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 to 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.

IV. 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 to the Comptroller General of the United States. EPA will submit 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 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: September 29, 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.

180.449 -- [AMENDED]

§ 180.449 Avermectin; tolerances for residues.

2. In § 180.449, in the table for paragraph (b), the entry for ''Basil'', change the date ''9/30/98'' to read ''1/31/00''.

[FR Doc. 98–26907 Filed 10–6–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300737; FRL 6036–2]

RIN 2070–AB78

Pyridate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a permanent tolerance for combined residues of pyridate, *O*-(6-chloro-3-phenyl-4-pyridazinyl)-*S*-octyl carbonothioate and its metabolite 6-chloro-3-phenyl-pyridazine-4-ol (known as CL–9673), and conjugates of CL–9673, expressed as pyridate, in or on chickpeas (also known as garbanzo beans). The tolerance was requested by the Interregional Research Project 4 (IR–4) under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective October 7, 1998. Objections and requests for hearings must be received by EPA on or before December 7, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, OPP–300737, 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–300737, 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@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 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number OPP–300737. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Sidney Jackson, 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) 305–7610, e-mail: jackson.sidney@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 5, 1998 (63 FR 41835) (FRL 6017–1) 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 a pesticide petition (PP) for tolerance by the Interregional Research Project 4 (IR–4). This notice included a summary of the petition prepared by Novartis Crop Protection, Inc. , the registrant.

The petition requested that 40 CFR 180. 462 be amended by establishing a tolerance for combined residues of the fungicide pyridate, *O*-(6-chloro-3-phenyl-4-pyridazinyl)-*S*-octyl carbonothioate and its metabolite 6-chloro-3-phenyl-pyridazine-4-ol (known as CL–9673), and conjugates of CL–9673, expressed as pyridate, in or on chickpeas at 0.1 part per million (ppm).

I. Risk Assessment and Statutory Findings

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. ''

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 November 26, 1997 (62 FR 62961) (FRL 5754–7).

II. 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 pyridate and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for combined residues of pyridate, *O*-(6-chloro-3-phenyl-4-pyridazinyl)-*S*-octyl carbonothioate and its metabolite 6-chloro-3-phenyl-pyridazine-4-ol (known as CL–9673), and conjugates of CL–9673, expressed as pyridate on chickpeas at 0.1 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by pyridate are discussed below.

1. *Acute toxicity*. The required battery of acute toxicity studies has been submitted and found adequate. The findings were as follows: oral toxicity shows a lethal dose $(LD)_{50}$, 5,993 milligrams (mg) / kilogram (kg) (males), and LD_{50}, 3,544 mg/kg (females) for a Category III toxicant classification; acute dermal toxicity is a LD_{50} > 2,000 mg/kg (Toxicity Category III); acute inhalation toxicity shows a lethal concentration $(LC)_{50}$ > 4.37 mg/liter (L) (four hour exposure) (Toxicity Category IV); primary eye irritation is Toxicity. Category IV, non-irritant; Primary Dermal Irritation is slightly irritating to the skin under conditions of test (Toxicity Category III); and dermal sensitization is positive for skin sensitizer.

2. *Genotoxicity*. Test results show pyridate does not elicit a mutagenic response in multiple assays. In Gene Mutation Assay (Ames Test), no appreciable increase in the reversion to histidine protrophy of 4 *S. typhimurium* strains at 1 to 10,000 micrograms (µg)/plate with and without S-9 activation. Gene Mutation Assay in mammalian cells shows pyridate to be nonclastogenic in Chinese Hamster Ovary Cells with and without metabolic activation up to 250 µg/mL.

Structural Chromosomal Aberration Assay *In vivo* cytogenetics did not induce chromosomal aberrations nonclastogenic with and without metabolic activation under the conditions of the study up to 4 grams/kg. Nonclastogenic in chromosomal aberrations in bone marrow cells sampled over the entire mitotic cycle at doses from 0.073 to 0.725 grams/mL resulted in a second such assay.

An Unscheduled DNA Synthesis Assay did not induce an increase in unscheduled DNA synthesis up to toxic dose (0.1–1000 µg/mL tested).

