tolerance final actions in this document, are not likely to result in a significant adverse economic impact on a substantial number of small entities. The factual basis for the Agency's determination, along with its generic certification under section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), appears at 63 FR 55565, October 16, 1998 (FRL–6035–7). This generic certification has been provided to the Chief Counsel for Advocacy of the Small Business Administration.

G. Does this Final Action Involve Technical Standards?

No. This tolerance final action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Section 12(d) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by voluntary consensus standards bodies. The NTTAA requires EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

H. Are there Any International Trade Issues Raised by this Final Action?

EPA is working to ensure that the U.S. tolerance reassessment program under FQPA does not disrupt international trade. EPA considers Codex Maximum Residue Limits (MRLs) in setting U.S. tolerances and in reassessing them. MRLs are established by the Codex Committee on Pesticide Residues, a committee within the Codex Alimentarius Commission, an international organization formed to promote the coordination of international food standards. When possible, EPA seeks to harmonize U.S. tolerances with Codex MRLs. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain in a **Federal Register** document the reasons for departing from the Codex level. EPA's effort to harmonize with Codex MRLs is summarized in the tolerance reassessment section of individual Reregistration Eligibility Decisions. The U.S. EPA has developed guidance concerning submissions for import tolerance support. This guidance will be made available to interested persons.

I. Is this Final Action Subject to Review under the Congressional Review Act?

Yes. The Congressional Review Act, 5 U.S.C. Sec. 801 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects 40 CFR Part 180

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

Dated: July 13, 1999.

Jack E. Housenger,

Acting Director, Special Review and Reregistration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended to read as follows:

PART 180—[AMENDED]

1. In part 180:

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

Authority: 21 U.S.C. 321(q), 346a and 371.

§§ 180.109, 180.125, 180.141, 180.201, and 180.216 [Removed]

b. By removing §§ 180.109, 180.125, 180.141, 180.201, and 180.216.

c. By revising § 180.252 to read as follows:

§ 180.252 2-Chloro-1-(2,4,5-trichlorophenyl) vinyl dimethyl phosphate; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide 2-chloro-1-(2,4,5-trichlorophenyl) vinyl dimethyl phosphate in or on the following food commodities:

Commodity	Parts per million
Alfalfa	110
Cattle, fat	1.5
Egg	0.1
Goat, fat	0.5
Hog, fat	1.5
Horse, fat	0.5
Milk, fat (reflecting negligible residues in whole milk)	0.5
Poultry, fat	0.75
Sheep, fat	0.5

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

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

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

§§ 180.265 and 180.266 [Removed]

d. By removing §§ 180.265 and 180.266.

e. By revising § 180.267 to read as follows:

§ 180.267 Captafol; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide captafol (cis-*N*-[(1,1,2,2-tetrachloroethyl)thio]-4-cyclohexene-1,2-dicarboximide) in or on the following food commodities:

Commodity	Parts per million
Onion	0.1
Potato	0.5
Tomato	15

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

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

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

§§ 180.282, 180.283, 180.398, 180.402, and 180.1013 [Removed]

f. By removing §§ 180.282, 180.283, 180.398, 180.402, and 180.1013.

[FR Doc. 99–18611 Filed 7–20–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300882; FRL–6086–7]

RIN 2070–AB78

Spinosad; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of spinosad in or on all commodities in connection with quarantine eradication programs against exotic, non-indigenous, fruit fly species, where a separate higher tolerance is not already established. In this same action, EPA is also establishing a time-limited tolerance for use of spinosad on cranberries. These actions are 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 under the conditions described above. This regulation establishes a maximum permissible level for residues of spinosad on 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 tolerance in connection with the use of spinosad in quarantine eradication programs will expire and is revoked on December 1, 2002. The time-limited tolerance for spinosad on cranberries will expire and is revoked on June 1, 2001.

DATES: This regulation is effective July 21, 1999. Objections and requests for hearings must be received by EPA on or before September 20, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300882], 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–300882], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300882]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Daniel J. Rosenblatt, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 286, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703–308–9375; rosenblatt.dan@epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to sections 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for residues of the insecticide spinosad on all commodities at 0.02 parts per million (ppm) when used in connection with quarantine eradication programs against exotic, non-indigenous, fruit fly species, where a separate higher tolerance is not already established. This tolerance will expire and is revoked on December 1, 2002. EPA is also establishing a tolerance for residues of spinosad on cranberries when used under a section 18 emergency exemption. The tolerance for cranberries will expire and is revoked on June 1, 2001. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Findings

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

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

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

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

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

II. Emergency Exemption for Spinosad

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA/APHIS) is responsible for ensuring that new and invasive pest species do not become established in the United States. In order to engage in emergency eradication programs should an infestation of a quarantined fruit fly

pest be discovered, USDA/APHIS applied for section 18 quarantine exemptions to use, among other things, the pesticide spinosad against these species in Florida.

