

2018 Opinion, affirm that the State revised the title V program provisions for judicial review as codified in NDAC section 33.1-15-14-6.8, effective as amended January 1, 2019. Therefore, North Dakota timely submitted revisions to address the deficiencies identified in our interim approval action within six months prior to the interim approval's expiration. Accordingly, the EPA finds that the North Dakota title V program fulfills all criteria for full final approval of the transfer. The EPA is now acting to fully approve the North Dakota title V program under 40 CFR part 70 and CAA section 502.

**V. Statutory and Executive Order Reviews**

Under the CAA, the Administrator is required to approve a state title V program submittal that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7661a(d); 40 CFR 70.1(c), 70.4(i). Thus, in reviewing title V program submittals, the EPA's role is to approve state choices, provided they meet the criteria of the CAA and the criteria, standards and procedures defined in 40 CFR part 70. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because Operating Permits Program approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104-4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this action is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 26, 2021. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

**List of Subjects in 40 CFR Part 70**

Environmental protection, Air pollution control, Intergovernmental relations, Title V.

Dated: February 11, 2021.

**Debra Thomas,**

*Acting Regional Administrator, Region 8.*

40 CFR part 70 is amended as follows:

**PART 70—STATE OPERATING PERMIT PROGRAMS**

■ 1. The authority citation for part 70 continues to read as follows:

**Authority:** 42 U.S.C. 7401, *et seq.*

■ 2. In appendix A to part 70 the entry for "North Dakota" is amended by revising paragraph (d) to read as follows:

**Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs**

\* \* \* \* \*

*North Dakota*

\* \* \* \* \*

(d) The State of North Dakota submitted on August 6, 2018, operating permit program revisions and a request to transfer authority to implement and enforce the operating permit program from the North Dakota Department of Health to the North Dakota Department of Environmental Quality. The recodified North Dakota title V operating permits program is codified in N.D. Admin. Code sections 33.1-15-14-06, 33.1-15-23-04, and 33.1-15-21. North Dakota also submitted on August 16, 2018 the, "Attorney General's Opinion Operating Permits Program," which was supplemented on December 12, 2018, with an "Addendum to August 16, 2018 Attorney General's Opinion Operating Permits Program," stating that the laws of the State provide adequate legal authority to carry out all aspects of the program. North Dakota also submitted revisions to state law effective January 1, 2019; full approval effective on April 26, 2021.

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2017-0233; FRL-10005-77]

**Tetraniliprole; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of tetraniliprole in or on multiple commodities that are identified and discussed later in this document. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective February 24, 2021. Objections and

requests for hearings must be received on or before April 26, 2021, 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-2017-0233, 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.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Marietta Echeverria, 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](mailto: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 Publishing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](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 FFDC 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-2017-0233 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 April 26, 2021. 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-2017-0233, 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 December 15, 2017 (82 FR 59604) (FRL-9970-50), EPA issued a document pursuant to FFDC section 408(d)(3), 21 U.S.C.

