establishing a precedent for any future request for revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

IV. Administrative Review

A. Executive Order 12866

This action has been classified as a Table 3 action for signature by the Regional Administrator under the procedures published in the Federal Register on January 19, 1989 (54 FR 2214–2225), as revised by a July 10, 1995 memorandum from Mary Nichols, Assistant Administrator for Air and Radiation. The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866 review.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 600 et seq., EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under sections 110 and 301, and subchapter I, part D of the CAA do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the CAA, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of State action. The CAA forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

C. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action proposed does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

D. Submission to Congress and the General Accounting Office

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

E. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 28, 1997. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2), 42 U.S.C. 7607(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: February 14, 1997.

Charles Findley,

Acting Regional Administrator.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart WW—Washington

2. Section 52.2470 is amended by adding paragraph (c)(70) to read as follows:

§ 52.2470 Identification of plan.

* * * * *

(c) * * *

(70) On January 24, 1996 the Director of WDOE submitted to the Regional Administrator of EPA regulations of the SWAPCA for the control of air pollution in Clark, Cowlitz, Lewis, Skamania and Wahkiakum Counties, Washington (SWAPCA 400—General Regulation for Air Pollution Sources).

(i) Incorporation by reference.

(A) The January 24, 1996, letter from WDOE to EPA submitting requests for revisions to the Washington SIP to include regulations of the SWAPCA for the control air of pollution in Clark, Cowlitz, Lewis, Skamania and Wahkiakum Counties, Washington, as revisions to the Washington SIP, State-effective September 21, 1995. EPA is approving the following sections of SWAPCA 400—General Regulation for Air Pollution Sources: 010; 020; 030 except the second sentence of (14), (45) and (80); 040 except (1)(c), (1)(d), (2), (4) and (6)(a); 050 except the exception provision of (3); 052; 060; 070 except (5); 074; 081; 091; 100 except the first sentence of (3)(a)(iv) and (4); 101; 105; 107; 109 except for (3)(b), (3)(c), (3)(g), (3)(h), and (3)(i), 110; 112; 113; 114; 151; 161; 171; 190; 200; 205; 210; 220; 230; 240; 250; 260; 270; and 280.

[FR Doc. 97–4659 Filed 2–25–97; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 180

[OPP–300454; FRL–5590–8]

RIN 2070–AC78

Spinosad; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This regulation establishes a time-limited tolerance with an

expiration date of November 15, 1999 for residues of the insecticide Spinosad in or on the raw agricultural commodity cottonseed. DowElanco submitted a petition to EPA under the Federal Food Drug and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170) requesting the tolerance.

EFFECTIVE DATE: This regulation becomes effective February 26, 1997. The tolerance expires on November 15, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300454], 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–300454], should be submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 22202. A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: OPP-docket@epamail.epa.gov.

Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [OPP–300454]. 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: George T. LaRocca, Product Manager (PM) 13, 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. 204, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305-6100, e-mail: larocca.george@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, issued a notice, published in the Federal Register of July 10, 1996, (61 FR 36373)(FRL–5380–7), which announced that DowElanco, 9330 Zionsville Road, Indianapolis, IN 46268–1054, had submitted a pesticide petition (PP 6F4735) to EPA requesting that the Administrator, pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), establish a tolerance for residues of the insecticide Spinosad in or on the raw agricultural commodity cottonseed at 0.02 parts per million (ppm). Spinosad is a fermentation derived tetracyclic macrolide product produced by the *actinomycete, saccharopolyspora spinosa* and consists of two structurally related compounds, namely, Spinosyn A (CAS No. 131928–60–7) and Spinosyn D (CAS No. 131929–63–) whose chemical structures differ by a single methyl group. Spinosyn A is 2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione. Spinosyn D is 2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-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[3,2-d]oxacyclododecin-7,15-dione.

In the Federal Register of November 22, 1996 (61 FR 59437) EPA issued a second notice of filing to amend the petition to bring it into conformity with the Food Quality Protection Act (FQPA) of 1996. The notice contained a summary of the petition prepared by the petitioner and this summary contained conclusions and assessments to support its conclusion that the petition complied with FQPA.

