(b) By November 18, 1996, Alaska shall revise the following rules, or otherwise modify its program, to:

(1) At 11 AAC 90.207(f), require the addition of a definition for the term ''self-bond'' and other financial terms used to describe self-bonds consistent with the Federal regulations at 30 CFR 800.5(c) and 800.23(a), and to require the applicant for a self-bond that is guaranteed by a corporate guarantor to retain his/her own agent for service in Alaska.

(2) At 11 AAC 90.321(d), require that water treatment facilities will be operated for as long as necessary, or add a definition of ''siltation structure'' that is no less effective than the Federal definition of this term at 30 CFR 701.5.

(3) At 11 AAC 90.323(a), replace ''siltation structures'' with ''treatment facilities,'' or add a definition of ''siltation structure'' that is no less effective than the Federal definition of this term at 30 CFR 701.5.

(4) At 11 AAC 90.325(a), require that water treatment facilities will be operated for as long as necessary or add a definition of ''siltation structure'' that is no less effective than the Federal definition of this term at 30 CFR 701.5.

(5) At 11 AAC 90.327(b)(1) and (c), require that ''erosion control structures'' be used when describing standards for stream channel diversions used to control erosion, and that the terms ''water treatment facilities'' and ''water treatment facility'' be retained or provide a definition of ''siltation structures'' that includes ''water-treatment facilities.''

(6) At 11 AAC 90.341(b)(2), require that any treatment facility used during the anticipated period of gravity discharge will be consistently maintained, or add a definition of ''siltation structure'' that is no less effective than the Federal definition of this term at 30 CFR 701.5.

(7) At 11 AAC 90.443(k), require that the topsoil on the area outside the mined-out area in nonsteep slope areas shall be removed, segregated, stored and redistributed in accordance with its topsoil removal provisions and that the spoil be backfilled and graded on the area in accordance with its provisions concerning performance standards or backfilling and grading, or add provisions to ensure that the disposal of spoil provisions are no less effective than the Federal regulations at 30 CFR 816.102(d) (2) and (3).

(8) At 11 AAC 90.491(f), require the addition of provisions concerning fords of perennial or intermittent streams, the alteration or relocation of natural stream channels, and structures for perennial or intermittent stream channel crossings that are no less effective than 30 CFR 816.151(b)(2), (d)(5), and (d)(6) and 817.151(b)(2), (d)(5) and (d)(6).

[FR Doc. 96–23677 Filed 9–16–96; 8:45 am]

BILLING CODE 4310–05–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300436; FRL–5395–8]

RIN 2070–AB78

Pyridaben; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of the insecticide/miticide pyridaben in or on the raw agricultural commodity apples and the processed feed commodity wet apple pomace in connection with EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of pyridaben on apples in Delaware, New Jersey, and Virginia. This regulation establishes maximum permissible levels for residues of pyridaben in these foods pursuant to section 408(l)(6) of the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170). The tolerances will expire and be revoked automatically without further action by EPA on August 23, 1997.

DATES: This regulation becomes effective September 17, 1996. This regulation expires and is revoked automatically without further action by EPA on August 23, 1997. Objections and requests for hearings must be received by EPA on November 18, 1996.

ADDRESSES: Written objections and hearing requests, identified by the docket number, [OPP–300436], 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 number, [OPP–300436], should be submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [OPP–300436]. 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: Pat Cimino, Registration Division (7505W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA 22202. (703) 308–8328, e-mail: cimino.pat@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for residues of the insecticide/miticide pyridaben [2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2*H*)-one] in or on apples at 0.5 part per million (ppm) and in or on wet apple pomace at 1.0 ppm. These tolerances will expire and be revoked automatically without further action by EPA on August 23, 1997.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures.

New section 408(b)(2)(A)(i) 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, 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 408(b)(2)(D) specifies factors EPA is to consider in establishing a tolerance. Section 408(b)(3) requires EPA to determine that there is a practical method for detecting and measuring levels of the pesticide chemical residue in or on food and that the tolerance be set at a level at or above the limit of detection of the designated method. Section 408(b)(4) requires EPA to determine whether a maximum residue level has been established for the pesticide chemical by the Codex Alimentarius Commission. If so, and EPA does not propose to adopt that level, EPA must publish for public comment a notice explaining the reasons for departing from the Codex level. Section 408(c) governs EPA's establishment of exemptions from the requirement for a tolerance using the same safety standard as section 408(B)(2)(A) and incorporating the provisions of section 408(b)(2)(C) and (D).

