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 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 action 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (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 (NTTAA) (15 U.S.C. 272 note).

VII. 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: June 22, 2017.

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 § 180.663, revise the entry for ''Hop, dried cones'' in the table in paragraph (a) to read as follows:

§ 180.663 Ametoctradin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Hop, dried cones	100
* * * * *	

* * * * *

[FR Doc. 2017–15762 Filed 7–26–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0405; FRL–9964–15]

Tolpyralate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tolpyralate in or on field corn, popcorn, and sweet corn. ISK Biosciences Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 27, 2017. Objections and requests for hearings must be received on or before September 25, 2017, 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–2015–0405, 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 EPA's tolerance regulations at 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–2015–0405 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 September 25, 2017. 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–2015–0405, 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. Summary of Petitioned for Tolerance

In the **Federal Register** of August 26, 2015 (80 FR 51759) (FRL–9931–74), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5F8359) by ISK Biosciences, Corporation, 7470 Auburn Rd., Suite A, Concord, OH 44077. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide, tolpyralate, 1-[[1-ethyl-4-[3-(2-methoxyethoxy)-2-methyl-4-(methylsulfonyl)benzoyl]-1H-pyrazol-5-yl]oxy]ethyl methyl carbonate, including its metabolite MT–2153, in or on the raw agricultural commodities of corn that include field corn (corn, field, grain; corn, field, forage; and corn, field, stover); sweet corn (corn, sweet, kernel + cob with husks removed; corn, sweet, forage; and corn, sweet, stover); and popcorn (corn, pop, grain and corn, pop, stover) at 0.01 parts per million (ppm). That document referenced a summary of the petition prepared by ISK Biosciences, Corporation the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

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 FFDCA section 408(b)(2)(D), and 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 for tolpyralate including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with tolpyralate 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 effects in the tolpyralate hazard database are similar to those seen with other hydroxyphenylpyruvate dioxygenase (HPPD) inhibiting chemicals, including eye opacity and developmental skeletal defects. The major target organs identified were the eyes, kidney, liver, thyroid and developing skeleton. Other effects included pancreatic acinar cell single cell necrosis, gall bladder calculi, fur loss and/or tactile hair loss, and decreased body weights. No systemic toxicity was observed following a 28-day dermal exposure in the rat.

Neurotoxicity was not observed in the acute or subchronic neurotoxicity studies in the rat. There was no indication of neurotoxicity to the fetus in developmental studies or during early postnatal development in a rat reproductive toxicity study. However, with chronic exposure, rats and mice showed effects on the nervous system that were indicative of a temporally-dependent response for neurotoxicity. Similar findings were not seen in the one-year dog study.

Developmental toxicity studies in the rat and rabbit showed that the main effects on fetuses in both species were skeletal variations that are consistent with those observed from exposure to other HPPD inhibitors. These skeletal effects are considered to be evidence of increased quantitative and qualitative prenatal susceptibility. No immunotoxic potential was observed in a mouse immunotoxicity study; however, in the dog, inflammation associated with hyperostosis and lymph node hyperplasia in males was observed.

In the rat, an increase in the incidence of squamous cell carcinomas of the eye was observed. The increase in this tumor type is considered to be related to the eye opacities typically observed with compounds producing HPPD inhibition. The Agency has determined that tolpyralate shows ''suggestive evidence of carcinogenicity to humans'' based on an increase in the incidence of squamous cell carcinoma of the eye in male rats in the rat carcinogenicity study. There was no evidence of carcinogenicity in female rats or in the mouse. Most genotoxicity studies did not show evidence of mutagenicity or clastogenicity. A mouse lymphoma cell gene mutation assay showed a dose-dependent, reproducible increase in mutant colonies, but the results of this study are considered inconclusive due to the insolubility of the test compound. However, all other genotoxicity studies, including an *in vivo* mouse micronucleus assay, were negative. Therefore, when considered as a whole, the available mutagenicity and clastogenicity studies did not indicate genotoxic potential.