In March 1995 Spinosad was accepted by EPA as a reduced risk pesticide. Reduce risk status was granted primarily due to Spinosad's low acute mammalian toxicity, low non-target organism toxicity and compatibility with integrated pest management. The criteria initiating EPA's reduced risk pesticide process are set forth in Pesticide Regulation Notice 93–9 dated July 21, 1993 and the January 22, 1993 Federal Register (58 FR 5854).

There were no comments or requests for referral to an advisory committee received in response to the notice.

I. Background and Statutory Authority

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

New section 408(b)(2)(A)(i) allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....'' Section 408(b)(2)(D) specifies factors EPA is to consider in establishing a tolerance. Section 408(b)(3) requires EPA to determine that there is a practical method for detecting and measuring levels of the pesticide chemical residue in or on food and that the tolerance be set at a level at or above the limit of detection of the designated method. Section 408(b)(4)requires EPA to determine whether a maximum residue level has been established for the pesticide chemical by the Codex Alimentarius Commission. If so, and EPA does not propose to adopt that level, EPA must publish for public comment a notice explaining the reasons for departing from the Codex level. Section 408(b)(2)(A) governs EPA's establishment of tolerances and incorporating the provisions of section 408(b)(2)(C) and (D).

II. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many

adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. For many of these studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (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 significant risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered acceptable by EPA.

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

In examining aggregate exposure, FQPA requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, and other non-occupational exposures, such as where residues leach into groundwater or surface water that is consumed as drinking water. Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100 percent of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately 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.

Consistent with sections 408(b)(2)(C) and (D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has also assessed the toxicology data base for spinosad in its evaluation of applications for registration on cotton. 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 the time-limited tolerances for residues of Spinosad on cottonseed at 0.02 ppm. EPA's assessment of the database, dietary exposures and risks associated with establishing these tolerances follows:

A. Toxicology Data Base

The data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the tolerance include the following:

1. A battery of acute toxicity studies placing the technical Spinosad in Toxicity Category III and IV.

2. In a 21–day dermal study in rabbits the NOEL for dermal and systemic toxicity was 1,000 milligrams per kilogram per day (mg/kg/day) (limit dose). New Zealand White strain rabbits were given 15 dermal applications at 0, 100, 500, or 1,000 mg/kg/day for 21 days . Under the conditions of the test, there was no evidence of treatment-related toxicity from dermal application at doses up to 1,000 mg/kg/day.

3. In a 13–week feeding neurotoxicity study, Fischer 344 strain rats were given daily levels of 0, 2.2, 4.3, 8.6, or 42.7 mg/kg body weight for males and 0, 2.6, 5.2, 10.4 or 52.1 mg/kg/day for females. There were no effects observed on the functional observational battery (FOB), motor activity, or histological observations of the nervous system. Therefore, the NOEL for acute mammalian neurotoxicity in rats is ≥42.7 or 52.1 mg/kg/day for male and female rats, respectively.

4. A chronic 2–year feeding study in dogs at dietary doses of 1.44, 2.68, or 8.46 mg/kg/day in males, and 1.33, 2.72 or 8.22 mg/kg/day respectively in females with a NOEL of 2.68 mg/kg/day (100/120 ppm).

5. Two mouse carcinogenicity studies have been submitted and fulfill the requirement for mouse carcinogenicity testing. In the first study mice were dosed at 0, 3.4, 11.4 and 50.9 mg/kg/day in males and 4.2, 13.8, and 67.0 mg/kg/day respectively in females with systemic NOEL of 11.4 mg/kg/day for males and 13.8 mg/kg/day in females. In the second study, involving only females, dosing was at 0, 1.3 and 41.5 mg/kg/day highest dose tested (HDT). These studies, along with additional information from the petitioner do not indicate a potential for carcinogenicity.