346a(d)(3), announcing the filing of a pesticide petition (PP 7F8558) by Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide, tetraniliprole in or on tuberous and corm vegetables, crop group 1C at 0.015 parts per million (ppm); potato, wet peel at 0.02 ppm; leafy vegetables, crop group 4-16 at 20 ppm; *Brassica* head and stem vegetables, crop group 5-16 at 1.5 ppm; fruiting vegetables, crop group 8-10 at 0.40 ppm; tomato paste at 1.5 ppm; citrus fruit, orange subgroup 10-10A at 0.50 ppm; citrus fruit, lemon/lime subgroup 10-10B at 0.80 ppm; citrus fruit, grapefruit subgroup 10-10C at 0.50 ppm; citrus oil at 4.0 ppm; pome fruit, crop group 11-10 at 0.40 ppm; stone fruit, crop group 12-12 at 1.0 ppm; plum, dried (prune) at 2.0 ppm; small fruit, vine climbing subgroup, except fuzzy kiwi, crop subgroup 13-07F at 1.5 ppm; tree nuts, crop group 14-12 at 0.03 ppm; almond hulls at 4.0 ppm; corn, field, grain at 0.015 ppm; corn, field, forage at 4.0 ppm; corn, field, stover at 15 ppm; corn, pop, grain at 0.015 ppm; corn, pop, stover at 15 ppm; corn, sweet, kernel plus cobs with husks removed at 0.01 ppm; corn, sweet, forage at 6.0 ppm; corn, sweet, stover at 20 ppm; cottonseed, crop group 20C at 0.40 ppm; cotton, gin byproducts at 30 ppm; soybean seed at 0.20 ppm; soybean hulls at 0.60 ppm; aspirated grain fractions at 45 ppm; soybean forage at 0.07 ppm; soybean hay at 0.20 ppm; alfalfa, forage and hay at 0.06 ppm; forage, fodder and straw of cereal grains, crop group 16, except field, pop and sweet corn at 0.10 ppm; foliage of legume vegetables, crop group 7, except soybeans at 0.03 ppm; milk at 0.06 ppm; fat of cattle, horses, sheep and goats at 0.30 ppm; muscle of cattle, horses, sheep and goats at 0.03 ppm; meat by-products of cattle, horses, sheep and goats at 0.30 ppm. That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has modified the levels at which tolerances are being established as well as some of the commodity definitions used. 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 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 tetraniliprole including exposure resulting from the tolerances established by this action. EPA’s assessment of exposures and risks associated with tetraniliprole 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 submitted animal toxicity studies on tetraniliprole demonstrate low toxicity, which is expected based on two factors. Tetraniliprole is an anthranilimide insecticide that targets the activation of insect ryanodine receptors, which leads to insect paralysis and death. In contrast, mammalian ryanodine receptors are substantially less sensitive (*i.e.*, 350 to >2,500 times less sensitive) to the effects of anthranilic diamides than insect ryanodine receptors. Moreover, available data indicate that tetraniliprole has limited absorption at the higher dose levels (>20 mg/kg),

which may contribute to the low toxicity seen in the animal testing.

In subchronic toxicity studies (28-day and 90-day) in rats and mice, no adverse effects were seen at dose levels ranging from approximately 600 to 1,228 mg/kg/day. In the subchronic studies (28-day and 90-day) in dogs, an increase in the incidence and frequency of salivation was found, but this finding did not show a dose related-response, was a common occurrence in dogs, and was not considered to be adverse.

No systemic or dermal toxicity was seen in a 28-day dermal toxicity study at 1,000 mg/kg/day; this finding was consistent with rather low dermal absorption as the DAF for humans was estimated to be approximately 9% (upper limit).

No adverse maternal or developmental effects were found at the limit dose (1,000 mg/kg/day) in the developmental toxicity studies in rats and rabbits. In the reproduction study, the offspring effect, slight decrease in pup weight near and above the limit dose, was found in the absence of any adverse parental effect. Because the potential increase in susceptibility occurred at the limit dose and on postnatal days (PND) 14 to 21 at which time the pups were exposed to the test material through both milk and food resulting in a higher compound intake, the Agency’s concern for the potential risk to infants and children is low. Tetraniliprole did not cause any effects on reproductive parameters.

The combined chronic/carcinogenicity study in rats showed a decrease in body weights, increased incidence of squamous cell hyperplasia in the cervix and vagina, and corpora lutea depletion in the ovary at the limit dose. In addition, a slight increase in the incidence of uterine tumor was observed at a dose slightly above the limit dose. No genotoxic potential was detected in the battery of genotoxicity studies. There were no treatment-related tumors seen in mice and no adverse effects were observed in male rats. The only adverse effects observed in female rats occurred at the limit dose, which was the only dose where pre-neoplastic or neoplastic lesions were observed. Furthermore, there is no concern for mutagenicity and none of the identified structurally-related compounds induced tumors in rats or mice. Based on the available data that indicates that the increased incidence of uterine tumor was seen in only one species (rat), one sex (female), and is only slightly outside of the historical control range, EPA has classified tetraniliprole as having “suggestive evidence of carcinogenic potential.”

