proposed by the petitioner including canola, refined oil at 0.03 ppm; flax, seed, oil at 0.03 ppm; grape, raisin at 5.0 ppm; mustard, seed, oil at 0.03 ppm and sesame, oil at 0.03 ppm.

V. Conclusion

Therefore, tolerances are established for residues of isofetamid, in or on almond at 0.01 ppm; almond, hulls at 0.01 ppm; canola, refined oil at 0.03 ppm; flax, seed, oil at 0.03 ppm; grape, raisin at 5.0 ppm; lettuce, head at 5.0 ppm; lettuce, leaf at 7.0 ppm; berry, low growing, subgroup 13–07G at 4.0 ppm; mustard, seed, oil at 0.03 ppm; rapeseed subgroup 20A at 0.015 ppm; sesame, oil at 0.03 ppm; and fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 3.0 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: July 21, 2015.

Jack Housenger,

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 § 180.681 to subpart C to read as follows:

§ 180.681 Isofetamid; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide isofetamid, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only isofetamid, *N*-[1,1-dimethyl-2-[2-methyl-4-(1-methylethoxy)phenyl]-2-oxoethyl]-3-methyl-2-thiophenecarboxamide, in or on the following commodities:

Commodity	Parts per million
Almond	0.01
Almond, hulls	0.01
Berry, low growing, subgroup 13–07G	4.0
Canola, refined oil	0.03
Flax, seed, oil	0.03
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F	3.0
Grape, raisin	5.0
Lettuce, head	5.0
Lettuce, leaf	7.0
Mustard, seed, oil	0.03
Rapeseed subgroup 20A	0.015
Sesame, oil	0.03

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

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

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

[FR Doc. 2015–18738 Filed 7–29–15; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0714; FRL–9927–63]

Benalaxyl-M; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of benalaxyl-M in or on grape and tomato. Since there are currently no U.S. registrations of benalaxyl-M for use on grape and tomato, this tolerance will allow the import of grape and tomato containing residues of benalaxyl-M. Technology Sciences Group, on behalf of Isagro S.p.A, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 30, 2015. Objections and requests for hearings must be received on or before September 28, 2015, 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–2013–0714, 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: Susan Lewis, 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.* To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

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–2013–0714 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 September 28, 2015. 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–2013–0714, 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 21, 2014 (79 FR 9870) (FRL–9904–98), 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 3E8162) by Technology Sciences Group on behalf of Isagro S.p.A., 1150 18th Street NW., Suite 1000, Washington, DC 20036. The petition requested that 40 CFR part 180 be amended by establishing import tolerances for residues of the fungicide benalaxyl-M in or on grape at 1.1 parts per million (ppm); grape juice at 1.1 ppm; grape wine at 1.1 ppm; grape raisin at 2.2 ppm; tomato at 0.25 ppm; and tomato processed at 0.25 ppm. That document referenced a summary of the petition prepared by Technology Sciences Group on behalf of Isagro S.p.A., the registrant, which is available in the docket, *http://www.regulations.gov.* No tolerance-related comments were submitted.

Based upon review of the data supporting the petition, EPA is establishing tolerances as follows: 3.0 ppm for grapes and 0.20 ppm for tomato. 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 benalaxyl-M including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with benalaxyl-M 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.

Benalaxyl-M has no significant acute toxicity via oral, dermal or inhalation route of exposure. It is not a skin irritant and does not cause skin sensitization.

The liver and thyroid are the primary target organs for benalaxyl-M. In rats, increased liver weights, clinical chemistry changes indicative of liver toxicity, hepatocellular hypertrophy, and thyroid follicular cell hypertrophy were seen following subchronic and chronic exposure. In mice, increased liver weight and microscopic lesions in the liver (hepatocellular hypertrophy, necrosis, eosinophilic foci) were observed following subchronic and chronic exposure. Additionally, chronic exposure in rats and mice led to increases in the incidence of liver (rat, mouse) and thyroid (rat) tumors. In dogs, increased liver weight, changes in clinical chemistry indicative of liver toxicity, and hepatocellular hypertrophy were observed following subchronic exposure *via* the diet, whereas clinical chemistry changes indicative of liver toxicity, fat vacuolation in the liver, and thyroid follicular cell hypertrophy were observed following chronic exposure *via* capsules.