6. A 24–month chronic feeding/carcinogenicity study in rats. The chronic feeding study using rats indicates that the rat is a less sensitive species than the dog with respect to Spinosad. The rat feeding study data support the NOEL selected from the dog feeding study as the basis of the RfD. The rat feeding study is currently determined to be supplemental since additional histopathology data on the animals that died during the study are required to upgrade the study from supplementary status. NOELs and lowest observed effect levels (LOELs) will be established for this study once the additional data are reviewed. There were no treatment related carcinogenic effects observed at any dose level.

7. Mutagenicity studies including an *in vitro* forward mutation assay (mouse lymphoma cells), *in vitro* chromosome aberration assay (Chinese hamster ovary cells), an *in vivo* micronucleus assay (mice), and an *in vitro* unscheduled DNA synthesis assay (primary rat hepatocytes) showed no mutagenic activity associated with Spinosad.

8. A metabolism study in rats demonstrates that there were no major differences between the bioavailability, routes of excretion, or metabolism of ^{14}C-Spinosad (Factor A) and ^{14}C-Spinosad (Factor D). Urine and fecal excretions were almost completed at 48 hours post-dosing.

9. An oral developmental toxicity study in rats with a developmental NOEL of ≥200 mg/kg/day highest dose tested (HDT). The NOEL for maternal toxicity is ≥200 mg/kg/day HDT. An oral developmental toxicity study in rabbits with a developmental NOEL of ≥50 mg/kg/day HDT. The NOEL for maternal toxicity is ≥50 mg/kg/day HDT. With respect to both studies there were no developmental effects that could be attributed to administration of Spinosad up to the HDT.

10. A two generation reproduction study in rats at dietary doses of 0, 3, 10, and 100 mg/kg/day with a NOEL for parental effects at 10 mg/kg/day based upon increases in heart, kidney, liver, spleen, and thyroid weights (both sexes), corroborative histopathology in the spleen and thyroid (both sexes), heart and kidney (males only), and histopathologic lesions in the lungs and mesenteric lymph nodes (both sexes), stomach (females only), and prostate in the high dose group (100 mg/kg/day).

The NOEL for reproductive effects was also 10 mg/kg/day based upon both maternal and reproductive effects including decreases in litter size, survival (F2 litters only), and body weights in the offspring, and increased incidence of dystocia and/or vaginal bleeding after parturition with associated increases in mortality in the dams in the high dose group (100 mg/kg/day).

B. Toxicological Profile

1. *Chronic effects.* Based on the available chronic toxicity data, EPA has established the Reference Dose (RfD) for spinosad at 0.0268 mg/kg/day based on a NOEL of 2.68 mg/kg/day and an uncertainty factor of 100. The NOEL is based on a 2–year dog chronic feeding study.

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

3. *Carcinogenicity.* Based on the available carcinogenicity studies in two rodent species Spinosad has not been determined to be a human carcinogen. A final cancer classification using the Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992) is pending; however, the current data does not indicate that a cancer risk assessment will be necessary.

III. Aggregate Exposure

1. *Food and fee uses.* For purposes of assessing the potential dietary exposure from use of Spinosad on cotton EPA has estimated aggregate exposure based on the TMRC from the tolerance for spinosad on cottonseed at 0.02 ppm. The TMRC is obtained by multiplying the tolerance level residue for cottonseed (0.02 ppm) by the food consumption factors for foods derived from cottonseed. Cottonseed is fed to animals thus exposure to residues in cottonseed might result if such residues are transferred to meat, milk, poultry or eggs. However, based upon the results of animal metabolism studies, EPA concludes there is no reasonable expectation of finite residues of spinosad in poultry tissues and eggs from cotton uses. With respect to meat and milk extrapolation from existing ruminant metabolism, studies indicates that secondary residues of spinosad in ruminant commodities are expected to be negligible. The analysis also included two commodities processed from cottonseed; cottonseed oil and cottonseed meal. Tolerance level residues on the oil and meal were assumed however EPA notes that Spinosad residues do not concentrate in processed commodities, and therefore this risk estimate is very conservative. The dietary risk assessment will be reevaluated with respect to secondary residues in ruminant tissues and milk upon submission and review of the field trial data for cotton gin by-products. There are no other established U.S. tolerances for Spinosad, and there are no registered uses for Spinosad on food or feed crops in the United States.

