K. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by *October 13, 2009.* 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. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Dated: May 12, 2009.

Laura Yoshii,

Acting Regional Administrator, Region IX.

■ 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 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c) (244)(i)(C)(*2*), (335)(i)(E), and (350)(i)(A)(*2*) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(244) * * *

(i) * * *

(C) * * *

(*2*) Rule 403.1, ''Fugitive Dust Control for the Searles Valley Planning Area'', adopted on June 22, 1994 and amended on November 25, 1996.

* * * * *

(335) * * *

(i) * * *

(E) Kern County Air Pollution Control District

(*1*) Rule 402, ''Fugitive Dust'', adopted on November 29, 1993 and amended on November 3, 2004.

* * * * *

(350) * * *

(i) * * *

(A) * * *

(*2*) Rule 401, ''Fugitive Dust'', adopted on September 5, 1974 and amended on December 04, 2006.

* * * * *

[FR Doc. E9–19338 Filed 8–12–09; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0805; FRL–8426–9]

Spinetoram; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the tolerances for the combined residues of spinetoram in or on almond, hulls; nut, tree, group 14; and pistachio and establishes tolerances for date; pomegranate; pineapple; pineapple, processed residue; spice, subgroup 19B, except black pepper; and hop, dried cones. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 13, 2009. Objections and requests for hearings must be received on or before October 13, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0805. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Samantha Hulkower, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 603–0683; e-mail address: *hulkower.samantha@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://*

www.epa.gov/opptsfrs/home/guidelin.htm.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0805 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before October 13, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2008–0805, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of December 3, 2008 (73 FR 73648) (FRL–8391–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E7450) by IR-4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W., Princeton, NJ 08540. The petition requested that 40 CFR 180.635 be amended by establishing tolerances for residues of the insecticide spinetoram, expressed as a combination of:

XDE-175-J: 1-H-as-indaceno[3,2-d] oxacyclododecin-7,15-dione,2 2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl-a-L-mannopyranosyl)oxy]-13-[[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,4,5,5a,5b,6,9, 10,11,12,13,14,16a,16b-hexadecahydro 14-methyl-,(2R,3aR,5aR,5bS,9S,13S,14R, 16aS,16bR);

XDE-175-L: 1H-as-indaceno[3,2-d]oxacyclododecin-7,15-dione, 2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl-a-L-mannopyranosyl)oxy]-13-[[(2R,5S,6R)-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-, (2S,3aR,5aS,5bS,9S,13S,14R,16aS,16bS);

ND-J:(2R,3aR,5aR,5bS,9S,13S, 14R,16aS,16bR)-9-ethyl-14-methyl-13-[[(2S,5S,6R)-6-methyl-5-(methylamino)tetrahydro-2H-pyran-2-yl]oxy]-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7,9,10,11,12,13, 14,15,16a,16b-octadecahydro-1H-as-indaceno[3,2-d]oxacyclododecin-2-yl 6-deoxy-3-O-ethyl-2,4-di-O-methyl-alpha-L-mannopyranoside; and

NF-J: (2R,3S,6S)-6-([(2R,3aR,5aR, 5bS,9S,13S,14R,16aS,16bR)-2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl-alpha-L-mannopyranosyl)o oxy]-9-ethyl-14-methyl-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7,9,10, 11,12,13,14,15,16a,16b-octadecahydro-1H-as-indaceno[3,2-d]oxacyclododecin-13-yl]oxy)-2-methyltetrahydro-2H-pyran-3-yl(methyl)formamide

in or on the raw agricultural commodities pineapple at 0.02 parts per million (ppm); pomegranate at 0.3 ppm; date at 0.1 ppm; spice, subgroup 19B, except black pepper at 1.7 ppm; hop, dried cones at 22 ppm; and pineapple, process residue at 0.08 ppm. Additionally, the petition proposed to increase the levels of existing tolerances for nut, tree, group 14 and pistachio from 0.04 to 0.08 ppm and almond, hulls from 2.0 ppm to 9.0 ppm. That notice referenced a summary of the petition prepared on behalf of IR-4 by Dow AgroSciences, LLC, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised tolerances to higher levels than proposed for almond, hulls; nut, tree, group 14; pistachio; pineapple; and pineapple, process residue. The reason for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of 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) of FFDCA 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) of FFDCA 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....''

