the regulatory change effective in the CFR.

Issued: December 14, 2020.

Kimberly D. Bose,

Secretary.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0053; FRL–10016–42]

Broflanilide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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

DATES: This regulation is effective December 17, 2020. Objections and requests for hearings must be received on or before February 16, 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–2018–0053, 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 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–2018–0053 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 February 16, 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–2018–0053, 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 July 24, 2018 (83 FR 34968) (FRL–9980–31), 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 7F8646) by BASF Corporation, 26 Davis Dr., P.O. Box 13528, Research Triangle Park, NC 27709. The petition requested to establish tolerances in 40 CFR part 180 for residues of the insecticide, broflanilide, including its metabolites and degradates, in or on grain, cereal, except rice, group 15; amaranth grain; quinoa, grain; spelt, grain; canihua, grain; chia, grain; cram-cram, grain; huauzontle, grain; teff, grain; and corn, sweet, kernel plus cob with husks removed at 0.01 parts per million (ppm); and vegetables, tuberous and corm, subgroup 1C at 0.04 ppm. Tolerances were also requested for cattle, meat; goat, meat; horse, meat; sheep, meat at 0.01 ppm; milk, fat and poultry, fat at 0.02 ppm; and cattle, fat; sheep, fat; and goat, fat at 0.05 ppm. Additionally, tolerances were requested for grain, cereal, forage, fodder and straw, group 16, except rice; quinoa, hay; teff, hay; and corn, sweet, stover; corn, sweet, forage at 0.01 ppm; corn, field, milled products at 0.015 ppm; and potato, wet peel at 0.1 ppm. In addition, BASF proposed to establish a tolerance of 0.01 ppm for residues of broflanilide in or on all food items in food handling establishments where food and food products are held, processed, prepared and/or served. That document referenced a summary of the petition prepared by BASF, the registrant, which

is available in the docket, *http://www.regulations.gov.* A comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

In the **Federal Register** of June 24, 2020 (85 FR 37806) (FRL–10010–82), EPA issued a second notice amending the previous NOF published in the **Federal Register** on July 24, 2018, by announcing additional commodities for which the petitioner was seeking tolerances. BASF requested to establish a tolerance in 40 CFR part 180 for residues of the insecticide, broflanilide, including its metabolites and degradates, in or on amaranth, stover; quinoa, forage; quinoa, straw; teff, forage; and teff, straw at 0.01 ppm. (EPA's notice inadvertently listed amaranth, grain, which had already been identified in the July 2018 notice, instead of amaranth, stover, but BASF's petition included a request for amaranth, stover.) BASF also requested tolerances for food items (animal origin) for hog, meat; poultry, meat; eggs; cattle, meat byproducts; goat, meat byproducts; hog, meat byproducts; horse, meat byproducts; poultry, meat byproducts; sheep, meat byproducts; hog, fat; and horse, fat at 0.02 ppm. No comments were received in response to this notice.

Based upon review of the data supporting the petition, EPA is establishing some tolerances at different levels than were petitioned for. The reason for these changes is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for broflanilide including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with broflanilide 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 target organs of broflanilide toxicity are the adrenal glands (rats, mice, and dogs) and ovaries (rats and mice). Adrenal effects include increased adrenal weights, increased incidence of adrenal cortex vacuolation, and adrenal cortex hypertrophy in both sexes. Ovarian effects include increased incidence of ovarian interstitial gland vacuolation.

There were no parental or developmental effects reported up to the limit dose tested (1000 mg/kg/day) in the developmental studies in rats and rabbits. In the reproduction study in rats, increased adrenal weights with corroborative histopathological findings (increased vacuolation and diffuse hypertrophy in the adrenal gland cortex) were observed in parental rats of both sexes and generations. Offspring showed decreased pup weights in F1 and F2 pups, which occurred at a higher dose level than the observed adverse effects in parental rats. Reproductive parameters showed increased ovarian weights and increased incidence of vacuolation of interstitial gland in the ovary at a higher dose level than the adverse effects in parental rats. There were no effects on fertility or other measured reproductive parameters.

There is no evidence of neurotoxicity in acute or subchronic neurotoxicity studies and broflanilide is not an immunotoxic chemical. In the subchronic inhalation study, there was an increase in absolute and relative adrenal weight and increased incidence of adrenal vacuolation in both sexes and increased incidence of ovarian vacuolation.