Florida is vulnerable to outbreaks of non-indigenous fruit fly species in the Tephritidae family. USDA/APHIS, working in conjunction with the Florida Department of Agriculture and Consumer Services, has eradicated numerous incipient populations of the Mediterranean fruit fly over the past two seasons. The discovery of an outbreak of a population of a new or non-established pest species carries significant trade implications. The economic losses associated with an established population of Mediterranean fruit flies or other Tephritidae pests would be severe.

EPA concurs that an emergency situation exists in relation to these pests and has authorized a section 18 quarantine exemption for use of spinosad in quarantine programs against exotic, non-indigenous, quarantined, fruit fly species. Time-limited tolerances are also needed to support this exemption in a generic manner because outbreaks of these pest species are possible in nearly all commercial agricultural settings.

Separately, EPA also authorized an emergency exemption for the use of spinosad on cranberries in order to control the sparganothis fruit worm. Growers are experiencing loss of efficacy connected with use of the historic pesticide controls and may be faced with yield loss at 20% of the crop over previous growing seasons. On heavily fruiting, early cultivars, damage may approach 35% crop loss. EPA concurs that emergency conditions exist and has authorized spinosad's use on cranberries in Massachusetts.

As part of its assessment of these emergency exemptions, EPA assessed the potential risks presented by residues of spinosad in or on cranberries and also on all commodities where a separate higher tolerance is not already established. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing 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 the dates specified elsewhere in this document, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on cranberries or all commodities where a separate higher tolerance is not established after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether spinosad meets EPA's registration requirements for use on cranberries or all commodities where a separate higher tolerance is not established or whether a permanent tolerance for this use 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 does this tolerance serve as the basis for any States other than those where the exemptions were issued to use this pesticide on these crops under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption, contact the Agency's Registration Division at the address provided under the ''ADDRESSES'' section.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of spinosad and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of spinosad on cranberries and all commodities where a separate higher tolerance is not established at 0.02 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

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

B. Toxicological Endpoint

1. *Acute toxicity*. No acute toxicity endpoint was selected by EPA because a single exposure dose did not produce toxicological effects.

2. *Short- and intermediate-term toxicity*. No toxicology endpoint was selected by EPA for these exposure durations.

3. *Chronic toxicity*. EPA has established the Reference Dose (RfD) for spinosad at 0.0268 milligram/kilogram/day (mg/kg/day). This RfD is based on a no observed adverse effect level (NOAEL) of 2.68 mg/kg/day established in a chronic toxicity study in dogs. The lowest observed adverse effect level (LOAEL) was 8.46 mg/kg/day based on vacuolation in glandular cells and lymphatic tissues, arteritis and increases in serum enzymes such as alanine aminotransferase, and aspartate aminotransferase, and triglyceride levels in dogs fed spinosad in the diet at dose levels 1.44, 2,68, or 8.46 mg/kg/day for 52 weeks. A 100-fold uncertainty factor (UF) was applied to the NOAEL of 2.68 mg/kg/day to account for inter- and intraspecies variation.

4. *Carcinogenicity*. EPA has determined that there is no evidence of carcinogenicity in studies involving spinosad in either the mouse or rat. Therefore, a carcinogenic risk assessment is not required.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.495) for the residues of spinosad, in or on a variety of raw agricultural commodities. For example, tolerances have been established for the citrus fruits group, the fruiting vegetables group, and on meat and milk. Risk assessments were conducted by EPA to assess dietary exposures and risks from 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. EPA did not identify a toxicity endpoint for this exposure duration. Therefore, a risk assessment for this exposure scenario is not needed.

ii. *Chronic exposure and risk*. Based on a NOAEL of 2.68 mg/kg/day and an uncertainty factor of 100, EPA performed a dietary risk assessment which considered exposure that may result from use under this section 18 as well as all other registered uses. The highest exposed population subgroup based on a Tier 1 exposure analysis from the dietary exposure evaluation system (DEEM) was children ages 1–6 years. This risk assessment also took into account the available information on spinosad concerning the additional safety factor called for by FQPA in order to protect infants and children. This calculation builds additional safety factors, as needed, into the risk assessment by using a ratio that compares the reference dose against the FQPA safety factor that is appropriate for a particular pesticide. This ratio is known as the population adjusted dose (PAD). In this case, EPA concluded that the additional 10x safety factor for spinosad could be removed. Section E of this unit contains the rationale for reducing the 10x safety factor for spinosad. EPA calculated that chronic dietary (food only) exposure at tolerance levels will occupy 39% of the PAD. Exposure estimates for adult populations are less than 29% of the PAD.