3. *Reproductive and developmental toxicity*—i. In a prenatal developmental toxicity study in Wistar/HAN rats, pyridate in carboxymethyl cellulose was administered at doses of 0, 55, 165, or 400 mg/kg/day by gavage on gestation days 6–15. For maternal toxicity, the No observed adverse effect level (NOAEL) was 165 mg/kg/day and the Lowest observed adverse effect level (LOAEL) was 400 mg/kg/day based on mortality, significant decrease in mean body weight and food consumption as well as clinical signs (ventral body position, dyspnea, sedation, and loss of reaction to external stimuli). The developmental NOAEL was 165 mg/kg/day and the developmental LOAEL was 400 mg/kg/day, based on increased incidences of missing and/or unossified sternebrae and dose-related decrease in mean fetal body weight.

ii. *Developmental toxicity*. Technical 89.5% pyridate was administered in a prenatal developmental toxicity study conducted in pregnant New Zealand white rabbits at doses by gavage of 0, 150, 300 or 600 mg/kg/day on gestation days 7–19. For maternal toxicity, the NOAEL was 300 mg/kg/day and the LOAEL was 600 mg/kg/day, based on decreased body weight and body weight gain, decreased food consumption, increased incidence of dried feces, and increased abortions. For developmental toxicity, the NOAEL ≧ was 600 mg/kg/day, the highest dose tested (HDT); a LOAEL was not established.

iii. *Three-generation reproduction study*. Sprague-Dawley rats received diets containing pyridate at doses of 0,

43, 216 or 1,350 ppm (0, 2.2, 10.8 or 67.5 mg/kg/day, respectively). Each generation of rats was mated to produce two litters. The parental systemic NOAEL was 216 ppm (10.8 mg/kg/day) and the LOAEL was 1,350 ppm (67.5 mg/kg/day) based on depression of maternal body weight gain. The NOAEL for offspring was 216 ppm (10.8 mg/kg/day) and the LOAEL was 1,350 ppm (67.5 mg/kg/day) based on decreased pup weight gains (at postnatal and day 14 and 21 in the first litters for both generations).

The oral rat and rabbit developmental studies and the oral rat reproduction study demonstrated no indication of increased sensitivity of rats or rabbits to *in utero* and postnatal exposure to pyridate.

4. *Subchronic toxicity*—i. Subchronic feeding in rats (13 weeks) resulted in hypoactivity and salivation in both sexes with a NOAEL = 62.5 mg/kg/day and the LOAEL at 177 mg/kg/day.

ii. A subchronic feeding in dogs (13 weeks) showed a NOAEL at 20 mg/kg/day and the LOAEL at 60 mg/kg/day based on emesis and ataxia in both sexes. Severe neurotoxicity and death were observed at 200 mg/kg/day (HDT).

iii. In a 21–day dermal study in rats, the NOAEL for systemic effects was > 1,000 mg/kg/day limit dose. No systemic toxicity was seen at any dose tested. A LOAEL for systemic effects was not established in this study.

5. *Chronic toxicity/carcinogenicity*—i. Technical (91.5%) pyridate material was fed by capsule to 5 dogs/group/dose at levels of 0, 5/30, 20/100, or 60/150 mg/kg/day for one year. A LOAEL of 100 mg/kg/day was based on excessive salivation, ataxia, mydriasis, dyspnea, tremors, increased respiration and prostration. The NOAEL is 20 mg/kg/day.

ii. *Carcinogenicity study in mice*. Technical (90.4%) pyridate test material was given to male and female B6C3F1 mice in diet for 18 months at 0, 400, 800, 1,600 ppm or 7,000 ppm; (0, 47.7, 97.1, 169.5, or 882.6 mg/kg/day for males; 0, 54.5, 114.6, 204.3, or 1,044.6 mg/kg/day for females. No statistically significant increase in tumor incidence relative to controls were observed in either sex at any dose, including the limit dose 7,000 ppm. Neither the NOAEL or the LOAEL could be established due to decreased weight gain in both sexes at all doses.

iii. *Chronic feeding/carcinogenicity study in rats*. Technical (90.3%) pyridate was administered to male and female SPF rats in diet for 24 months at 0, 43, 215 and 1,350 ppm; (0, 2.2, 10.8 or 67.5 mg/kg/day). Decrease in body weight in males at 67.5 mg/kg/day was basis of the LOAEL. NOAEL is 10.8 mg/kg/day.

