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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0524; FRL-9337-9]

Trinexapac-ethyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of trinexapac-ethyl in or on multiple commodities which are identified and discussed later in this document. Syngenta Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

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-2010-0524. 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: Bethany Benbow, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 347-8072; e-mail address: *benbow.bethany@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 Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 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*. To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

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-2010-0524 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-2010-0524, 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. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 4, 2010, (75 FR 46925) (FRL-8834-9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of two pesticide petitions (PP 0F7719 and 0F7720) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419. Petition 0F7719 requested that 40 CFR part 180 be amended by establishing tolerances for residues of the plant growth regulator, trinexapac-ethyl and its primary metabolite CGA-179500, in or on grass, forage, grown for seed at 1.60 parts per million (ppm); grass, hay, grown for seed at 3.5 ppm; grass, seed screenings, grown for seed at 45.0 ppm; grass, straw, grown for seed at 12 ppm; cattle (fat, meat, meat byproducts) at 0.05 ppm; goat (fat, meat, meat

byproducts) at 0.05 ppm; horse (fat, meat, meat byproducts) at 0.05 ppm and sheep (fat, meat, meat byproducts) at 0.05 ppm. Petition 0F7720 requested that 40 CFR part 180 be amended by establishing tolerances for residues in or on barley, grain at 1.6 ppm; barley, hay at 0.7 ppm; barley, straw at 0.35 ppm; cattle, kidney at 0.05 ppm; hog, kidney at 0.05 ppm; oat, forage at 1.0 ppm; oat, grain at 4.1 ppm; oat, hay at 1.3 ppm; oat, straw at 0.7 ppm; sugarcane, cane at 0.8 ppm; wheat, forage at 1.0 ppm; wheat, grain at 4.1 ppm; wheat, hay at 1.3 ppm and wheat, straw at 0.7 ppm.

That notice referenced a summary of the petitions prepared by Syngenta Crop Protection, Inc., the registrant, which is available in the docket, *http://www.regulations.gov*.

Based upon review of the data supporting the petition, EPA has revised most of the proposed tolerance levels, added tolerances for hog fat and meat, and deleted the proposed tolerance for cattle kidney. The reasons 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 trinexapac-ethyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with trinexapac-ethyl follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The acute toxicity of trinexapac-ethyl is low via the oral, eye, dermal, or inhalation routes of exposure, and it is not a dermal sensitizer.

In adult animals (rats, rabbits, mice, dogs), no systemic adverse effects are seen below the limit dose following subchronic or chronic oral exposure with the exception of dogs. The 90-day subchronic dog study showed decreased body weight gain and food consumption, diffuse thymic atrophy, and changes in the epithelial cells of the renal tubules at 516/582 milligrams/kilogram/day (mg/kg/day) (males/females). Following chronic exposure, dose-related neuropathology of the brain was seen at ≥365/357

mg/kg/day in male and female dogs respectively. The lesions remained confined to the supporting cells in the central nervous system and did not progress to more advanced or more extensive damage of the nervous tissue. They were not associated with other neuropathological findings or overt neurological signs so their biological significance is unknown. Similar lesions were not observed in the rat or mouse following acute, subchronic or chronic dietary exposure, and there was no other evidence in any other species tested to indicate a neurotoxicity potential. Furthermore, the brain lesions observed in the chronic dog study were not observed in the sub-chronic dog study up to 890 mg/kg/day and are thus not likely to develop from a short-term exposure.

Evidence of increased qualitative and quantitative susceptibility to offspring exists at or above the limit dose of the developmental and reproduction studies. Developmental toxicity was observed in the rat (increased incidence of asymmetrical sternebrae) and rabbit (decreased number of live fetuses/litter and increased post-implantation loss) at the highest dose tested, with no evidence of maternal toxicity observed in either species. In the rat reproduction study, reproductive toxicity was not observed, but decreased pup survival and decreased pup body weight/body-weight gain during lactation were observed above the limit dose with only reduced body weight and food consumption observed in the parental animals (>1,200 mg/kg/day).

Trinexapac-ethyl is classified as “Not likely to be carcinogenic to humans.” The combined chronic toxicity/carcinogenicity study in the rat did not demonstrate an increase in any tumor type that would be relevant to humans. In the mouse, there was no evidence of carcinogenicity. The mutagenicity database is also complete, with no evidence of mutagenicity.

