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 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 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 24, 1998.

Arnold E. Layne,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. In § 180.1001 the table in paragraph (d) is amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(d) * * *

Inert ingredients	Limits	Uses
* * * * * * *		
Alder bark		Seed germination stimulator
* * * * * * *		

[FR Doc. 98–26618 Filed 10–2–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300725; FRL–6031–5]

RIN 2070–AB78

Pyridaben; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of pyridaben and its metabolites PB–7 (2-tert-butyl-5-[4-(1-carboxy-1-methylethyl) benzylthio]-4-chloropyridazin-3 (2*H*)-one) and PB–9 (2-tert-butyl-4-chloro-5-[4-(1,1-dimethyl-2-hydroxyethyl) benzylthio]-chloropyridazin-3 (2*H*)-one) in or on cranberries. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on cranberries. This regulation establishes a maximum permissible level for residues of pyridaben in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on December 31, 1999.

DATES: This regulation is effective October 5, 1998. Objections and requests for hearings must be received by EPA on or before December 4, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300725], 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–300725], 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 file format or ASCII file format. All copies

of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300725]. 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: David Deegan, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9358, e-mail: deegan.dave@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to sections 408(e) and (l)(6) of the FFDCA, 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for combined residues of the insecticide pyridaben and its metabolites PB–7 (2-tert-butyl-5-[4-(1-carboxy-1-methylethyl) benzylthio]-4-chloropyridazin-3 (2*H*)-one) and PB–9 (2-tert-butyl-4-chloro-5-[4-(1,1-dimethyl-2-hydroxyethyl) benzylthio]-chloropyridazin-3 (2*H*)-one), in or on cranberries at 0.75 part per million (ppm). This tolerance will expire and is revoked on December 31, 1999. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

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

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

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

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

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

II. Emergency Exemption for Pyridaben on Cranberries and FFDCA Tolerances

The southern red mite is a sporadic but serious pest of cranberries in Massachusetts. Until 1996, propargite (Omite) was commonly used to control this pest. However, in 1996 propargite was voluntarily cancelled by the product's registrant, leaving no product registered for control of the mite species. After having reviewed the submission, EPA concurs that emergency conditions exist for this state. EPA has authorized under FIFRA section 18 the use of pyridaben on cranberries for control of Southern Red Mites in Massachusetts.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of pyridaben in or on cranberries. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance 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 this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on December 31, 1999, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on cranberries after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions EPA has not made any decisions about whether pyridaben meets EPA's registration requirements for use on cranberries or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of pyridaben 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 Massachusetts to use this pesticide on this crop 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 exemption for pyridaben, contact the Agency's Registration Division at the address provided above.

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 pyridaben and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for combined residues of pyridaben and its metabolites PB–7 and PB–9 on cranberries at 0.75 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 pyridaben are discussed below.

1. *Acute toxicity*— i. *Subpopulation females 13+ years old. NOAEL = 13 mg/kg.* In a developmental toxicity study, Sprague-Dawley rats (22/group) from Charles River, U.K., received NC–129 (Pyridaben, 98.0% active ingredient (a.i.)) via gavage at dose levels of 0, 2.5, 5.7, 13.0, or 30.0 milligrams/kilogram/day (mg/kg/day) from gestation day 6 through 15, inclusive. Natural mating was used. Maternal toxicity, observed at 13.0 and 30.0 mg/kg/day, consisted of decreased body weight/weight gain and food consumption during the dosing period. Based on these effects, the Maternal Toxicity LOEL is 13.0 mg/kg/day and the Maternal Toxicity NOAEL is 4.7 mg/kg/day (82% of 5.7 mg/kg/day based on concentration analysis). Developmental toxicity NOAEL is 13.0 mg/kg/day based on observed decreased fetal body weight and increased incomplete ossification in selected bones at 30.0 mg/kg/day (LOEL). With the 100 uncertainty factor (UF) (10X for inter-species extrapolation and 10X for intra-species variability) the acute Reference dose (RfD) for females 13+ is 0.13 mg/kg/day.