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. Generally, these regulations allow a State or Federal agency to apply for an exemption to allow use of a pesticide for which that pesticide is not registered to alleviate an emergency condition. The regulations set forth information requirements, procedures, and standards for EPA's approval or denial of such exemptions.

Prior to FQPA, when EPA granted an emergency exemption under section 18 in connection with use of a pesticide that could result in residues of the pesticide chemical in or on food, EPA did not establish a tolerance or exemption from the requirement for a tolerance under FFDCA. Rather, EPA advised the Food and Drug Administration (FDA) of the emergency exemption and of the level of residues that EPA concluded would be present in or on affected foods as a result of the emergency use. However, new section 408(l)(6) requires EPA to establish a 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. Section 408(l)(6) also requires EPA to promulgate regulations by August 3, 1997, governing the establishment of tolerances and exemptions under section 408(l)(6) and requires that the regulations be consistent with section 408(b)(2) and (c)(2) and FIFRA section 18.

Section 408(e) gives EPA general authority to establish tolerances and exemptions from the requirement for a tolerance through notice and comment rulemaking procedures upon EPA's initiative. Section 408(l)(6) allows EPA to establish tolerances or exemptions from the requirement for a tolerance, in connection with EPA's granting of FIFRA section 18 emergency exemptions, without providing notice or a period for public comment. Thus, consistent with the need to act expeditiously on requests for emergency exemptions under FIFRA, EPA can establish such tolerances or exemptions under authority of section 408(e) and (l)(6) without notice and comment rulemaking. The other procedures set out in section 408(e) and (g) are applicable to these tolerances and exemptions. Tolerances and exemptions issued under section 408(l)(6) must be consistent with the safety standards in section 408(b)(2) and (c)(2), respectively, that are applicable to all tolerances and exemptions under section 408, and with FIFRA section 18. Section 408(l)(6) specifies that such tolerances and exemptions must have an expiration date but does not specify how EPA is to set such an expiration date.

In light of FQPA, EPA is engaged in an intensive process, including consultation with registrants, States, and other interested stakeholders, to make decisions on the new policies and procedures that will be appropriate as a result of enactment of FQPA. This process will generally delay the review of food use applications, particularly those involving exposure to children. However, recognizing the importance of FIFRA section 18 emergency exemptions and their time sensitive nature, EPA will continue to process section 18 applications for food uses which clearly are emergencies and which clearly are consistent with the new FFDCA section 408 safety standard and with FIFRA section 18. EPA will publish a notice in the Federal Register soon summarizing the requirements of FQPA, indicating how EPA intends to meet those requirements, and describing actions necessary to assure that EPA complies with the law. EPA intends to promulgate the procedural rule required under section 408(l)(6) by August 3, 1997, but EPA also intends to continue to grant appropriate section 18 emergency exemptions and issue the associated tolerances and exemptions in the interim pending promulgation of that rule. EPA also intends to issue interim guidance to States and others on how EPA will implement section 18 of FIFRA and section 408(l)(6) in the near future.

EPA intends to address how it will provide an expiration date for section 408(l)(6) tolerances and exemptions in the general procedural rule to be promulgated by August 3, 1997. In the interim, EPA has decided to proceed as follows. Section 408(l)(5) specifies that, if a tolerance or exemption from the requirement for a tolerance for a pesticide chemical residue in or on a food has been revoked under section 408, food containing the residue is not unsafe (and thus subject to action by FDA as ''adulterated'') if ''the residue is present as the result of an application or use of a pesticide at a time and in a manner that was lawful'' under FIFRA and ''the residue does not exceed a level that was authorized at the time of that application or use to be present on the food under a tolerance....'' Taking section 408(l)(5) and (6) together, EPA has concluded that the best way to effect an ''expiration date'' during this interim period for a tolerance or exemption established in connection with EPA's grant of a FIFRA section 18 emergency exemption is to specify that the tolerance or exemption will expire and be revoked automatically, without further action by EPA, as of a specified date. That date will generally be approximately 1 year from the date of issuance of the emergency exemption. Under section 408(l)(5), food that contains residues of the pesticide chemical as a result of lawful use under the terms of the section 18 emergency exemption, and at levels that are within those set by the tolerance or exemption that was established under section 408(l)(6) in connection with the section

18 action, would remain lawful after the tolerance or exemption is automatically revoked. EPA believes that handling the section 18-related tolerances and exemptions in this manner will allow EPA to respond promptly to emergency conditions during this interim period and will ensure that food containing pesticide residues as a result of use under an emergency exemption will not be considered ''adulterated.''