2. *From drinking water*. No chemical-specific drinking water monitoring data are available. However, EPA used modeling data involving both ground and surface water situations to determine conservative estimated environmental concentrations (EECs). Also, EPA back-calculated drinking water levels of comparison (DWLOCs) to determine whether exposure to spinosad via drinking water is likely to be of concern given the modeled EECs. EPA has concluded that drinking water is not expected to be a significant source of exposure to spinosad.

Data suggests that spinosad is not mobile or persistent, and therefore, has little potential to leach to ground water or to be transported to surface water in high concentrations. Although spinosad has been shown to photolyze rapidly, EPA used the conservative soil photolysis value of 82 days in modeling the persistence of the chemical in surface waters.

i. *Acute exposure and risk*. The high-end EEC is based on the highest registered application rate and results in an EEC of 0.092 micrograms/liter. The highest exposed population subgroup is children 1–6 years. The calculated DWLOC for that population subgroup is 165 micrograms/liter. This EEC value is over 1,000 times less than the lowest DWLOC. Therefore, EPA concludes that drinking water is not expected to be a significant source of exposure to spinosad.

ii. *Chronic exposure and risk*. The characteristics of spinosad suggest that the exposure and risks from spinosad in drinking water are analogous for acute and chronic exposures. No separate chronic analysis is needed.

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 (RfDs or acute dietary NOAELs) 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 it 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 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 is granted.

3. *From non-dietary exposure*. Spinosad is currently registered for use on the following residential non-food site: turf grass. This registration creates the possibility of exposure to children involved in pica behavior with the ingestion of grass or treated dirt. EPA performed a qualitative analysis of the risks connected with this type of exposure and concluded that based on the toxicology profile of spinosad as well as a reasonable exposure situation that risk to children from the turf use does not exceed the Agency's level of concern.

i. *Acute exposure and risk*. Because no toxicological endpoint was selected for acute exposures to spinosad, it is not necessary to calculate a risk assessment to evaluate the acute non-dietary exposure scenario.

ii. *Chronic exposure and risk*. EPA's Health Effect Division (HED) performed a qualitative risk assessment to characterize the chronic risks from non-dietary exposure to spinosad. Based on the low application rate on turf (0.41 lb., AI/A.), its non-systemic nature, its short half-life (especially in sunlight), and the rapid incorporation of spinosad metabolites into the general carbon pool, EPA believes that residues of spinosad on turf grass after application would be low and decrease rapidly over time. EPA believes that a quantitative risk assessment for this exposure duration is not reasonable as it is unlikely that children would eat grass/dirt for greater than 6 months continuously. Therefore, EPA believes it is appropriate to use a qualitative assessment of this situation. EPA believes that the risk from children eating turf grass does not exceed the level of concern.

iii. *Short- and intermediate-term exposure and risk*. Because no toxicological endpoint was selected for short- and intermediate-term exposures to spinosad, it is not necessary to calculate a risk assessment to evaluate this non-dietary exposure scenario.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether 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. For more information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such

chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Acute risk*. As mentioned previously, no toxicology endpoint was identified for this exposure duration. Thus, an aggregate risk assessment for this situation is not needed.

2. *Chronic risk*. Using the theoretical maximum residue contribution (TMRC) exposure assumptions described in this unit, EPA has concluded that aggregate exposure to spinosad from food will utilize 29% of the chronic PAD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children ages 1–6 years. A separate risk assessment for this population subgroup is described in section E of this unit. EPA generally has no concern for exposures below 100% of the RfD or PAD 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 and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD or the PAD.

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.

No toxicology endpoint was selected for spinosad for these exposure durations. Thus, a separate risk assessment for this exposure duration for the U.S. population was not conducted by EPA.

4. *Aggregate cancer risk for U.S. population*. Toxicology data suggest that spinosad does not induce cancer. Thus, a cancer risk assessment was not performed and is not necessary.

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

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

1. *Safety factor for infants and children*—i. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of spinosad, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2–generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intraspecies variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*. In a prenatal developmental toxicity study in rabbits, the NOAEL for maternal toxicity is ≥50 mg/kg/day. There were no developmental effects that could be attributed to administration of spinosad. The NOAEL for developmental toxicity is ≥50 mg/kg/day (highest dose tested).

