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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2020-0009; FRL-8785-01-OCSPP]

Metalaxyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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SUMMARY: This regulation establishes tolerances for residues of

metalaxyl in or on black pepper. American Spice Trade Association

requested these tolerances under the Federal Food, Drug, and Cosmetic

Act (FFDCA).

DATES: This regulation is effective September 24, 2021. Objections and

requests for hearings must be received on or before November 23, 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-2020-0009, is available at [http://www.regulations.gov](http://www.regulations.gov/) or at the Office of Pesticide Programs Regulatory

Public Docket (OPP Docket) in the Environmental Protection Agency

Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334,

1301 Constitution Ave. NW, Washington, DC 20460-0001. The Public

Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through

Friday, excluding legal holidays. The telephone number for the Public

Reading Room is (202) 566-1744, and the telephone number for the OPP

Docket is (703) 305-5805.

 Due to the public health 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-2020-0009 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

November 23, 2021. Addresses for mail and hand delivery of objections

and hearing requests are provided in 40 CFR 178.25(b), although at this

time, EPA strongly encourages those interested in submitting objections

or a hearing request, to submit objections and hearing requests

electronically. See Order Urging Electronic Service and Filing (April

10, 2020), <https://www.epa.gov/sites/production/files/2020-05/documents/2020-04-10_-_order_urging_electronic_service_and_filing.pdf>.

At this time, because of the COVID-19 pandemic, the judges and staff of

the Office of Administrative Law Judges are working remotely and not

able to accept filings or correspondence by courier, personal deliver,

or commercial delivery, and the ability to receive filings or

correspondence by U.S. Mail is similarly limited. When submitting

documents to the U.S. EPA Office of Administrative Law Judges (OALJ), a

person should utilize the OALJ e-filing system, at <https://yosemite.epa.gov/OA/EAB/EAB-ALJ_upload.nsf>.

 Although EPA's regulations require submission via U.S. Mail or hand

deliver, EPA intends to treat submissions filed via electronic means as

properly filed submissions during this time that the Agency continues

to maximize telework due to the pandemic; therefore, EPA believes the

preference for submission via electronic means will not be prejudicial.

If it is impossible for a person to submit documents electronically or

receive service electronically, e.g., the person does not have any

access to a computer, the person shall so advise OALJ by contacting the

Hearing Clerk at (202) 564-6281. If a person is without access to a

computer and must file documents by U.S. Mail, the person shall notify

the Hearing Clerk every time it files a document in such a manner. The

address for mailing documents is U.S. Environmental Protection Agency,

Office of Administrative Law Judges,

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Mail Code 1900R, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

 In addition to filing an objection or hearing request with the

Hearing Clerk as described in 40 CFR part 178, please submit a copy of

the filing (excluding any Confidential Business Information (CBI)) for

inclusion in the public docket. Information not marked confidential

pursuant to 40 CFR part 2 may be disclosed publicly by EPA without

prior notice. Submit the non-CBI copy of your objection or hearing

request, identified by docket ID number EPA-HQ-OPP-2020-0009, by one of

the following methods:

 Federal eRulemaking Portal: [http://www.regulations.gov](http://www.regulations.gov/).

Follow the online instructions for submitting comments. Do not submit

electronically any information you consider to be CBI or other

information whose disclosure is restricted by statute.

 Mail: OPP Docket, Environmental Protection Agency Docket

Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC

20460-0001.

 Hand Delivery: To make special arrangements for hand

delivery or delivery of boxed information, please follow the

instructions at <http://www.epa.gov/dockets/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 May 29, 2020 (85 FR 32338) (FRL-10009-

84), 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

9E8811) by American Spice Trade Association, 1101 17th Street NW, Suite

700, Washington, DC 20036. The petition requested that 40 CFR 180.408

be amended by establishing tolerances for residues of the fungicide

metalaxyl, methyl N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-DL-

alaninate, in or on pepper, black at 1 part per million (ppm). That

document referenced a summary of the petition prepared by American

Spice Trade Association, the registrant, which is available in the

docket, [http://www.regulations.gov](http://www.regulations.gov/). Comments were received on the

notice of filing. EPA's response to these comments is discussed in Unit

IV.C. Based upon review of the data supporting the petition, EPA has

modified the tolerance levels on black pepper. The reason for these

changes is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

 FFDCA section 408(b)(2)(A)(i) 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 metalaxyl including exposure