Specific information on the studies received and the nature of the adverse effects caused by trinexapac-ethyl as well as the no-observed-adverse-effect-level and the lowest-observed-adverse-effect-level from the toxicity studies can be found at *http://www.regulations.gov* in the document, "Trinexapac-ethyl: Human Health Risk Assessment for the Section 3 Registration Action on Cereal Grains, Sugarcane, and Grasses Grown for Seed*"* p. 48 in docket ID number EPA-HQ-OPP-2010-0524.

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 (LOC) 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 (U/SF) 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 trinexapac-ethyl used for human risk assessment is shown in Table 1 of this unit.

Table 1.—Summary of Toxicological Doses and Endpoints for Trinexapac-ethyl for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13-49 years of age)	NOAEL = 60 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.6 mg/kg/day aPAD = 0.6 mg/kg/day	*Developmental rabbit study* LOAEL = 360 mg/kg/day, based on a decrease in mean number of fetuses/litter and an increase in post-implantation loss
Acute dietary (General population including infants and children)	No appropriate endpoint for the general population including infants and children.		
Chronic dietary (All populations)	NOAEL= 31.6 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.32 mg/kg/day cPAD = 0.32 mg/kg/day	*Chronic oral toxicity study – dog* LOAEL = 357 mg/kg/day, based on elevated serum cholesterol values in females, mucoid feces in females and bloody feces in both sexes, and minimal, focal vacuolation of the dorsal medial hippocampus and/or lateral midbrain in both sexes

Incidental oral (short and intermediate-term)	No appropriate endpoint for the incidental oral scenario for children		
Dermal & Inhalation (short- and intermediate-term - adults only)	Dermal (or oral) study NOAEL = 60 mg/kg/day (dermal absorption rate = 77.5% UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE = 100 Occupational LOC for MOE= 100	*Developmental rabbit study* LOAEL = 360 mg/kg, based on a decrease in mean number of fetuses/litter and an increase in post-implantation loss
Cancer (Oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans"		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. Mg/kg/day – milligrams per day.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to trinexapac-ethyl, EPA considered exposure under the petitioned-for tolerances. There are no tolerances currently established for trinexapac-ethyl. EPA assessed dietary exposures from trinexapac-ethyl 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. In estimating acute dietary exposure, EPA used food consumption information from the U.S. 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 that residues are present in all commodities at the tolerance level and that 100% of

commodities with tolerances are treated with trinexapac-ethyl. Dietary Exposure Evaluation Model (DEEM™) 7.81 default concentration factors were used to estimate residues of trinexapac-ethyl in processed commodities. The acute dietary exposure was only estimated for females 13 to 49 years old based on an *in utero* effect (decrease in mean number of fetuses/litter and an increase in post-implantation loss) identified in the rabbit developmental study. An endpoint of concern was not identified for the general U.S. population; however, the acute dietary assessment is protective of women that may become pregnant.

ii. *Chronic exposure*. In estimating chronic dietary exposure, EPA used food consumption information from the USDA 1994-1996 and 1998 CSFII. As to residue levels in food, EPA assumed that residues are present in all commodities at the tolerance level and that 100% of commodities with tolerances are treated with trinexapac-ethyl. DEEM™ 7.81 default concentration factors were used to estimate residues of trinexapac-ethyl in processed commodities.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that trinexapac-ethyl does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk was not conducted.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for trinexapac-ethyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of trinexapac-ethyl. 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 Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of trinexapac-ethyl for acute exposures are estimated to be 12.61 parts per billion (ppb) for surface water and 0.009 ppb for ground water. Chronic exposures for non-cancer assessments are estimated to be 1.56 ppb for surface water and 0.009 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration of value 12.61 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 1.56 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). Trinexapac-ethyl is currently registered for the following uses that could result in residential exposures: Residential lawns, athletic fields, parks, and golf courses. EPA assessed residential exposure with the assumption that homeowner handlers wear shorts, short-sleeved shirts, socks, and shoes, and that they complete all tasks associated with the use of a pesticide product including mixing/loading, if needed, as well as the application. Residential handler exposure scenarios for both dermal and inhalation are considered to be short-term only, due to the infrequent use patterns associated with homeowner products.