ii. *General population including infants and children*. NOAEL = 50 mg/kg. In an acute neurotoxicity study, CD Rats (10/sex/group) were administered a single oral dose (gavage) of NC–129 in 1% aqueous carboxymethyl cellulose of 0 (vehicle), 50, 100, and 200 mg/kg (a.i. equivalents: 44.3, 79.6, and 190.0 mg/kg for males and 44.5, 99.7, and 190.0 mg/kg body weight for females). The animals were observed for mortality and clinical signs of toxicity for 14 days post-dosing. During the first 5 days, compound-related decreases in body weight gain were noted in mid-dose males (17%) and females (36%) and high-dose males (74%); the high-dose females lost weight (4 g) during the first 4 days of the observation period. Food consumption was low in all treated groups on the day of dosing with severe effect seen in the high-dose males (73% lower than controls). Dose-dependent increases in clinical signs (piloerection, hypoactivity, tremors, and partially closed eyes) were seen in mid-dose males and high-dose males and females. These effects were reversible by observation Day 4. Treatment-related findings in the functional observational battery consisted of lower body temperature and reduced motor activity (≧ 44%) among the high-dose males. No treatment-related gross or microscopic neuropathologic findings were present. The NOAEL for systemic toxicity is 50 mg/kg for both sexes. The LOEL of 100 mg/kg/day is based on systemic toxicity including clinical signs and decreased food consumption and body weight gain. With the 100 UF (10X for inter-species extrapolation and 10X for intra-species variability) the Acute RfD for the general population is calculated to be 0.5 mg/kg/day.

2. *Short-and intermediate-term toxicity.* NOAEL = 100 mg/kg/day. In a 21–day dermal toxicity study, repeated doses of pyridaben were applied topically to approximately 10% of the body surface area of rats at doses of 0, 30, 100, 300, or 1,000 mg/kg/day for 21 days. Increased squamous cell hyperplasia and/or surface accumulation of desquamated epithelial cells were noted sporadically in the 100, 300, and 1,000 mg/kg/day dose groups. These findings appear to be due to abrasions of the skin when the powdered substance was applied onto the skin, rather than a dose-related effect. No gross dermal irritation effects were noted. Based on the results of the study, the systemic dermal toxicity NOAEL is 100 mg/kg/day. The systemic dermal toxicity LOEL is determined to be 300 mg/kg/day based on decreased body weight in the females. The dermal irritation NOAEL is 100 mg/kg/day. (Note: In agreement, a dermal equivalent dose of 94 mg/kg/day is derived if the maternal oral NOAEL of 4.7 mg/kg/day (based on decreased body weight/weight gain and food consumption) in the rat oral developmental toxicity study is adjusted by the proposed 5% dermal absorption rate).

3. *Chronic toxicity*. EPA has established the RfD for pyridaben at 0.005 mg/kg/day. This RfD is based on a 1–year feeding study in dogs with a NOAEL of 0.5 mg/kg/day and an uncertainty factor of 100 based on decreased body weight, emesis, and ptyalism.

4. *Carcinogenicity*. Because pyridaben has been classified by EPA as a Group E chemical-''no evidence of carcinogenicity to humans,'' no additional analysis is necessary regarding carcinogenicity of this chemical.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.494) for the combined residues of pyridaben and its metabolites PB–7 (2-tert-butyl-5-[4-(1-carboxy-1-methylethyl)benzylthio]-4-chloropyridazin-3(2*H*)-one) and PB–9 (2-tert-butyl-4-chloro-5-[4-(1,1-dimethyl-2-hydroxyethyl) benzylthio]-chloropyridazin-3(2*H*)-one), in or on a variety of raw agricultural commodities, ranging from 0.05 ppm on almonds to 10 ppm in citrus oil. Tolerances have also been established for the combined residues of pyridaben and its metabolites PB–7 and PB–9 in or on animal commodities at levels ranging from 0.01 in milk to 0.05 ppm in cattle commodities. Risk assessments were conducted by EPA to assess dietary exposures and risks from pyridaben 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. In conducting this acute dietary risk assessment, HED has made very conservative assumptions--100% of the necessary section 18 tolerance and all commodities having published pyridaben tolerances will contain pyridaben regulable residues, those residues will be at the level of the tolerance, and plant residues will be adjusted using the ratio of organosoluble residues to pyridaben (see ''Metabolism in Plants'' section below)--all of which result in an overestimation of human dietary exposure. Thus, in making a safety determination for this tolerance, EPA is taking into account this conservative exposure assessment.

