



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0653; FRL-10019-99]

Picarbutrazox; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of picarbutrazox in or on multiple commodities which are identified and discussed later in this document.

Nippon Soda Co., Ltd c/o Nisso America, 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: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2017-0653, 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.

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.

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

Under FFDCFA 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-2017-0653 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 (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-2017-0653, 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 March 6, 2018 (83 FR 9471) (FRL-9973-27), 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 7F8623) by Nippon Soda Co., Ltd c/o Nisso America, Inc., 88 Pine Street, 14th Floor, New York, NY 10005. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide picarbutrazox, 1,1-Dimethylethyl N-(6-(((Z)-((1-methyl-1H-tetrazol-5-yl)phenylmethylene) amino)oxy)methyl)-2-pyridinyl)carbamate, in or on corn, forage at 0.01 parts per million (ppm); corn, grain at 0.01 ppm; corn, stover at 0.01 ppm; corn, sweet, forage at 0.01 ppm; corn, sweet, kernel plus cob with husks removed at 0.01 ppm; corn, sweet, stover at 0.01 ppm; crop group 9, cucurbit vegetables at 0.20 ppm, crop subgroup 4-16A, leafy greens at 10 ppm; popcorn, grain at 0.01 ppm; soybean, forage at 0.01 ppm; soybean, hay at 0.01 ppm and soybean, seed at 0.01 ppm. That document referenced a summary of the petition prepared by Nippon Soda Co., Ltd c/o Nisso America, the registrant, which is available in the docket, <http://www.regulations.gov>. Nine comments were received on the notice of filing. However, they were not germane to this submission.

Based upon review of the data supporting the petition, EPA is establishing, in accordance with section 408(d)(4)(a)(i), tolerances that vary in some respects from what the petitioner requested. Also, EPA is not establishing tolerances for Crop Group 9, Cucurbit Vegetables and Crop Subgroup 4-16A, Leafy Greens, as the petitioner withdrew the request for those tolerances after submitting the petition. The Agency's underlying rationale for those variations are explained in Unit IV.C.

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 picarbutrazox including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with picarbutrazox 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 primary target organs for picarbutrazox are the liver and the thyroid gland across species and durations (except acute). The rat was the most sensitive species, followed by the mouse and the dog. Both the liver and the thyroid showed increases in organ weights and histopathological changes. In the liver, changes included hepatocyte hypertrophy, periportal vacuolation, cytoplasmic inclusions, and portal inflammatory cell infiltration. In the thyroid, there were increased incidences of thyroid hypertrophy which

corresponded with increased thyroid weights in both parental animals and neonates. Disruption of thyroid hormones was also observed across the guideline studies, for the short-term and long-term durations in rats (alterations in triiodothyronine (T3), thyroxine (T4), and thyroid stimulating hormone (TSH)). Thyroid follicular tumors were observed in rats following 2 years of oral exposure. No treatment-related effects were observed in mice following 78 weeks of exposure. There is no evidence of genotoxicity or mutagenicity in the picarbutrazox hazard database.

There is no evidence of increased prenatal susceptibility in rats or rabbits or postnatal susceptibility in rats. There were no adverse fetal or maternal effects in the available developmental toxicity studies in rats or rabbits. Both studies tested up to the limit dose. In the multi-generation reproductive study, adverse thyroid effects were observed in the parental animals and occurred at doses lower than offspring effects. There were no adverse reproductive effects up to the highest dose tested (46/63 mg/kg/day).

Subchronic studies in rats were performed for the numerous plant metabolites generated from parent picarbutrazox. All were less toxic than the parent molecule. No signs of neurotoxicity were observed in the acute neurotoxicity study up to the limit dose (2,000 mg/kg/day). No dermal toxicity was observed in rats up to the limit dose (1,000 mg/kg/day). Picarbutrazox is categorized as having low acute lethality through the oral, dermal, and inhalation routes. It is minimally irritating to the eye and is neither a dermal irritant nor sensitizer.

In accordance with the EPA's Final Guidelines for Carcinogen Risk Assessment (March 2005), the Agency classified picarbutrazox as "Suggestive Evidence of Carcinogenic Potential" based on an increase in the incidence of thyroid follicular cell tumors, driven by adenomas in male and female rats and combined thyroid follicular adenomas/carcinomas in male rats. There is no concern for genotoxicity or mutagenicity

and no treatment-related tumors were observed in mice. Based on its weight-of-evidence analysis, the Agency has determined that quantification of risk using a non-linear approach (i.e., chronic reference dose (cRfD)) will adequately account for all chronic toxicity, including potential carcinogenicity, that could result from exposure to picarbutrazox. The chronic reference dose is several times lower than the dose at which tumors were observed.

Specific information on the studies received and the nature of the adverse effects caused by picarbutrazox 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 document “Picarbutrazox. Human Health Risk Assessment in Support of a New Active Ingredient for Use on Corn and Soybean Seed and Turf”, dated December 18, 2020, hereinafter “Picarbutrazox Human Health Risk Assessment” in docket ID number EPA-HQ-OPP-2017-0653.

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-pesticide>.