Typically, for chemicals so classified, EPA recommends that a non-linear or RfD approach be used because the RfD would be protective for all toxicity, including carcinogenicity. However, in the case of tetraniliprole, EPA determined that the existing data do not support establishing toxicity endpoints and that a qualitative assessment is more appropriate for assessing tetraniliprole. This analysis is discussed more fully in Unit III.B. below. Similarly, because of the suggestive nature of the carcinogenicity effects and the fact that the only tumor effects are seen at doses above the limit dose, EPA has determined that a qualitative risk assessment would be appropriate in this case to account for all toxicity including carcinogenicity.

No acute and subchronic neurotoxicity studies were submitted for tetraniliprole because this requirement was waived. However, no evidence of neurotoxicity was seen in any of the other studies in the tetraniliprole database.

Specific information on the studies received and the nature of the adverse effects caused by tetraniliprole 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 titled “Tetraniliprole: New Active Ingredient, First Food Use. Human Health Risk Assessment for the Establishment of Permanent Tolerances on *Brassica* Head and Stem Vegetables, Corn (Field, Pop and Sweet), Citrus Fruit, Fruiting Vegetables, Leafy Vegetables, Pome Fruit, Small Fruit Vine Growing (except Fuzzy Kiwifruit) including Grape, Soybean, Stone Fruit, Tree Nuts, and Tuberos and Corm Vegetables, Plus Registration for Seed Treatment Uses on Corn (Field, Pop and Sweet), Use on Tobacco, and Use on Golf Course Turf, Sport Fields, and Sod Farms” on pages 33–69 in docket ID number EPA–HQ–OPP–2017–0233.

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

Based on a thorough analysis of the toxicology database of tetraniliprole, the Agency has determined that a qualitative risk assessment is more appropriate for tetraniliprole based on the following reasons:

- All the adverse effects (decrease in pup body weights and non-neoplastic uterine lesions, characterized by prolapsed vagina, squamous cell hyperplasia in the cervix) in rats were found at or slightly above the limit dose. Although informative for hazard characterization for purposes of risk assessment, a toxicity test dose at or above the limit dose of 1,000 mg/kg/day represents an exposure that is not expected to occur either daily or over an extended period of time and therefore is not relevant to exposure levels expected from the use of tetraniliprole.

- EPA determined that the body weight reduction effects seen in the 90-day and 1-year oral studies with the dog, (approximately 500 mg/kg/day) were not robust enough to be employed as a toxicity endpoint for risk assessment, due to the marginal nature of those effects and the fact that the rat (for which effects were seen at the 1,000 mg/kg/day, limit dose) was more sensitive, based on a human equivalent dose analysis.

- Available data indicate no potential inhalation risk of concern.

- Available data indicate no adverse systemic effects at the limit dose (1,000 mg/kg/day) for dermal exposure.

- Potential offspring susceptibility was not of concern as the decrease in pup weight seen in the reproduction study was marginal and occurred at or above the limit dose (890/1,032 mg/kg/day (males/females)). In addition, the decrease occurred on postnatal days (PND) 14 to 21, at which time the pups were likely to be exposed to the test

material through both milk and feed resulting in a much higher compound intake.

- Finally, taking into account expected exposures, EPA does not anticipate dietary exposure levels to occur daily, or over an extended period of time that would reach levels anywhere near that of the limit dose (1,000 mg/kg/day). An unrefined chronic dietary (food only) exposure estimate of tetraniliprole was calculated using tolerance-level residues for all crops and assuming 100% crop treated, as well as default processing factors. The screening estimate indicated that the highest exposure group is children 1 to 2 years old, with an estimated exposure of 0.027 mg/kg/day. To reach a dose of 1,000 mg/kg/day, an individual of this subpopulation would need to ingest 37,000 times the estimated dietary exposure. Further, the highest current application rate is approximately 0.18 lb ai/acre; and in order to yield residues that would lead to dietary exposures of 1,000 mg/kg/day, the application rate would have to be greater than 6,000 lb ai/acre. Consequently, EPA does not believe that an effect at or about the limit dose is relevant to human health risk assessment for tetraniliprole.