In the chronic toxicity/carcinogenicity study in rats, there were treatment-related increases in Leydig cell adenomas in male rats, and in luteomas and granulosa cell tumors in the ovaries, as well as in uterine adenocarcinomas, and adrenal cortex carcinomas in female rats. No treatment-related increase in tumor incidences was observed in mice. All mutagenicity studies were negative for both the parent and major metabolites (DM–8007, S(PFP–OH)-8007, DC–8007, DC–DM–8007, MFBA, AB-oxa, S9Br-OH)-8007).

Specific information on the studies received and the nature of the adverse effects caused by broflanilide as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document titled ''Broflanilide: New Active Ingredient Human Health Risk Assessment'' (hereinafter ''Broflanilide Human Health Risk Assessment'') on pages 42–58 in docket ID number EPA–HQ–OPP–2018–0053.

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 broflanilide used for human risk assessment can be found in the Broflanilide Human Health Risk Assessment.

C. Exposure Assessment

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

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the 2003–2008 food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, for all commodities in the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID), EPA used tolerance-level residues, highest average field trials (HAFT) residue values, anticipated residues, 100 percent crop treated (PCT), and default processing factors resulting from agricultural uses, and the food handling establishment (FHE) values (½ FHE LOQ tolerance and 4.65% FHE treatment).

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that broflanilide should be classified as ''Likely to be Carcinogenic to Humans'' and a linear approach has been used to quantify cancer risk. The cancer risk assessment used the same assumptions as the chronic assessment.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- *Condition a:* The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- *Condition b:* The exposure estimate does not underestimate exposure for any significant subpopulation group.
- *Condition c:* Data are available on pesticide use and food consumption in a particular area and the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The chronic and cancer assessments assumed 100 PCT for agricultural uses and the treatment value of 4.65% for FHE uses.

EPA estimates the percent of commodities treated in Food Handling Establishments (FHE) for new uses of active ingredients based on the best available information. This includes survey information on pesticide usage related to the number of facilities being treated, product forms used (*e.g.,* liquids and aerosols), and treatment schedule by FHE segments (*e.g.,* warehouse, food processor, distributor, and restaurant). EPA also incorporated the best available information related to the transfer of commodities between various segments of food handling establishments and the percent of food consumed by location, either in the home or outside the home.

All information currently available has been considered and EPA has concluded that for any active ingredient, including broflanilide, there is at most a 4.65% likelihood that a food commodity could contain potential residues resulting from one or more treatments while in the food handling establishment channel of trade. Similar to estimates of agricultural use, this estimate should be reconsidered in 5 years.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which broflanilide may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for broflanilide alone as well as for the combined residues of concern (ROC), broflanilide and DC–8007 in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of broflanilide and the ROC, broflanilide and DC–8007. 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.*

Based on the Pesticide in Water Calculator (PWC) model and using the Total Residue (TR) method for the ROCs, the estimated drinking water concentrations (EDWCs) of broflanilide and DC–8007 for chronic exposures for non-cancer assessments are estimated to be 0.9 ppb for surface water and for chronic exposures for cancer assessments are estimated to be 0.7 ppb for surface water. Since breakthrough of broflanilide into groundwater is incomplete after 100 years of simulation, post-breakthrough EDWCs are negligible. Due to the high Freundlich adsorption coefficient (K_F) of broflanilide, peak EDWCs in groundwater were negligible as well.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the chronic dietary risk assessment, the water concentration value of 0.9 ppb was used to assess the contribution to drinking water. For the cancer dietary risk assessment, the water concentration value of 0.7 ppb was used to assess the contribution to drinking water.

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).

There are several proposed residential uses for broflanilide. These uses include, but are not limited to, insecticide treatments in and around homes, apartments, schools, picnic areas, hospitals, and nursing homes. In addition, there are several proposed termiticide products that may be used around the exterior of homes, apartments, schools, and other residential use sites. EPA assessed residential exposure using the following assumptions:

- *Residential handler:* Although there is one proposed broflanilide product label with residential use sites (*e.g.,* homes, apartments, mobile homes), this product is formulated as a ready-to-use pressurized can, which, once dispensed, rapidly expands to generate a dry foam. One ounce (weight) of the product is being dispensed in approximately 5 seconds, and the ready-to-use pressurized can produces about 1 quart of foam. Based on the areas to which it is applied (*i.e.,* with actuators in voids, cracks, and other places where insects harbor), dermal exposure is expected to be negligible. In addition, considering the low vapor pressure of broflanilide (6.7×10^{-11} mmHg) and formulation into foam, inhalation exposure is also expected to be negligible. Therefore, neither a quantitative non-cancer nor cancer residential handler exposure and risk assessment was conducted.
- *Post-application exposure:* There is the potential for short-term post-application exposure for individuals exposed as a result of being in an environment that has been previously treated with broflanilide. Due to a lack of dermal hazard for broflanilide, a dermal non-cancer assessment was not conducted. The quantitative non-cancer exposure and risk assessment for residential short-term post-application exposures is based on the following maximum application rate scenarios: Inhalation and incidental oral exposure from indoor crack and crevice, banded, and spot applications.