From the acute dietary (food only) risk assessment, the calculated exposure yields dietary (food only) percentage of the acute RfD for females 13+ years old ranging from 29% for females 13+ years old--not pregnant, non-nursing, to 42% for females 13+ years old--pregnant, not nursing. The calculated exposure yields dietary (food only) percentage of the acute RfD for the remainder of the population ranging from 9% for males 13–19 years old to 77% for nursing

infants < 1 year old. This risk estimate should be viewed as highly conservative; refinement using anticipated residue values and percent crop-treated data in conjunction with a Monte Carlo analysis will result in a lower acute dietary exposure estimate.

ii. *Chronic exposure and risk.* In conducting this chronic dietary risk assessment, EPA has made somewhat conservative assumptions--that 100% of cranberries will contain pyridaben residues and those residues will be at the level of the tolerance plus the ratio of organosoluble residues to pyridaben, and all commodities having published and pending pyridaben tolerances will contain pyridaben regulable residues, those residues will be at the anticipated residue level for the commodity, no percent crop treated data were used, and plant anticipated residues will be adjusted using the ratio of organosoluble residues to pyridaben (see ''Metabolism in Plants'' section below)--all of which result in an overestimation of human dietary exposure. Thus, in making a safety determination for this tolerance, EPA is taking into account this somewhat conservative exposure assessment. The existing pyridaben tolerances (published, pending, and including the necessary section 18 tolerance) result in an Anticipated Residue Contribution (ARC) that is equivalent to the following percentages of the RfD:

Subpopulation	ARC_{food}	%RfD
U.S. Population (48 States)	0.001016	20
All Infants (< 1 year old)	0.003404	68
Nursing infants (< 1 year old)	0.001335	27
Non-nursing infants (< 1 year old)	0.004275	86
Children (1–6 years old)	0.003829	77
Children (7–12 years old)	0.001651	33
Males (13–19 years old)	0.000528	11
Females (13+ nursing)	0.001525	31
U.S. Population (Autumn)	0.001203	24
U.S. Population (Winter)	0.001162	23
Northeast Region	0.001148	23
Pacific Region	0.001211	24
Western Region	0.001162	23
Non-Hispanic Whites	0.001064	21
Non-Hispanic Others	0.001178	23

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

2. *From drinking water.* Based on information currently available to EPA, pyridaben is immobile and thus unlikely to leach to groundwater. There is no established Maximum Contaminant Level for residues of pyridaben in drinking water. No health advisory levels for pyridaben in drinking water have been established.

EPA uses the Generic expected enviromental concentration (GENEEC) and SCI-GROW screening models to estimate surface and groundwater concentrations for first-tier exposure assessments. As screening models designed to estimate the concentrations found in surface and groundwater for use in ecological risk assessment, they provide upper-bound values on the concentrations that might be found in ecologically sensitive environments because of the use of a pesticide.

The models predict that as much as 2.3 ppb and 0.0003 ppb of pyridaben may be found in surface and groundwater, respectively. The modeling data were compared to the results from modeling equations used to calculate the acute and chronic drinking water level of concern (DWLOC) for pyridaben in surface and ground water.

i. *Acute exposure and risk.* Acute drinking water levels of concern have been calculated by EPA at the following amounts: U.S. Population-> 14,000 µg/L; Adult Male 20+ years old-- > 15,000 µg/L; Adult Female 13+, Pregnant, Not-nursing--> 2,200 µg/L; Infant < 1, nursing-- > 1,100 µg/L.

ii. *Chronic exposure and risk.* Chronic Drinking Water Level of Concern have been calculated by EPA at the following amounts: U.S. Population--140 µg/L; Adult Male, 13–19 years old--160 µg/L; Adult Female 13+, Nursing--100 µg/L; Infant <1, non-nursing--7 µg/L.

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

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

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

EPA does not have, at this time, available data to determine whether pyridaben 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, pyridaben 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 pyridaben 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).

