



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0392; FRL-9966-73]

Fenpicoxamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenpicoxamid (XDE 777) in or on banana, rye, and wheat. Dow AgroSciences LLC 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-2016-0392, 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. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION, CONTACT: Michael L. Goodis, 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 Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

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

Under FFDCFA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2016-0392 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-2016-0392, 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 December 20, 2016 (81 FR 92758) (FRL-9956-04), EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5E8440) by Dow AgroSciences LLC, 9330 Zionsville Rd, Indianapolis, IN 46268. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide fenpicoxamid (XDE-777) in or on banana at 0.1 parts per million (ppm), rye, grain and wheat, grain at 0.7 ppm; and residues of fenpicoxamid and its metabolite X12326349 expressed as fenpicoxamid equivalents in or on meat and fat from cattle, goats, and sheep at 0.01 ppm;

and meat byproducts of cattle, goats, and sheep at 0.02 ppm. That document referenced a summary of the petition prepared by Dow AgroSciences LLC, 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 is establishing tolerances as follows: 0.15 ppm for banana and 0.60 ppm for rye, grain and wheat, grain. In addition, EPA has concluded that no tolerances are needed for livestock commodities at this time. The reason 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 fenpicoxamid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fenpicoxamid 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. Fenpicoxamid has no significant acute toxicity via oral, dermal or inhalation route of exposure. Moreover, it is not a skin irritant and does not cause skin sensitization. Liver effects were consistently observed in mice regardless of duration; however, the severity, magnitude, and diversity of the liver response progressed from adaptive in subchronic exposures to adverse in chronic exposures. Mice exposed to fenpicoxamid in the diet for 80 weeks experienced liver weight increase accompanied by microscopic changes including very slight to moderate centrilobular/midzonal hepatocellular hypertrophy with altered tinctorial properties (increased cytoplasmic eosinophilia), vacuolization consistent with fatty change, and very slight hepatocyte necrosis. These liver effects also coincided with an increased incidence of microscopic calculi within the gallbladder in both sexes. A treatment-related increase in liver tumors were seen in male mice and is the basis for the Agency's classification of the chemical as "Suggestive Evidence of Carcinogenic Potential". The Agency determined that a non-linear approach

adequately accounted for all chronic toxicity, including carcinogenicity, that could result from chronic exposure to fepicoxamid and, therefore, quantification of carcinogenic potential was not required. This decision was based on the following considerations: 1) there was limited evidence of carcinogenicity in the fepicoxamid toxicity database; 2) the concern for mutagenicity and genotoxicity is low; and 3) there was no evidence of carcinogenicity at doses at or below the chronic reference dose.

Rats were likewise only adversely affected by treatment following chronic exposures. Chronic dietary exposure elicited treatment-related changes in the kidneys (increased severity of chronic progressive glomerulonephropathy) that were considered detrimental to the rat's health. However, unlike mice, chronic exposure did not elicit an increase in neoplasms in any tissue. Rabbits and dogs tolerated oral exposure up to doses of 495 and 1,115 milligrams/kilogram/day (mg/kg/day), respectively, without any signs of deteriorating health. There was no evidence of fetal susceptibility in rats or rabbits, or offspring susceptibility in rats. None of the available studies produced evidence of treatment-induced immunotoxicity or neurotoxicity.

Specific information on the studies received and the nature of the adverse effects caused by fepicoxamid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document "Fepicoxamid (XDE-777): Human Health Risk Assessment to Establish Tolerances for Bananas, Wheat, and Rye Commodities Without U.S. Registration" at pages 10 through 20 in docket ID number EPA-HQ-OPP-2016-0392.

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://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for fenpicoxamid used for human risk assessment is shown in the Table of this unit.

Table Summary of Toxicological Doses and Endpoints for Fenpicoxamid for Use in Human Health Risk Assessments

Exposure/ Scenario	Point of Departure	Uncertainty/ FQPA Safety Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (General Population, including Infants and Children)	There were no effects in the toxicity database that could be attributed to a single dose; therefore, an acute POD was not identified.			
Chronic Dietary (All Populations)	NOAEL = 40 mg/kg/day	UF _A = 10x UF _H = 10x FQPA SF = 1x	cRfD = 0.40 mg/kg/day cPAD = 0.40 mg/kg/day	Carcinogenicity study – mouse MRID 49731126 LOAEL = 156 and 388 mg/kg/day for males and females, respectively, based on treatment-related adverse liver effects in males (increased liver weight, hypertrophy, hepatocyte necrosis and fatty change) and females (increased liver weight, hypertrophy and fatty change) and gall bladder calculi.
Cancer (oral, dermal, inhalation)	“Suggestive Evidence of Carcinogenic Potential” based on the presence of liver tumors in male mice only. The cRfD is protective of carcinogenic effects.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human

population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fenpicoxamid, EPA assessed dietary exposures from fenpicoxamid 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 fenpicoxamid; therefore, a quantitative acute dietary exposure assessment is unnecessary.