As indicated above, in conducting this exposure assessment, EPA has made very conservative assumptions—100 percent of cottonseed will contain spinosad residues including cottonseed oil and meal, and those residues would be at the level of the tolerance —which results in an overestimate of human exposure. Thus, in making a safety determination for these tolerances, EPA is taking into account this conservative exposure assessment.

2. *Potable water.* There is no established Maximum Concentration Level (MCL) for residues of Spinosad in drinking water. Because the Agency lacks specific water-related exposure data for most pesticides, EPA has begun and nerly 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. EPA then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOELs) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. This analysis can be found in the Special Record for the FQPA. While EPA has not yet pinpointed the appropriate bounding figure for consumption of contaminated water, the ranges EPA is continuing to examine are all well below the level that would cause spinosad to exceed the RfD, if the tolerance being considered in this document are granted. EPA has therefore concluded that the potential exposure associated with spinosad in water, even at the higher levels EPA is considering as a conservative upper bound, would not prevent EPA from determining that there is a reasonable certainty of no harm if the proposed tolerance on cottonseed is granted.

3. *Non-dietary uses.* EPA has not estimated non-occupational exposure for Spinosad since there are no chronic or acute residential risks expected from the use of Spinosad on cotton. The potential for non-occupational exposure to the general population is, thus, not expected to be significant.

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.'' While 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 in a meaningful way. EPA is commencing 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 enable the Agency to apply common mechanism issues to its pesticide risk assessments. At present, however, the Agency does not know how to apply the information in its files concerning common mechanism issues to risk assessments, and therefore believes that in most cases there is no available information concerning common mechanism that can be scientifically applied to tolerance decisions. Where it is clear that a particular pesticide may share a significant common mechanism with other chemicals, a tolerance decision may be affected by common mechanism issues. The Agency expects that most tolerance decisions will fall into the area in between, where EPA can not reasonably determine whether a pesticide does or does not share a

common mechanism of toxicity with other chemicals (and, if so, how that common mechanism should be factored into a risk assessment). In such circumstances, the Agency will reach a tolerance decision based on the best, currently available and useable information, without regard to common mechanism issues. However, the Agency will also revisit such decisions when the Agency learns how to apply common mechanism information to pesticide risk assessments.

In the case of Spinosad, it is unlikely that this pesticide shares a common mechanism of toxicity with other pesticides since Spinosad is a unique insecticide structurally unrelated to other registered pesticides. However since EPA has determined that it does not now have the capability to apply the information in its files to a resolution of common mechanism issues in a manner that would be useful in a risk assessment, this tolerance determination does not take into account common mechanism issues. The Agency will reexamine the tolerance for Spinosad, if reexamination is appropriate, after the Agency has determined how to apply common mechanism issues to its pesticide risk assessments.

IV. Determination of Safety for Infants and Children

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 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.

Available data indicate that no developmental toxicity was observed in the rabbit study at the HDT (50 mg/kg/day). Slight maternal toxicity was observed in the rabbit at the HDT and consisted of marginal reductions in body weight gain, defecation, and food consumption. In the rat developmental study, a slight 1–day reduction in maternal body weight gain and body weight was observed at the HDT, but otherwise no developmental or maternal toxicity was observed at a high dose level (200 mg/kg/day). Developmental toxicity studies established the NOELs for maternal and developmental toxicity at ≥50 mg/kg/day in rabbits (HDT) and ≥200 mg/kg/day in rats HDT.

Reproductive toxicity appears to be related to systemic maternal toxicity, and was characterized by decreases in mean litter size and body weight throughout lactation. The NOEL for reproductive toxicity is 10 mg/kg/day.

FFDCA section 408 provides that EPA shall apply an additional safety factor for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that such additional factor is not necessary to protect the safety of infants and children. EPA believes that reliable data support using a different safety factor (usually 100x) and not the additional safety factor when EPA has a complete data base 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 traditional safety factors.

Based on current data requirements, the database relative to pre- and post-natal toxicity is complete. These data taken together suggest minimal concern for developmental or reproductive toxicity and do not indicate any increased pre- or postnatal sensitivity.