In a prenatal developmental toxicity study in rats, the NOAEL for maternal toxicity is ≥200 mg/kg/day (highest dose tested). There were no developmental effects that could be attributed to administration of spinosad. The NOAEL for developmental toxicity is ≥200 mg/kg/day (highest dose tested).

iii. *Reproductive toxicity study*. In a 2–generation reproduction study, for parental systemic toxicity, the NOAEL was 10 mg/kg/day and the LOAEL was 100 mg/kg/day, based on increased heart, kidney, liver, spleen and thyroid weights. For offspring toxicity, the NOAEL was 10 mg/kg/day and the LOAEL was 100 mg/kg/day, based on decreased litter size, survival (F_2), and body weights. Reproductive effects at that dose level included increased incidence of dystocia and or vaginal bleeding after parturition with associated increase in mortality of dams.

iv. *Pre- and postnatal sensitivity*. There was no increased susceptibility to rats or rabbits following *in utero* and or postnatal exposure to spinosad.

v. *Conclusion*. Based on the existing toxicological data base, no indication of increased susceptibility of rat or rabbit fetuses to *in utero* and or postnatal exposure, and that there is no requirement for a developmental neurotoxicity study, EPA determined that the 10x safety factor for increased sensitivity of infants and children can be removed (i.e., 1x).

2. *Acute risk*. No toxicology endpoint was selected for exposure to spinosad based on acute exposure. Thus, EPA did not calculate a risk assessment for this exposure duration for infants and children.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to spinosad from food will utilize 39% of the chronic PAD for infants and children. EPA generally has no concern for exposures below 100% of the chronic PAD because the RfD or PAD 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 and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk*. No toxicology endpoint was selected for exposure to spinosad based on short- or intermediate-term exposure. Thus, EPA did not calculate a risk assessment for these exposure durations for infants and children.

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

IV. Other Considerations

A. Metabolism in Plants and Animals

EPA has reviewed the results of plant and animal metabolism studies in numerous crops and animals. The metabolism of spinosad is adequately understood. EPA has concluded that the metabolism and fermentation impurities of spinosad were of no more toxicological concern than the two parent compounds (spinosyns Factor A and Factor D).

B. Analytical Enforcement Methodology

Enforcement methods have already been accepted and published to enforce tolerances for spinosad.

C. Magnitude of Residues

No field trial data are available from the proposed use of spinosad against the exotic fruit flies. However, based on the low use rate and photodegradability of spinosad, EPA does not expect residues to be detectable. An analysis of the expected residue level was calculated based on the highest registered use rate for spinosad. Based on its rapid incorporation into the general carbon pool, EPA believes that residues will be most strongly influenced by the last application rather than the seasonal rate. The low use rate suggests that residues will be at or below 0.02 ppm, the level of quantitation.

D. International Residue Limits

No international tolerances for spinosad have been established that correspond to these actions.

E. Rotational Crop Restrictions

There are no rotational crop restrictions connected with these actions.

V. Conclusion

Therefore, the tolerances are established for residues of spinosad in or on all commodities at 0.02 ppm when its use is associated with quarantine eradication programs against exotic, non-indigenous, fruit fly species where a separate higher tolerance is not already established. Also, a tolerance of 0.02 ppm is established for spinosad on cranberries when it is used in accordance with a FIFRA section 18 exemption.

VI. Objections and Hearing Requests

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

Any person may, by September 20, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

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

VII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300882] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov

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

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

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

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(l)(6), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

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

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

C. Executive Order 13084

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

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

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: June 30, 1999.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346(a), and 371.

2. Section 180.495, is amended, by adding new paragraph (b) to read as follows:

§180.495 Spinosad; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Factor A is 2-[(6-deoxy-2,3,4-tri-O-methyl-o-L-mannopyranosyl)oxy]-13-[[5-(dimethlamino)- tetrahydro-6-methyl-2H-pyran-2-yl]oxy]9-ethyl-2,3,3a,5a,6,9,10,11,12,13,14,16a, 6b,tetradecahydro-14-methyl-1H-as-Indaceno[3,2d]oxacyclododecin-7,15-dione. Factor D is 2-[6-deoxy-2,3,4-tri-O-methyl-o-L-mannopyranosyl)oxy]13-[[5-(dimethylamino)-tetrahydri-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14,dimethyl-1H-as-Indaceno[3,2d]oxacyclododecin-7,15-dione.

Commodity	Parts per million	Expiration/ Revocation date
Cranberries	0.02	06/01/01
All commodities in connection with quarantine eradication programs against exotic, non-indigenous, fruit fly species, where a separate higher tolerance is not already established	0.02	12/01/02

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