No evidence of increased quantitative or qualitative susceptibility was seen in the benalaxyl-M hazard database following *in utero* exposure with rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction study. No evidence of maternal toxicity or developmental effects was observed in the developmental toxicity studies in rabbits or rats. There is no reproductive concern. No neurotoxic effects were observed in the acute and subchronic neurotoxicity studies in rats, and no immunotoxic effects were observed in the immunotoxicity study in rats.

Benalaxyl-M was classified as ''Likely to be Carcinogenic to Humans''. This determination was based on the treatment-related liver tumors observed in male mice, liver tumors observed in male and female rats; and thyroid follicular cell tumors observed in female rats. No treatment-related tumors were observed in female mice. A linear low-dose extrapolation model (Q^*_1) was used to estimate cancer risk, based on the male mouse liver tumor rates. There is no mutagenicity concern from the *in vivo* or *in vitro* genetic toxicity assays.

Specific information on the studies received and the nature of the adverse effects caused by benalaxyl-M 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://

''Benalaxyl-M. Human-Health Risk Assessment for Tolerances in/on Imported Grape and Tomato'' on pages 10 through 20 in docket ID number EPA–HQ–OPP–2013–0714.

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 benalaxyl-M used for human risk assessment is shown in the Table of this unit.

Table—Summary of Toxicological Doses and Endpoints for Benalaxyl-M for Use in Human Health Risk Assessment

TABLE 4.5.4.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR BENALAXYL-M FOR USE IN DIETARY 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, Children, and females 13+).	No appropriate acute endpoint was identified.			
Chronic Dietary ..... (All Popyulations)	NOAEL= 20 mg/kg/day.	UF_A= 10x ..... UF_H= 10x ..... FQPA UF_{DB} = 10x.	Chronic RfD = ... cPAD = 0.02 mg/kg/day.	Chronic Toxicity/Carcinogenicity Study—rat (49040634) LOAEL = 135 mg/kg/day based on based on an increase in γ-glutamyl transferase (GGT) in males, slight increases liver weight in both sexes, increased incidence of hepatocellular hypertrophy in both sexes, increased incidence of thyroid follicular cell hypertrophy in both sexes, increased incidence of thyroid cell hyperplasia in females, increased incidence of thyroid follicular ectasia in females, and an increased incidence of ovarian stromal cell hyperplasia in females.

TABLE 4.5.4.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR BENALAXYL-M FOR USE IN DIETARY HUMAN HEALTH RISK ASSESSMENTS—Continued

Exposure/Scenario	Point of departure	Uncertainty/ FQPA safety factors	RfD, PAD, Level of concern for risk assessment	Study and toxicological effects
Cancer (oral)	Classification: ''Likely to be Carcinogenic to Humans''. Based on male mouse liver tumors, Q_1*= 5.90×10^{3} (mg/kg/day) [1].			

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). UF_{DB} = to account for the absence of a comparative thyroid study. FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (c = chronic). RfD = reference dose.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to benalaxyl-M, EPA assessed dietary exposures from benalaxyl-M in food as follows:

i. *Acute exposure.* No such effects were identified in the toxicological studies for benalaxyl-M; 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 USDA 2003–2008 CSFII. As to residue levels in food, EPA used tolerance-level residues 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. If quantitative cancer risk assessment is appropriate, cancer risk may be quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that benalaxyl-M should be classified as ''Likely to be Carcinogenic to Humans'' and a linear approach has been used to quantify cancer risk. Cancer risk was quantified using the same 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 benalaxyl-M. Tolerance level residues and/or 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* An assessment of residues in drinking water is not required for this assessment because there is no drinking water exposure in the U.S. associated with the establishment of an import tolerance.

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). Benalaxyl-M 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 benalaxyl-M to share a common mechanism of toxicity with any other substances, and benalaxyl-M does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that benalaxyl-M 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 Web site 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 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.* No evidence of increased quantitative or qualitative susceptibility was seen following *in utero* exposure to benalaxyl-M with rats or rabbits in the prenatal developmental toxicity studies or in young rats in the 2-generation reproduction study. The 2-generation reproduction study resulted in no effects on reproductive function or fertility. The offspring effects occurred at the same dose that caused parental effects. No evidence of developmental delay or developmental toxicity was observed in developmental toxicity studies in rabbits or in rats.

