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[Rules and Regulations]

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[FR Doc No: 2021-23836]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2020-0391; FRL-8991-01-OCSPP]

Benzobicyclon; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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SUMMARY: This regulation increases a tolerance for residues of

benzobicyclon in or on rice grain and removes any restriction on

regional use. Gowan Company requested this tolerance increase under the

Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 2, 2021. Objections and

requests for hearings must be received on or before January 3, 2022,

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-2020-0391, 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 emergency, the EPA Docket Center (EPA/DC)

and Reading Room is closed to visitors with limited exceptions. The

staff continues to provide customer service via email, phone, and

webform. For the latest status information on EPA/DC services, docket

access, visit <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director,

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>.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), 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-2020-0391 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

January 3, 2022. 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-2020-0391, 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/where-send-comments-epa-dockets>.

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 April 22, 2021 (86 FR 21317) (FRL-10022-

59) 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

0F8831) by

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Gowan Company, P.O. Box 5569, Yuma, AZ 85364. The petition requested to

amend the tolerance in 40 CFR 180.693 for residues of the herbicide

benzobicyclon in or on rice to 0.15 parts per million (ppm). That

document referenced a summary of the petition prepared by Gowan, the

petitioner, which is available in the docket, [http://www.regulations.gov](http://www.regulations.gov/). There were no comments received in response to the

notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a

tolerance (the legal limit for a pesticide chemical residue in or on a

food) only if EPA determines that the tolerance is ``safe.'' Section

408(b)(2)(A)(ii) of FFDCA defines ``safe'' to mean that ``there is a

reasonable certainty that no harm will result from aggregate exposure

to the pesticide chemical residue, including all anticipated dietary

exposures and all other exposures for which there is reliable

information.'' This includes exposure through drinking water and in

residential settings but does not include occupational exposure.

Section 408(b)(2)(C) of FFDCA requires EPA to give special

consideration to exposure of infants and children to the pesticide

chemical residue in establishing a tolerance and to ``ensure that there

is a reasonable certainty that no harm will result to infants and

children from aggregate exposure to the pesticide chemical residue . .

.''

Consistent with FFDCA section 408(b)(2)(D), and the factors

specified therein, 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 benzobicyclon, including exposure resulting from

the tolerance established by this action. EPA's assessment of exposures

and risks associated with benzobicyclon follows.

In an effort to streamline its publications in the Federal

Register, EPA is not reprinting sections that repeat what has been

previously published for tolerance rulemaking of the same pesticide

chemical. Where scientific information concerning a particular chemical

remains unchanged, the content of those sections would not vary between

tolerance rulemaking, and EPA considers referral back to those sections

as sufficient to provide an explanation of the information EPA

considered in making its safety determination for the new rulemaking.

EPA has previously published a tolerance rulemaking for

benzobicyclon, in which EPA concluded, based on the available

information, that there is a reasonable certainty that no harm would

result from aggregate exposure to benzobicyclon and established a

tolerance for residues of that chemical. See the benzobicyclon

tolerance rulemaking published in the Federal Register of April 25,

2017 (82 FR 18995) (FRL-9961-02). EPA is incorporating previously

published sections from that rulemaking that remain unchanged, as

described further in this rulemaking.

Toxicological profile. There have been updates to the toxicological

profile from the previous assessment. The parent compound,

benzobicyclon, is a pro-pesticide, which means it requires hydrolysis

of the thiophenyl group to generate the anticipated pesticidal active

moiety, metabolite B (also referred to as 1315P-070). The toxicological

database is considered complete for risk assessment purposes for both

the parent, benzobicyclon, and metabolite B. The enzyme 4-

hydroxyphenylpyruvate dioxygenase (HPPD) is involved in the catabolism

of tyrosine, an essential amino acid for mammals. While benzobicyclon

may be referred to as an HPPD inhibitor, typical HPPD-inhibiting

effects are not observed in its toxicological database. However,

metabolite B does exhibit HPPD-inhibiting effects and is therefore

considered an HPPD-inhibiting chemical. The initiating event in the

mode-of-action (MOA)/adverse-outcome pathway (AOP) for HPPD-inhibiting

chemicals, including metabolite B, involves binding of the chemical to

the HPPD enzyme causing complete or virtually complete enzyme

inhibition, which leads to a build-up of systemic tyrosine levels

(tyrosinemia) and a spectrum of tyrosine-mediated effects. In

laboratory animals, these have been identified as ocular and skeletal

developmental effects. Species differences exist in laboratory animals

related to the ability of a species to clear excess tyrosine from its

system, which can impact its sensitivity to HPPD-inhibiting chemicals

and its relevance for human health risk assessment. In this risk

assessment, endpoints were selected for both benzobicyclon and

metabolite B. Taking into account species differences, endpoints for

human health risk assessment of HPPD inhibitors, including metabolite

B, were selected from studies available in mice and dogs. Studies from

other HPPD inhibitors were used for bridging to metabolite B as needed.