Therefore, EPA concludes that reliable data support use of a 100-fold safety factor and an additional 10-fold safety factor is not needed to protect the safety of infants and children.

V. Determination of Safety for U.S. Population Including Infants and Children

1. *Reference dose (RfD).* A chronic dietary exposure/risk assessment was performed for Spinosad using an RfD of 0.02 mg/kg/day based on a NOEL of 2.68 mg/kg/day from a 2–year dog feeding study with an uncertainty factor of 100. Using the conservative exposure assumptions described above and based on the completeness and reliability of the toxicity data base, EPA has concluded that aggregate exposure to Spinosad from it use on cotton will utilize less than 1 percent of the RfD for the U.S. population and for all of the 22 population subgroups including children and infants. EPA generally has no concern for exposures below 100 percent of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose significant risks to human health.

2. *Aggregate risks*. Based upon the available toxicity and exposure data and worst case assumptions for dietary exposure aggregate chronic risks are expected to be less than 1% of the RfD for the general U.S. population, including all population subgroups. As indicated above although EPA has not yet identified a water exposure figure based on available environmental data, Spinosad is not expected to be mobile in soil or water environments and poses relatively little threat to ground and drinking water. EPA therefore concludes that there is reasonable certainty that no harm will result to consumers, including infants and children, from aggregate exposure to spinosad residues.

VI. Other Considerations

A. Endocrine Effects

An evaluation of the potential effects on the endocrine systems of mammals has not been determined; however no evidence of such effects were reported in the toxicology studies described above. There is no evidence at this time that Spinosad causes endocrine effects.

B. Metabolism in Plants and Animals

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

C. Summary of Findings

Tolerances are time limited to allow for development and review of residue field trials on cotton gin by products. The analysis for Spinosad using tolerance level residues shows that the proposed use on cotton will not cause exposure to exceed the levels at which EPA believes there is an appreciable risk. All population subgroups examined by EPA are exposed to Spinosad residues at levels well below 100 percent of the RfD for chronic effects. Based on the information and data considered, EPA concludes that the proposed time-limited tolerance will be safe. Therefore, the tolerance is established as set forth below.

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 the new section 408(d) 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 its current procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by April 28, 1997, file written objections to any aspect of this regulation (including the automatic revocation provision) and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Docket

A record has been established for this rulemaking under docket number [OPP–300454]. A public version of this record, 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 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

The official record for this rulemaking, as well as the public version, as described above, is kept in paper form. Accordingly, in the event there are objections and hearing requests, 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. 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

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

Pursuant to the requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

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

List of Subjects In 40 CFR Part 180

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

Dated: February 13, 1997.

Daniel M.Barolo,

Director, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is amended as follows:

PART 180—[AMENDED]

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

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

b. By adding a new § 180.495 to read as follows:

§ 180.495 Spinosad; tolerances for residues.

(a) [Reserved]

(b) A time-limited tolerance is established for residues of the insecticide Spinosad. Factor A is 2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a, 6b-tetradecahydro-14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione. Factor D is 2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-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[3,2-d]oxacyclododecin-7,15-dione.

Commodity	Parts per million	Expiration Date
Cottonseed	0.02	November 15, 1999

[FR Doc. 97–4625 Filed 2–25–97; 8:45 am]
BILLING CODE 6560–50–F

40 CFR Part 261

[FRL–5694–6]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Final Exclusion; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: On July 18, 1996, the Environmental Protection Agency (EPA or Agency) published a final rule granting a petition submitted by United Technologies Automotive, Inc. (UTA), Dearborn, Michigan, to exclude (or ''delist''), conditionally, on a one-time, upfront basis, a certain solid waste generated by UTA's chemical stabilization treatment of lagoon sludge at the Highway 61 Industrial Site in Memphis, Tennessee, from the lists of hazardous wastes in §§ 261.31 and 261.32. Based on careful analyses of the waste-specific information provided by the petitioner, the Agency concluded that UTA's petitioned waste will not adversely affect human health and the environment. Delisting levels for cadmium, chromium, lead, nickel, and cyanide which would be protective of human health and the environment were calculated and promulgated. This action addresses the fact that the actual volume of waste to be disposed is 39,400 cubic yards, instead of the 20,500 cubic yards estimated by the petitioner prior to publication of the final rule. Therefore, today's document corrects the delisting levels for the constituents of concern by using the dilution attenuation factor (DAF) of 79 for 40,000 cubic yards, instead of the DAF of 96 for 20,500 cubic yards.