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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 and to make a determination on aggregate exposure for the petitioned-for tolerances for combined residues of spinetoram on almond, hulls at 19 ppm; nut, tree, group 14 at 0.10 ppm; pistachio at 0.10 ppm; date at 0.10 ppm; pomegranate at 0.30 ppm; pineapple at 0.04 ppm; pineapple, processed residue at 0.15 ppm; spice, subgroup 19B, except black pepper at 1.7 ppm; and hop, dried cones at 22 ppm. EPA's assessment of exposures and risks associated with establishing tolerances 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.

Spinetoram has low acute toxicity via the oral, dermal and inhalation routes of exposure. It is a dermal sensitizer but not an eye or dermal irritant. In subchronic toxicity studies conducted in rats, mice and dogs, spinetoram produces multi-organ toxicity. Treatment had no adverse effects on

survival but decreases in body weight, body weight gain and/or food consumption were observed in all three species. Treatment-related findings included the presence of a mild anemia, alterations in clinical chemistry parameters, increased liver weights, presence of histiocytic aggregates of macrophages in various organs and tissues, and degeneration with regeneration of the kidney tubules. Dogs appear to be the most sensitive species. In the subchronic study with dogs, lower thymus weights, atrophy of the thymic cortex, arteritis and/or perivascular inflammation in numerous organs with necrosis of the bone marrow leading to regenerative anemia was seen. In the chronic study with dogs, there were no treatment-related effects on survival, body weight, hematology, clinical chemistry or gross pathology. Treatment-related changes were limited to arteritis and necrosis of the arterial walls of the epididymides in males and thymus, thyroid, larynx, and urinary bladder in females. It is postulated that chronic treatment exacerbated the spontaneous arteritis in genetically predisposed Beagle dogs (it is called the ''Beagle Pain Syndrome''). In developmental toxicity studies, there is no evidence of increased susceptibility following *in utero* exposures in rats and rabbits. In the 2-generation reproduction study, no adverse effects were observed on the offspring at dose levels that produced parental toxicity. EPA has concluded that spinetoram is toxicologically identical to another pesticide, spinosad. Based on the structural similarity of spinetoram and spinosad and the similarity of the toxicological database for the currently available studies, spinetoram is classified as ''not likely to be carcinogenic to humans'' based on lack of evidence for carcinogenicity of spinosad in mice and rats. No indication of neurotoxicity was observed in the acute neurotoxicity screening battery in rats, or in the subchronic and chronic toxicity studies conducted on spinetoram. All the mutagenicity studies conducted on spinetoram were negative. The no-observed-adverse-effect-level (NOAEL) derived from the chronic dog study is well characterized, and together with the traditional uncertainty/safety factors will provide adequate protection for effects observed in laboratory animals. Specific information on the studies received and the nature of the adverse effects caused by spinetoram as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document Human Health Risk Assessment for Application of spinosad to date and pomegranate and spinetoram to pineapple, date, pomegranate, hopes, and spices (crop subgroup 19B, except black pepper) on page 4 and attachment 3 pages 49–54 in docket ID number EPA–HQ–OPP–2008–0805.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the level of concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*. The Agency has concluded that spinosad should be considered toxicologically identical to another pesticide, spinetoram. This conclusion is based on the following: Spinetoram and spinosad are large molecules with nearly identical structures; and the toxicological profiles for each are similar (generalized systemic toxicity) with similar doses and endpoints chosen for human-health risk assessment.

Spinosad and spinetoram should be considered toxicologically identical in the same manner that metabolites are generally considered toxicologically identical to the parent. Although, as stated above, the doses and endpoints for spinosad and spinetoram are similar, they are not identical due to variations in dosing levels used in the spinetoram and spinosad toxicological studies. EPA compared the spinosad and spinetoram doses and endpoints for each exposure scenario and selected the lower of the two doses for use in human risk assessment.