resulting from the tolerances established by this action. EPA's

assessment of exposures and risks associated with metalaxyl 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. EPA conducted a human health risk assessment to evaluate the

safety of the requested tolerances and the assessment ``Metalaxyl Human

Health Risk Assessment for the Proposed Tolerances in/on White and

Black Pepper without a U.S. Registration'' is found in docket ID number

EPA-HQ-OPP-2020-0009 at [www.regulations.gov](http://www.regulations.gov/). In that document, EPA

evaluated the available hazard and exposure data to conduct dietary,

residential, and aggregate assessment to determine risk to human health

and refers back to the full discussions of the hazard profile, residue

chemistry database, and residential exposures contained in the previous

human health risk assessment conducted for the registration review of

metalaxyl/mefenoxam. The human health risk assessment ``Metalaxyl,

Mefenoxam (metalaxyl-m) Human Health Draft Risk Assessment for

Registration Review'' is located in docket EPA-HQ-OPP-2009-0863-0023.

 The Draft Risk Assessment reflects both mefenoxam and metalaxyl.

The Agency compared the available chemistry and toxicity data for

mefenoxam and metalaxyl and concluded that the toxicity studies for

both chemicals can be combined for hazard characterization and dose-

response assessment because the two chemicals have similar toxicity and

identical chemical structures.

 In rat and dog repeat dose (i.e., subchronic and chronic) oral

toxicity studies, there were no indications of adverse effects up to

the highest dose tested (HDT). Adverse effects (i.e., convulsions that

occurred minutes after dosing) were only observed from acute exposure

to rats.

 There was no evidence of increased susceptibility following pre- or

post-natal exposure in the prenatal developmental toxicity studies or

the reproduction and fertility effects study in the animals treated

with metalaxyl. In the rat developmental toxicity study of metalaxyl,

maternal toxicity consisted of dose-related increased incidence of

convulsions that occurred shortly after dosing, as well as other

clinical signs. In a range-finding acute neurotoxicity study of

mefenoxam, females showed abnormal functional observation battery

findings at doses lower than males, but higher than in the rat

developmental study. However, there was no indication of toxicity up to

the HDT in the mefenoxam subchronic neurotoxicity study, which confirms

the lack of adverse effects observed in all other repeat-dose studies.

 There was no indication of immunotoxicity in a mouse immunotoxicity

study of mefenoxam.

 Metalaxyl is classified as ``Not Likely to be Carcinogenic to

Humans'' based on the lack of evidence of carcinogenicity in the

metalaxyl carcinogenicity study in mice and the combined chronic

toxicity and carcinogenicity study in rats.

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

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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 metalaxyl used for the

human health risk assessment is shown in the Metalaxyl Human Health

Risk Assessment for the Proposed Tolerances in/on White and Black

Pepper without a U.S. Registration, and further explanation can be

found in ``Metalaxyl, Mefenoxam (metalaxyl-m) Human Health Draft Risk

Assessment for Registration Review''.

C. Exposure Assessment

 1. Dietary exposure from food and feed uses. In evaluating dietary

exposure to metalaxyl, EPA considered exposure under the existing

tolerances for mefenoxam and the existing and petitioned-for tolerances

for metalaxyl. EPA assessed dietary exposures 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.

 In conducting acute 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). A partially refined acute dietary exposure

assessment was conducted for metalaxyl. The refinement was based on a

tolerance level adjustment to account for all residues of concern and

anticipated residues were used for livestock commodities. The analysis

used tolerance-level residues, adjusted to include additional residues

of concern, and 100 percent crop treated (PCT).

 ii. Chronic exposure. Because no chronic dietary endpoint was

selected, a chronic dietary exposure assessment was not conducted.

Nevertheless, for purposes of assessing short-term aggregate risk, EPA

calculated average dietary exposures. In conducting the chronic dietary

exposure assessment, EPA used tolerance level values adjusted for

additional residues of concern and 100 PCT.

 iii. Cancer. Metalaxyl is classified as ``Not Likely to Be

Carcinogenic to Humans'' therefore, a cancer assessment is not needed.