The PODs for the oral and inhalation routes are based on the same effects: Therefore, oral and inhalation routes can be combined. Since the LOCs for both incidental oral and inhalation are different (100 and 30), the aggregate risk index (ARI) approach was used:

Aggregate Risk Index (ARI) = 1 ÷ [(Incidental Oral LOC ÷ Incidental Oral MOE) + (Inhalation LOC ÷ Inhalation MOE)].

Although a non-cancer dermal risk assessment was not performed due to the lack of an adverse effect in the non-cancer dermal study, a dermal cancer exposure and risk assessment was performed because dermal exposure does contribute to the overall cancer risk for broflanilide.

Post-application cancer risk estimates for adults were calculated using a linear low-dose extrapolation approach in which a Lifetime Average Daily Dose (LADD) is first calculated and then compared with a Q_1* that has been calculated for broflanilide based on dose response data in the appropriate toxicology study (Q_1* = 2.48×10^{-3} $(mg/kg/day)^{-1}$).

The residential exposure scenario used in the adult non-cancer aggregate assessment is short-term post-application inhalation exposure following an indoor surface directed spot application. The residential exposure scenario used in the non-cancer aggregate assessment of children 1 to less than 2 years old is the combined inhalation and hand-to-mouth exposures from short-term post-application exposure to indoor perimeter/spot coarse and pin stream surface spray applications on carpet.

The residential exposure scenario used in the adult cancer aggregate assessment is post-application dermal and inhalation exposure following an indoor surface directed perimeter/spot application.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.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 broflanilide to share a common mechanism of toxicity with any other substances, and broflanilide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that broflanilide 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.* Broflanilide did not demonstrate any evidence of increased qualitative or quantitative susceptibility in the rat and rabbit developmental toxicity studies or the 2-generation rat reproduction study. In the rabbit and rat developmental toxicity studies, there were no developmental effects up to the limit dose tested (1000 mg/kg/day). In the reproduction study in rats, decreased pup weights in F1 and F2 pups occurred at a higher dose levels than the dose with adverse parental findings.

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 broflanilide is complete.

ii. Acute and subchronic neurotoxicity studies showed no evidence of neurotoxicity in male or female rats. There was no other evidence in any species tested to indicate neurotoxicity potential. Therefore, there is no concern for acute or subchronic neurotoxicity resulting from exposure to broflanilide.

iii. There is no evidence that broflanilide 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 for agricultural uses, a treatment value of 4.65% for FHE uses, and some anticipated residue data. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to broflanilide 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 broflanilide.

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, broflanilide 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 broflanilide from food and water will utilize less than 1% of the cPAD for children 1 to 2 years 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 broflanilide is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Broflanilide is proposed for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to broflanilide.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate ARIs of 320 for adults and 4.4 for children 1 to <2 years old. Because EPA's level of concern for broflanilide is an ARI of 1 or below, these ARIs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, broflanilide is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no 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 intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for broflanilide.

5. *Aggregate cancer risk for U.S. population.* A cancer aggregate risk assessment was completed for the proposed residential and dietary uses of broflanilide using the linear slope factor (Q1 *) of 2.48×10^{-3}. The assessment incorporates the adult post-application dermal and inhalation exposure following an indoor surface directed perimeter/spot application. The residential assessment is a conservative calculation which assumes 12 retreatments a year as allowed by the label at the maximum rate proposed, 365 days of exposure in the residential setting, and 10% dissipation of residues per day. The cancer dietary exposure estimate for adults 20–49 years old, the most highly-exposed adult population subgroup, assumed 100% crop treated for agricultural uses and the FHE treatment value of 4.65% for FHE uses. The resulting aggregate cancer risk estimate is 1×10^{-6}.

EPA generally considers cancer risks (expressed as the probability of an increased cancer case) in the range of 1 in 1 million (or 1×10^{-6}) or less to be negligible. Accordingly, EPA has concluded the aggregate cancer risk for all broflanilide uses fall within the range of 1×10^{-6} and are thus negligible.

6. *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 broflanilide residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The petitioner proposed a multi-residue method, BASF method D1417/01, based on QuEChERS (quick, easy, cheap, effective, rugged, safe) for the determination of broflanilide residues in plant matrices. This method has been proven to be suitable for the determination of residues of broflanilide in plant matrices.