A summary of the toxicological endpoints for spinetoram/spinosad used for human risk assessment can be found at *http://www.regulations.gov* in the document Human Health Risk Assessment for Application of spinosad to date and pomegranate and spinetoram to pineapple, date, pomegranate, hopes, and spices (crop subgroup 19B, except black pepper) on page 8 in docket ID number EPA–HQ–OPP–2008–0805.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to spinetoram/spinosad, EPA considered exposure under the petitioned-for tolerances as well as all existing spinetoram/spinosad tolerances in 40 CFR 180.635. EPA assessed dietary exposures from spinetoram/spinosad in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure.

No such effects were identified in the toxicological studies for spinetoram/spinosad; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. Spinosad is registered for application to all of the same crops as spinetoram, with similar pre-harvest and retreatment intervals, and application rates greater than or equal to spinetoram. Further, both products control the same pest species. For this reason, EPA has concluded it would overstate exposure to assume that residues of both spinosad and spinetoram would appear on the same food. Rather, EPA aggregated exposure by either assuming that all commodities contain spinosad residues (because side-

by-side spinetoram and spinosad residue data indicated that spinetoram residues were less than or equal to spinosad residues) or summing the percentage of a crop that would be treated with spinosad and the percentage that would be treated with spinetoram.

In conducting the chronic dietary exposure assessment EPA used the food consumption data from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, the chronic analysis assumed 100% crop treated for all food crop commodities; average field-trial residues for apple, Brassica leafy vegetables, citrus, fruiting vegetables, herbs, banana, and strawberry; tolerance-level residues for the remaining food crop commodities; DEEM™ (ver. 7.81) default processing factors for all commodities excluding orange juice, field corn (meal, starch, flour, and oil), grape juice, and wheat (flour and germ) where the spinosad processing factors were assumed. Residues in livestock were refined through the incorporation of a refined dietary burden (average feed-crop residues and percent crop treated estimates) and through the incorporation of average residues from the feeding and dermal magnitude of the residue studies.

iii. *Cancer*. Spinetoram is considered to be ''not likely to be a carcinogen to humans'' based on its similarity to another spynosin pesticide, spinosad. Preliminary results of a carcinogenicity study in mice indicate that spinetoram is not carcinogenic to mice at doses up to 37.5 milligram/kilogram/day (mg/kg/day). Consequently, a quantitative cancer exposure and risk assessment is not appropriate for spinetoram.

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such Data Call-Ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The EPA assumed 100% crop treated for all food crop commodities; however, in calculating beef and dairy cattle dietary burdens, the Agency used combined spinosad and spinetoram projected percent crop treated (PPCT) information as follows:

39% sweet corn forage.

50% leaves of root and tuber vegetables.

5% sorghum grain.

5% soybean seed meal.

EPA estimates an upper bound of PPCT for a new pesticide use by assuming that its actual PCT during the initial 5 years of use on a specific use site will not exceed the average PCT of the market leader (i.e., the one with the greatest PCT) on that site. EPA calls this the market leader PPCT estimate. In this specific case, the new use to be estimated is the combined use of spinosad together with that of spinetoram since most new use of spinetoram will likely replace previous use of spinosad. An average market leader PCT, based on three recent surveys of pesticide usage, if available, is used for chronic risk assessment. The average market leader PCT may be based on one or two survey years if three are not available. Also, with limited availability of data, the average market leader PCT may be based on a cross-section of state PCTs. Comparisons are only made among pesticides of the same pesticide type (i.e., the leading insecticide on the use site is selected for comparison with the new insecticide), or, for refined estimates, among pesticides targeting the same pests. The market leader PCTs used to determine the average may consist of PCTs for the same pesticide or for different pesticides for any year since the same or different pesticides may dominate for each year. Typically, EPA uses USDA/National Agricultural Statistics Service (USDA/NASS) as the source for raw PCT data because it is publicly available. When a specific use site is not surveyed by USDA/NASS, EPA uses other sources including proprietary data.