In deciding to continue to act on section 18 emergency exemptions and to issue the associated tolerances and exemptions early in the process of FQPA implementation, EPA recognizes that it will be necessary to make decisions about the new FFDCA section 408, including the new safety standard. In establishing section 18-related tolerances and exemptions during this interim period before EPA issues the section 408(l)(6) procedural regulation and before EPA makes its broad policy decisions concerning the interpretation and implementation of the new section 408, EPA does not intend to set precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Rather, these early section 18 tolerance and exemption decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further rulemaking and policy development. EPA intends to act on section 18-related tolerances and exemptions that clearly qualify under the new law.

II. Emergency Exemptions for Pyridaben on Apples and FFDCA Tolerances

On August 23, 1996, EPA approved emergency exemptions under FIFRA section 18 for the states of Delaware, New Jersey and Virginia for use of pyridaben on apples in those states to control European red mite and two-spotted spider mite. Emergency conditions are determined to exist since there are no effective pesticides available for late-season use in Integrated Pest Management (IPM) programs for control of mites in Delaware, New Jersey and Virginia. The available data indicate that pyridaben is effective for mite control and is compatible with mid-Atlantic apple IPM programs.

As part of its assessment of these applications for emergency exemptions, EPA assessed the potential risks presented by residues of pyridaben in or on apples and all foods derived from such apples. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided to grant the section 18 exemptions only after concluding that the necessary tolerances under FFDCA section 408(l)(6) would clearly be consistent with the new safety standard and with FIFRA section 18. These tolerances for pyridaben will permit the marketing of apples treated in accordance with the provisions of the section 18 emergency exemptions. Consistent with the need to move quickly on the emergency exemptions and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment under section 408(e) as provided in section 408(l)(6). Although these tolerances will expire and be revoked automatically without further action by EPA on August 23, 1997, under FFDCA section 408(l)(5), residues of pyridaben not in excess of the amounts specified in the tolerances remaining in or on apples and wet apple pomace (and foods derived from such apples) after that date will not be unlawful, provided the pesticide is applied during the term of, and in accordance with all the conditions of, the emergency exemptions. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

EPA has not made any decisions about whether pyridaben meets the requirements for registration under FIFRA section 3 for use on apples or whether permanent tolerances for pyridaben for apples and wet apple pomace would be appropriate. This action by EPA does not serve as a basis for registration of pyridaben by a State for special local needs under FIFRA section 24(c). For additional information regarding the emergency exemptions for pyridaben, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. For many of these studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no observed effects level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered acceptable by EPA.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or margin of exposure calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, and other non-occupational exposures, such as where residues leach into groundwater or surface water that is consumed as drinking water. 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. 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 percent of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately 1 in 1 million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. Pyridaben is already registered by EPA for greenhouse use on non-food ornamental plants. EPA has also assessed the toxicology data base for pyridaben in its evaluation of applications for registration on apples and citrus. Thus, while EPA has made no decision on the pending registration application for apples and citrus, 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 the time-limited tolerances for residues of pyridaben on apples at 0.5 ppm and apple pomace at 1.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

1. *Chronic effects.* Based on the available chronic toxicity data, EPA has established the RfD for pyridaben at 0.005 milligrams(mg)/kilogram(kg)/day. The RfD for pyridaben is based on a 1–year feeding study in dogs with a No-Observed Adverse Effect Level (NOAEL) of 0.5 mg/kg/day and an uncertainty factor of 100. For this chemical, EPA has used the NOAEL instead of a NOEL because effects that were judged by EPA to be minor were observed at the lowest dose tested (0.5 mg/kg/day). The effects observed at the NOAEL were vomiting, excessive salivation, and soft stool/diarrhea (all clinical signs unassociated with changes in biochemical parameters and histopathology). EPA questioned the biological significance of the small increase in these effects as compared to effects noted in the control group. Futher, after consideration of the frequency, severity, and transient nature of effects observed, EPA concluded that any effects noted at the 0.5 mg/kg/day feeding level (the NOAEL) were sufficiently negligible as to not require the application of an additional uncertainty factor above the 100-fold factor already applied to the NOAEL.