6. *Metabolism in rats*. Following is a summary of rat metabolism values and categories for pyridate:

i. Rapidly absorbed and excreted. Greater than 95% was eliminated by 24 hrs. Extensively metabolized prior to excretion. Metabolic patterns similar for both sexes.

ii. Completely and rapidly absorbed. Extensively metabolized and rapidly and essentially completely excreted. Elimination of label from single dose of 5.45 mg/rat of C^{14}-pyridate.

iii. Multiple oral doses 5 mg/rat/day for 10, 15, or 20 days result in bioaccumulation in liver, spleen and fat. Clearance from all tissues was slower after repeated exposure. Female rats eliminated radioactivity slower than males.

7. *Neurotoxicity*. Neurotoxicity was observed in the 90 day rat and dog studies and the 1–year dog study. Clinical signs indicative of neurotoxicity characterized as ataxia and emesis were observed within 1–3 hours post-dosing on the first day and persisted for duration of study.

B. Toxicological Endpoints

1. *Acute toxicity*. The acute dietary endpoint selected for risk assessment was the NOAEL of 20 mg/kg/day based on test results where groups of beagle dogs (4/sex/dose) received gelatin capsules containing pyridate at doses of 0, 20, 60 or 200 mg/kg/day for 90 days. The LOAEL was 60 mg/kg/day based on ataxia and emesis observed within 1–3 hours dosing beginning on the first day. All dogs at 200 mg/kg/day exhibited severe emesis and severe ataxia 1 to 3 hours post dosing and signs of opisthotonos, nystagmus and mydriasis also occurred within 3 hours after dosing.

2. *Short - and intermediate - term toxicity*. The short- and intermediate-term endpoints are derived from a 90–day feeding study in dogs. The NOAEL for both short- and intermediate-term exposures is 20 mg/kg/day.

Although a 21–day dermal toxicity study in rats was available and no dermal or systemic toxicity was demonstrated in that study at the Limit-Dose, an oral dose from the 90–day dog study was selected for short- and intermediate-term endpoints because:

i. Dogs were shown to be the sensitive species for pyridate-induced neurotoxic effects.

ii. The effects seen on the first day persisted for the duration of study. Since an oral dose was selected, a dermal absorption rate no more than 20% is used for risk assessments.

For short-and intermediate-term inhalation exposure, pyridate, based on the LC_{50} value of 4.37 mg/L, is placed in Toxicity Category IV. An inhalation risk assessment may not be required. This is supported by the absence of residential uses of pyridate.

Since only an acute inhalation toxicity study was available, EPA used oral NOAELs for the inhalation exposure risk assessments. Because of the low acute inhalation toxicity of pyridate, and minimal volatility (vapor pressure of pyridate is 1.01×10^{-7} mm mercury (Hg), inhalation exposure is considered very low (less than 6%) to occupational workers. For this reason, an inhalation MOE for workers was not calculated.

There are currently no residential uses for pyridate and no residential exposure study was performed. The Agency concludes that no risk assessment for short- and intermediate-term risk is required.

3. *Chronic toxicity*. EPA has established the RfD for pyridate at 0.11 mg/kg/day. This RfD is based on a study where rats (15/sex/dose) were fed diets containing pyridate 0, 2.2, 10.8 or 67.5 mg/kg/day for 104 weeks. The NOAEL was 10.8 mg/kg/day and the LOAEL 67.5 mg/kg/day based on decreased body weight gain in males. For chronic dietary risk assessment, an uncertainty factor (UF) of 100 is adequate for the protection of all subpopulation from exposure to pyridate.

4. *Carcinogenicity*. Pyridate is classified as Category E, a non-carcinogen, based on studies from two acceptable animals studies which showed no significant increase in tumor incidence in male or in female test animals at dose levels up to 7,000 ppm.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.462) for the combined residues of pyridate, *O*-(6-chloro-3-phenyl-4-pyridazinyl)-*S*-octyl carbonothioate and its metabolite 6-chloro-3-phenyl-pyridazine-4-ol (known as CL–9673), and conjugates of CL–9673 expressed as pyridate, in or on a variety of raw agricultural commodities. Permanent tolerances are established for residues of pyridate (40 CFR 180.462) on cabbage, corn (forage, fodder, grain, silage), and peanuts (hulls, nutmeat) at 0.03 ppm. There are no food or feed additive tolerances. No tolerances have been established on animal commodities. Pyridate is not registered for outdoor residential or greenhouse uses. Risk assessments were conducted by EPA to assessed dietary exposures from pyridate as follows:

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.

2. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The endpoint selected by the Agency for assessment of acute dietary risk is 20 mg/kg/day (NOAEL), based on a 90–day feeding study in dogs. This acute dietary (food) risk assessment assumed that all food for which there are tolerances would have residues at the tolerance level. Using the acute endpoint, NOAEL (mg/kg/day) and these exposure assumptions margin of exposure (MOE) for subgroups can be calculated as follows:

MOE = Acute Endpoint (NOAEL, mg/kg/day) / Exposure (TMRC, mg/kg/day)

For the U.S. Population (48 states) subgroup, the MOE is 100,000. For Infants, < 1 year old, the most highly exposed subgroup, the MOE is 40,000. All population subgroups show a MOE well above the critical level, MOE = 100, for which the Agency is concerned. The Agency concludes that there is reasonable certainty that public health will not be harmed by acute exposure and risk from pyridate uses at the proposed tolerance levels. This is due to the conservative assumptions leading to the overestimation of pyridate acute dietary exposure.

3. *Chronic exposure and risk.* The chronic dietary exposure analysis from food sources was conducted using the reference dose (RfD) of 0.11 mg/kg/day. The RfD is based on the NOAEL of 10.8 mg/kg/day in male rats from the chronic toxicity/carcinogenicity study in rats, and an uncertainty factor of 100 applicable to all population subgroups.

In conducting this chronic dietary risk assessment, EPA has made very conservative assumptions: 100% of chickpeas and all other commodities having pyridate tolerances will contain pyridate residues at the level of the established tolerance. This results in an overestimate of human dietary exposure. Thus, in making a safety determination for this tolerance, EPA is taking into account this conservative exposure assessment.

The existing pyridate tolerances (published, pending, and including the necessary section 18 tolerances) result in exposure that is equivalent to the following percentages of the RfD:

Population Subgroup	%RfD
U.S. Population (48 states) ..	0.014
Nursing Infants < 1 year old	0.009
Non-Nursing Infants	0.028 < 1 year old
Children 1–6 years old	0.033
Children 7–12 years old	0.025
Southern Region	0.016
Western Region	0.015
Hispanics	0.018
Non-Hispanic Others	0.020
Males 13–19 years old	0.015

The subgroups listed above are:

i. The U.S. population (48 states).

ii. Those for infants and children.

iii. The other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 states).

4. *From drinking water.* The generic expected environmental concentration (GENEEC) model and the SCI-GROW model were run to produce estimates of pyridate concentrations in surface and ground water respectively. The primary use of these models is to provide a coarse screen for sorting out pesticides for which EPA has a high degree of confidence that the true levels of the pesticide in drinking water will be less than the human health drinking water levels of concern (DWLOCs). A human health DWLOC is the concentration of a pesticide in drinking water which would result in unacceptable aggregate risk, after having already factored in all food exposures and other non-occupational exposures for which EPA has reliable data.

5. *Acute and chronic exposure and risk.* The calculated drinking water levels of concern (DWLOCs) for acute exposure to pyridate in surface and ground water are 7,000 µg/liter(L) for all 3 population subgroups evaluated. For chronic (non-cancer) exposure to pyridate in surface and ground water, the DWLOCs are 3,850 µg/L for males (13 yrs+), 3,300 µg/L for females (13 yrs+) and 1,100 µg/L for children (1–6 yrs). To calculate the DWLOC for acute exposure relative to an acute toxicity endpoint, the acute dietary food exposure (from the dietary risk evaluation system (DRES) analysis) was subtracted from the ratio of the acute NOAEL (used for acute dietary assessments) to the ''acceptable'' for aggregate exposure to obtain the acceptable acute exposure to pyridate in drinking water. To calculate the DWLOC for chronic (non-cancer) exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure from DRES was subtracted from the RfD to obtain the acceptable chronic (non-cancer) exposure to pyridate in drinking water. DWLOCs were then calculated using default body weights and drinking consumption figures.

Estimated Environmental Concentrations (EEC) of pyridate in surface and ground water are 97 and 5 ppb respectively. Estimated average concentrations of pyridate in surface and ground water are 25 (after adjustment) and 5 ppb respectively. The EEC of pyridate in surface and ground water are less than EPA's levels of concern for pyridate in drinking water as a contribution to acute and chronic aggregate exposure. Therefore, EPA concludes with reasonable certainty that residues of pyridate in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk.

