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. In § 180.589:

■ a. In the table to paragraph (a):

■ i. Add in alphanumeric order entries for ''*Brassica,* leafy greens, subgroup 4–16B, except watercress''; ''Celtuce''; ''Fennel, Florence''; ''Kohlrabi''; ''Leaf petiole vegetable subgroup 22B''; ''Leafy greens subgroup 4–16A''; ''Pea and bean, dried shelled, except soybean, subgroup 6C''; ''Pea and bean, succulent shelled, subgroup 6B''; ''Vegetable, *Brassica,* head and stem, group 5–16''; ''Vegetable, cucurbit, group 9''; and ''Vegetable, root, except sugar beet, subgroup 1B''; and

■ ii. Remove the entries ''*Brassica,* head and stem, subgroup 5A''; ''*Brassica,* leafy greens, subgroup 5B''; ''Cucumber''; ''Leaf petioles, subgroup 4B''; ''Leafy greens, subgroup 4A, except head lettuce and leaf lettuce''; ''Lettuce, head''; ''Lettuce, leaf''; ''Pea and bean, dried shelled, except soybean, subgroup 6C, except cowpea, field pea, and grain lupin''; ''Pea and bean, succulent shelled, subgroup 6B, except cowpea''; ''Turnip, greens''; ''Vegetable, cucurbit, group 9, except cucumber''; ''Vegetable, root, subgroup 1A, except sugar beet, garden beet, radish, and turnip''.

■ b. Remove from the table in paragraph (d) the entries ''Beet, garden, roots''; ''Cowpea, seed''; ''Lupin, grain, grain''; ''Pea field, seed''; ''Radish, roots''; and ''Turnip, roots''.

The additions read as follows:

§ 180.589 Boscalid; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Brassica, leafy greens, subgroup 4–16B, except watercress	60
* * * * *	
Celtuce	45
* * * * *	
Fennel, Florence	45
* * * * *	
Kohlrabi	6.0
Leaf petiole vegetable subgroup 22B	45
Leafy greens subgroup 4–16A	70
* * * * *	
Pea and bean, dried shelled, except soybean, subgroup 6C	2.5
Pea and bean, succulent shelled, subgroup 6B	0.60
* * * * *	
Vegetable, *Brassica,* head and stem, group 5–16	6.0
* * * * *	
Vegetable, cucurbit, group 9	3.0
* * * * *	
Vegetable, root, except sugar beet, subgroup 1B	2.0
* * * * *	

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0098; FRL–9984–70]

Tetrahydrofurfuryl Alcohol; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the exemption from the requirement of a tolerance for residues of tetrahydrofurfuryl alcohol (THFA) (CAS Reg. No. 97–99–4) when used as an inert ingredient in pesticide formulations to add one herbicide application prior to the preboot stage on buckwheat, oats, rye, sorghum, triticale, rice and wild rice; extend use on canola to the early bolting stage; extend use on soybeans prior to the bloom growth stage; and allow use in herbicides with two applications to field corn and popcorn prior to 36 inches tall (V8 stage). Toxcel, LLC, on behalf of Penn A Kem, LLC, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an amendment to an existing exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of tetrahydrofurfuryl alcohol.

DATES: This regulation is effective October 19, 2018. Objections and requests for hearings must be received on or before December 18, 2018, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2013–0098, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

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://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 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–2013–0098 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 December 18, 2018. 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 (excluding any Confidential Business Information (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 the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2013–0098, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Petition for Exemption

In the **Federal Register** of February 27, 2013 (78 FR 13295) (FRL–9380–2), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 2E8080) by Toxcel, LLC, 7140 Heritage Village Plaza, Gainsville, VA 20156 on behalf of Penn A Kem, LLC, 3324 Chelsea Avenue, Memphis, TN 38108. The petition requested amendment of the exemption from the requirement of a tolerance in 40 CFR 180.1263 for residues of tetrahydrofurfuryl alcohol (THFA) (CAS Reg. No. 97–99–4) when used as an inert ingredient (solvent/cosolvent) to include allowance of one herbicide application prior to the preboot stage to all small cereal grains; extended use on canola to the early bolting stage; and extended use on soybeans up to the bloom growth stage. That document referenced a summary of the petition prepared by Toxcel, LLC, on behalf of Penn A Kem, LLC, the petitioner, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Toxcel, LLC, on behalf of Penn A Kem, LLC, submitted a revised pesticide petition to supersede the previously submitted petition. EPA issued a document in the **Federal Register** of April 6, 2015 (80 FR 18327) (FRL–9924–00), pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of this revised petition. The revised petition requested that 40 CFR 180.1263 be amended to allow one herbicide application prior to the preboot stage for wheat, buckwheat, barley, oats, rye, sorghum, triticale, rice, and wild rice; extend the use on canola to the early bolting stage; extend the use on soybeans up to the bloom growth stage; and allow two herbicide applications to field corn and popcorn up to 36 inches tall (V8 stage). That document referenced a summary of the petition prepared by Toxcel, LLC, on behalf of Penn A Kem, LLC, the petitioner, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(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. In making this safety finding, EPA is required to take into account the considerations set forth in section 408(b)(2)(C) and (D). 21 U.S.C. 346a(c)(2)(B). 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. . . .''