Taking all the foregoing into consideration, EPA has concluded that a qualitative analysis of tetraniliprole is appropriate.

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* There is potential for exposure to tetraniliprole via food and feed based on the proposed uses. However, no adverse effects were observed in the submitted toxicological studies for tetraniliprole regardless of the route of exposure. Thus, no quantitative dietary exposure assessments are needed for EPA to conclude with reasonable certainty that dietary exposures to tetraniliprole do not pose a significant human health risk.

2. *Dietary exposure from drinking water.* There are no residues of toxicological concern expected in drinking water from the use of tetraniliprole. Thus, no drinking water exposure assessments are needed for the Agency to conclude with reasonable certainty that drinking water exposures to tetraniliprole do not pose a significant human health risk.

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).

Based upon the proposed labels, EPA does not anticipate residential handler exposures. Tetraniliprole is being proposed for registration as a liquid formulation for use on golf course turf and sports fields that could result in residential post-application exposures. However, no adverse effects were observed in the submitted toxicological studies for tetraniliprole regardless of the route of exposure; therefore, a quantitative residential post-application exposure assessment was not conducted. Thus, no residential exposure assessments are needed for the Agency to conclude with reasonable certainty that residential exposures to tetraniliprole do not pose a significant human health risk.

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 tetraniliprole to share a common mechanism of toxicity with any other substances, and tetraniliprole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that tetraniliprole 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

#### D. Safety Factor for Infants and Children

Section 408(b)(2)(C) requires the application of an additional tenfold margin of safety to account for potential risks to infants and children, in the case of threshold effects. For tetraniliprole, EPA has not identified any toxicological endpoints of concern associated with any threshold effects and is conducting a qualitative assessment. That qualitative assessment does not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children. EPA has also evaluated the available data and concluded that there are no residual uncertainties concerning the

potential risks to infants and children that would impact its conclusions about threshold effects.

#### *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.

No adverse effects were observed in the submitted toxicological studies at doses relevant to human health pesticide risk assessment for tetraniliprole regardless of the route of exposure. Effects observed in the data base (e.g., decreased body weight) were both marginal, and only seen at doses not expected to occur daily or over an extended period. Based on a lack of toxicity at exposure levels expected from approved application rates and an expectation that aggregate exposures to residues of tetraniliprole will not reach the levels required to cause any adverse effects, 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 tetraniliprole residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

An adequate analytical method (01414) which uses high-performance liquid chromatography with tandem mass spectrometry (HPLC/MS/MS) to quantitate residues of tetraniliprole in various crops is available for enforcement. An adequate HPLC/MS/MS method, Method FV-002-A16-01, is proposed as the enforcement method for determination of residues of tetraniliprole in livestock matrices. The methods 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](mailto: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 any MRLs for tetraniliprole.

##### *C. Response to Comments*

Five comments were received to the notice of filing. Four of the comments were not related specifically to tetraniliprole or pesticides in general, dealing instead with “anti-environmental morons”, electric cars, and wind farms and their impact on birds and bats. The fifth comment was submitted on behalf of the Center for Biological Diversity that was primarily concerned about EPA’s consideration of the impacts of tetraniliprole on the environment, pollinators, and endangered species. None of these comments are relevant to the Agency’s evaluation of safety of the tetraniliprole tolerances under section 408 of the FFDCA, which requires the Agency to evaluate the potential harms to human health, not effects on the environment.

##### *D. Revisions to Petitioned-For Tolerances*

The Agency is establishing tolerances based on the Organization for Economic Cooperation and Development (OECD) rounding class practice and to reflect the preferred commodity definitions currently used by the Agency, which results in some variations between established tolerances and the tolerances the petitioner requested.

For field corn and popcorn, the available data support a tolerance of 0.01 ppm, slightly lower than the petitioned-for tolerance (0.015 ppm).

The petitioner requested tolerances on dried fruit (prune) and potato wet peel. The available data indicates that residues on those commodities do not concentrate so the new tolerances on stone fruit group 12-12 (1.0 ppm) and vegetable, tuberous and corm, subgroup 1C (0.015 ppm), respectively, are adequate to cover residues in these commodities.