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

1. *Acute risk.* Using the published and pending tolerances, the dietary (food only) percentage of the acute RfD range from 9% for males 13–19 years old to 77% for nursing infants < 1 year old, with the U.S. population at 18%. This risk estimate should be viewed as highly conservative; refinement using additional anticipated residue values and percent crop-treated data in conjunction with Monte Carlo analysis will result in a lower acute dietary exposure estimate. The acute dietary exposure does not exceed EPA's level of concern.

Pyridaben is immobile and thus unlikely to leach to groundwater. The modeling data for pyridaben in drinking water indicate levels less than EPA's DWLOC for acute exposure. Since a refined acute risk for food only would not exceed EPA's levels of concern for acute dietary exposures and the monitoring and modeling levels in water are less than the acute DWLOC, EPA does not expect aggregate acute exposure to pyridaben will pose an unacceptable risk to human health.

2. *Chronic risk.* Using the somewhat conservative ARC exposure assumptions described in Unit III.B. of this preamble, EPA has concluded that aggregate exposure to pyridaben from food will utilize 20% 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. The residues of pyridaben in drinking water do not exceed EPA's DWLOC. Pyridaben does not have any residential uses. 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 uses. Since there are no residential uses, a short-or intermediate-term aggregate risk assessment is not required.

4. *Aggregate cancer risk for U.S. population.* Since pyridaben has been classified as a Group E chemical-''no evidence of carcinogenicity to humans,'' a cancer risk assessment is not required.

5. *Endocrine disrupter effects.* EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed three years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

6. *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 pyridaben residues.

D. 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 pyridaben, 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 pre-and post-natal effects from exposure to pyridaben, 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*— a. *Rats.* In a developmental toxicity study in rats, the maternal (systemic) NOAEL was 4.7 mg/kg/day. The maternal LOEL of 13 mg/kg/day was based on decreases in body weight, body weight gain, and food consumption during the dosing period (GD 6–15). The developmental (fetal) NOAEL was 13 mg/kg/day. The developmental LOEL of 30 mg/kg/day was based on decreased fetal body weight and increased incomplete ossification in selected bones.

b. *Rabbits.* In an oral developmental toxicity study in rabbits, the maternal (systemic) NOAEL was not established. The maternal LOEL of < 1.5 mg/kg/day was based on decreases in body weight gain and food consumption. There was no developmental toxicity observed at any dose tested. Therefore, the developmental (fetal) NOAEL is > 15 mg/kg/day at the highest dose tested.

iii. *Reproductive toxicity study—Rats.* In the 2–generation reproductive toxicity study in rats, the parental (systemic) NOAEL was 2.3 mg/kg/day. The parental(systemic) LOEL of 7 mg/kg/day was based on decreased body weight, decreased body weight gains, and decreased food efficiency. The reproductive (pup) NOAEL was > 7 mg/kg/day and the LOEL was > 7 mg/kg/day at the highest dose tested.

iv. *Pre-and post-natal sensitivity.* The toxicological data base for evaluating pre-and post-natal toxicity for pyridaben is complete with respect to current data requirements. There are no pre-or post-natal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies as well as the 2–generation rat reproductive toxicity study. Based on the above, EPA has concluded that reliable data support removing the 10X safety factor for protection of infants and children.

v. *Conclusion.* There is a complete toxicity data base for pyridaben and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

2. *Acute risk.* Using the somewhat conservative exposure assumptions described above, the percentage of the acute RfD that will be utilized by dietary (food) exposure to residues of pyridaben for infants and children range from 16% for children 7–12 years old to 77% for nursing infants < 1 year old. The acute

DWLOC does not exceed EPA's level of concern.

Taking into account the completeness and reliability of the toxicity data and this conservative exposure assessment, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from acute aggregate exposure to pyridaben residues.

3. *Chronic risk.* Using the somewhat conservative exposure assumptions described above, EPA has calculated that the percentage of the RfD that will be utilized by dietary (food) exposure to residues of pyridaben ranges from 27 percent for nursing infants less than 1 year old, up to 85 percent for non-nursing infants less than 1 year old. The chronic DWLOC does not exceed HED's level of concern. There are no residential uses for pyridaben.

Taking into account the completeness and reliability of the toxicity data and this conservative exposure assessment, HED concludes that there is a reasonable certainty that no harm will result to infants and children from chronic aggregate exposure to pyridaben residues.

