ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0492; FRL-10018-86]

Fluxametamide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluxametamide in or on tea, dried and tea, instant. Nissan Chemical Corporation 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-2019-0492, 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 http://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 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-2019-0492 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-2019-0492, 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 February 11, 2020 (85 FR 7708) (FRL-10005-02), 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 9E8757) by Nissan Chemical Corporation, 5–1, Nihonbashi 2-Chome Chuo-Ku, Tokyo 101–6119 Japan, c/o Lewis and Harrison, 2461 South Clark Street, Suite 710, Arlington, VA 22202. The petition requested that 40 CFR part 180 be amended by establishing
tolerances for residues of the insecticide fluxametamide, including its metabolites and degradates, in or on tea at 5 parts per million (ppm). That document referenced a summary of the petition prepared by Nissan Chemical Corporation c/o Lewis and Harrison, the registrant, which is available in the docket, http://www.regulations.gov. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the commodity definition and is establishing a tolerance for tea, dried and tea, instant. The reasons for these changes 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 fluxametamide including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluxametamide 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.

Fluxametamide belongs to a class of compounds called isoxazolines, which are potent inhibitors of \( \gamma \)-aminobutyric acid (GABA)-, glutamate-, and glycine-gated chloride channels in insects. However, this pesticidal mode of action (MOA) does not seem to be operative in mammals as neurotoxicity was not found in either the acute or subchronic neurotoxicity studies at the limit dose.

The available studies show different organs can be affected. For the dietary toxicity studies in rats (neurotoxicity study, chronic/carcinogenicity, and reproductive toxicity studies), a common effect on the gastrointestinal (GI) tract was observed. The effects consisted of gross pathology (an increase incidence of abnormally pale color duodenum and jejunum) and histopathology (increased incidence of enterocyte epithelial vacuolation of the jejunum). Most of the effects seen in the subchronic neurotoxicity study were reproduced in the combined chronic and carcinogenicity study with increased severity and at lower dose level. In addition, consistent adverse effects were found in the lung (aggregate alveolar macrophages and cholesterol cleft) and liver (centrilobular hepatocellular vacuolation and periportal hepatocellular vacuolation). These adverse effects were present at a dose as low as 9 mg/kg/day in the carcinogenicity study.

Fluxametamide is classified as having “suggestive evidence of carcinogenic potential” based on thyroid tumors in male rats and liver tumors in male mice. The reasons for this classification are (1) both tumor types are driven by adenomas, (2) these increased tumor incidences are seen at the highest doses tested (877 mg/kg/day for male mice and 899 mg/kg/day for male rats); these doses are approaching the limit dose (1000 mg/kg/day) for a carcinogenicity study, (3) there is no hyperplasia of the liver in either male or female mice, (4) no increase in treatment-related tumors has been observed in female mice or female rats, and
(5) no genotoxicity is observed in the required battery of mutagenic studies. Due to the lack of genotoxicity and the fact that the tumors are seen only at doses more than 100-fold above the chronic reference dose, EPA has determined that a non-linear approach relying on the chronic reference dose (RfD) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to fluxametamide.

The *in-utero* and perinatal treatment with fluxametamide in rats resulted in toxicity and increased quantitative susceptibility in developing animals. In the 2-generation reproduction study, fluxametamide produced no parental effect at the highest dose tested (19 mg/kg/day), while at the same dose level produced offspring effect which consisted of the observation that the pups had distended abdomens and affected pups had to be sacrificed for humane reason.

The dermal toxicity study did not show systemic toxicity at the limit dose (1000 mg/kg/day).

Specific information on the studies received and the nature of the adverse effects caused by fluxametamide, 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 titled “Fluxametamide: Human Health Risk Assessment to Support the Establishment of a Tolerance without U.S. Registration in/on Tea. First Food Use” hereinafter “Fluxametamide Human Health Risk Assessment” at pages 16-22 in docket ID number EPA-HQ-OPP-2019-0492.

**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 fluxametamide used for human risk assessment can be found in the Fluxametamide Human Health Risk Assessment.

C. Exposure Assessment

1. Dietary exposure from food and feed uses. In evaluating dietary exposure to fluxametamide, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from fluxametamide 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 fluxametamide; therefore, a quantitative acute dietary exposure assessment is unnecessary.

   ii. Chronic exposure. In conducting the chronic dietary exposure assessment EPA used 2003-2008 food consumption data from the United States Department of Agriculture’s (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance-level residues of fluxametamide on tea and 100% crop treated.

   iii. Cancer. EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach will adequately account for all chronic toxicity,
including carcinogenicity, that could result from exposure to fluxametimide. A separate cancer dietary exposure and risk assessment is not required. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., chronic exposure.

