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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-0783; FRL-9332-9]

Spirotetramat; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of spirotetramat in or on onion, dry bulb under section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(l)(6). This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on dry bulb onions. This regulation establishes a maximum permissible level for residues of spirotetramat in or on these commodities. The time-limited tolerances expire on December 31, 2014.

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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-2011-0783. All documents in the docket are listed in the docket index available in *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: Libby Pemberton**,** Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9364; e-mail address: *pemberton.libby@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:

- 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 provides 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 Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, 21 U.S.C. 346a(g), 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-2011-0783 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-0783, 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. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of FFDCA, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing time-limited tolerances for combined residues of spirotetramat, including its metabolites and degradates, in or on onion, dry bulb at 0.3 parts per million (ppm). This time-limited tolerance expires on December 31, 2014.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of section 408 of FFDCA and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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. . . ."

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that "emergency conditions exist which

require such exemption." EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemptions for Spirotetramat on Dry Bulb Onions and FFDCA Tolerances

Thrips rasp the onion tissue and drain the exuding sap, causing stunted and deformed plants. High thrip populations during bulbing can reduce yield. In addition, high thrip populations and the associated damage can shift the onion bulb size distribution downward and reduce onion quality. Of even more concern, thrips can infect plants with iris yellow spot virus. The virus in conjunction with thrips feeding activity can result in an average 25-35% decrease in yield with yield losses observed as high as 53% in some fields. Onion thrips thrive under hot, dry conditions, and can increase and spread very quickly. In addition to their ability to rapidly increase in population, thrips also migrate into onion fields from adjacent crops. For example, as nearby cereal crops dry down in the early summer and alfalfa fields are harvested, large populations of thrips can migrate to onions. There are a number of products registered for thrips control on onions. Many were never effective or have become ineffective due to development of resistance. Due to the label restrictions on the available effective insecticides, it is currently infeasible for producers to control thrips for the entire production season with the available insecticides in most areas of onion production.

After having reviewed the submissions, EPA determined that an emergency condition exists for eleven states (Colorado, Idaho, Michigan, Minnesota, Nevada, New York, Oregon, Texas, Utah, Washington, and Wisconsin), and that the criteria for approval of emergency exemptions are met. EPA has authorized specific exemptions

under FIFRA section 18 for the use of spirotetramat on dry bulb onion for control of onion thrips (*Thrips tabaci*) in the 11 states listed in this unit.

As part of its evaluation of the emergency exemption applications, EPA assessed the potential risks presented by residues of spirotetramat in or on onion, dry bulb. In doing so, EPA considered the safety standard in section 408(b)(2) of FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of FFDCA. Although this time-limited tolerance expires on December 31, 2014, under section 408(l)(5) of FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on onion, dry bulb after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this time-limited tolerance at the time of that application. EPA will take action to revoke this time-limited tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this time-limited tolerance is being approved under emergency conditions, EPA has not made any decisions about whether spirotetramat meets FIFRA's registration requirements for domestic use on dry bulb onions or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of

spirotetramat by a State for special local needs under FIFRA section 24(c). Nor does this tolerance by itself serve as the authority for persons in any State other than the 11 states listed in this unit to use this pesticide on the applicable crops under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for spirotetramat, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with the factors specified in FFDCA section 408(b)(2)(D)**,** EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure expected as a result of this emergency exemption request and the time-limited tolerances for combined residues of spirotetramat and its metabolites and degradates on onion, dry bulb at 0.3 ppm. EPA's assessment of exposures and risks associated with establishing time-limited tolerances follows.

A. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are

identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). 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 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*.

A summary of the toxicological endpoints for spirotetramat used for human risk assessment is discussed in Unit III. of the final rules published in the **Federal Register** of July 9, 2008 (73 FR 39251) (FRL-8367-1) and May 18, 2011 (76 FR 28675) (FRL-8865-8). The final rule of July 9, 2008 established a number of tolerances for residues of spirotetramat, including onion, bulb, subgroup 3A-07. Subsequently, in the final rule published in the **Federal Register** of May 18, 2011, EPA added a footnote to the established tolerance for onion, bulb, subgroup 3A-07 to indicate that currently there are no U.S. registrations for onions. Use on onions at that time was assessed for import tolerances only.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to spirotetramat, EPA considered exposure under the time-limited tolerances established by this action as well as all existing spirotetramat tolerances in 40 CFR 180.641. EPA assessed dietary exposures from spirotetramat 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. Such effects were identified for spirotetramat. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance-level residues for all foods. Empirical and Dietary Exposure Evaluation Model (DEEM^{TM}) (ver. 7.81) default processing factors were used for processed commodities. Residues in drinking water were addressed by incorporating directly in the dietary assessment the acute concentrations of spirotetramat residues in surface water estimated by the First Index Reservoir Screening Tool (FIRST) model.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 CSFII. As to residue levels in food, EPA conducted a conservative chronic dietary assessment assuming tolerance-level residues, empirical and DEEM^{TM} (ver. 7.81) default processing factors, and 100 PCT. Drinking water was incorporated directly in the dietary assessment using the chronic concentrations for surface water.