An estimated PPCT, based on the average PCT of the market leaders, is appropriate for use in chronic dietary risk assessment. This method of estimating PPCT for a new use of a registered pesticide or a new pesticide produces high-end estimate that is unlikely, in most cases, to be exceeded during the initial 5 years of actual use. Predominant factors that bear on whether the PPCT could be exceeded may include PCTs of similar chemistries, pests controlled by alternatives, pest prevalence in the market and other factors. All relevant information currently available for predominant factors has been considered for the combined use of spinetoram and spinosad on each of these several crops. Of greatest relevance here is that both spinosad and spinetoram control a relatively narrow range of pests compared to the market leaders. Based on this analysis, EPA believes that it is unlikely that actual combined PCTs for spinetoram and spinosad will exceed the corresponding estimated PPCTs during the next 5 years.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which spinetoram may be applied in a particular area.

2. *Dietary exposure from drinking water.*The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for spinetoram/spinosad in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of spinetoram/spinosad. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of spinetoram for acute exposures are estimated to be 14.419 parts per billion (ppb) for surface water and 0.072 ppb for ground water. For chronic exposures for non-cancer assessments are estimated to be 6.171 ppb for surface water and 0.072 ppb for ground water. EDWCs for spinosad for acute exposures are estimated to be 34.5 ppb for surface water and 1.1 ppb for ground water. For chronic exposures for non-cancer assessments are estimated to be 10.5 ppb for surface water and 1.1 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 10.5 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

The Agency has concluded that spinosad and spinetoram are toxicologically equivalent; therefore, residential exposure to both spinosad and spinetoram was evaluated. Spinosad is currently registered for homeowner application to turf grass and ornamentals. Spinetoram is registered for homeowner applications to gardens, lawns/ornamentals and turf grass. No dermal endpoints for either spinetoram or spinosad were identified. Therefore, only short-term incidental oral exposures to toddlers were evaluated for the registered turf and ornamental application scenarios for spinosad and spinetoram and short-term inhalation exposure to handler/applicators for the registered home garden, turf, and ornamental application scenarios.

There is potential for residential handler and post-application exposures to both spinosad and spinetoram. Since spinosad and spinetoram control the same pests, EPA concludes that these products will not be used for the same uses in combination with each other and thus combining spinosad and spinetoram residential exposures would overstate exposure. Short-term residential inhalation risks were estimated for adult residential handlers, as well as short-term post-application incidental oral risks for toddlers, based on applications to home lawns, home gardens and ornamentals.

EPA notes that for spinosad the registered fruit fly bait application scenario permits application to non-crop vegetation and this use may result in residential exposures. Based on the application rates (fruit fly bait - 0.0003 lb ai/acre; turf/ornamental - 0.41 lbs ai/acre), EPA concludes that residential exposure resulting from the fruit fly application will be insignificant when compared to the exposure resulting from homeowner uses on the turf/ornamentals. Therefore, quantitative analysis of the residential exposure resulting from the fruit fly bait application was not performed.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA 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 has not found spinetoram/spinosad to share a common mechanism of toxicity with any other substances, and spinetoram/spinosad does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that spinetoram/spinosad does not have a common mechanism of toxicity with other substances. For 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 EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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 database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There is no evidence of increased susceptibility of rat and rabbit fetuses to *in-utero* exposure to spinosad or spinetoram. In the spinosad and spinetoram rat and rabbit developmental toxicity studies, no developmental toxicity was observed at dose levels that did not induce maternal toxicity. In the spinosad 2-generation reproduction studies, maternal and offspring toxicity were equally severe, indicating no evidence of increased susceptibility. In the spinetoram 2-generation reproduction study, no adverse effects were observed on the offspring at dose levels that produced parental toxicity. Therefore, there is no evidence of increased susceptibility and there are no concerns or residual uncertainties for pre-natal and/or post-natal toxicity.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for spinetoram is complete, except for immunotoxicity testing. Recent changes to 40 CFR part 158 make immunotoxicity testing (OPPTS Harmonized Guideline 870.7800) required for pesticide registration; however, the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios, and for evaluation of the requirements under the FQPA.