BASF method D1604/01 is proposed as the enforcement method for the determination of residues of broflanilide and DM–8007 in livestock commodities by LC–MS/MS. This method has been proven to be suitable for the determination of residues of broflanilide and DM–8007 in livestock matrices.

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

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.

Broflanilide is a new active ingredient and no MRLs have yet been established by Codex.

C. Response to Comments

One comment was received in response to the Notice of Filing. The comment stated in part that ''the notice of the application for these uses does not contain any information about human toxicity, water solubility, granular transmissibility, or other information which could help evaluate the risk of higher levels of use of

broflanilide'' and that ''perhaps EPA should reissue the notice with attached information on toxicity and transmission levels.'' A supporting document summarizing the information on the residue chemistry, toxicological profile, as well as an estimate of the aggregate exposure expected was available in the docket at the time the notice was published. The NOF published on July 24, 2018, referred to the docket and noted that the summary was available. That document provided information to help evaluate the risks of broflanilide.

D. Revisions to Petitioned-For Tolerances

EPA is establishing the tolerance in/on potato, wet peel at 0.08 ppm rather than the petitioned-for tolerance of 0.1 ppm. The Agency's practice is to use the HAFT value from the field trials and the median processing factor. Based on these data, the appropriate tolerance for potato, wet peel is 0.08 ppm.

EPA is not establishing a separate tolerance for corn, sweet, kernel plus cob with husks removed because it is covered under grain, cereal, group 15, except rice. Similarly, separate tolerances for corn, sweet, stover; and corn, sweet forage are not being established because they are covered under grain, cereal, forage, fodder, and straw, group 16, except rice.

EPA is including the livestock metabolite DM–8007 as a residue of concern for tolerance enforcement and risk assessment. Therefore, the tolerance expression for livestock commodities is being revised to include the metabolite DM–8007.

EPA is establishing a tolerance for residues in milk at 0.02 ppm to harmonize with Canadian livestock LOQ MRLs. The tolerance of 0.02 ppm for residues in milk is higher than the anticipated residues in milk fat; therefore, although the available data support a tolerance for residues in milk fat at 0.01 ppm, a separate milk fat tolerance is not necessary at this time.

Lastly, the commodity definitions for the FHE use, egg and crop group 16 are being modified to be consistent with Agency nomenclature.

V. Conclusion

Therefore, tolerances are established for residues of broflanilide, including its metabolites and degradates, in or on the following plant commodities: Amaranth, grain, grain at 0.01 ppm; Amaranth, grain, stover at 0.01 ppm; Cañihua, grain at 0.01 ppm; Chia, grain at 0.01 ppm; Corn, field, milled byproducts at 0.015 ppm; Cram-cram, grain at 0.01 ppm; Grain, cereal, group 15, except rice at 0.01 ppm; Food and feed commodities (other than those covered by a higher tolerance) at 0.01 ppm; Grain, cereal, forage, fodder, and straw, group 16, except rice at 0.01 ppm; Huauzontle, grain at 0.01 ppm; Potato, wet peel at 0.08 ppm; Quinoa, forage at 0.01 ppm; Quinoa, grain at 0.01 ppm; Quinoa, hay at 0.01 ppm; Quinoa, straw at 0.01 ppm; Spelt, grain at 0.01 ppm; Teff, forage at 0.01 ppm; Teff, grain at 0.01 ppm; Teff, hay at 0.01 ppm; Teff, straw at 0.01 ppm; and Vegetable, tuberous and corm, subgroup 1C at 0.04 ppm.

Tolerances are also established for residues of broflanilide, including its metabolites and degradates, in or on the following livestock commodities: Cattle, fat at 0.02 ppm; Cattle, meat at 0.02 ppm; Cattle, meat byproducts at 0.02 ppm; Egg at 0.02 ppm; Goat, fat at 0.02 ppm; Goat, meat at 0.02 ppm; Goat, meat byproducts at 0.02 ppm; Hog, fat at 0.02 ppm; Hog, meat at 0.02 ppm; Hog, meat byproducts at 0.02 ppm; Horse, fat at 0.02 ppm; Horse, meat at 0.02 ppm; Horse, meat byproducts at 0.02 ppm; Milk at 0.02 ppm; Poultry, fat at 0.02 ppm; Poultry, meat at 0.02 ppm; Poultry, meat byproducts at 0.02 ppm; Sheep, fat at 0.02 ppm; Sheep, meat at 0.02 ppm; and Sheep, meat byproducts at 0.02 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.

Dated: November 30, 2020.