Since benzobicyclon does not exhibit HPPD-inhibiting properties,

endpoints were selected from the most sensitive species and effects in

its database (not restricted to mice and dogs).

Benzobicyclon: An acute dietary endpoint was not selected for

benzobicyclon, as there were no effects attributable to a single dose

identified in the database. The chronic dietary, incidental oral, and

inhalation endpoints were based on increased incidence of hydropic

degeneration (basophilic cells) in the pituitary observed in the two-

generation reproduction toxicity study in rats. A dermal endpoint was

not selected since no hazard was identified in the dermal toxicity

study and there was no evidence of increased quantitative

susceptibility in the database. Benzobicyclon is classified as ``Not

Likely to be Carcinogenic to Humans'' based on the absence of

treatment-related tumors in two adequate rodent carcinogenicity

studies.

Metabolite B: There were no effects attributable to a single dose

available in the metabolite B database or in studies from other HPPD

inhibitors; therefore, an acute dietary endpoint was not selected for

metabolite B. The chronic dietary endpoint is based on gallstones,

eosinophilic cytoplasmic alteration, subepithelial mixed cell

infiltrate, and dilatation in/of the gallbladder; hepatocellular

vacuolation, hepatocellular hypertrophy, and increased liver weight in

males and females; and papillary mineralization of the kidney and

changes in hematological parameters indicative of anemia in females

observed in the chronic/carcinogenicity study in mice from another HPPD

chemical available for bridging (tembotrione). Since the only

anticipated exposure is through drinking water, no additional points of

departure (PODs) were selected for metabolite B. There are no

carcinogenicity studies available for metabolite B; however,

carcinogenicity studies are available for bridging for all of the other

currently registered HPPD inhibitors. Overall, potential

carcinogenicity is not a concern for the HPPD inhibitors, and the

chronic dietary endpoint and POD for metabolite B is considered

protective of any potential carcinogenicity.

Additional information is available in the docket for this action

in the document titled ``Benzobicyclon: Section 3 Risk Assessment for

Proposed New Formulation, Increase to the Established Tolerance, and

National Use Expansion on Rice'' (hereafter, the ``Benzobicyclon Human

Health Risk Assessment'').

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Toxicological points of departure/Levels of concern. For a summary

of the Toxicological Points of Departure/Levels of Concern for

benzobicyclon and metabolite B used for human health risk assessment,

please reference section 4.6.3 on pages 25-27 of the ``Benzobicyclon

Human Health Risk Assessment''.

Exposure assessment. EPA's dietary exposure assessments have been

updated to include the additional exposure from the tolerance increase

on rice grain and national use expansion.

No effects attributable to a single dose were observed for

benzobicyclon or metabolite B; therefore, acute dietary exposure

assessments were not conducted.

Based on the toxicological effects of benzobicyclon and metabolite

B, separate chronic dietary exposure and risk assessments were

conducted. The assessments were conducted using Dietary Exposure

Evaluation Model software with the Food Commodity Intake Database

(DEEM-FCID) Version 3.16, which uses food consumption data from the

U.S. Department of Agriculture's (USDA's) National Health and Nutrition

Examination Survey, What We Eat in America, (NHANES/WWEIA). This

dietary survey was conducted from 2003 to 2008.

The benzobicyclon chronic dietary exposure assessment assumed

tolerance-level residues for rice, 100 percent crop treated (PCT), and

a modeled estimated drinking water concentration (EDWC) of 0.199 parts

per billion (ppb). The DEEM default processing factor of 1.25 was used

for both rice flour and rice bran.

There is no anticipated exposure in food to metabolite B. As

metabolite B is only a residue of concern in drinking water, the

chronic dietary exposure assessment was conducted for drinking water

only. The chronic analysis used a modeled EDWC of 4.27 ppb and assumed

100 PCT.

There are no residential (non-occupational) exposures associated

with benzobicyclon or metabolite B.

Cumulative exposure. The Agency is required to consider the

cumulative risks of chemicals sharing a common mechanism of toxicity.