For citrus fruits (subgroups 10-10A, 10B, and 10C), the Agency used the

OECD statistical calculation procedures to determine the appropriate tolerance value based on the available field trial residue data, which resulted in a higher tolerance value for each of these subgroups than what the petitioner requested.

Based on the highest average field trial (HAFT) (0.767 ppm) for lime and using a processing factor of 8.6, the Agency calculated that a tolerance of 7 ppm is necessary to cover residues in citrus oil. Similarly, based on the HAFT (0.136 ppm) for soybean seed and using a processing factor of 2.6, the Agency determined that a tolerance of 0.4 ppm is appropriate for soybean hulls.

Although the petitioner did not expressly identify certain tolerances as intended to cover indirect or inadvertent residues in rotational crops, because certain crops are only approved as crops that may be rotated into treated fields on the label, EPA is establishing tolerances for indirect or inadvertent residues for those commodities: alfalfa, forage at 0.015 ppm; alfalfa, hay at 0.06 ppm; cottonseed subgroup 20C at 0.4 ppm; cotton, gin byproducts at 30 ppm; grain, cereal, forage, fodder, and straw, group 16, except field corn, popcorn, and sweet corn at 0.1 ppm; and vegetable, foliage of legume, except soybean, subgroup 7A.

All the proposed tolerances for livestock commodities were revised based on calculation of the dietary burden.

#### **V. Conclusion**

Therefore, tolerances are established for residues of tetraniliprole, including its metabolites and degradates. Compliance with the tolerance levels is to be determined by measuring only tetraniliprole 1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-methyl-6-[(methylamino)carbonyl]phenyl]-3-[[5-(trifluoromethyl)-2H-tetrazol-2-yl]methyl]-1H-pyrazole-5-carboxamide, in or on almond, hulls at 4 ppm; cattle, fat at 0.04 ppm; cattle, meat at 0.02 ppm; cattle, meat byproducts at 0.3 ppm; corn, field, forage at 4 ppm; corn, field, grain at 0.01 ppm; corn, field, stover at 15 ppm; corn, pop, grain at 0.01 ppm; corn, pop, stover at 15 ppm; corn, sweet, forage at 6 ppm; corn, sweet, kernel plus cob with husks removed at 0.01 ppm; corn, sweet, stover at 20 ppm; fruit, citrus, group 10-10, oil at 7 ppm; fruit, pome, group 11-10 at 0.5 ppm; fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 1.5 ppm; fruit, stone, group 12-12 at 1 ppm; goat, fat at 0.04 ppm; goat, meat at 0.02 ppm; goat, meat byproducts at 0.3 ppm; grain, aspirated fractions at 50 ppm; grapefruit

subgroup 10–10C at 0.9 ppm; horse, fat at 0.04 ppm; horse, meat at 0.02 ppm; horse, meat byproducts at 0.3 ppm; lemon/lime subgroup 10–10B at 1.5 ppm; milk at 0.05 ppm; nut, tree, group 14–12 at 0.03 ppm; orange subgroup 10–10A at 1 ppm; sheep, fat at 0.04 ppm; sheep, meat at 0.02 ppm; sheep, meat byproducts at 0.3 ppm; soybean, forage 0.07 ppm; soybean, hay at 0.2 ppm; soybean, hulls at 0.4 ppm; soybean, seed at 0.2 ppm; tomato, paste at 1.5 ppm; vegetable, *brassica*, head and stem, group 5–16 at 1.5 ppm; vegetable, fruiting, group 8–10 at 0.4 ppm; vegetable, leafy, group 4–16 at 20 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.015 ppm.

Additionally, tolerances are established for inadvertent residues of tetraniliprole, including its metabolites and degradates. Compliance with the tolerance levels is to be determined by measuring only tetraniliprole 1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-methyl-6-[[methylamino]carbonyl]phenyl]-3-[[5-(trifluoromethyl)-2H-tetrazol-2-yl]methyl]-1H-pyrazole-5-carboxamide in or on alfalfa, forage at 0.015 ppm; alfalfa, hay at 0.06 ppm; cotton, gin byproducts at 30 ppm; cottonseed subgroup 20C at 0.4 ppm; grain, cereal, forage, fodder and straw, group 16, except field corn, popcorn, and sweet corn at 0.1 ppm; and vegetable, foliage of legume, except soybean, subgroup 7A at 0.03 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), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). 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: January 19, 2021.