The rabbit was tested at the limit dose (1000 mg/kg/day), and no maternal or developmental toxicity was observed. No significant developmental or maternal toxicity occurred at the highest dose level tested in the rat study, but the

limit dose was not tested. It is not necessary to require the submission of an additional rat study since a study at higher dose levels would not result in a lower NOAEL and the point of departure is already 10-fold lower than the NOAEL in the rat 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 retained at 10×. That decision is based on the following findings:

i. The toxicity database for benalaxyl-M is complete for purposes of assessing the exposures from the use of benalaxyl-M on imported grapes and tomatoes. However, there remains some uncertainty regarding the potential for benalaxyl-M effects on thyroid. Thyroid toxicity was seen following subchronic and chronic exposures to adult rats. There are, however, no data regarding the potential effects of benalaxyl-M on thyroid homeostasis in the young animals. This lack of characterization creates uncertainty with regards to potential life stage sensitivities due to exposure to benalaxyl-M. For future uses with higher exposure potential, the Agency will require a comparative thyroid assay in rats to assess the potential impact of benalaxyl-M exposure on thyroid function in the young given the pivotal role of thyroid hormones in brain development.

ii. There is no indication that benalaxyl-M 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 benalaxyl-M 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, benalaxyl-M 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 benalaxyl-M from food will utilize 1.4% of the cPAD for the general U.S. population and all population sub-groups. The most highly exposed population subgroup was children 1–2 years old with an estimated risk of 7.1% cPAD.

3. *Aggregate cancer risk for U.S. population.* The cancer dietary assessment made use of the same input assumptions as the chronic analysis. Benalaxyl-M has been classified as ''Likely to be Carcinogenic to Humans''. A linear low-dose extrapolation model (Q_1*) was used to estimate cancer risk, with a $Q_1^* = 5.90 \times 10^{-3}$ (mg/kg/day) $^{-1}$. The cancer risk estimate to the U.S. population is 1.7×10^{-6}. EPA generally considers cancer risks in the range of 10^{-6} or less to be negligible. The precision which can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of magnitude on the log scale; for example, risks falling between 3×10^{-7} and 3×10^{-6} are expressed as risks in the range of 10^{-6}. Considering the precision with which cancer hazard can be estimated, the conservativeness of low-dose linear extrapolation, and the rounding procedure described above in this unit, cancer risk should generally not be assumed to exceed the benchmark level of concern of the range of 10^{-6} until the calculated risk exceeds approximately 3×10^{-6}. This is particularly the case where some conservatism is maintained in the exposure assessment.

4. *Determination of safety.* There are no existing or proposed US registrations of benalaxyl-M and the only route of exposure is via dietary ingestion from imported grape and tomato commodities. Therefore, aggregate exposure and risk estimates are equivalent to the dietary exposures and risk estimates. 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 benalaxyl-M residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (RA.09.01, a high-performance liquid chromatography method with tandem mass spectrometry detection (HPLC/MS/MS) 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 established MRLs for benalaxyl-M at 0.3 and 0.2 ppm in or on grape and tomato, respectively. As a result, the EPA recommendations will result in harmonization of the U.S. tolerance with the Codex MRL for tomato, but not for grape since benalaxyl-M residues from the grape trials in Argentina were significantly higher than the Codex MRL.

C. Revisions to Petitioned-for Tolerances

The requested tolerance levels differ from those being established by EPA. The petitioner used the NAFTA calculator to propose tolerance levels while EPA used OECD MRL calculation procedures. Additionally, for determination of the grape and tomato tolerance levels, the petitioner included the results from all trials. In contrast, EPA included only those data that matched the critical Good Agricultural Practice (cGAP). The tolerance for grape, raisin was not recommended because it is covered by the grape tolerance. No separate tolerances are needed for grape juice, grape wine, or processed tomato products as processing studies showed that residues of benalaxyl-M do not concentrate in these processed commodities.

V. Conclusion

Therefore, tolerances are established for residues of benalaxyl-M, in or on grape and tomato at 3.0 and 0.20 ppm, respectively.

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: July 24, 2015.

Marty Monell,

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 § 180.684 to subpart C to read as follows:

§ 180.684 Benalaxyl-M; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide benalaxyl-M, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only benalaxyl [methyl N-(2,6-dimethylphenyl)-N-(phenylacetyl)-DL-alaninate] in or on the commodity.

Commodity	Parts per million
Grape [1]	3.0
Tomato [1]	0.20

[1] There is no U.S. registration for use on this commodity as of July 30, 2015.

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

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

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

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