iii. *Cancer.* Based on the data summarized in Unit IV.A., EPA has concluded that spirotetramat does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for spirotetramat. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for spirotetramat in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of spirotetramat. 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 and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of spirotetramat for acute exposures are estimated to be 0.212 parts per billion (ppb) for surface water; and 3.96 x 10^{-4} ppb for ground water.

For chronic exposures for non-cancer assessments, the EDWCs are estimated to be 1.37 $\times 10^{-3}$ ppb for surface water and 3.96 $\times$ 10^{-4} ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For acute dietary risk assessment, the most conservative water concentration value of 0.212 ppb was used to assess the contribution to drinking water based on the use of spirotetramat on pome fruit (0.4 lb ai/A/year).

For chronic dietary risk assessment, the most conservative water concentration of value 1.37 x 10^{-3} ppb was used to assess the contribution to drinking water, based on the use of spirotetramat on Christmas trees (0.32 lb ai/A/year).

3. *Sources of 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). Spirotetramat is not registered for any specific use patterns that would result in residential exposure.

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 spirotetramat to share a common mechanism of toxicity with any other substances, and spirotetramat does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that spirotetramat 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*.

C. 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 SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There was no evidence of increased susceptibility of rat or rabbit to prenatal or postnatal exposure to spirotetramat. In the rat developmental toxicity study, toxicity to offspring was observed at the same dose as maternal toxicity, which was also the limit dose. In the developmental toxicity study in the rabbit, only maternal toxicity was observed. In both reproductive toxicity studies, toxicity to offspring (decreased body weight) was observed at the same dose as parental toxicity. Therefore, no evidence of increased susceptibility of offspring was found across four relevant toxicity studies with spirotetramat.

3. *Conclusion*. EPA has determined that reliable data show that the safety of infants and children are adequately protected at the FQPA SF of 1X. That decision is based on the following findings:

i. The toxicity database for spirotetramat is complete except for an immunotoxicity study and a subchronic neurotoxicity study which are considered to be outstanding due to recent amendments to the data requirements in 40 CFR part 158. Despite the absence of these studies, other related studies indicate that the immunotoxicity study and subchronic neurotoxicity study are unlikely to show risks to infants and children that would warrant an additional safety factor. The only indication of possible immunotoxicity in the toxicology database for spirotetramat is a 90-day oral toxicity study in dogs that shows effects in the thymus gland, an organ of the immune system. However, the endpoint selected for risk assessment is protective against these

thyroid effects, as it was based on accelerated thymus involution and decreased thyroid hormone levels in the dog. Moreover, thymus involution has been demonstrated to occur in animals when the thyroid is induced to decrease hormone levels, so it is reasonable to conclude that the thymus involution in these dogs was secondary to the thyroid effects, rather than a direct effect on the immune system. The dose at which these effects were observed was chosen as a point of departure because there was some consistency of dose and effect seen across the subchronic and chronic toxicity studies. However, the effects occurred in relatively few animals and thus selection of this endpoint is considered a very protective point of departure; it is at least tenfold lower than any other potential point of departure. With respect to immunotoxicity, no immunotoxic effects were seen in rats or mice, the species in which immunotoxicity studies are conducted. Thus, the Agency does not believe that conducting a functional immunotoxicity study in any rodent species will result in a lower POD than that currently used for overall risk assessment. For this reason and because the current POD is considered extremely protective, an uncertainty factor (UF_{DB}) is not needed to account for the lack of this study. Data regarding neurotoxicity is discussed in Unit III.C.3.ii.

