comment would be impracticable because of the limited time provided for making this determination, and would be contrary to the public interest because it would divert agency resources from the critical substantive review of the section 126 petitions.

C. Effective Date Under the APA

Today's action will be effective on October 14, 1997. Under the APA, 5 U.S.C. 553(d)(3), agency rulemaking may take effect before 30 days after the date of publication in the **Federal Register** if the agency has good cause to mandate an earlier effective date. Today's action—a deadline extension—must take effect immediately because its purpose is to move back by one month the October 14, 1997 deadlines for several of the section 126 petitions, and the deadlines for the other section 126 petitions that follow shortly thereafter. Moreover, EPA intends to use immediately the one-month extension period to continue to develop an appropriate schedule for ultimate action on the section 126 petitions, and to continue to develop the technical analysis needed to develop the notice of proposed rulemaking. These reasons support an effective date prior to 30 days after the date of publication.

D. Executive Order 12866

The Office of Management and Budget has exempted this regulatory action from Executive Order 12866 review.

E. Unfunded Mandates

Under the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501 *et seq.*, EPA must undertake various actions in association with proposed or final rules that include a Federal mandate that may result in estimated costs of $100 million or more to the private sector or to State, local, or tribal governments in the aggregate. In addition, before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, EPA must have developed a small government agency plan. EPA has determined that these requirements do not apply to today's action because this rulemaking (i) is not a Federal mandate—rather, it simply extends the date for EPA action on a rulemaking; and (ii) contains no regulatory requirements that might significantly or uniquely affect small governments.

F. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA), 5 U.S.C. 600 *et seq.*, EPA must propose a regulatory flexibility analysis assessing the impact on small entities of any rule subject to the notice-and-comment rulemaking requirements. Because this action is exempt from such requirements, as described above, it is not subject to RFA.

G. Submission to Congress and the General Accounting Office

Under 5 U.S.C. of the APA, 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), EPA submitted, by the date of publication of this rule, 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. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2), as amended.

H. Paperwork Reduction Act

This rule does not contain any information collection requirements which require OMB approval under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*)

I. Judicial Review

Under CAA section 307(b)(1), a petition to review today's action may be filed in the Court of Appeals for the District of Columbia within 60 days of October 22, 1997.

Dated: October 14, 1997.

Carol M. Browner,

Administrator.

[FR Doc. 97–27977 Filed 10–21–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300560; FRL–5746–6]

RIN 2070–AB78

Spinosad; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for spinosad (Factors A and D) in or on fruiting vegetables (except cucurbits) crop group (8), tomato paste, leafy vegetables (except Brassica vegetables) crop group (4), and Brassica (cole) leafy vegetables crop group (5). This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on fruiting vegetables (except cucurbits) crop group (8), leafy vegetables (except Brassica vegetables) crop group (4), and Brassica (cole) leafy vegetables crop group (5). This regulation establishes maximum permissible levels for residues of spinosad in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and are revoked on September 30, 1998.

DATES: This regulation is effective October 22, 1997. Objections and requests for hearings must be received by EPA on or before December 22, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300560], 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–300560], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services 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.

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 control number [OPP–300560]. 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 (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) 308–9357, 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 spinosad (Factors A and D) in or on fruiting vegetables (except cucurbits) crop group (8), tomato paste, leafy vegetables (except Brassica vegetables) crop group (4), and Brassica (cole) leafy vegetables crop group (5) at 0.25, 0.50, 10.0 and 10.0 parts per million (ppm) respectively. These tolerances will expire and are revoked on September 30, 1998. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq*. The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described 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 Spinosad on Fruiting Vegetables (except Cucurbits) Crop Group (8), Leafy Vegetables (except Brassica Vegetables) Crop Group (4), and Brassica (Cole) Leafy Vegetables Crop Group (5) and FFDCA Tolerances

Florida Department of Agriculture & Consumer Services submitted a regional specific exemption request for Florida, Georgia and Arkansas for the use of spinosad (Spintor 2SC) to control Western Flower Thrips, *Frankliniella occidentalis*, on tomatoes, peppers, eggplant and other members of fruiting vegetable (excluding cucurbits) crop group (8). Season long control measures for western flower thrip and the disease that it vectors, tomato spotted wilt virus, are currently not available and significant economic losses have already occurred.