There was some evidence of adverse effects on the organs of the immune system at the LOAEL in three short-term studies with spinosad or spinetoram. In these studies, anemia was observed in multiple species (rats, mice and dogs) with the presence of histiocytic aggregates of macrophages in various organs and tissues (lymph nodes, spleen, thymus, and bone marrow). Aggregation of macrophages was indicative of immune stimulation in response to insults of the chemical exposure and was considered secondary effects of the toxic effect to the hematopoetic system. Therefore, these effects are not considered to be indicative of frank immunotoxicity. In the chronic study with dogs, areteritis and necrosis of the areterial walls of the

thymus was seen in one female dog at the HDT. This finding is attributed to the exacerbation of the spontaneous arteritis present in genetically predisposed Beagle dogs (''Beagle Pain Syndrome''), not immunotoxicity. Further, a clear NOAEL was attained in each of these studies, and the observed histopathologies were generally observed in the presence of other organ toxicity. In addition, spinosad and spinetoram do not belong to a class of chemicals (e.g., the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be immunotoxic.

Based on the above considerations, EPA does not believe that conducting a special series 870.7800 immunotoxicity study will result in a POD less than the NOAEL of 2.49 mg/kg/day already set for spinosad and spinetoram. Consequently, an additional database uncertainty factor does not need to be applied.

ii. There is no indication that spinetoram/spinosad is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that spinetoram/spinosad results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments utilized 100 PCT and tolerance-level residues, and DEEM™ default processing factors for all registered and proposed commodities and refined livestock estimates. These refinements are based on reliable data. The EPA used PPCT information when calculating livestock dietary burdens for sweet corn forage, leaves of root and tuber vegetables, sorghum grain, and soybean seed meal. EPA believes that the PPCT estimates used are conservative estimates. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to spinetoram/spinosad in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by spinetoram/spinosad.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. No adverse effect resulting from a single-oral exposure was identified and no acute dietary endpoint was selected. Therefore, spinetoram/spinosad is not expected to pose an acute risk.

2. *Chronic risk.* Since there are no registered/proposed uses which result in chronic residential exposures, the chronic aggregate exposure assessment consists of exposure from food and water. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to spinetoram/spinosad from food and water will utilize 95% of the cPAD for children 1–2 years old the population group receiving the greatest exposure.

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

Spinetoram/spinosad is currently registered for uses that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to spinetoram/spinosad.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures aggregated result in aggregate MOEs of ≥160. Short-term aggregate risk does not exceed the LOC for EPA (MOE of <100).

4. *Intermediate-term risk.* Spinetoram/spinosad is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to spinetoram/spinosad through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population.* The Agency considers spinetoram to be ''Not Likely to be Carcinogenic to Humans.'' See Unit III.C.iii. for more detailed information.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

FDA Multiresidue Methods (MRMs): XDE-175-J, XDE-175-L, ND-J, NF-J, ND-L, and NF-L were screened through the Food and Drug Administration Pesticide Analytical Methods Volume I (PAM I) MRMs. None of the test substances were found to be fluorescent using procedures outlined in Protocol A. All test substances were subjected to Protocol C, modules DG1, DG5, DG13, DG17, and DG18. Test substances were determined to be non-chromatographable by the chosen gas chromatography modules described in Protocol C. Due to the poor sensitivity of the test substances to detection by methods described in Protocol C, no further analyses were performed by Protocols D, E, or F. Since the test substances are not acids, phenols, or substituted ureas, analyses were not performed using Protocols B or G. The test substances were not detectable through FDA PAM I Protocols A and C; therefore, these methods are unsuitable for enforcement. The MRM results were forwarded to the FDA.

Adequate enforcement methodology. Plants: Method GRM 05.03 (HPLC/MS/MS). Livestock: Method GRM 05.15 HPLC/mass spectrometry (MS) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are currently no established Codex, Canadian, or Mexican MRLs for residues of spinetoram on the requested crops.

C. Revisions to Petitioned-For Tolerances

The tolerance expression for spinetoram includes residues of XDE-

175-J, XDE-175-L, ND-J, and NF-J. EPA is establishing tolerances for the following commodities at levels higher than proposed: nut, tree, group 14 and pistachio raised to 0.10 ppm; almond, hulls raised to 19 ppm; pineapple to 0.04 ppm; and pineapple, processed residue 0.15 ppm. These changes are based on the residue field trial data and the North American Free Trade Agreement (NAFTA) MRL Spreadsheet.