2. *Acute toxicity.* Based on the available acute toxicity data, EPA has determined that pyridaben does not pose any acute dietary risks.

3. *Carcinogenicity.* Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), EPA has classified pyridaben as Group ''E'' for carcinogenicity (no evidence of carcinogenicity) based on the results of carcinogenicity studies in two species. There was no evidence of carcinogenicity in an 18–month feeding study in mice and a 2–year feeding study in rats at the dosage levels tested. The doses tested are adequate for identifying a cancer risk. Thus, a cancer risk assessment would not be appropriate.

B. Aggregate Exposure

For purposes of assessing the potential dietary exposure under these tolerances, EPA has estimated aggregate exposure based on the TMRC from the tolerance for pyridaben on apples at 0.5 ppm and apple pomace at 1.0 ppm. The TMRC is obtained by multiplying the tolerance level residue for apples (0.5 ppm) by the consumption data which estimates the amount of apples and apple products eaten by various population subgroups. Apple pomace is fed to animals; thus exposure of humans to residues in apple pomace might result if such residues are transferred to meat, milk, poultry, or eggs. However, based on the results of animal metabolism studies and the amount of pyridaben residues expected in animal feeds, EPA has concluded that there is no reasonable expectation that measurable residues of pyridaben will occur in meat and milk under the terms of this emergency exemption. Apple pomace is not a poultry feed item, thus no residues are expected in poultry or eggs. There are no other established U.S. tolerances for pyridaben, and there are no registered uses for pyridaben on food or feed crops in the United States. In conducting this exposure assessment, EPA has made very conservative assumptions—100% of apples will contain pyridaben residues and those residues would be at the level of the tolerance—which result in an overestimate of human exposure. Thus, in making a safety determination for these tolerances, EPA is taking into account this conservative exposure assessment.

Other potential sources of exposure of the general population to residues of pesticides are residues in drinking water and exposure from non-occupational sources. Based on the available studies used in EPA's assessment of environmental risk, EPA does not anticipate exposure to residues of pyridaben in drinking water. There is no established Maximum Concentration Level for residues of pyridaben in drinking water. EPA has not estimated non-occupational exposure for pyridaben since the current registration for pyridaben is limited to commercial greenhouse use for non-food ornamental plants and the only other use will be for commercial apple production under the conditions of the section 18 emergency exemptions EPA just granted. The potential for non-occupational exposure to the general population is, thus, not expected to be significant.

EPA also considered the potential for cumulative effects of pyridaben and other substances that have a common mechanism of toxicity. EPA concluded that consideration of a common mechanism of toxicity is not appropriate at this time. EPA does not have reliable information to indicate that toxic effects produced by pyridaben would be cumulative with those of any other chemical compounds; thus EPA is considering only the potential risks of pyridaben in its aggregate exposure assessment.

C. Safety Determinations

1. *U.S. population in general.* Using the conservative exposure assumptions described above, based on the completeness and reliability of the toxicity data, EPA has concluded that aggregate exposure to pyridaben will utilize 6.8 percent of the RfD for the U.S. population. EPA generally has no concern for exposures below 100 percent of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to pyridaben residues.

2. *Infants and children.* 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 pesticide exposure during prenatal

development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

Developmental toxicity (delayed ossification) was observed in studies using rats and rabbits. The (NOEL's) for developmental effects were established at 13 mg/kg/day in the rat study and 15 mg/kg/day in the rabbit study. The developmental effect observed in these studies is believed to be a secondary effect resulting from maternal stress (decreased body weight gain and food consumption).

In a 2-generation reproduction study in rats, pups from the high dose group, which were fed diets containing 80 ppm pyridaben, gained less weight beginning on lactation day 14. The only effects seen in pups were decreased body weight gain, indicating that they were receiving the test compound from the diet. Parental systemic toxicity including decreased body weights, body weight gains and food efficiency in males, and slightly decreased body weights and body weight gains in females during lactation was also observed in the high dose group. The LOEL for parental systemic toxicity is 80 ppm (equivalent to 6.31 and 7.82 mg/kg/day in male and females, respectively). The NOEL for parental systemic toxicity is 28 ppm (equivalent to 2.20 and 2.41 mg/kg/day in male and females, respectively). There was no effect on reproductive parameters at all dose levels tested in this study.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database. Based on the current toxicological data requirements, the database relative to pre- and post-natal effects for children is complete. Further, for the chemical pyridaben, the NOAEL at 0.5 mg/kg/day from the dog study, which was used to calculate the RfD (discussed above), is already lower than the NOEL's from the developmental studies in rats and rabbits by a factor of more than 10-fold. As to the reproduction study, the lack of severity of the pup effects observed (decreased body weight) in the reproduction study at the systemic LOEL and the fact that the effects began at day 14 and continued through adulthood suggests that there is no additional sensitivity for infants and children. Therefore; EPA concludes that an additional uncertainty factor is not warranted and that the RfD at 0.005 mg/kg/day is appropriate for assessing aggregate risk to infants and children.