The Agency concluded that the eye tumors resulted from long-term exposure to increased blood tyrosine levels as a result of HPPD inhibition. The eye is a target organ for HPPD inhibitors and causes opacities and keratitis with subchronic or chronic exposure. Eye tumors have been

reported in male rats following chronic exposure to some other HPPD inhibitors. Since the development of the eye tumors in the rat is considered to be dependent upon ocular toxicity, and not to a linear (non-threshold), genotoxic mechanism, tumors will not develop at doses that are protective of eye toxicity. Eye effects from exposure to tolpyralate were observed at the LOAEL in males in the rat chronic toxicity/carcinogenicity study but not at the NOAEL. The NOAEL from this study is therefore considered protective of this tumor type and was used as the basis of the chronic reference dose. Quantification of cancer risk is not required because the chronic reference dose, which is protective of eye toxicity, is considered to be protective of cancer risk.

The acute toxicity of tolpyralate is low, and it is not an eye or skin irritant or a dermal sensitizer.

Specific information on the studies received and the nature of the adverse effects caused by tolpyralate as well as the NOAELs and the LOAELs from the toxicity studies can be found at *http://www.regulations.gov* in document titled ''Tolpyralate—New Active Ingredient Human Health Risk Assessment for Proposed Uses on Sweet Corn, Field Corn, and Popcorn'' at page 35 in docket ID number EPA–HQ–OPP–2015–405.

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 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

No adverse effects resulting from a single exposure and relevant for the general population were identified for tolpyralate; therefore, a point of departure for assessing acute risk for this population was not established. The fetal skeletal effects noted above are suitable for acute assessment of women of child-bearing age. The no-adverse effect level (NOAEL) for skeletal variations in the rabbit developmental toxicity study is 5 mg/kg body weight (bw)/day (lowest adverse effect level (LOAEL) = 50 mg/kg bw/day). Chronic exposure is being assessed based on the systemic effects (fur loss; eye opacity; liver; pancreas; kidney; thyroid and cerebellar effects) noted in the chronic oral toxicity study in rats, with a NOAEL of 0.93 mg/kg bw/day and a LOAEL of 97/126 (male/female) mg/kg bw/day. A summary of the toxicological endpoints for tolpyralate used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR TOLPYRALATE 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 (General population including infants and children).	.....	.....	An appropriate endpoint was not identified for this exposure scenario. An adverse effect resulting from a single oral exposure was not identified for the general population.
Acute dietary (Females 13–49 years of age).	NOAEL = 5 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.05 mg/kg/day. aPAD = 0.05 mg/kg/day	Developmental toxicity study in the rabbit (gavage; range-finding and main studies considered together). Developmental LOAEL = 50 mg/kg/day based an increased incidence of skeletal abnormalities (range-finding study).
Chronic dietary (All populations including infants and children and females 13–49 years of age).	NOAEL= 0.925 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.0093 mg/kg/day. cPAD = 0.0093 mg/kg/day	Chronic oral toxicity in the rat (dietary). LOAEL = 97/126 mg/kg/day based on fur loss, eye opacity/neovascularization/keratitis, increased relative liver weight, thyroid follicular cell hypertrophy, hepatocellular centrilobular fatty change, increased pancreatic acinar cell necrosis, renal tubule basophilic change, increased molecular layer vacuolation in the cerebellum (males).
Cancer (Oral, dermal, inhalation).	Classification: Suggestive evidence of carcinogenic potential in humans, based on squamous cell carcinoma of the eye in male rats. The chronic RfD is protective of carcinogenicity.		

