbicide dicamba (3,6-dichloro-*o*-anisic acid) and its metabolites 3,6-dichloro-5-hydroxy-*o*-anisic acid and 3,6-dichloro-2-hydroxybenzoic acid.

### II. Why is this Technical Correction Issued as a Final Rule?

EPA is publishing this action as a final rule without prior notice and comment because the Agency believes that providing notice and comment is unnecessary and would be contrary to the public interest. As explained in Unit II of this preamble, the corrections contained in this action will correct errors in the preamble and the amendatory instructions to a previously published Final rule. EPA finds that there is ''good cause'' under section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)(3)(B) to make this amendment without prior notice and comment.

### III. Do Any of the Regulatory Assessment Requirements Apply to this Action?

No. This final rule does not impose any new 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). This action does not impose any enforceable duty, contain any unfunded mandate, or impose any significant or unique impact on small governments as described in the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require prior