The Agency has determined that the (p-hydroxyphenyl-pyruvate

dioxygenase) HPPD inhibitors share a common mechanism of toxicity as

discussed in the document titled ``HPPD Inhibiting Herbicides: State of

the Science,'' which is available in the docket for this action. As

explained in that document, the members of this group of chemicals

share the ability to bind to and inhibit the HPPD enzyme resulting in

elevated systemic tyrosine levels and common apical outcomes that are

mediated by tyrosine, including ocular and developmental effects. In

2021, after establishing a common mechanism grouping for the HPPD

inhibitors, the Agency conducted the ``P-Hydroxyphenyl-Pyruvate

Dioxygenase (HPPD) Inhibitors Cumulative Risk Assessment:

Benzobicyclon, Bicyclopyrone, Isoxaflutole, Mesotrione, Pyrasulfotole,

Tembotrione, Tolpyralate, and Topramezone,'' which is available in the

docket for the action, and concluded that cumulative exposures to HPPD

inhibitors (based on proposed and registered pesticidal uses at the

time the assessment was conducted) did not present risks of concern.

Safety Factor (SF) for Infants and Children. The Food Quality

Protection Act (FQPA) section has been updated since the last

assessment. EPA has determined that the required FQPA SF of 10X for the

protection of infants and children be reduced to 1X for all exposure

scenarios for benzobicyclon (parent). For metabolite B, since the

chronic dietary endpoint is based on a study with no No-Observed-

Adverse-Effect Level (NOAEL), a 10X FQPA SF/Uncertainty Factor

(UFL) has been retained for extrapolation from a Lowest-

Observed-Adverse-Effect Level (LOAEL) to a NOAEL.

Completeness of the Toxicology Database: The existing toxicological

database for benzobicyclon is adequate for FQPA evaluation.

Developmental and two-generation reproduction studies in rats are

available for benzobicyclon. However, the active moiety of

benzobicyclon, metabolite B, has been shown to be more toxic than the

parent compound. Therefore, studies were conducted with metabolite B,

including a developmental toxicity study in mice. Additionally, 2-

generation reproduction toxicity studies are available from other HPPD

inhibitors for bridging.

Evidence of Neurotoxicity: There was no neurotoxicity observed

throughout the database for benzobicyclon or metabolite B. The

subchronic neurotoxicity study with benzobicyclon tested up to 1,290

mg/kg with no adverse effects observed, nor was there evidence of

neurotoxicity in any of the guideline studies in the databases for

either chemical.

Evidence of Sensitivity/Susceptibility in the Developing or Young

Animal: For benzobicyclon, there was no increased qualitative or

quantitative susceptibility observed in the two-generation reproduction

or developmental toxicity studies in rats. A developmental study in

rabbits was submitted but was considered unacceptable and subsequently

waived by EPA.

For metabolite B, a developmental toxicity study in mice did not

show any increased qualitative or quantitative susceptibility. A 2-

generation reproduction study is not available for metabolite B;

however, there are 2-generation reproduction studies from other HPPDs

inhibitors that can be used for bridging. In one of the 2-generation

studies in mice for another HPPD inhibitor (mesotrione), quantitative

susceptibility was observed in offspring. However, concern is low

because there are clear NOAEL/LOAEL values for the observed effects,

the offspring LOAEL of 300 mg/kg/day from the mesotrione 2-generation

reproduction toxicity study was set conservatively based on a low

incidence of opaque/cloudy eyes, and the selected endpoints used in

this risk assessment are protective of any potential sensitivity

observed in mice.

Residual Uncertainty in the Exposure Database: The exposure

databases are complete or are estimated based on data that reasonably

account for potential exposures. There are no registered or proposed

residential uses and/or commercial uses at residential sites for

benzobicyclon at this time. Therefore, a residential exposure

assessment is not required. The dietary exposure assessments (food and

drinking water) are considered to be conservative estimates of

exposure. Tolerance-level residues for rice and 100 PCT were assumed

for the food exposure assessment. Drinking water exposure estimates

(for both benzobicyclon and metabolite B) are based on conservative

models assuming maximum use rates and are not expected to underestimate

the exposure. The Agency is confident that the assessments do not

underestimate risk from dietary exposure to benzobicyclon or metabolite

B.

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 population-adjusted dose

(aPAD) and the chronic population-adjusted dose (cPAD). Short-,

intermediate-, and chronic term risks are evaluated by comparing the

estimated aggregate food, water, and residential exposure to the

appropriate points of departure to ensure that an adequate margin of

exposure (MOE) exists. For linear cancer risks, EPA calculates the

lifetime probability of acquiring cancer given the estimated aggregate

exposure.

There are no acute dietary endpoints for benzobicyclon or

metabolite B; therefore, an acute risk assessment is

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unnecessary. Chronic dietary risks are below the Agency's level of

concern of 100% of the cPAD for both benzobicyclon and metabolite B. It

is less than 1% of the cPAD for benzobicyclon for all population

subgroups and 5.8% of the cPAD for metabolite B for all infants less

than 1-year old, the population subgroup with the highest exposure

estimate for both benzobicyclon and metabolite B.