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), 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 tetrahydrofurfuryl alcohol including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with tetrahydrofurfuryl alcohol follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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. Specific information on the studies received and the nature of the adverse effects caused by tetrahydrofurfuryl alcohol as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document ''Hazard Assessment for the Tolerance Reassessment of Tetrahydrofurfuryl alcohol (THFA)(CAS Reg. No. 97–99–4)'' at pp 8–12 in docket ID number EPA–HQ–OPP–2013–0098. A summary of the toxicity of tetrahydrofurfuryl alcohol as given in that document follows.

Acute toxicity information is available for the oral route with an LD_{50} for the rat of 1.6–3.2 g/kg. Tetrahydrofurfuryl alcohol was not irritating to the skin of mice but was irritating to the eyes of rabbits. Acute dermal and inhalation toxicity, as well as dermal sensitization information, currently are not available. However, there are reports that suggest tetrahydrofurfuryl alcohol may be moderately irritating via the dermal and inhalation routes of exposure to humans.

Although data on chronic effects is unavailable, subchronic studies indicate that systemic effects from repeated dermal and oral exposure to tetrahydrofurfuryl alcohol include decreased body weight and body weight gain. Tetrahydrofurfuryl alcohol also exhibits adverse reproductive and developmental effects, and potential effects on the endocrine system.

Males are not only quantitatively more sensitive to the subchronic effects of tetrahydrofurfuryl alcohol than females, but the male reproductive system appears to be a target for tetrahydrofurfuryl alcohol. Consistent decreases in male reproductive organ weights (testicular, epididymal, and seminal vesicle) were observed in rats in the 90-day dietary (LOAEL 339 mg/kg/day), dermal (LOAEL 300 mg/kg/day), and inhalation (LOAEL <0.21 mg/L/day) toxicity studies. In addition, a 90-day oral (dietary) study in dogs revealed decreased testes weights of males in all treated groups (1,000, 3,000, 6,000 ppm, equivalent to approximately 25, 75, and 150 mg/kg/day), compared to controls, with severe testicular atrophy in all males at the highest dose (6,000 ppm or 150 mg/kg/day). Decreased spermatogenic activity was noted in males of the 3,000 ppm group (75 mg/kg/day) and was interpreted as a prodromal sign of atrophy.

A 28-day repeated oral (gavage) study in rats revealed significant decreases in absolute testes and epididymal weights after 28 days at a dose level of 600 mg/kg/day which continued through the 14-day recovery period. Necrosis of the seminiferous tubular epithelium of the testes was also observed in males of the 150 and 600 mg/kg/day group at 28 days. Necrosis of the testes was also observed in males of the 600 mg/kg/day group at the end of the 14-day recovery period.

In the reproduction/developmental toxicity screening test in rats, no reproductive parameters were affected except slightly increased gestation length at the high dose of 150 mg/kg/day.

The endocrine system may also be a target for tetrahydrofurfuryl alcohol. Alterations in pituitary, thymus, adrenal, and thyroid weights have been reported after subchronic exposure (28 days) to 600 mg/kg/day in male rats and pituitary weights at 150 mg/kg/day in female rats. Decreased absolute and relative adrenal weights were observed in males and females receiving 5,000 ppm (equivalent to 339 mg/kg/day males and 401 mg/kg/day females).

In one developmental toxicity study in rats a quantitative susceptibility based on decreased fetal body weights and a qualitative susceptibility based on increased incidence of filamentous tail was observed. However, in a more recent reproduction/developmental toxicity screening test (OECD 421 guideline study) in rats, an increased incidence of filamentous tail was not evident nor was there any other evidence of increased qualitative susceptibility. Based on the overall weight of evidence for developmental toxicity, it is determined that there is increased quantitative susceptibility but not increased qualitative susceptibility.