4. *Short-or 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 uses. Since the chronic food and chronic DWLOC do not exceed HED's level of concern and there are currently no indoor or outdoor residential uses of pyridaben, the short-and intermediate-term aggregate risk does not exceed EPA's level of concern.

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 pyridaben residues.

IV. Other Considerations

A. Metabolism in Plants and Animals

1. *Metabolism in plants.* The nature of the residue in plants is adequately understood. The residue of concern is pyridaben per se as specified in 40 CFR 180.494.

EPA has determined that the tolerance expression for plant commodities will include residues of pyridaben per se. EPA has also concluded that all organosoluble residues may be presumed to be of comparable toxicity to the parent. Thus, the risk assessment for human dietary consumption of pyridaben treated plant commodities will include all organosoluble residues. EPA has calculated a value of 2.3 for the ratio of organosoluble residues to pyridaben (O/P Ratio) based upon the low dose pyridaben apple and orange metabolism studies. For dietary risk evaluation (DRES) analyses, tolerance levels of pyridaben in/on plant commodities will be multiplied by the ratio of organosoluble residues to pyridaben (2.3). The use of anticipated residues for pyridaben DRES analysis has been previously conducted.

2. *Metabolism in animals.* The nature of the residue in animals is adequately understood. The residue of concern is pyridaben and its metabolites PB–7 (2-tert-butyl-5-[4-(1-carboxy-1-methylethyl)benzylthio]-4-chloropyridazin-3(2*H*)-one) and PB–9 (2-tert-butyl-4-chloro-5-[4-(1,1-dimethyl-2-hydroxyethyl) benzylthio]-chloropyridazin-3(2*H*)-one) as specified in 40 CFR 180.494.

For livestock commodities, EPA determined that the tolerance expression for ruminant commodities will include pyridaben and its metabolites PB–7 and PB–9. As all organosoluble residues are presumed to be of comparable toxicity to the parent, the risk assessment for human dietary consumption of commodities from livestock exposed to pyridaben will include all organosoluble residues. As tolerance levels for meat and milk are based upon a ruminant feeding study in which the dose levels were exaggerated by a factor of approximately seven, it is not necessary to further adjust the levels to be utilized in the dietary exposure analysis.

B. Analytical Enforcement Methodology

For the purpose of the associated section 18 exemption only, the BASF gas chromatography/electron capture (GC/EC) Method D9312 is adequate for enforcement purposes. Adequate enforcement methodology (example-gas chromotography) is available to enforce the tolerance expression. The method 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 22202, (703–305–5229).

C. Magnitude of Residues

The cranberry data supplied with the submission is minimal (a three line summary table). The table listed an average residue of 0.28 ppm and a maximum residue of 0.39 ppm. EPA has translated existing field trial residue data for grapes (maximum residue = 0.68 ppm) to establish the cranberry tolerance. Residues of pyridaben and its regulated metabolites are not expected to exceed 0.75 ppm in/on cranberries as a result of this section 18 use.

Applying the o/p ratio described in Unit IV.A.1 of this preamble to the anticipated residue for pyridaben on cranberries yields 0.64 (0.28 ppm × 2.3). Since this level is lower than the proposed tolerance, and the cranberry residue data are minimal, for this section 18, the tolerance level has been used for the chronic and acute dietary risk analyses. Secondary residues are not expected in animal commodities as no feed items are associated with this section 18 use.

D. International Residue Limits

There are no CODEX, Canadian, or Mexican Maximum Residue Limits (MRL) established for pyridaben on cranberries.

E. Rotational Crop Restrictions

Since cranberries are not rotated to other crops, a discussion of rotational crop residues is not germane to this action.

V. Conclusion

Therefore, the tolerance is established for combined residues of pyridaben and its metabolites PB–7 (2-tert-butyl-5-[4-(1-carboxy-1-methylethyl) benzylthio]-4-chloropyridazin-3 (2*H*)-one) and PB–9 (2-tert-butyl-4-chloro-5-[4- (1,1-dimethyl-2-hydroxyethyl) benzylthio]-chloropyridazin-3(2*H*)-one) in cranberries at 0.75 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 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 4, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket

for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300725] (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 Highway, 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.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under FFDCA section 408 (l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the *Paperwork Reduction Act* (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the *Unfunded Mandates Reform Act of 1995* (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established 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 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 acations 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.