V. Conclusion

Therefore, tolerances are established for combined residues of spinetoram, expressed as a combination of:

XDE-175-J: 1-H-as-indaceno[3,2-d] oxacyclododecin-7,15-dione,2 2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl-a-L-mannopyranosyl)oxy]-13-[[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,4,5, 5a,5b,6,9,10,11,12,13,14,16a,16b-hexadecahydro14-methyl-, (2R,3aR,5aR,5bS,9S,13S, 14R,16aS,16bR);

XDE-175-L: 1H-as-indaceno[3,2-d]oxacyclododecin-7,15-dione, 2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl-a-L-mannopyranosyl)oxy]-13-[[(2R,5S,6R)-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-, (2S,3aR,5aS,5bS,9S,13S,14R,16aS,16bS);

ND-J:(2R,3aR,5aR,5bS,9S,13S,14R, 16aS,16bR)-9-ethyl-14-methyl-13-[[(2S,5S,6R)-6-methyl-5-(methylamino)tetrahydro-2H-pyran-2-yl]oxy]-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7,9,10,11, 12,13,14,15,16a,16b-octadecahydro-1H-as-indaceno[3,2-d]oxacyclododecin-2-yl 6-deoxy-3-O-ethyl-2,4-di-O-methyl-alpha-L-mannopyranoside; and

NF-J: (2R,3S,6S)-6-([(2R,3aR,5aR,5bS,9S,13S, 14R,16aS,16bR)-2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl-alpha-L-mannopyranosyl)o oxy]-9-ethyl-14-methyl-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7, 9,10,11,12,13,14,15,16a,16b-octadecahydro-1H-as-indaceno[3,2-d]oxacyclododecin-13-yl]oxy)-2-methyltetrahydro-2H-pyran-3-yl(methyl)formamide

in or on the following commodities is increased to almond, hulls at 19 ppm; nut, tree, group 14 at 0.10 ppm; pistachio at 0.10 ppm; date at 0.10 ppm; pomegranate at 0.30 ppm; pineapple 0.04 ppm; pineapple, processed residue at 0.15 ppm; spice, subgroup 19B, except black pepper at 1.7 ppm; and hop, dried cones at 22 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

This 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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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 this final rule in the **Federal Register**. This final 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: July 31, 2009.

Lois Rossi,

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), 346a and 371.

■ 2. Section 180.635 is amended by revising the entries in the table in paragraph (a) for almond, hulls; nut, tree, group 14; and pistachio and alphabetically adding entries for date; hop, dried cones; pineapple; pineapple, processed residue; pomegranate; and spice, subgroup 19b, except black pepper, to read as follows:

§ 180.635 Spinetoram; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Almond, hulls	19
* * * * *	
Date	0.10
* * * * *	
Hop, dried cones	22

Commodity	Parts per million
* * * * *	
Nut, tree, group 14	0.10
* * * * *	
Pineapple	0.04
Pineapple, processed residue	0.15
Pistachio	0.10
Pomegranate	0.30
* * * * *	
Spice, subgroup 19B, except black pepper	1.7
* * * * *	

* * * * *

[FR Doc. E9–19195 Filed 8–12–09; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. NHTSA–2009–0145]

RIN 2127–AK04

Federal Motor Vehicle Safety Standards; Controls, Telltales and Indicators

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: In an August 2005 final rule, we updated our standard regulating motor vehicle controls, telltales and indicators. The standard specifies requirements for the location, identification, and illumination of these items. In May 2006, we published a response to four petitions for reconsideration, including one asking us to reconsider a requirement for color contrast between identifiers and their backgrounds. We denied this petition for reconsideration.

In response to another petition for reconsideration from the Alliance of Automobile Manufacturers (the Alliance) of the color contrast requirement, specifically for the horn control identifier, in this final rule, we amend the standard to provide that an identifier is not required if the horn control is placed in the middle of the steering wheel. If the horn control is placed elsewhere in the motor vehicle, the control would be required to be identified by the specified horn symbol in a color that stands out clearly against the background.