A neurotoxicity study is not available for tetrahydrofurfuryl alcohol, however no neurotoxic effects were observed in the available subchronic oral, dermal and inhalation toxicity studies.

Mutagenicity studies indicate tetrahydrofurfuryl alcohol is not mutagenic in *Salmonella typhimurium* or *E. coli* with or without metabolic activation. Tetrahydrofurfuryl alcohol was also negative for causing structural chromosomal aberrations or polyploidy with or without metabolic activation in cultured Chinese hamster lung cells.

There are currently no chronic toxicity or cancer studies available for tetrahydrofurfuryl alcohol. The Agency used a qualitative structure activity relationship (SAR) database, DEREK Nexus, to determine if there were structural alerts for potential carcinogenicity for tetrahydrofurfuryl alcohol. No structural alerts for carcinogenicity were identified for tetrahydrofurfuryl alcohol. In the absence of any structural alerts and lack of mutagenicity concerns, tetrahydrofurfuryl alcohol is not expected to be carcinogenic.

B. 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 discussion of the toxicological endpoints for tetrahydrofurfuryl alcohol used for human risk assessment can be found at *http://www.regulations.gov* in the document ''Hazard Assessment for the Tolerance Reassessment of Tetrahydrofurfuryl alcohol (THFA) (CAS Reg. No. 97–99–4) at pp. 6–8 in docket ID number EPA–HQ–OPP–2013–0098''. A summary of the toxicological dose and endpoints for THFA follows:

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR TETRAHYDROFURFURYL ALCOHOL FOR USE IN HUMAN RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13–50 years of age).	NOAEL = [50] mg/kg/day. UF_A = [10] x UF_H = [10]x FQPA SF = [10]x	Acute RfD = [0.5] mg/kg/day. aPAD = [0.05] mg/kg/day	[Developmental rat]. LOAEL = [100] mg/kg/day based on [decreased fetal body weight and increased incidence of filamentous tail, complete resorptions at 500 and 1,000 mg/kg/day].
Acute dietary (General population including infants and children).	None	NA	No acute effects relevant to the general population were observed in the available studies.
Chronic dietary (All populations)	NOAEL= [50] mg/kg/day. UF_A = [10]x UF_H = [10]x FQPA SF = [10]x	Chronic RfD = [0.5] mg/kg/day. cPAD = [0.05] mg/kg/day	[Developmental rat]. LOAEL = [100] mg/kg/day based on [decreased fetal body weight and increased incidence of filamentous tail, complete resorptions at 500 and 1,000 mg/kg/day].
Incidental oral short-term (1 to 30 days).	NOAEL= [50] mg/kg/day. UF_A = [10]x UF_H = [10]x FQPA SF = [10]x	LOC for MOE = [1,000].	[Developmental, rat]. LOAEL = [100] mg/kg/day based on [decreased fetal body weight and increased incidence of filamentous tail, complete resorptions at 500 and 1,000 mg/kg/day].
Dermal short-term (1 to 30 days).	Dermal study NOAEL = [100] mg/kg/day. UF_A = [10]x UF_H = [10]x FQPA SF = [10]x	LOC for MOE = [1,000].	[90-day dermal, rat]. LOAEL = [300 and 1,000] mg/kg/day M/F respectively based on [decreased sperm count and sperm production rate in males, lower body weight/gains in females].
Inhalation short-term (1 to 30 days).	Inhalation study LOAEL=0.21 mg/l. UF_A = [10]x UF_H = [10]x FQPA SF = [10]x	LOC for MOE = [1000].	[90-day inhalation, rat]. LOAEL = [0.21] mg/L (50 ppm; approx. 60 mg/kg/day) based on. Decreased body weight of males at 150 and 500 ppm. Multiple effects on sperm number, motility, and morphology at interim and terminal necropsy of males at both 150 and 500 ppm].
Cancer (Oral, dermal, inhalation).	Classification: No structural alerts for carcinogenicity were identified for tetrahydrofurfuryl alcohol using a qualitative structure activity relationship (SAR) database, DEREK Nexus. In the absence of any structural alerts and lack of mutagenicity concerns, tetrahydrofurfuryl alcohol is not expected to be carcinogenic.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_{DB} = to account for the absence of data or other data deficiency. UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to tetrahydrofurfuryl alcohol, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from tetrahydrofurfuryl alcohol in food as follows:

2. *Acute and chronic exposure.* In conducting the acute and chronic dietary exposure assessments using the Dietary Exposure Evaluation Model DEEM–FCID™, Version 3.18, EPA used food consumption information from the U.S. Department of Agriculture's (USDA's) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA).