On July 15, 1997 the Arizona Department of Agriculture requested a specific exemption for use of spinosad (Success) to control beet armyworm on leafy vegetables (except Brassica) crop group (4) and Brassica leafy vegetables crop group (5). A specific exemption request for use of tebufenozide (Confirm) to control this pest on these crops in Arizona was granted earlier this year; however, the state indicates that tebufenozide alone will not provide adequate control of beet armyworm in the fall-season planted crops due to high pest pressure. Beet armyworm pest pressure on Arizona's fall-season planted crops is, on average, three times greater than pressure on its winter-season planted crops. Arizona indicates that both pesticides are needed for the fall-season planting and is recommending the following Integrated Pest Management (IPM) program for use of both pesticides: (1) spinosad and tebufenozide may be used where resistance to currently registered pesticides is occurring; (2) a total of three applications per crop of spinosad are permitted and may be used from plant emergence to thinning when beet armyworm populations exceed 1 larva per 100 plants and after head formation begins (and comparable susceptibility stage for non-head forming vegtables in these crop groups); a total of three applications per crop of tebufenozide are permitted from plant emergence to thinning if beet armyworm populations are less than 1 larva per 100 plants and from thinning to head formation. After having reviewed the requests, EPA concurs: that emergency conditions exist for the states and; with Arizona's IPM recommendations for use of both tebufenozide and spinosad for beet armyworm control under emergency exemption specifications.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of spinosad in or on fruiting vegetables (except cucurbits) crop group (8), tomato paste, leafy vegetables (except Brassica vegetables crop group (4), and Brassica (cole) leafy vegetables crop group (5). In doing so, EPA considered the new 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 new safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on September 30, 1998, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on fruiting vegetables (except cucurbits) crop group (8), tomato paste, leafy vegetables (except Brassica vegetables crop group (4), and Brassica

(cole) leafy vegetables crop group (5) after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions EPA has not made any decisions about whether spinosad meets EPA's registration requirements for use on fruiting vegetables (except cucurbits) crop group (8), leafy vegetables (except Brassica vegetables) crop group (4), and Brassica (cole) leafy vegetables crop group (5) or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of spinosad by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Arizona, Florida, Georgia and Arkansas to use this pesticide on this crop under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for spinosad, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

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

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

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows:

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1–7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least seven days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1–7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least seven days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

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

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

B. Aggregate Exposure

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

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (non-hispanic other than black or caucasian subgroup) was not regionally based.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of spinosad and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for spinosad (Factors A and D) in or on fruiting vegetables (except cucurbits) crop group (8), tomato paste, leafy vegetables (except Brassica vegetables) crop group (4), and Brassica (cole) leafy vegetables crop group (5) at 0.25, 0.50, 10.0 and 10.0 ppm, respectively. 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 spinosad are discussed below.

1. *Acute toxicity.* None. For acute dietary risk assessment, the Agency did not select an endpoint based on available data and determined that this risk assessment is not required.

2. *Short - and intermediate - term toxicity.* No short- or intermediate-term toxicological endpoints have been identified. Therefore, a short- or intermediate-term aggregate risk assessment is not required.

3. *Chronic toxicity.* EPA has established the RfD for spinosad at 0.0268 milligrams/kilogram/day (mg/kg/day). The RfD was established based on a 1-year feeding study in dogs. The NOEL was 2.68 mg/kg/day with an uncertainty factor of 100. The LOEL of 8.22 mg/kg/day was based on increases in serum alanine aminotransferase, aspartate aminotransferase, and triglycerides levels, and the presence of tissue abnormalities including vacuolated cell aggregations, arteritis, and glandular cell vacuolation (parathyroid).

4. *Carcinogenicity.* The Agency determined that there was no evidence of carcinogenicity in two species.

B. Exposures and Risks

1. *From food and feed uses.* A time-limited tolerance which expires November 15, 1999 has been established (40 CFR 180.495) for the residues of spinosad (Factors A and D) in or on cottonseed at 0.02 ppm. There are no other tolerances established for spinosad. Risk assessments were conducted by EPA to assess dietary exposures and risks from spinosad 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. No acute dietary endpoint of concern was identified by the Agency, therefore this risk assessment is not required.

ii. *Chronic exposure and risk.* In conducting the chronic dietary risk assessment, the Agency used conservative TMRC assumptions as follows: 100% of the leafy vegetables (except Brassica vegetables) crop group commodities, Brassica (cole) leafy vegetables crop group commodities, fruiting vegetable (except cucurbits) crop group commodities, and cotton commodities tolerances will contain spinosad residues and those residues will be at the level of the tolerance.

2. *From drinking water.* Based on information in the EFED One-liner Database (updated 5/6/97), spinosad is not persistent and not mobile. There are no established Maximum Contaminant Levels (MCLs) for residues of spinosad in drinking water. No health advisory levels for spinosad in drinking water have been established. There is no entry for spinosad in EPA's Pesticides in Ground Water Database (9/92).

Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water-related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for exposure from contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause spinosad to exceed the RfD

if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with spinosad in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance are granted.

3. *From non-dietary exposure.* Spinosad is currently registered for residential, outdoor, non-food sites, which include: ornamental turf, and ornamental herbaceous and woody plants. Under current Agency guidelines, these uses do not fall under a chronic scenario, but may constitute a short- and/or intermediate-term exposure scenario. However, no short- or intermediate-term toxicological endpoints of concern have been identified and the risk assessment is not required for short- and/or intermediate-term exposure.

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

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

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

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

1. *Acute risk.* No acute dietary endpoint of concern was identified by the Agency, so this risk assessment is not required.

2. *Chronic risk.* Using the conservative TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to spinosad from food will utilize 20% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-hispanics other than blacks or caucasians and aggregate exposure to spinosad from food will utilize 32% of the RfD for this subpopulation. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to spinosad in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD. Under current Agency guidelines, the registered residential non-dietary uses do not fall under a chronic scenario. EPA concludes that there is a reasonable certainty that no harm will result from chronic aggregate exposure to spinosad residues from food and water.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure.

Under current Agency guidelines, the registered residential non-dietary uses do not fall under a chronic scenario, but may constitute a short- and/or intermediate-term exposure scenario. However, no short- or intermediate-term toxicological endpoints have been identified. Therefore, a short- or intermediate-term aggregate risk assessment is not required.

D. Aggregate Cancer Risk for U.S. Population

The Agency determined that there was no evidence of carcinogenicity in two species. Therefore, a cancer risk assessment is not required.

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

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

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability)) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the

severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

b. *Developmental toxicity studies.*— i. *Rats.* In the developmental study in rats, both the maternal (systemic) NOEL and the developmental (fetal) NOEL were ≥ 200 mg/kg/day at the highest dose tested.

ii. *Rabbits.* In the developmental toxicity study in rabbits, both the maternal (systemic) NOEL and the developmental (fetal) NOEL were ≥ 50 mg/kg/day at the highest dose tested. The Agency concluded that spinosad is not a developmental toxicant.

c. *Reproductive toxicity study. Rats.* In the 2-generation reproductive toxicity study in rats, the parental (systemic) NOEL was 10 mg/kg/day. The parental (systemic) LOEL of 100 mg/kg/day was based on increases in heart, kidney, liver, spleen, and thyroid weights (both sexes). In addition, histopathological lesions were found in the lungs and mesenteric lymph nodes (both sexes), stomach (females), and prostate, and increased incidence of dystocia and/or vaginal bleeding after parturition with associated increases in mortality in the dams. The NOEL for reproductive toxicity was 10 mg/kg/day. The LOEL for reproductive toxicity of 100 mg/kg/day was based on decreases in litter size, survival (F_2 litters), and body weights in the offspring.

d. *Pre- and post-natal sensitivity.* The toxicological data base for evaluating pre- and post-natal toxicity for spinosad 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 and the 2-generation rat reproductive toxicity study.

e. *Conclusion.* Based on the data examined above, the Agency concludes that reliable data support use of the standard 100-fold uncertainty factor and that an additional uncertainty factor is not needed to protect infants and children.

2. *Acute risk.* No endpoint of concern was identified by the Agency, so this risk assessment is not required.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that percentage of the RfD that will be utilized by dietary exposure to residues of spinosad from food ranges from 2 percent for nursing infants less than 1 year old, up to 23% for children 7-12 years old. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to spinosad in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD. Under current Agency guidelines, the registered residential non-dietary uses do not fall under a chronic scenario. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from chronic aggregate (food plus water) exposure to spinosad 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.

Under current Agency guidelines, the registered residential non-dietary uses do not fall under a chronic scenario, but may constitute a short- and/or intermediate-term exposure scenario. However, no short- or intermediate-term toxicological endpoints have been identified. Therefore, a short- or intermediate-term aggregate risk assessment is not required.

F. 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 3 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.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants is adequately understood based on acceptable metabolism studies on cotton, apples, cabbage, tomatoes, and turnips. The results of the metabolism studies have not yet been reviewed by the Agency's Metabolism Committee but, for the purposes of these section 18s only, the residues of concern are the parent compounds (Factors A and D) only, as specified in 40 CFR 180.495.

B. Analytical Enforcement Methodology

For the purposes of these section 18 requests, DowElanco method GRM 95.04 high pressure liquid chromatography/ultraviolet (HPLC/UV) should be adequate to enforce the tolerance expression for the fruiting vegetable (except cucurbits) crop group, and method GRM 94.22 (HPLC/UV) should be adequate to enforce the tolerance expression for the leafy vegetables (except Brassica vegetables) crop group and Brassica (cole) leafy vegetables crop subgroup.