6. *From non-dietary exposure.* Pyridate is not currently registered for use on any the following residential non-food sites. Pyridate is not registered for outdoor residential or greenhouse uses, therefore, no residential exposure study is required. Although it is shown to be a skin sensitizer, all other required acute toxicological studies placed pyridate in either Toxicity Categories III or IV, representing a low level toxicant. Pyridate has a complete toxicological data base and no other concerns regarding acute toxicity have been identified.

Occupational exposure estimates for pyridate did not exceed the Agency's level of concern. However, due to potential for exposure, risk assessments are being required for short- and intermediate-term dermal exposure, as well as, short-, intermediate, and long-term exposure. A long-term risk assessment would be required if a long-term exposure senarios were present.

However, at this time, pyridate is not used in any long-term senarios.

7. *Short- and intermediate-term exposure and risk*. The short and intermediate occupational and residential endpoint selected for risk assessment was the NOAEL of 20 mg/kg/day based on ataxia and emesis at 60 mg/kg/day as determined by a 90–day dog feeding study..

A dermal absorption study was not available for evaluation. Although a 21–day dermal toxicity study in rats was available and no dermal or systemic toxicity was demonstrated in that study at the Limit-Dose (1,000 mg/kg/day), an oral dose from the 90–day dog study was selected because:

i. Dogs were shown to be the sensitive species for pyridate-induced neurotoxic effects.

ii. The effects seen on the first day persisted for the duration of study. The Agency estimated a dermal absorption rate of 20% percent based on the interpretation of data from oral and dermal studies in rats.

8. *Inhalation exposure*. In general, a risk assessment for inhalation route is not necessary for pesticides placed in Toxicity Category IV (i.e., low toxicity concern). Pyridate, based on the LC_{50} value of 4.37 mg/L is placed in Toxicity Category IV. However, because of the potential for exposure via this route, a risk assessment may be required. Since only an acute inhalation toxicity study was available, the Agency relies on the oral NOAELs for the inhalation exposure risk assessments.

Since only an acute inhalation toxicity study was available, the oral NOAELs for the inhalation exposure risk assessments were used. The 90–day dog feeding study was chosen for short- and intermediate-term inhalation exposure. NOAEL = 20 mg/kg/day and the chronic toxicity/carcinogenicity rat feeding study was chosen for long-term inhalation exposure. NOAEL = 10.8 mg/kg/day.

9. *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 pyridate 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, pyridate 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 pyridate has a common mechanism of toxicity with other substances. For 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 November 26, 1997 (62 FR 62961) (FRL 5754–7).

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

1. *Acute risk*. From the acute dietary (food only) risk assessment, the following high end exposure estimates were calculated: 0.00018 mg/kg/day for the general U.S population; 0.00012 mg/kg/day for males (13 + yrs); 0.00012 mg/kg/day for females (13 + years); 0.0005 mg/kg/day for infants (< 1 yr); 0.0003 mg/kg/day for children (1–6 yrs). These exposures yield dietary (food only) MOEs ranging from 40,000 to 170,000 for these population subgroups. The maximum estimated concentrations of pyridate in surface and ground water are less than EPA's levels of concern for pyridate in drinking water as a contribution to acute aggregate exposure. Therefore, EPA concludes with reasonable certainty that residues of pyridate in drinking water do not contribute significantly to the aggregate acute human health risk at the present time when considering the present uses and the uses proposed by this action. Thus, the aggregate acute risk (food and water) is not expected to exceed the Agency level of concern for acute dietary exposure.

2. *Chronic risk*. Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to pyridate from food will utilize 0.014% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is ''discussed 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 pyridate 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 from chronic aggregate exposure to pyridate residues.

3. *Short- and intermediate-term risk*. Pyridate is not currently registered for any residential uses. Therefore, no residential exposure (short- or intermediate-term) is anticipated and a short- and intermediate-term aggregate risk assessment is not required.

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. For the U.S. population, 0.014% of the RfD is occupied by dietary (food) exposure. Because pyridate has no residential uses, no chronic residential exposure is anticipated. The estimated average concentrations of pyridate in surface and ground water are less than EPA's level of concern for pyridate in drinking water as a contribution to chronic aggregate exposure. Therefore, EPA concludes with reasonable certainty that residues of pyridate in drinking water do not contribute significantly to the short- and intermediate-term aggregate human health risk at the present time when considering the present uses and uses proposed by this action.

4. Aggregate cancer risk for U.S. population. Pyridate has been classified as a Group E chemical, with no evidence of carcinogenicity for humans in two acceptable animal (mouse and rat) studies. Thus, a cancer risk assessment is not required.