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

2. Dietary exposure from drinking water. EPA assumes that there is no exposure through drinking water because fluxametamide is not registered for use in the United States. Because residues are not expected in drinking water, dietary risk estimates include exposures from food only.

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). Fluxametamide is not being proposed to be registered for any specific use patterns that would result in residential exposure.

4. Cumulative effects from substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to fluxametamide and any other substances and fluxametamide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that fluxametamide has a common mechanism of toxicity with other substances.

D. Safety Factor for Infants and Children
1. In general. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. Prenatal and postnatal sensitivity. There is an increase in quantitative susceptibility in two-generation reproductive toxicity study in rats. In this study, parental animals showed no adverse effects at 19 mg/kg/day (highest dose tested, HDT), whereas some pups had to be euthanized due to distended abdomen at the same dose. However, the concern is low because there was a clear NOAEL for the offspring effect (6 mg/kg/day) and the POD selected for chronic dietary exposure assessment (1 mg/kg/day) is protective of the offspring effects seen in the reproductive toxicity study.

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 fluxametamide is complete.

   ii. There is no indication that fluxametamide is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

   iii. There is evidence of an increase in quantitative susceptibility in the 2-generation reproductive toxicity study in rats. In this study, parental animals showed no adverse effects at 19 mg/kg/day highest dose tested, (HDT), whereas some pups had to be euthanized due to distended abdomen at the same dose. However, the concern is low because there was a clear NOAEL for the offspring effect (6 mg/kg/day) and the POD selected for chronic dietary exposure assessment (1 mg/kg/day) is protective of the offspring effects seen in the reproductive toxicity
study. The selected points of departure for risk assessment are protective of the quantitative increase in susceptibility seen in the rat reproductive toxicity study, for which a clear NOAEL and LOAEL are established.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. These assessments will not underestimate the exposure and risks posed by fluxametamide.

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.

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, fluxametamide 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 fluxametamide from food only will utilize less than 1% of the cPAD for all population subgroups. There are no residential uses for fluxametamide.

3. Short-and intermediate-term risk. Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because fluxametamide is not registered in the United States, the only exposures will be dietary, from residues in or on imported tea; therefore, no short-term or intermediate-term residential exposure is expected. Because there is no short- or intermediate-term residential exposure and chronic dietary
exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for fluxametamide.

4. **Aggregate cancer risk for U.S. population.** As stated in Unit III.A., EPA has concluded that the chronic reference dose (RfD) will adequately account for all repeated exposure/chronic toxicity, including carcinogenicity, which could result from exposure to fluxametamide. Based on the lack of chronic risk at regulated levels of exposure, EPA concludes that exposure to fluxametamide will not pose an aggregate 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 fluxametamide residues.

**IV. Other Considerations**

**A. Analytical Enforcement Methodology**

Adequate enforcement methodology (high-performance liquid chromatography method with tandem mass spectrometry detection (LC/MS/MS), Method NCI-2012-101/NCI-2013-017) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: residuemethods@epa.gov.

**B. International Residue Limits**

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an
international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established an MRL for fluxametamide.

C. Revisions to Petitioned-For Tolerances

The petition requested a tolerance for residues of fluxametamide in or on tea. Since dried tea is the commodity that enters commerce, EPA is establishing the tolerance for the processed commodity tea, dried rather than tea, plucked leaves. EPA is also establishing a tolerance for tea, instant, which is another processed commodity of tea, plucked leaves, and EPA has determined that the same tolerance of 5 ppm is appropriate for instant tea.

V. Conclusion

Therefore, tolerances are established for residues of fluxametamide, including its metabolites and degradates, in or on tea, dried at 5 ppm and tea, instant at 5 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:


2. Add § 180.715 to subpart C to read as follows:

§ 180.715 Fluxametamide; tolerances for residues.

   (a) General. Tolerances are established for residues of the insecticide fluxametamide, 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 residues of fluxametamide, 4-[5-(3,5-dichlorophenyl)-4,5-dihydro-5-(trifluoromethyl)-3-isoxazolyl]-N-[(methoxyamino)methylene]-2-methylbenzamide in or on the commodities:

   Table 1 to Paragraph (a)

<table>
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<tr>
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<td>5</td>
</tr>
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</table>

(b) - (d) [Reserved]

[FR Doc. 2021-03179 Filed: 2/16/2021 8:45 am; Publication Date: 2/17/2021]