DATES: *Effective Date:* The effective date for this final rule is February 9, 2010. The compliance date for vehicles under 10,000 pounds GVWR for S5.4.3 continues to be September 1, 2011.

Compliance date for the extension of the standard's control, indicator, and telltale requirements to vehicles at 10,000 pounds GVWR or greater over continues to be September 1, 2013.

Optional early compliance is permitted as of the date today's final rule is published.

Petitions for reconsideration: Petitions for reconsideration of today's final rule must be received not later than September 28, 2009.

ADDRESSES: Petitions for reconsideration of the final rule must refer to the docket number set forth above and be submitted to the Administrator, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: For non-legal issues you may call Ms. Gayle Dalrymple, Office of Crash Avoidance Standards at (202) 366–5559. Her FAX number is (202) 366–7002. For legal issues, you may call Ms. Dorothy Nakama, Office of the Chief Counsel at (202) 366–2992. Her FAX number is (202) 366–3820. You may send mail to both of these officials at National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

I. Background

NHTSA issued Federal Motor Vehicle Safety Standard (FMVSS) No. 101, *Controls and Displays,* in 1967 (32 FR 2408) as one of the initial FMVSSs. The standard applies to passenger cars, multipurpose passenger vehicles (MPVs), trucks, and buses. The purpose of FMVSS No. 101 is to assure the accessibility and visibility of motor vehicle controls and displays under daylight and nighttime conditions, in order to reduce the safety hazards caused by the diversion of the driver's attention from the driving task, and by mistakes in selecting controls.

At present, FMVSS No. 101 specifies requirements for the location (S5.1), identification (S5.2), and illumination (S5.3) of various controls and displays. It specifies that those controls and displays must be accessible and visible to a driver properly seated wearing his or her safety belt. Table 1, ''Controls, Telltales and Indicators with Illumination or Color Requirements,'' and Table 2, ''Identifiers for Controls, Telltales and Indicators with No Color or Illumination Requirements,'' indicate which controls and displays are subject to the identification requirements, and how they are to be identified, colored, and illuminated. For the horn control, Table 2 specifies the horn symbol in Column 2, and the word ''Horn'' in Column 3.

II. 2005 and 2006 Final Rules

In a final rule published in the **Federal Register** (70 FR 48295) on August 17, 2005, NHTSA amended FMVSS No. 101 by extending the standard's telltale and indicator requirements to vehicles of Gross Vehicle Weight Rating (GVWR) 4,536 kilograms (10,000 pounds) and over, updating the standard's requirements for multi-function controls and multi-task displays to make the requirements appropriate for advanced systems, and reorganizing the standard to make it easier to read. Table 1 and Table 2 continue to include only those symbols and words previously specified in the controls and displays standard or in another applicable FMVSS.

The final rule specified an effective date of February 13, 2006 for requirements applicable to passenger cars, multipurpose passenger vehicles, trucks and buses under 4,536 kg GVWR (10,000 pounds).[1]

NHTSA received petitions for reconsideration of the August 17, 2005 final rule, including one from the Alliance. In the August 17, 2005 final rule, the requirement that the identifier for each telltale must be in a color that stands out clearly against the background was extended to identifiers for controls and indicators (see S5.4.3). The Alliance asked for reconsideration of this requirement, stating that not all identifiers are in a color that stands out clearly against the background. The Alliance further stated that it is not needed, citing as an example the horn identifier.

Most vehicle models use the horn symbol as the identifier, which is molded into the air bag cover, without a color ''that stands out clearly against the background'' filled in. The Alliance commented that: ''The symbol is the same color as the background, but it can still be recognized because the embossment stands out against the background.'' The Alliance petitioned for the regulatory text at S5.4.3 to be changed to: ''The identification required by Table 1 or Table 2 for a telltale, control or indicator shall contrast with the background.''

In the May 15, 2006 final rule, response to petitions for reconsideration (71 FR 27964), we noted that over the years, the agency had received numerous complaints regarding the

[1] The effective date was subsequently extended to September 1, 2006 (71 FR 3786, January 24, 2006).