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 pyridate residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children —In general*. In assessing the potential for additional sensitivity of infants and children to residues of pyridate, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the r at. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure 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 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.

2. *Pre- and post-natal sensitivity*. The oral perinatal and prenatal data demonstrated no indication of increased sensitivity of rats or rabbits to *in utero* and postnatal exposure to pyridate.

3. *Conclusion*. There is a complete toxicity database for pyridate and exposure data are complete or estimated based on data that reasonably account for potential exposures. EPA concludes that reliable data support removal of the additional tenfold safety factor.

4. *Acute risk*. The acute dietary endpoint selected for risk assessment was the NOAEL of 20 mg/kg/day based on a 90–day feeding study in dogs.

From the acute dietary (food only) risk assessment, risk calculations for infants <1 yr old is 0.0005 mg/kg/day and 0.0003 mg/kg/day for children (1–6 yrs). These exposures yield dietary (food only) MOEs of 40,000 and 70,000, respectively, for these population subgroups.

The maximum estimated concentrations of pyridate in surface and ground water are less than EPA's levels of concern for pyridate in drinking water as a contribution to acute aggregate exposure. Therefore, EPA concludes with reasonable certainty that residues of pyridate in drinking water do not contribute significantly to the aggregate acute human health risk at the present time when considering the present uses and the uses proposed by this action.

EPA's bases this determination on a comparison of estimated concentrations of pyridate in surface and ground water to levels of concern for pyridate in drinking water. The estimates of pyridate in surface and ground water are derived from water quality models that use conservative assumptions regarding the pesticide transport from the point of application to surface and ground water. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with the pesticide's uses, levels of concern in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impact of pyridate in drinking water as part of the aggregate acute risk assessment process.

5. *Chronic risk*. Using the exposure assumptions described above, EPA has concluded that aggregate exposure to pyridate from food will utilize 0.033% of the RfD for 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. Despite the potential for exposure to pyridate in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the chronic aggregate exposure to exceed 100% of the RfD.

6. *Short- or intermediate-term risk*. Pyridate is not registered for residential use. No residential exposure or short- or intermediate-term risk is therefore expected. A short- and intermediate-term risk assessment is not required.

7. *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 pyridate residues.

III. Other Considerations

A. Metabolism In Plants and Animals

The metabolism of pyridate in plants is well understood based on studies with broccoli, corn, and peanuts. Pyridate is rapidly broken down by hydrolysis and further conjugated to glucoside and degraded. Adequate acceptable metabolism studies have also been conducted in lactating goats, cows and laying hens.

Based on those studies, the nature of the residue in plants and ruminants is considered to be adequately understood. The total toxic residue consists of pyridate, its metabolite 6-chloro-3-phenyl-pyridazine-4-ol CL-9673, and conjugates of that metabolite, all expressed as pyridate.

B. Analytical Enforcement Methodology

The residue analytical method used is a total residue procedure. Pyridate, CL–9673, and conjugated CL–9673 are hydrolyzed to CL–9673 and measured as such by UV-HPLC. The limit of determination is 0.03 ppm. The method has undergone validation in EPA laboratories and is suitable to gather residue data and to enforce tolerances. It was sent to FDA for inclusion in PAM II. The multi residue recovery data have been sent for inclusion in PAM I.

C. Magnitude of Residues

Results from field studies show that the maximum residue pyridate, CL–9673, and hydrolyzable CL–9673 in sum, expressed as CL–9673 recovered in any bean sample from garbanzo plants treated twice at the proposed label rate of 0.9 lbs ai/A was 0.057 ppm. The maximum pyridate residue recovered in bean plus hull samples from garbanzo plants treated twice at the proposed label rate of 0.9 lbs ai/A was < 0.030 ppm.

The maximum residue (pyridate, CL–9673, and hydrolyzable CL–9673 in sum, expressed as CL–9673) recovered in any bean sample from garbanzo plants treated twice at the proposed label rate of 1.8 lbs ai/A was < 0.030 ppm. The maximum pyridate residue recovered in bean plus hull samples from garbanzo plants treated twice at the proposed label rate of 1.8 lbs ai/A was < 0.030 ppm. Therefore, the combined residues of pyridate *O*-(6-chloro-3-phenyl-4-pyridazinyl)-*S*-octyl-carbonothioate, the metabolite 6-chloro-3-phenyl-pyridazine-4-ol and conjugates of 6-chloro-3-phenyl-pyridazine-4-ol, expressed as pyridate resulting from the proposed use will not exceed 0.1 ppm in chickpeas.

