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[Pages 12829-12833]

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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.

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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 March 5, 2021. Objections and

requests for hearings must be received on or before May 4, 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-2017-0653, is available at [http://www.regulations.gov](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/

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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-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

May 4, 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-2017-0653, by one of

the following methods:

 Federal eRulemaking Portal: [http://www.regulations.gov](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](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).

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 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](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 >=30). Further information regarding EPA standard

assumptions and generic

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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 FFDCA

section 408(b)(4). The Codex Alimentarius is a joint United Nations

Food and Agriculture Organization/World Health Organization food

standards program,

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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.

 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

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

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

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

Sec. 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-1H-

tetrazol-5-yl)phenylmethylene]amino]oxy]methyl]-2-pyridinyl]carbamate

in or on the commodity.

 Table 1 to Paragraph (a)

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 Parts per

 Commodity million

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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

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 (b)-(d) [Reserved]

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