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 § 180.714 to subpart C to read as follows:

§ 180.714 Broflanilide; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of broflanilide, 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 broflanilide, 3-(benzoylmethylamino)-*N*-[2-bromo-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-6-(trifluoromethyl)phenyl]-2-fluorobenzamide, in or on the commodity.

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
Amaranth, grain, grain	0.01
Amaranth, grain, stover	0.01
Cañihua, grain	0.01
Chia, grain	0.01
Corn, field, milled byproducts	0.015
Cram-cram, grain	0.01
Grain, cereal, group 15, except rice	0.01
Food and feed commodities (other than those covered by a higher tolerance)	0.01
Grain, cereal, forage, fodder, and straw, group 16, except rice	0.01
Huauzontle, grain	0.01
Potato, wet peel	0.08
Quinoa, forage	0.01
Quinoa, grain	0.01
Quinoa, hay	0.01
Quinoa, straw	0.01
Spelt, grain	0.01
Teff, forage	0.01
Teff, grain	0.01
Teff, hay	0.01
Teff, straw	0.01
Vegetable, tuberous and corm, subgroup 1C	0.04

(2) Tolerances are established for residues of broflanilide, including its metabolites and degradates, in or on the commodities to Table 2 of this section. Compliance with the tolerance levels specified in Table 2 is to be determined by measuring the sum of broflanilide, 3-(benzoylmethylamino)-*N*-[2-bromo-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-6-(trifluoromethyl)phenyl]-2-fluorobenzamide, and its metabolite 3-benzamido-*N*-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluorobenzamide, calculated as the stoichiometric equivalent of broflanilide, in or on the commodity.

TABLE 2 TO PARAGRAPH (a)(2)

Commodity	Parts per million
Cattle, fat	0.02
Cattle, meat	0.02
Cattle, meat byproducts	0.02
Egg	0.02
Goat, fat	0.02
Goat, meat	0.02
Goat, meat byproducts	0.02
Hog, fat	0.02
Hog, meat	0.02
Hog, meat byproducts	0.02
Horse, fat	0.02
Horse, meat	0.02
Horse, meat byproducts	0.02
Milk	0.02
Poultry, fat	0.02
Poultry, meat	0.02
Poultry, meat byproducts	0.02
Sheep, fat	0.02
Sheep, meat	0.02
Sheep, meat byproducts	0.02

(b)–(d) [Reserved]

[FR Doc. 2020–27906 Filed 12–16–20; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 76

[MB Docket Nos. 20–70, 17–105, 11–131; FCC 20–162; FRS 17261]

Review Procedures; Modernization of Media Regulation Initiative; Program Carriage Rules

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission revises the rules governing the resolution of program carriage disputes between video programming vendors and multichannel video programming distributors (MVPDs) and parallel procedural rules, which govern program access, open video system (OVS), and good-faith retransmission consent complaints. Specifically, the document amends the third prong of the statute of limitations for filing program carriage complaints so that it no longer undermines the fundamental purpose of a statute of limitations. To harmonize the rules, the document similarly amends the statutes of limitations for filing program access, OVS, and good-faith retransmission consent complaints. The document also revises the effective date and review procedures for initial decisions issued by an administrative law judge (ALJ) in program carriage, program access, and OVS proceedings to make them consistent with the Commission's generally applicable procedures and adopts an aspirational shot clock to encourage quick resolution of appeals of such decisions. The Commission concludes that these changes will help to ensure a clear and expeditious program access, program carriage, retransmission consent, and OVS complaint process for potential complainants and defendants.

DATES: Effective January 19, 2021.

FOR FURTHER INFORMATION CONTACT: For additional information on this proceeding, contact John Cobb, *John.Cobb@fcc.gov,* of the Policy Division, Media Bureau, (202) 418–2120.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Report and Order,* MB Docket Nos. 20–70, 17–105, 11–131; FCC 20–162, adopted and released on November 18, 2020. The full text of this document is available via ECFS (*http://www.fcc.gov/cgb/ecfs/*). (Documents will be available electronically in ASCII, Word, and/or Adobe Acrobat.) To request these documents in accessible formats (computer diskettes, large print, audio recording, and Braille), send an email to *fcc504@fcc.gov* or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

In this *Report and Order* (*Order*), we adopt proposed changes to the rules governing the resolution of program carriage disputes between video programming vendors and multichannel video programming distributors (MVPDs) and parallel procedural rules in part 76 of our rules, which govern program access, open video system (OVS), and good-faith retransmission consent complaints. Specifically, we amend the third prong of the statute of limitations for filing program carriage complaints so that it no longer undermines the fundamental purpose of a statute of limitations. To harmonize our rules, we similarly amend the statutes of limitations for filing program