EFFECTIVE DATE: July 18, 1996.

ADDRESSES: The RCRA regulatory docket for the final rule and today's document is located at the EPA Library, U.S. Environmental Protection Agency, Region 4, 100 Alabama Street, S.W., Atlanta, Georgia 30303, and is available for viewing from 9:00 a.m. to 4:00 p.m., Monday through Friday, excluding Federal holidays.

The reference number for this docket is R4–96–UTEF. The public may copy material from any regulatory docket at no cost for the first 100 pages, and at a cost of $0.15 per page for additional copies. For copying at the Tennessee Department of Environment and Conservation, please see below.

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA Hotline, toll free at (800) 424–9346, or at (703) 412–9810. For technical information concerning this notice, contact Judy Sophianopoulos, Enforcement and Compliance Branch, (Mail Code 4WD–RCRA), U.S. Environmental Protection Agency, Region 4, 100 Alabama Street, S.W., Atlanta, Georgia 30303–3104, (404) 562–8604, or call, toll free, (800) 241–1754, and leave a message, with your name and phone number, for Ms. Sophianopoulos to return your call. You may also contact Wayne Gregory, Tennessee Department of Environment and Conservation (TDEC), 5th Floor, L & C Tower, 401 Church Street, Nashville, Tennessee 37243–1535, (615) 532–0847. If you wish to copy documents at TDEC, please contact Mr. Gregory for copying procedures and costs.

SUPPLEMENTARY INFORMATION:

I. Reasons and Basis for Today's Document

Each delisting level in the final rule was calculated by multiplying the health-based level for each constituent of concern by the dilution attenuation factor (DAF) of 96 for a one-time disposal of an estimated volume of 20,500 cubic yards of petitioned waste. See 61 FR 37399, July 18, 1996. The petitioner reported that the actual volume to be disposed is 39,400 cubic yards. The DAF for this volume is 79. See the proposed rule for this petitioned waste at 61 FR 14703, April 3, 1996.

Therefore, today's document corrects the delisting level for each constituent of concern by multiplying each health-based level by 79.

II. Corrections to the Preamble of Final Rule

On page 37399, of the Federal Register of July 18, 1996, Table 1 of the Preamble:

The delisting level for chromium is corrected to read: ''7.9; delisting level is set at less than 5.0, the toxicity characteristic level.''

The delisting level for cyanide is corrected to read: ''15.8; (cyanide extraction must be conducted using deionized water.)''

The delisting levels for cadmium, lead, and nickel are corrected to read: ''0.40,'' ''1.18,'' and '' 7.9,'' respectively.

List of Subjects in 40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

Dated: January 31, 1997.

Jewell A. Harper,

Deputy Director, Waste Management Division.

Correction to Final Rule

PART 261—[CORRECTED]

Appendix IX [Corrected]

On page 37402, of the Federal Register of July 18, 1996, in appendix IX to part 261, in the third column of table 1, condition (3) is corrected to read as follows:

Appendix IX to Part 261—Wastes Excluded Under §§ 260.20 and 260.22

TABLE 1.—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES

Facility	Address	Waste description
*	*	* * *
		(3) *Delisting Levels:* All leachable concentrations for these constituents must not exceed the following levels (ppm): Cadmium—0.40; cyanide—15.8; lead—1.18; and nickel—7.9. The leachable concentration of chromium must be less than 5.0 ppm. Metal concentrations in the waste leachate must be measured by the method specified in 40 CFR 261.24. The cyanide extraction must be conducted using deionized water. Total cyanide concentration in the leachate must be measured by Method 9010 or Method 9012 of SW–846.
*	*	* * *

[FR Doc. 97–4755 Filed 2–25–97; 8:45 am]
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