Pyridate is not registered of direct use on potable water, aquatic food and feed crops, or for use in food handling establishments. Moreover, there are no processed commodities and no animal feed items associated with chickpeas.

D. International Residue Limits

There are no CODEX, Canadian, or Mexican tolerances for pyridate residues on chickpeas.

E. Rotational Crop Restrictions

A confined accumulation in rotational crops study with pyridate has previously been submitted to the Agency. Confined rotational crop data using ^{14}C-pyridate at an application rate of 1.8 kg/ha showed no detectable uptake (<0.01 ppm) of residues of pyridate by lettuce, carrots, or barley after a rotational interval of 1 and 2 months. These findings were supported by data showing the rapid metabolism in soil of pyridate residues.

IV. Conclusion

Therefore, the tolerance is established for combined residues of pyridate, *O*-(6-chloro-3-phenyl-4-pyridazinyl)-*S*-octyl carbonothioate and its metabolite 6-chloro-3-phenyl-pyridazine-4-ol (known as CL–9673), and conjugates of CL–9673, expressed as pyridate, in or on chickpeas at 0.1 ppm.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by December 7, 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 or a request for a fee waiver as specified by 40 CFR 180.33. 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 Confidential Business Information (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.

VI. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number OPP–300737 (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.

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition 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 tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

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 to 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.

VIII. 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 to the Comptroller General of the United States. EPA will submit 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 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: September 29, 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. §180.462, is amended by adding alphabetically ''chickpeas'' to the table in paragraph (a), and by removing and reserving paragraph (b) to read as follows:

§180.462 Pyridate; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
* * * *	* * *
Chickpeas	0.1
* * * *	* * *

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

* * * * *

[FR Doc. 98–26908 Filed 10–6–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 264 and 265

[FRL–6173–2]

Project XL Site-Specific Rulemaking for OSi Specialties, Inc., Sistersville, WV

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical correction.

SUMMARY: The EPA is implementing a project under the Project XL program for the OSi Specialties, Inc. plant, a wholly owned subsidiary of Witco Corporation, located near Sistersville, West Virginia (the ''Sistersville Plant''). The terms of the XL project are defined in a Final Project Agreement (''FPA''). Following public review and comment, the FPA was signed by delegates from the EPA, the West Virginia Division of Environmental Protection (''WVDEP''), and Witco Corporation on October 17, 1997. The EPA published a final rule, applicable only to the Sistersville Plant, on September 15, 1998 (See 63 FR 49384). That action was a site-specific regulatory deferral from the Resource Conservation and Recovery Act (''RCRA'') organic air emission standards, commonly known as RCRA Subpart CC. The EPA expects this XL project to result in superior environmental performance at the Sistersville Plant, while deferring significant capital expenditures, and thus providing cost savings for the Sistersville Plant.

Since publication of the final rule on September 15, 1998, it has come to the EPA's attention that the **Federal Register** notice contained a typographical error in the regulatory language that could result in some confusion regarding the time allowed for an owner or operator to conduct a performance test. Today's action makes the technical corrections to that published regulatory text.

EFFECTIVE DATE: This technical correction to the final rule is effective on October 7, 1998.

ADDRESSES: Docket. Three dockets contain supporting information used in developing the September 15, 1998 published final rule, and are available for public inspection and copying at the EPA's docket office located at Crystal Gateway, 1235 Jefferson Davis Highway, First Floor, Arlington, Virginia. The public is encouraged to phone in advance to review docket materials. Appointments can be scheduled by phoning the Docket Office at (703) 603–9230. Refer to RCRA docket numbers F–98–MCCP–FFFFF, F–98–MCCF–FFFFF, and F–98–MCCA–FFFFF.

A duplicate copy of each docket is available for inspection and copying at U.S. EPA, Region 3, 1650 Arch Street, Philadelphia, PA, 19103–2029, during normal business hours. Persons wishing to view a duplicate docket at the Philadelphia location are encouraged to contact Mr. Tad Radzinski in advance, by telephoning (215) 814–2394.

FOR FURTHER INFORMATION CONTACT: Mr. Tad Radzinski, U.S. Environmental Protection Agency, Region 3 (3WC11), Waste and Chemicals Management Division, 1650 Arch Street, Philadelphia, PA, 19103–2029, (215) 814–2394.