In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper-bound exposure estimates for the subject inert ingredient. Upper-bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides and fungicides. A complete discussion of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled ''Alkyl Amines Polyethoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessment for the Inerts'' (D361707, S. Piper 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

In the case of tetrahydrofurfuryl alcohol residues resulting from foliar applications, EPA made specific adjustments to the dietary exposure assessments to account for the use limitations of tetrahydrofurfuryl alcohol as well as some residue chemistry data (plant uptake data) submitted with the petition. The use of the dietary estimated exposure model (DEEM) for upper-bound dietary risk assessments as described above was modified to include only those commodities on which pesticide formulations containing tetrahydrofurfuryl alcohol are being

used or are proposed to be used. Specifically, the dietary exposure assessment considered foliar uses of tetrahydrofurfuryl alcohol on wheat, buckwheat, barley, oats, rye, sorghum, triticale, rice and wild rice, canola, cotton, field corn, and popcorn as contained in the existing tolerance exemption expression and that are the subject of the present petitions. A residue chemistry study (a radiolabeled plant uptake study with THFA in corn, tomato, and wheat) suggest that the highest reported detectable level of tetrahydrofurfuryl alcohol residues resulting from foliar application in these crops is 0.5 ppm and this value is used in the dietary exposure assessment for the commodities included in the tolerance exemption.

For seed treatment use, it was conservatively assumed that all of the following commodities (which represent an agglomeration of all commodities for which seed treatment pesticide products are approved for use) could potentially be treated with a seed treatment pesticide containing tetrahydrofurfuryl alcohol: barley, corn (field, pop, sweet and corn for seed production), legume vegetables (dried shelled peas and beans), brassica and bulb vegetables, alfalfa, cucurbits, rye, wheat, cotton, sugar beets, and sunflowers. For seed treatment use, in the absence of THFA-specific data, residue chemistry data for active ingredients with seed treatment uses were utilized. Residue levels for pesticide active ingredients used for seed treatment are all below the limit of detection, so a highly conservative value of 0.05 ppm is used in the dietary exposure assessment as a residue value for THFA for all seed treatment commodities based on application of Agency policies for assigning values to nondetected/nonquantified pesticide residues.

3. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for tetrahydrofurfuryl alcohol a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

4. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Tetrahydrofurfuryl alcohol is contained in a pesticide currently registered for uses that could result in residential exposures. The use pattern of the product includes application to dogs. EPA assessed this residential exposure using the Agency's Standard Operating Procedures for Residential Pesticide Exposure Assessment Residential Exposure (Residential SOP). Based on the Treated Pets section of the Residential SOP, the following assumptions are made: for residential handlers, exposure (dermal and inhalation) is expected to be short-term only. Residential post-application dermal exposure (short-term only) was assessed for adults and children. Residential post-application inhalation exposure is generally not assessed for pet treatment product uses as such exposure is typically considered to be negligible. Incidental oral post-application exposure was assessed for children 1 to 2 years old. All post-application exposures are expected to be short-term in duration. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

5. *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 tetrahydrofurfuryl alcohol to share a common mechanism of toxicity with any other substances, and tetrahydrofurfuryl alcohol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that tetrahydrofurfuryl alcohol 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.* The data available for evaluation suggest there is evidence of increased quantitative susceptibility of the offspring after *in utero* exposure to tetrahydrofurfuryl alcohol. No reproductive parameters were affected except slightly increased gestation length at the high dose of 150 mg/kg/day in the OECD 421 study in rats. There is also a concern for the effects of tetrahydrofurfuryl alcohol on the developing male reproductive system. Subchronic and reproductive toxicity studies consistently revealed decreased testicular epididymis and seminal vesicle weights as well as atrophy of the epididymis and seminal vesicles and abnormal morphology and motility of sperm. The level at which tetrahydrofurfuryl alcohol may affect the reproductive system during development is currently not known.