EPA uses the term "post-application" to describe exposure to individuals that occur as a result of being in an environment that has been previously treated with a pesticide. Trinexapac-ethyl can be used in many areas that can be frequented by the general population including residential areas (e.g., home lawns, recreational turf). As a result, individuals can be exposed by entering these areas if they have been previously treated. Therefore, short-term dermal post-application exposures and risks were also assessed for trinexapac-ethyl. There is the potential for incidental oral exposure; however, since there is no toxicological endpoint of concern for that route, a quantitative assessment was not conducted. 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*.

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 trinexapac-ethyl to share a common mechanism of toxicity with any other substances, and trinexapac-ethyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that trinexapac-ethyl 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 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*. Evidence of increased susceptibility to offspring exists at or above the limit dose of the developmental and reproduction studies. Developmental toxicity was observed in the rat (increased incidence of asymmetrical sternebrae) and rabbit (decreased number of live fetuses/litter and increased post-implantation loss) at the highest dose tested, with no evidence of maternal toxicity observed in either species. In the rat reproduction study, reproductive toxicity was not observed, but decreased pup survival and decreased pup body weight/body-weight gain during lactation were observed above the limit dose with only reduced body weight and food consumption observed in the parental animals (>1,200 mg/kg/day).

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 toxicology database for trinexapac-ethyl is largely complete, with the exception of a subchronic neurotoxicity study, which is a new data requirement under 40

CFR part 158 for registration of a pesticide (food and non-food uses OPPTS 870.6200b). Though dose-related neuropathology of the brain was observed in the dog, EPA has concluded that there is no need for a developmental neurotoxicity (DNT) study or additional UFs to account for neurotoxicity for the following reasons:

- These effects in the dog study were observed only at high doses (>357 mg/kg/day) and with chronic exposure, and no associated neurological signs or other neuropathology were observed. Furthermore, the lesions remained confined to the supporting cells in the central nervous system (CNS) and did not progress to more advanced or more extensive damage of the nervous tissue. There are clear NOAELs/LOAELs for this effect; in which the NOAEL dose is 10-fold lower than the LOAEL dose at which neuropathology is observed, and is therefore sufficiently protective. Furthermore, similar lesions were not observed in the rat or mouse following subchronic or chronic dietary exposure, and there was no other evidence in any species tested to indicate a neurotoxicity potential.
- Results of the acute neurotoxicity study show no indications of neurotoxicy at the highest dose.

Although subchronic inhalation data on trinexapac-ethyl are not available and an oral study was selected for inhalation risk assessment, the selected points of departure are considered adequately protective for all exposed populations. Therefore, an additional 10x database UF was not retained for lack of inhalation toxicity data and these data are not being required.

ii. Although there is evidence of susceptibility in the rat and rabbit developmental studies and in the rat reproduction study, EPA's concern for these effects is low, and

there are no residual uncertainties since the effects only occurred at the highest doses tested (360-1,200 mg/kg/day), for each study, and there were clearly identified NOAELs (60-593 mg/kg/day) for each fetal/offspring effect.

iii. There are no residual uncertainties in the exposure database. Because the acute and chronic dietary exposure estimates were based on several conservative assumptions (100% of crops treated with residues present at tolerance levels, default processing factors and screening level drinking water estimates), EPA is confident that the dietary exposure assessments do not underestimate risk to the general U.S. population and various population subgroups. Similarly, EPA does not believe that the non-dietary residential exposures are underestimated because they are based on the conservative assumptions of EPA's Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments (December 1997), and updates contained in the Science Advisory Council Policy 12 (February 2001) as well as the uses specified in the proposed labels.

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 aPAD and 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.* Acute aggregate risk takes into account exposure to residues in food and drinking water alone. Therefore, acute aggregate risk is equivalent to the acute dietary risk as discussed in Unit III.C.1.i. All risk estimates are below EPA's level of

concern. The acute dietary exposure estimate for females 13to 49 years old will only utilize 2% of the aPAD, which is well below the Agency's level of concern (100% of the aPAD).

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to trinexapac-ethyl from food and water will utilize 6% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Based on the residential use patterns for trinexapac-ethyl, chronic residential exposure to residues is not expected.