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_H = potential variation in sensitivity among members of the human population (intraspecies). DAF = dermal absorption factor.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to tolpyralate, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from tolpyralate 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 tolpyralate. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA)

under the Continuing Survey of Food Intake by Individuals (CSFII) and the CDC under the National Health and Nutrition Examination Survey/What We Eat in America (NHANES/WEIA) 2003–2008. EPA assumed tolerance-level residues for all commodities and 100% crop treated. There is no expectation of finite residues in either livestock commodities or rotational crops; therefore, no residues have been entered for these commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WEIA 2003–2008. EPA assumed tolerance-level residues for all commodities and 100% crop treated.

iii. *Cancer.* The Agency has determined that quantification of risk using a non-linear approach (*i.e.,* RfD), for tolpyralate will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to tolpyralate. As a result, the chronic dietary exposure assessment is protective for potential cancer risk, and a separate cancer exposure assessment was not conducted.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for tolpyralate. Tolerance level residues and/or 100% CT 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 tolpyralate in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of tolpyralate. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

The groundwater value was generated using the Pesticide Root Zone Model for Groundwater (PRZM–GW) Model, and the surface water values were generated using the Pesticide Root Zone Model (PRZM5) and the Variable Volume Water Model (VVWM). The EDWCs of tolpyralate for acute exposures are estimated to be 6.75 parts per billion (ppb) for surface water and 11.53 ppb for ground water. For chronic exposures assessments are estimated to be 0.65 ppb for surface water and 10.18 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 value of 11.53 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 10.18 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).

Tolpyralate 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.''

Although tolpyralate belongs to the class of chemicals whose mechanism of toxicity is the inhibition of HPPD, EPA has not made a common mechanism of toxicity finding as to tolpyralate and other HPPD-inhibiting substances. There are marked differences among species in the ocular toxicity and other effects typically associated with tolpyralate and other substances that the inhibit HPPD. Ocular effects following treatment with HPPD-inhibitor herbicides are seen in the rat but not in the mouse. Monkeys also seem to be recalcitrant to the ocular toxicity induced by HPPD inhibition. One explanation for this species-specific response in ocular opacity may be related to species differences in the clearance of tyrosine. A metabolic pathway that involves the liver enzyme tyrosine aminotransferase (TAT) exists to remove tyrosine from the blood. In contrast to rats where ocular toxicity is observed following exposure to HPPD-inhibiting herbicides, mice and humans are unlikely to achieve the levels of plasma tyrosine necessary to produce ocular opacities because the activity of TAT in these species is much greater compared to rats.

HPPD inhibitors (*e.g.,* nitisinone) are used as an effective therapeutic agent to treat patients suffering from rare genetic diseases of tyrosine catabolism. Treatment starts in childhood but is often sustained throughout patient's lifetime. The human experience indicates that a therapeutic dose (1 mg/kg/day dose) of nitisinone has an excellent safety record in infants, children, and adults and that serious adverse health outcomes have not been observed in a population followed for approximately a decade. Rarely, ocular effects are seen in patients with high plasma tyrosine levels; however, these effects are transient and can be readily reversed upon adherence to a restricted protein diet. This observation indicates that an HPPD inhibitor in and of itself cannot easily overwhelm the tyrosine-clearance mechanism in humans.

Based on the available information about the potential mechanism of toxicity and the variability of effects between species, EPA has not assumed, for purposes of this tolerance action, that tolpyralate has a common mechanism of toxicity with other substances.

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.* Quantitative and qualitative evidence of increased susceptibility, as compared to adults, of fetuses to in utero exposure to tolpyralate was observed in developmental toxicity studies in rats and rabbits. Concern for this evidence is low because (1) clear NOAELs/LOAELs were identified for the observed effects; (2) the relevant developmental effects were observed at LOAELs that were well above (10-fold greater) the NOAELs; and (3) the selected endpoints are protective of these effects.