Using the conservative exposure assumptions described above, EPA has concluded that the percent of the RfD that will be utilized by aggregate exposure to residues of pyridaben ranges from 9.6 percent for children 7 to 12 years old, up to 63 percent for non-nursing infants. Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to pyridaben residues.

D. Other Considerations

The metabolism of pyridaben in plants and animals is adequately understood for the purposes of these tolerances. There are no Codex maximum residue levels established for residues of pyridaben on apples or wet apple pomace. There is a practical analytical method for detecting and measuring levels of pyridaben in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set in these tolerances. EPA has provided information on this method to FDA. The method is available to anyone who is interested in pesticide residue enforcement from: By mail, Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: Crystal Mall #2, Rm 1128, 1921 Jefferson Davis Hwy., Arlington, VA 22202, 703–305–5805.

E. Conclusion

Therefore, tolerances in connection with the FIFRA section 18 emergency exemptions are established for residues of pyridaben in apples at 0.5 ppm and wet apple pomace at 1.0 ppm. These tolerances will expire and be automatically revoked without further action by EPA on August 23, 1997.

IV. 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 November 18, 1996, file written objections to any aspect of this regulation (including the automatic revocation provision) 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 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.

V. Public Docket

A record has been established for this rulemaking under docket number [OPP–300436] (including comments and data submitted electronically as described below). 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 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can 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 all comments 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 address in ''ADDRESSES'' at the beginning of this document.

VI. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and, since this action does not impose any information collection requirements as defined by the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because FFDCA section 408(l)(6) permits establishment of this regulation without a notice of proposed rulemaking, analysis under the Regulatory Flexibility Act, 5 U.S.C. 604(a), is not required.

Under 5 U.S.C. 801(a)(1)(A) of the Administrative Procedure Act (APA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104–121, 110 Stat. 847), EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's Federal Register. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2) of the APA as amended.

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 6, 1996.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is amended as follows:

PART 180— [AMENDED]

1. In part 180:

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

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

b. By adding a new § 180.494 to read as follows:

§ 180.494 Pyridaben; tolerances for residues.

(a) [Reserved].

(b) *Time-limited tolerances.* Time-limited tolerances are established for residues of the insecticide/miticide pyridaben [2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one] in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances are specified in the following table. Each tolerance expires and is automatically revoked on the date specified in the table without further action by EPA.

Commodity	Parts per million	Expiration/Revocation Date
Apples	0.5	August 23, 1997
Apples, pomace, wet	1.0	August 23, 1997

[FR Doc. 96–23905 Filed 9–16–96; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 950725189–6245–04 ; I.D. 060696A]

RIN 0648–AI92

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic; Changes in Catch Limits

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: In accordance with the framework procedure for adjusting management measures of the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic (FMP), NMFS implements commercial vessel trip limits for the Atlantic migratory group of king mackerel. The intended effects of this rule are to preclude an early closure of the commercial fishery, protect king mackerel from overfishing, and maintain healthy stocks while still allowing catches by important commercial fisheries.

EFFECTIVE DATE: September 23, 1996.

FOR FURTHER INFORMATION CONTACT: Mark F. Godcharles, 813–570–5305.

SUPPLEMENTARY INFORMATION: The fisheries for coastal migratory pelagic resources are managed under the FMP. The FMP was prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils and is implemented by regulations at 50 CFR part 622 under the authority of the Magnuson Fishery Conservation and Management Act (Magnuson Act).

In accordance with the framework rulemaking procedures of the FMP, the South Atlantic Council (Council) recommended, and NMFS published, a proposed rule to establish commercial vessel trip limits for the Atlantic migratory group of king mackerel (61 FR 34785, July 3, 1996). That proposed rule described the FMP framework procedures through which the Council recommended the trip limits and explained the need and rationale for