C. Magnitude of Residues

Residues of spinosad (Factors A and D) are not expected to exceed 0.25 ppm in/on the fruiting vegetable (except cucurbits) crop grouping and 0.50 ppm in/on tomato paste as a result of this section 18 use. Residues are not expected to concentrate in/on tomato puree. Residues of spinosad (Factors A and D) are not expected to exceed 10 ppm in/on the leafy vegetables (except Brassica vegetables) crop group and 10 ppm in/on the Brassica (cole) leafy vegetables crop group as a result of this section 18 use. Secondary residues are not expected in animal commodities as no feed items are associated with these section 18 uses.

D. International Residue Limits

No Codex, Canadian, and/or Mexican MRLs tolerances have been established for spinosad.

E. Rotational Crop Restrictions

The results of a confined rotational crop study indicate that the parent compound does not appear to be taken up and/or be translocated within the plants tested (wheat, lettuce, and radish). Pending review of the plant metabolism and confined rotational crop studies by the Agency's Metabolism Committee, rotational crop field studies and rotational crop tolerances will not need to be established to support future section 3 permanent tolerance requests. For the purposes of these section 18 requests, the residues of concern in plants are the parent compounds (Factors A and D) only, and rotational crop restrictions and/or tolerances will not be needed.

VI. Conclusion

Therefore, tolerances are established for residues of spinosad (Factors A and D) in or on fruiting vegetables (except cucurbits) crop group (8), tomato paste, leafy vegetables (except Brassica vegetables) crop group (4), and Brassica (cole) leafy vegetables crop group (5) at 0.25, 0.50, 10.0 and 10.0 ppm respectively.

VII. Objections and Hearing Requests

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

Any person may, by December 22, 1997, 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 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.

VIII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300560] (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 Rm. 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), 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.

IX. Regulatory Assessment Requirements

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

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408 (d), such as the time-limited 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 actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

X. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 1, 1997.

James Jones,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.495 is amended as follows:

a. By adding a heading to paragraph (a).

b. In paragraph (b) by adding a heading and alphabetically adding the following commodities.

c. Paragraphs (c) and (d) are added and reserved with headings.

§ 180.495 Spinosad; tolerances for residues.

(a) *General.* [Reserved]

(b) *Section 18 emergency exemptions.*

* * *

Commodity	Parts per million	Expiration/Revocation Date
Brassica (Cole) Leafy Vegetables Crop Group (5)	10.0	9/30/98
* * *	* * * *	
Fruiting Vegetables (except Cucurbits) Crop Group (8)	0.25	9/30/98
Leafy Vegetables (except Brassica vegetables) Crop Group (4)	10.0	9/30/98
Tomato paste	0.50	9/30/98

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

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

[FR Doc. 97–27727 Filed 10–21–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300548; FRL–5742–5]

RIN 2070–AB78

Pyrithiobac Sodium Salt; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends the time-limited tolerance for residues of the herbicide pyrithiobac sodium salt (sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate) in or on cottonseed at 0.02 parts per million (ppm). E.I. du Pont de Nemours & Co., Inc., requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1966 (Pub. L. 104–170). The tolerance will expire on September 30, 1999.

DATES: This regulation is effective October 22, 1997. Objections and requests for hearings must be received by EPA on or before December 22, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300548], 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–300548], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services 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.

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 control number [OPP–300548]. 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: James A. Tompkins, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, e-mail: tompkins.james@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 11, 1997 (62 FR 37241)(FRL–5728–7), EPA, issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP 4F4391) for tolerance by E.I. du Pont de Nemours & Co., Inc., Barley Mill Plaza, P.O. Box 80038, Wilmington, DE 19880–0038. This notice included a summary of the petition prepared by du Pont. There were two comments received in response to the notice of filing from cotton growers urging the extension of the time limited tolerance.

The petition requested that 40 CFR 180.487 be amended by extending the time-limited tolerance for residues of the herbicide pyrithiobac sodium salt (sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate) in or on cottonseed at 0.02 ppm. This tolerance will expire on September 30, 1999.

In the **Federal Register** of October 25, 1995 (60 FR 54607)(FRL–4982–8), EPA established a time limited tolerance for residues of the herbicide pyrithiobac sodium in or on cottonseed at 0.02 ppm. The time limited tolerance will expire on September 30, 1997.

I. Risk Assessment and Statutory Findings

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