As noted earlier, there are no residential uses associated with

benzobicyclon. Because there is no short- or intermediate-term

residential exposure and chronic dietary exposure has been assessed

under the appropriately protective cPAD, EPA relies on the chronic

dietary risk assessment for evaluating short- and intermediate-term

risk for benzobicyclon and metabolite B.

Based on the lack of evidence of carcinogenicity in two adequate

rodent carcinogenicity studies, benzobicyclon is not expected to pose a

cancer risk to humans. For metabolite B, potential carcinogenicity is

not a concern for the HPPD inhibitors and the chronic dietary endpoint

and POD for metabolite B is considered protective of any potential

carcinogenicity.

Therefore, based on the risk assessments and information described

above, EPA concludes there is reasonable certainty that no harm will

result to the general population, or to infants and children, from

aggregate exposure to benzobicyclon or metabolite B residues. More

detailed information can be found at [http://www.regulations.gov](http://www.regulations.gov/) in the

Benzobicyclon Human Health Risk Assessment in docket ID number EPA-HQ-

OPP-2020-0391.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method,

see Unit IV.A. of the April 25, 2017 rulemaking (82 FR 18995) (FRL-

9961-02).

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 has not established an MRL for residues of benzobicyclon

in or on rice grain.

V. Conclusion

Therefore, the tolerance for residues of benzobicyclon on rice,

grain is increased from 0.01 ppm to 0.15 ppm and is no longer a

tolerance with regional restrictions.

VI. Statutory and Executive Order Reviews

This action increases a tolerance 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 to Executive Order 13045,

entitled ``Protection of Children from Environmental Health Risks and

Safety Risks'' (62 FR 19885, April 23, 1997). This action does not

contain any information collections subject to OMB approval under the

Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.), nor does it

require any special considerations under Executive Order 12898,

entitled ``Federal Actions to Address Environmental Justice in Minority

Populations and Low-Income Populations'' (59 FR 7629, February 16,

1994).

Since tolerances and exemptions that are established on the basis

of a petition under FFDCA section 408(d), such as the tolerance in this

final rule, do not require the issuance of a proposed rule, the

requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et

seq.), do not apply.

This action directly regulates growers, food processors, food

handlers, and food retailers, not States or Tribes, nor does this

action alter the relationships or distribution of power and

responsibilities established by Congress in the preemption provisions

of FFDCA section 408(n)(4). As such, the Agency has determined that

this action will not have a substantial direct effect on States or

Tribal Governments, on the relationship between the National Government

and the States or Tribal Governments, or on the distribution of power

and responsibilities among the various levels of government or between

the Federal Government and Indian Tribes. Thus, the Agency has

determined that Executive Order 13132, entitled ``Federalism'' (64 FR

43255, August 10, 1999) and Executive Order 13175, entitled

``Consultation and Coordination with Indian Tribal Governments'' (65 FR

67249, November 9, 2000) do not apply to this action. In addition, this

action does not impose any enforceable duty or contain any unfunded

mandate as described under Title II of the Unfunded Mandates Reform Act

(UMRA) (2 U.S.C. 1501 et seq.).

This action does not involve any technical standards that would

require Agency consideration of voluntary consensus standards pursuant

to section 12(d) of the National Technology Transfer and Advancement

Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.),

EPA will submit a report containing this rule and other required

information to the U.S. Senate, the U.S. House of Representatives, and

the Comptroller General of the United States prior to publication of

the rule in the Federal Register. This action is not a ``major rule''

as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure,

Agricultural commodities, Pesticides, and pests, Reporting and

recordkeeping requirements.

Dated: October 27, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending

40 CFR chapter 1 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. Revise Sec. 180.693 to read as follows:

Sec. 180.693 Benzobicyclon; tolerances for residues.

(a) General. Tolerances are established for residues of the

herbicide benzobicyclon, including its metabolites and degradates, in

or on the commodity in the table below. Compliance with the tolerance

level specified below is to be determined by measuring only

benzobicyclon, 3-[2-chloro-4-(methylsulfonyl)benzoyl]-4-

(phenylthio)bicyclo-[3.2.1]oct-3-en-2-one), in or on the following raw

agricultural commodity:

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Table 1 to Sec. 180.693(a)

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Parts per

Commodity million

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Rice, grain............................................. 0.15

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(b)-(d) [Reserved]

[FR Doc. 2021-23836 Filed 11-1-21; 8:45 am]

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