A summary of the toxicological endpoints for picarbutrazox used for human risk assessment can be found on pages 19-20 in the Picarbutrazox Human Health Risk Assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to picarbutrazox, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from picarbutrazox 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. No such effects were identified in the toxicological studies for picarbutrazox; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA conducted an unrefined chronic dietary exposure assessment using tolerance-level residues, 100 percent crop treated (PCT), and default processing factors.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to picarbutrazox. Quantification of risk using a non-linear approach (i.e., cRfD) will adequately account for

all chronic toxicity, including potential carcinogenicity, that could result from exposure to picarbutrazox.

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

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for picarbutrazox in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of picarbutrazox. 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>.

Using the Pesticides in Water Calculator (PWC) ver. 1.52, EPA calculated the estimated drinking water concentrations (EDWCs) of picarbutrazox for chronic exposures in surface and ground water. The groundwater estimates were significantly lower. EPA used the modeled EDWC of 2.56 ppb directly in dietary exposure model to account for the contribution of picarbutrazox residues in drinking water for the chronic dietary risk assessment.

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). Picarbutrazox is currently proposed for turf uses that could result in residential exposures. EPA assessed residential exposure using the following assumptions: there is the potential for post-application exposure for adults and children following turf treatments made by professional applicators with picarbutrazox. A dermal exposure assessment was not

quantitatively conducted because a dermal POD was not selected. The quantitative exposure/risk assessment for residential post-application exposures is based only on incidental oral scenarios for children 1 to <2 years old from hand to mouth activities on treated turf. Post-application exposure and risk estimates indicate that the short-term incidental oral MOEs, ranging from 970 to 360,000, are not of concern (i.e., MOEs \geq 30). Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

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

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.* There is no evidence of increased prenatal susceptibility in rats or rabbits or postnatal susceptibility in rats, with no adverse effects observed in the developmental toxicity studies.

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 toxicity database for picarbutrazox is complete.
- ii. There is no indication that picarbutrazox is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. There is no evidence that picarbutrazox results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.
- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT, tolerance-level residues, default processing factors, and modeled drinking water estimates. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to picarbutrazox in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by picarbutrazox.

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). 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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, picarbutrazox is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to picarbutrazox from food and water will utilize <1% of the cPAD for all infants (<1 year old), the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of picarbutrazox is not expected.

3. *Short-term and Intermediate-term risk.* Short-term and intermediate-term aggregate exposure takes into account short-term or intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Picarbutrazox is currently proposed for uses that could result in short-term and intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term or intermediate-term residential exposures to picarbutrazox.

Using the exposure assumptions described in this unit for short-term and intermediate-term exposures, EPA has concluded the combined short-term or intermediate-term food, water, and residential exposures result in aggregate MOE of 950 for children 1 to <2 years old from dietary (food and drinking water) and incidental oral

exposure from hand-to-mouth activities from post-application exposure to turf applications. Because EPA's level of concern for picarbutrazox is an MOE of 30 or below, these MOEs are not of concern.

4. *Aggregate cancer risk for U.S. population.* As stated in Unit III.A., a separate cancer analysis was not conducted as the chronic assessment adequately accounts for all chronic toxicity, including potential carcinogenicity. Based on the lack of chronic risk, EPA concludes that aggregate exposure to picarbutrazox will not pose a cancer risk.

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 picarbutrazox residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography with tandem mass spectroscopy (LC/MS/MS) and high-performance liquid chromatography (HPLC/MS/MS)) is available to enforce the tolerance expression.

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 FFDC 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, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Picarbutrazox is a new active ingredient, and no maximum residue limits (MRLs) have yet been established by Codex.

C. Revisions to Petitioned-For Tolerances

The Agency is establishing tolerances for picarbutrazox using tolerance expression and commodity definitions that conform to current practices. Additionally, the Agency is establishing a tolerance on corn, pop, stover and corn, field, stover; the petitioner requested a tolerance on “corn, stover”, but the correct terminology is “corn, pop, stover” and “corn, field, stover”.

V. Conclusion

Therefore, tolerances are established for residues of picarbutrazox, 1,1-Dimethylethyl N-(6-(((Z)-((1-methyl-1H-tetrazol-5-yl) phenylmethylene) amino)oxy)methyl)-2-pyridinyl)carbamate, in or on corn, field, forage at 0.01 ppm; corn, field, grain at 0.01 ppm; corn, field, stover at 0.01 ppm; corn, pop, grain at 0.01 ppm; corn, pop, stover at 0.01 ppm; corn, sweet, forage at 0.01 ppm; corn, sweet, kernel plus cob with husks removed at 0.01 ppm; corn, sweet, stover at 0.01 ppm; soybean, forage at 0.01 ppm; soybean, hay at 0.01 ppm and soybean, seed 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), 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 tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This 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.

Edward Messina,

Acting Director, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Add § 180.718 to subpart C to read as follows:

§ 180.718 Picarbutrazox; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide picarbutrazox, including its metabolites and degradates, in or on the commodities to Table 1 of this section. Compliance with the tolerance levels specified in Table 1 is to be

determined by measuring only picarbutrazox (1,1-dimethylethyl *N*-[6-[[[(*Z*)-[(1-methyl-1*H*-tetrazol-5-yl)phenylmethylene]amino]oxy]methyl]-2-pyridinyl]carbamate in or on the commodity.

Table 1 to paragraph (a)

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
Soybean, forage	0.01
Soybean, hay	0.01
Soybean, seed	0.01

(b) – (d) [Reserved]

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