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 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 24, 1998.

Arnold E. Layne,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180— [AMENDED]

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

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

2. In § 180.494, by revising paragraph (b) to read as follows:

§ 180.494 Pyridaben; tolerance for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the combined residues of pyridaben and its metabolites PB–7 (2-tert-butyl-5-[4- (1-carboxy-1-methylethyl) benzylthio]-4-chloropyridazin-3 (2*H*)-one) and PB–9 (2-tert-butyl-4-chloro-5-[4- (1,1-dimethyl-2-hydroxyethyl) benzylthio]-chloropyridazin-3 (2*H*)-one) in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerance is specified in the following table:

Commodity	Parts per million	Expiration/ Revocation Date
Cranberries	0.75	12/31/99

* * * * *

[FR Doc. 98–26617 Filed 10–2–98; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 409, 410, 411, 413, 424, 483 and 489

[HCFA–1913–CN]

RIN 0938–AI47

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Correction

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Correction of interim final rule with comment period.

SUMMARY: This document corrects technical errors that appeared in the interim final rule with comment period published in the **Federal Register** on May 12, 1998 entitled ''Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities.''

EFFECTIVE DATE: These corrections are effective July 1, 1998.

FOR FURTHER INFORMATION CONTACT: Bill Ullman, (410) 786–5667.

SUPPLEMENTARY INFORMATION:

Background

In FR Doc. 98–12208 of May 12, 1998 (63 FR 26252), there were a number of technical errors. In the preamble, the errors relate to incorrect listings in two tables, technical errors in the discussion of one issue, a typographical error in a table, and an incorrect paragraph designation. In the regulations text, the errors relate to two incorrect paragraph designations, a misspelled word in the heading to a section, and a grammatical correction. In addition, we inadvertently erased a change made by the regulation titled ''Medicare Program; Scope of Medicare Benefits and Application of the Outpatient Mental Health Treatment Limitation to Clinical Psychologist and Clinical Social Worker Services (HCFA–3706–F)'' published in the **Federal Register** April 23, 1998 at 63 FR 20110. That regulation's revision to 42 CFR 424.32(a)(2) (see 63 FR 20130), regarding basic requirements for claims, was inadvertently erased by the interim final rule, which this notice corrects, titled ''Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities'' published May 12, 1998 when it subsequently revised the same section (see 63 FR 26311). This correction notice incorporates the revisions made by both rules. Finally, we are correcting § 483.20 (Resident assessment) because we erroneously used a superseded version of regulations text when revising that section. The corrections appear in this document under the heading ''Correction of Errors.''

Correction of Errors

In FR Doc. 98–12208 of May 12, 1998 (63 FR 26252), we are making the following corrections:

Corrections To Preamble

Page 26262, Table 2.C

1. The dot lead-in between the ''Category'' column and the ''ADL index'' column and between the ''End splits'' column and the ''MDS RUG–III codes'' column is removed.

2. *First column titled ''Category''*

Under the heading ''IMPAIRED COGNITION,'' the first line is corrected to read as follows: ''Score on MDS2.0 Cognitive Performance Scale >=3.'' The second and third lines under the heading are retained but are blank.

3. *Second column titled ''ADL index''*

After existing line 29, line 30 is added to read ''4–5.''

Existing line 34 is removed.

Existing line 37 is removed.

After existing line 38, line 39 is added to read ''11-15.''

4. *Third column titled ''End splits''*

Line 28 is corrected to read ''Nursing rehabilitation.''

Line 29 is corrected to read ''Not receiving nursing rehabilitation.''

Line 30 is corrected to read ''Nursing rehabilitation.''

Line 31 is corrected to read ''Not receiving nursing rehabilitation.''

Line 32 is corrected to read ''Nursing rehabilitation.''

Line 33 is corrected to read ''Not receiving nursing rehabilitation.''

Line 34 is corrected to read ''Nursing rehabilitation.''

Line 35 is corrected to read ''Not receiving nursing rehabilitation.''