ii. EPA has concluded that spirotetramat is not a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity. Although a subchronic neurotoxicity study is now required as part of the revisions to 40 CFR part 158, the existing toxicological database indicates that spirotetramat is not a neurotoxic chemical in mammals. The only clinical signs at any dose in the acute neurotoxicity study were staining of the fur or perianal region with urine and decreased motor activity. The urine staining that was identified is not considered a

neurotoxic effect and was likely due to a colored metabolite that was excreted into the urine or feces or to a change in the pH of the urine due to an excreted metabolite. The decreased motor activity observed is not considered evidence of neurotoxicity because there were no effects on movement or gait and there were no confirmatory findings of neurological pathology. Thus, both of these effects are considered signs of general toxicity (malaise). Further, the effects seen in the acute neurotoxicity study are not corroborated by any other study in the database. Although brain dilation was found in one dog in the one-year dog study, EPA concluded that this effect was most likely not caused by administration of spirotetramat given evidence showing this to be a congenital anomaly in the test species, and because there is no other evidence of brain pathology in the database. Finally, the conclusion that spirotetramat is not a neurotoxic chemical is supported by the fact that the acute, subchronic and developmental neurotoxcity studies available for structurally-related compounds (spirodiclofen and spiromesifen) do not show evidence of neurotoxicity in adults or young.

iii. There is no evidence that spirotetramat 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. There was no evidence of increased susceptibility of offspring following pre- or post-natal exposure in any study. In the rat developmental toxicity study, toxicity to offspring was observed at the same dose as maternal toxicity, which was also the limit dose. In the developmental toxicity study in the rabbit, only maternal toxicity was observed. In both reproductive toxicity studies, toxicity to offspring (decreased body weight) was observed at the same dose as parental toxicity. Therefore,

no evidence of increased susceptibility of offspring was found across four relevant toxicity studies with spirotetramat.

iv. There are no residual uncertainties identified in the exposure databases. The dataset used to establish a tolerance for spirotetramat and its metabolites on onion, bulb, subgroup 3A-07 consisted of field trial data representing application rates of ~0.26 a.i./A (Northern EU, 100 OD formulation) with a 7-day PHI. As specified by the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* SOP, the field trial application rates and PHIs are within 25% of the maximum label application rate and minimum label PHI, respectively. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to spirotetramat in drinking water. These assessments will not underestimate the exposure and risks posed by spirotetramat.

D. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer 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 appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to spirotetramat will occupy

11% of the aPAD for children 1-2 yrs old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to spirotetramat from food and water will utilize 93% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. There are no residential uses for spirotetramat.

3. *Short-term risk*. Spirotetramat is not registered for any use patterns that would result in short-term residential exposure.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Spirotetramat 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 spirotetramat 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*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, spirotetramat is not expected to pose a cancer risk to humans.

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 spirotetramat residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography with tandem mass spectrometry (HPLC–MS/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

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The U.S. provided the primary review of the available toxicology studies, and Canada provided the primary review of the residue chemistry data. All of the residues of concern for tolerances and MRLs have been harmonized among Austria, Canada and the U.S. All toxicology endpoints have been harmonized, with the exception of the acute reference dose (aRfd), which has been harmonized with Canada. The Codex has not established MRLs for spirotetramat on onion, dry bulb. This

time-limited tolerance is harmonized with the Canadian MRL for spirotetramat on onion, dry bulb.

VI. Conclusion

Therefore, time-limited tolerances are established for combined residues of spirotetramat, including its metabolites and degradates in or on onion, dry bulb at 0.3 ppm. These tolerances expire on December 31, 2014.

VII. Statutory and Executive Order Reviews

This final rule establishes tolerances under sections 408(e) and 408(l)(6) of FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). 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 in accordance with sections 408(e) and 408(l)(6) of FFDCA, such as the tolerances 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).

VIII. 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: February 1, 2012.

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 180.641 is amended by revising paragraph (b) to read as follows:

§ 180.641 Spirotetramat; tolerances for residues.

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(b) *Section 18 emergency exemptions*. Time-limited tolerances specified in the following table are established for residues of the spirotetramat, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only the sum of spirotetramat (cis-3-(2,5-dimethlyphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl-ethyl carbonate) and its metabolites cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, cis-3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione, cis-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl beta-D-glucopyranoside, and cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one, calculated as the stoichiometric equivalent of spirotetramat, in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. The tolerances expire on the date specified in the table.

Commodity	Parts per million	Expiration date
Onion, dry bulb	0.3	December 31, 2014

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