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 database for tolpyralate is considered complete with respect to FQPA assessment.

ii. There is no concern for neurotoxicity from single or subchronic exposures. Although neuropathology was observed at the LOAELs in the rat

and the mouse long-term studies, the chronic LOAELs were almost 100-fold greater than the chronic NOAELs. The POD and endpoint for chronic dietary exposure are selected from the rat chronic study. Therefore, the chronic PAD (cPAD) is protective of potential neuropathology. It is also protective of increased susceptibility of offspring for neurotoxicity in the absence of a developmental neurotoxicity study, since neurotoxicity in adult animals was only observed as an effect following long-term dosing. There was no neurotoxicity observed in the database with exposure up to 90 days, including no evidence of neurotoxicity in the rat or rabbit developmental toxicity studies or the rat reproductive toxicity study. An additional uncertainty factor to account for the absence of data or other data deficiency (10x UFDB) is therefore not needed to account for this study.

iii. Evidence of quantitative and qualitative prenatal susceptibility was observed in the rat and rabbit developmental toxicity studies based on findings of fetal skeletal abnormalities at doses below those causing maternal toxicity. However, clear NOAELs and LOAELs were identified in both species and there are no residual uncertainties regarding the points of departure PODs or the endpoints of concern.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to tolpyralate in drinking water. These assessments will not underestimate the exposure and risks posed by tolpyralate.

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 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 tolpyralate will occupy 1.3% of the aPAD for females of child-bearing age (13–49 years old), the only population relevant for assessing acute exposure to tolpyralate.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to tolpyralate from food and water will utilize 6.2% of the cPAD for all infants (<1 year-old), the population group receiving the greatest exposure. There are no residential uses for tolpyralate.

3. *Short-term risk.* A short-term adverse effect was identified; however, tolpyralate is not registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-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 short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for tolpyralate.

4. *Intermediate-term risk.* An intermediate-term adverse effect was identified; however, tolpyralate is not 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 tolpyralate.

5. *Aggregate cancer risk for U.S. population.* Based on the discussion in Unit III.A., the chronic dietary exposure assessment is protective for potential cancer risk.

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 tolpyralate residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (ISK Biosciences Method JSM0433) for plant commodities is a LC–MS/MS method that can be used to analyze for parent tolpyralate and the metabolite MT–2153 concurrently. It has been developed and independently validated, and is available to enforce the tolerance expression. For all matrices and analytes, the level of quantification (LOQ), defined as the lowest level of method validation (LLMV) or lowest spiking level where acceptable precision and accuracy data were obtained, was determined to be 0.01 ppm. The limit of detection (LOD) was 0.004 ppm.

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; email 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 United Nations 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 Codex has not established a MRL for tolpyralate.

V. Conclusion

Therefore, tolerances are established for residues of the herbicide tolpyralate in or on field corn (corn, field, grain; corn, field, forage; and corn, field, stover), sweet corn (corn, sweet, kernel + cob with husks removed; corn, sweet, forage; and corn, sweet, stover), and popcorn (corn, pop, grain and corn, pop, stover) at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances 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 action has been exempted from review under

Executive Order 12866, this action 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 action 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 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 action 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (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 (NTTAA) (15 U.S.C. 272 note).

VII. 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: July 11, 2017.

Richard P. Keigwin, Jr.,

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. Add § 180.696 to subpart C to read as follows:

§ 180.696 Tolpyralate; tolerances for residues.

(a) *General.* Tolerances are established for residues of tolpyralate, 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 only tolpyralate, 1-[[1-ethyl-4-[3-(2-methoxyethoxy)-2-methyl-4-(methylsulfonyl)benzoyl]-1*H*-pyrazol-5-yl]oxy]ethyl methyl carbonate, in or on the commodity.

Commodity	Parts per million
Corn, field, forage	0.01
Corn, field, grain	0.01
Corn, field, stover	0.01
Corn, pop, grain	0.01
Corn, pop, stover	0.01
Corn, sweet, forage	0.01
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	0.01

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

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

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

[FR Doc. 2017–15717 Filed 7–26–17; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 91

Inspection and Certification

CFR Correction

■ In Title 46 of the Code of Federal Regulations, parts 90 to 139, revised as of October 1, 2016, on page 24, in § 91.40–3, in paragraph (a)(2), Table 91.40–3(a) is removed and Table 91.40–3(b) is reinstated to read as follows:

§ 91.40–3 Drydock examination, internal structural examination, cargo tank internal examination, and underwater survey intervals.

(a) * * *

(2) * * *