3. *Conclusion.* EPA has determined that based on evidence of quantitative and qualitative susceptibility the safety of infants and children would be adequately protected if the FQPA SF was retained at 10x for all scenarios. That decision is based on the following findings:

i. The toxicity database for tetrahydrofurfuryl alcohol consists of a 28-day and 90-day oral toxicity studies in rats, dogs, 90-day dermal toxicity study in rats, 90-day inhalation toxicity study in rats, several mutagenicity studies, developmental/reproductive toxicity screening study in rats, and a developmental toxicity study and reproductive toxicity study in rats.

ii. Slight atrophy of thymus was seen in high dose animal groups in the 28-day oral toxicity study, which may be indicative of an immune response, however no guideline immunotoxicity study is available.

iii. Evidence of increased quantitative susceptibility of offspring is seen in the developmental toxicity study.

iv. Additionally, alterations in the male reproductive system from subchronic exposure to tetrahydrofurfuryl alcohol does indicate

a concern for effects to the developing male reproductive system.

v. The FQPA factor of 10X is considered adequate to account for potential immunotoxicity and uncertainty regarding the developing reproductive system in males because clear NOAELs are established in the available database.

vi. There are no residual uncertainties identified in the exposure databases. As described earlier, EPA used highly conservative assumptions for the dietary food exposure assessment. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to tetrahydrofurfuryl alcohol in drinking water. EPA used similarly conservative assumptions to assess residential exposures of children to tetrahydrofurfuryl alcohol. These assessments will not underestimate the exposure and risks.

E. 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, EPA has concluded that acute exposure to tetrahydrofurfuryl alcohol from food and water will utilize 8.88% of the aPAD for females 13–49 years old.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to tetrahydrofurfuryl alcohol from food and water will utilize 8.5% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of tetrahydrofurfuryl alcohol is not expected.

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). Tetrahydrofurfuryl alcohol is contained in a pesticide 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 tetrahydrofurfuryl alcohol.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined chronic food, water, and short-term residential exposures result in aggregate MOEs of 13,100 for adults and 9,800 for children 1–2 years old. Because EPA's level of concern for tetrahydrofurfuryl alcohol is a MOE of 1,000 or below, these MOEs are not of concern.

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).

An intermediate-term adverse effect was identified; however, tetrahydrofurfuryl alcohol is not contained in any pesticide products registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for tetrahydrofurfuryl alcohol.

5. *Cancer.* Based on the lack of genotoxicity and a DEREK assessment of tetrahydrofurfuryl alcohol that revealed no structural alerts suggestive of carcinogenicity, tetrahydrofurfuryl alcohol is therefore not expected to pose a cancer risk to humans.

6. *Determination of safety.* Taking into consideration all available information on tetrahydrofurfuryl alcohol, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to tetrahydrofurfuryl alcohol resulting from the limited uses contained in 40 CFR 180.1263. Therefore, the amendment of the exemption from requirement of a tolerance at 40 CFR 180.1263 for residues of tetrahydrofurfuryl alcohol when used as an inert ingredient in pesticide formulations to include allowance of one herbicide application prior to the pre-boot stage to wheat, buckwheat, barley, oats, rye, sorghum, triticale, rice and wild rice; extended use on canola to the early bolting stage; extended use on soybeans up to the bloom stage; and allowance of two applications to field corn and popcorn up to 36 inches tall (V8 stage) is safe under FFDCA section 408.

V. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

VI. Conclusion

Therefore, the exemption from the requirement of a tolerance under 40 CFR 180.1263 is amended to add exemption from the requirement of a tolerance for residues of tetrahydrofurfuryl alcohol (CAS Reg. No. 97–99–4) when used as an inert ingredient (solvent) in herbicides applied to wheat, buckwheat, barley, oats, rye, sorghum, triticale, rice and wild rice prior to the pre-boot stage; use on canola to the early bolting stage; use on soybeans up to the bloom stage; and two applications to field corn and popcorn up to 36 inches tall (V8 stage).

VII. Statutory and Executive Order Reviews

This final rule establishes exemptions from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). 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 FFDCA section 408(d), such as

the exemptions 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 FFDCA section 408(n)(4). 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) (2 U.S.C. 1501 *et seq.*).

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) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: October 9, 2018.

Michael Goodis,

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. In § 180.1263, revise paragraphs (d) and (e), and add paragraphs (f) and (g) to read as follows:

§ 180.1263 Tetrahydrofurfuryl alcohol; exemption from the requirement of a tolerance.

* * * * *

(d) For use in herbicides with one application to wheat, buckwheat, barley, oats, rye, sorghum, triticale, rice, and wild rice prior to the pre-boot stage.

(e) For use in herbicides with two applications to field corn and popcorn up to 36 inches tall (V8 stage).

(f) For use in herbicides with two applications to canola prior to the early bolting stage.

(g) For use in herbicides with two applications to soybeans prior to the bloom growth stage.

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