3. *Short- and intermediate-term risk*. Since the short- and intermediate-term toxicological endpoints for trinexapac-ethyl are the same for each route of exposure, only short-term exposures were assessed. Trinexapac-ethyl is currently registered for uses that could result in short- and intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water (considered to be a background exposure level) with adult post-application dermal exposure estimates for trinexapac-ethyl.

Using the exposure assumptions described in this unit, EPA has concluded the combined food, water, and adult post-application dermal exposures result in aggregate MOEs of 761 for liquid products and 601 for granular products. Because EPA's level of concern for trinexapac-ethyl is a MOE of 100 or below, these MOEs are not of concern.

4. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, trinexapac-ethyl is not expected to pose a cancer risk to humans.

5. *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 trinexapac-ethyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Method GRM020.01A, which utilizes high performance liquid chromatography with triple-quadrupole mass spectrometry (LC-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.

There are no established or proposed Codex, Canadian, or Mexican MRLs for trinexapac-ethyl in or on any food or feed crops.

C. Response to Comments

An anonymous citizen objected to the presence of any pesticide residues on food. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned completely. However, the existing legal framework provided by section 408 of FFDCA contemplates that tolerances greater than zero may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

D. Revisions to Petitioned-For Tolerances

Many of the proposed tolerances are different from the tolerances being set by EPA. EPA is setting different levels than were proposed based on EPA's analysis of the field trial data using the Organization for Economic Cooperation and Development tolerance calculation procedures. Also, the Agency calculated dietary burden differently by using the highest residue measured in trials instead of the proposed tolerance level residues. Table 2.2.3, "Tolerance Summary for Trinexapac-ethyl" summarizes these differences on page 8 of the document, "Trinexapac-ethyl: Human Health Risk Assessment for the Section 3 Registration Action on Cereal Grains, Sugarcane, and Grasses Grown for Seed" which is located in docket ID number EPA-HQ-OPP-2010-0524.

V. Conclusion

Therefore, tolerances are established for residues of trinexapac-ethyl, including its metabolites and degradates, as set forth in the regulatory text. Compliance with the tolerance levels is to be determined by measuring both trinexapac-ethyl, ethyl 4-(cyclopropylhydroxymethylene)-3,5-dioxocyclohexanecarboxylate and the associated metabolite trinexpac, 4-(cyclopropylhydroxymethylene)-3,5-dioxocyclohexanecarboxylic acid, calculated as the stoichiometric equivalent of trinexapac-ethyl.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to petitions 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: February 16, 2012.

Steven Bradbury,

Director, 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 180.662 is added to subpart C to read as follows:

§ 180.662 Trinexapac-ethyl; tolerances for residues.

(a) *General*. Tolerances are established for residues of the plant growth inhibitor, trinexapac-ethyl, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring both trinexapac-ethyl, ethyl 4-(cyclopropylhydroxymethylene)-3,5-dioxocyclohexanecarboxylate and the associated metabolite, trinexpac, 4-(cyclopropylhydroxymethylene)-3,5-dioxocyclohexanecarboxylic acid, calculated as the stoichiometric equivalent of trinexapac-ethyl, in or on the commodity.

Commodity	Parts per million
Barley, grain	2.0
Barley, hay	0.8
Barley, straw	0.4
Cattle, fat	0.02
Cattle, meat	0.02
Cattle, meat byproducts	0.04
Goat, fat	0.02
Goat, meat	0.02
Goat, meat byproducts	0.04
Grass, forage	1.5
Grass, hay	4.0
Grass, seed screenings	40.0
Grass, straw	10.0
Hog, fat	0.02
Hog, kidney	0.03
Hog, meat	0.02

Horse, fat	0.02
Horse, meat	0.02
Horse, meat byproducts	0.04
Oat, forage	1.0
Oat, grain	4.0
Oat, hay	1.5
Oat, straw	0.9
Sheep, fat	0.02
Sheep, meat	0.02
Sheep, meat byproducts	0.04
Sugarcane, cane	0.8
Wheat, forage	1.5
Wheat, grain	4.0
Wheat, hay	1.5
Wheat, middlings	6.5
Wheat, straw	0.9

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

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

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

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