**Edward Messina**,  
*Acting 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 § 180.709 to read as follows:

**§ 180.709 Tetraniliprole; tolerances for residues.**

(a) *General.* Tolerances are established for residues of tetraniliprole, including its metabolites and degradates, in or on the commodities in table 1 in this paragraph (a). Compliance with the tolerance levels specified in table 1 in this paragraph (a) is to be determined by measuring only tetraniliprole 1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-methyl-6-[[methylamino]carbonyl]phenyl]-3-[[5-(trifluoromethyl)-2H-tetrazol-2-yl]methyl]-1H-pyrazole-5-carboxamide.

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Almond, hulls .....	4
Cattle, fat .....	0.04
Cattle, meat .....	0.02
Cattle, meat byproducts .....	0.3
Corn, field, forage .....	4
Corn, field, grain .....	0.01
Corn, field, stover .....	15

TABLE 1 TO PARAGRAPH (a)—Continued

Commodity	Parts per million
Corn, pop, grain	0.01
Corn, pop, stover	15
Corn, sweet, forage	6
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	20
Fruit, citrus, group 10–10, oil	7
Fruit, pome, group 11–10	0.5
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F	1.5
Fruit, stone, group 12–12	1
Goat, fat	0.04
Goat, meat	0.02
Goat, meat byproducts	0.3
Grain, aspirated fractions	50
Grapefruit subgroup 10–10C	0.9
Horse, fat	0.04
Horse, meat	0.02
Horse, meat byproducts	0.3
Lemon/lime subgroup 10–10B	1.5
Milk	0.05
Nut, tree, group 14–12	0.03
Orange subgroup 10–10A	1
Sheep, fat	0.04
Sheep, meat	0.02
Sheep, meat byproducts	0.3
Soybean, forage	0.07
Soybean, hay	0.2
Soybean, hulls	0.4
Soybean, seed	0.2
Tomato, paste	1.5
Vegetable, brassica, head and stem, group 5–16	1.5
Vegetable, fruiting, group 8–10	0.4
Vegetable, leafy, group 4–16	20
Vegetable, tuberous and corm, subgroup 1C	0.015

(b)–(c) [Reserved]  
 (d) *Indirect or inadvertent residues.*  
 Tolerances are established for indirect or inadvertent residues of tetraniliprole, including its metabolites and

degradates, in or on the commodities in table 2 in this paragraph (d). Compliance with the tolerance levels specified in table 2 in this paragraph (d) is to be determined by measuring only

tetraniliprole 1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-methyl-6-[(methylamino)carbonyl]phenyl]-3-[[5-(trifluoromethyl)-2H-tetrazol-2-yl]methyl]-1H-pyrazole-5-carboxamide.

TABLE 2 TO PARAGRAPH (d)

Commodity	Parts per million
Alfalfa, forage	0.015
Alfalfa, hay	0.06
Cotton, gin byproducts	30
Cottonseed subgroup 20C	0.4
Grain, cereal, forage, fodder and straw, group 16, except field corn, popcorn and sweet corn	0.1
Vegetable, foliage of legume, except soybean, subgroup 7A	0.03

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**45 CFR Parts 160 and 164**

**Enforcement Discretion Regarding Online or Web-Based Scheduling Applications for the Scheduling of Individual Appointments for COVID–19 Vaccination During the COVID–19 Nationwide Public Health Emergency**

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notification of Enforcement Discretion.

**SUMMARY:** This Notification is to inform the public that the Department of Health and Human Services (HHS) is exercising its discretion in how it applies the Privacy, Security, and Breach Notification Rules promulgated under the Health Insurance Portability and Accountability Act of 1996 and the Health Information Technology for Economic and Clinical Health (HITECH) Act (“HIPAA Rules”). As a matter of