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

iii. *Cancer.* As discussed in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to fenpicoxamid.

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

2. *Dietary exposure from drinking water.* Because there are no domestic uses of fenpicoxamid registered in the United States, there will not be residues of fenpicoxamid in drinking water. Therefore, a drinking water assessment is not required.

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). Fenpicoxamid is not 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.”

EPA has not found fenpicoxamid to share a common mechanism of toxicity with any other substances, and fenpicoxamid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fenpicoxamid 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://www.epa.gov/pesticides/cumulative>.

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 Food Quality Protection Act Safety Factor (FQPA 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.* Developmental toxicity was not observed in the rat or rabbit developmental studies and, no reproductive or offspring effects were observed in the reproduction toxicity study. As a result, EPA concluded there is low concern for prenatal or postnatal sensitivity from fenpicoxamid exposure.

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 for all exposure scenarios. That decision is based on the following findings:

- i. The toxicity database for fenpicoxamid is complete
- ii. There is no indication that fenpicoxamid is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that fenpicoxamid 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.

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, fenpicoxamid 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 fenpicoxamid from food for the highest exposed population subgroup, children 1-2 years of age, is 0.002737 mg/kg/day or <1.0% of the cPAD. The chronic dietary exposure estimate for the general population is 0.001022 mg/kg/day or <1.0% of the cPAD.

3. *Short-term and intermediate-term risk.* Because fenpicoxamid is not registered for any uses that may result in residential exposure, fenpicoxamid is not expected to cause any short-term or intermediate-term risk not already accounted for in the Agency's assessment of chronic risk.

4. *Aggregate cancer risk for U.S. population.* Based on the Agency's assessment of chronic risk, the Agency concludes that fenpicoxamid is not expected to pose a cancer risk.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to fenpicoxamid 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 No. 120615) is available to enforce the tolerance expression.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and

Agriculture Organization/World Health Organization food standards program, 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, FFDCFA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Codex has not established any MRLs for residues of fenpicoxamid.

C. Revisions to Petitioned-For Tolerances

EPA is establishing tolerances for wheat, grain and rye, grain (at 0.60 ppm) that differ from what the petition requested (0.7 ppm). The petitioner included only wheat grain residues for individual growing season/area combinations. Including all residues for wheat grain in the OECD MRL calculator in accordance with Agency policy results in a tolerance level of 0.60 ppm. Because the wheat grain data can be used to assess residues in rye grain, the Agency is establishing a tolerance at 0.60 ppm for rye grain as well. Finally, although the notice of filing and the petition summary indicate that the petitioner was seeking tolerances for wheat and rye, the section of the petition that listed actual requested tolerances more narrowly sought only “wheat, grain” and “rye, grain” tolerances because those are the forms in which the wheat and rye will be imported. Accordingly, EPA is establishing tolerances for the commodities “wheat, grain” and “rye, grain”.

EPA is establishing a different tolerance level for banana than what was requested based on available residue data and the OECD calculator, and in order to harmonize with Canada’s MRL.

EPA is not establishing any of the petitioned-for tolerances for livestock commodities. Based on the results of the livestock feeding studies, the residues of concern for livestock commodities (fenpicoxamid and X12326349) would be below the limit of quantification (LOQ) of the enforcement analytical method. Therefore, the Agency concludes, as indicated in 40 CFR 180.6(a)(3), that there is no reasonable expectation of finite residues and no tolerances are needed for livestock commodities at this time.

V. Conclusion

Therefore, tolerances are established for residues of fenpicoxamid and its metabolites and degradates, in or on banana at 0.15 ppm, and rye and wheat grain at 0.60 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). 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: September 6, 2017.

Richard P. Keigwin, Jr.,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

2. Add § 180.109 to subpart C to read as follows:

§ 180.109 Fenpicoxamid; Tolerances for residues.

(a) *General.* Tolerances are established for residues of fenpicoxamid including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels for fenpicoxamid is to be determined by measuring only fenpicoxamid ([4-methoxy-2-[[[(3*S*,7*R*,8*R*,9*S*)-9-methyl-8-(2-methyl-1-oxopropoxy)-2,6-dioxo-7-(phenylmethyl)-1,5-dioxonan-3-yl]amino]carbonyl]-3-pyridinyl]oxy)methyl 2-methylpropanoate) in or on the commodity.

Commodity	Parts per million
Banana*	0.15
Wheat, grain*	0.60
Rye, grain*	0.60

*There are no U.S. registrations for use of fenpicoxamid on this commodity.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

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