 2. Dietary exposure from drinking water. Drinking water exposures

are not impacted by the import tolerances on black pepper; therefore,

the assessment for this tolerance action relied on the second

refinement for the drinking water exposure assessment (DWA) for

metalaxyl and mefenoxam, in support of the Agency human health

assessment for Registration Review for the estimated drinking water

concentrations (EDWCs). See ``Metalaxyl/Mefenoxam: Second Refinement

Addendum to Drinking Water Exposure Assessment in Support of

Registration Review'', which is located at [https://www.regulations.gov](https://www.regulations.gov/)

in docket ID number EPA-HQ-OPP-2009-0863.

 That assessment modeled drinking water exposures using the

Pesticide Root Zone Model (PRZM, v5, November 15, 2006) and the

Variable Volume Water Body Model (VVWM, March 6, 2014) for surface

water and the PRZM-GW for groundwater. Using those models, EPA

calculated the following EDWCs for use in exposure assessment: 350 ppb

for acute exposure assessment and 135 ppb for chronic exposure

assessment.

 3. 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).

 Mefenoxam and metalaxyl are currently registered for the following

uses that could result in residential exposures: Lawns, ornamentals,

gardens, and trees. EPA assessed residential exposure using the

following assumptions: For residential handlers, all registered

metalaxyl and mefenoxam product labels with residential use sites

(lawns, ornamentals and garden and trees) require that handlers wear

specific clothing (e.g., long-sleeve shirt/long pants) and chemical-

resistant gloves. Therefore, EPA has made the assumption that these

products are not for homeowner use and has not conducted a quantitative

residential handler assessment.

 There is potential for residential post-application exposures to

metalaxyl. Since no dermal endpoints were identified, only incidental

oral post-application exposures to small children ages 1 to <2 have

been assessed. Metalaxyl and mefenoxam are registered for use on home

lawns; therefore, there is the potential for incidental oral exposure

(hand-to-mouth, object-to-mouth, soil ingestion and granular

ingestion).

 The recommended residential exposure for use in the children 1 to

<2 years old aggregate assessment reflects hand-to-mouth incidental

oral exposures from treated turf using a liquid formulation. Ingestion

of granules is considered an episodic event and not a routine behavior.

Because the Agency does not believe that this would occur on a regular

basis, the concern for human health is related to acute poisoning

rather than short-term residue exposure. Therefore, an acute dietary

dose is used to estimate exposure and risk resulting from episodic

ingestion of granules. For these same reasons, the episodic ingestion

scenario was not included in the aggregate assessment.

 A summary of the residential exposures for metalaxyl used for the

human health risk assessment can be found in ``Metalaxyl, Mefenoxam

(metalaxyl-m) Human Health Draft Risk Assessment for Registration

Review'' docket ID number EPA-HQ-OPP-2009-0863-0023.

 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. FFDCA section 408(b)(2)(D)(v) requires that, when considering

whether to establish, modify, or revoke a tolerance, the Agency

consider ``available information'' concerning the cumulative effects of

a particular pesticide's residues and ``other substances that have a

common mechanism of toxicity.''

 Unlike other pesticides for which EPA has followed a cumulative

risk approach based on a common mechanism of toxicity, EPA has not made

a common mechanism of toxicity finding as to mefenoxam and any other

substances and mefenoxam does not appear to produce a toxic metabolite

produced by

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other substances. For the purposes of this action, therefore, EPA has

not assumed that mefenoxam has a common mechanism of toxicity with

other substances.

D. Safety Factor for Infants and Children

 1. In general. Section 408(b)(2)(C) of FFDCA provides that EPA

shall apply an additional tenfold (10X) margin of safety for infants

and children in the case of threshold effects to account for prenatal

and postnatal toxicity and the completeness of the database on toxicity

and exposure unless EPA determines based on reliable data that a

different margin of safety will be safe for infants and children. This

additional margin of safety is commonly referred to as the FQPA Safety

Factor (SF). In applying this provision, EPA either retains the default

value of 10X, or uses a different additional safety factor when

reliable data available to EPA support the choice of a different

factor.

 2. Prenatal and postnatal sensitivity. There was no evidence of

increased susceptibility in offspring in the prenatal developmental or

the 2-generation reproductive toxicity studies. In adult rats treated

with metalaxyl or mefenoxam, clinical signs and abnormal functional

observation battery (FOB) findings were noted after a bolus gavage dose

but not in repeated dose studies.

 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 databases for metalaxyl and mefenoxam are adequate

to assess the potential for prenatal and postnatal toxicity for infants

and children.

 ii. In the rat prenatal developmental toxicity with metalaxyl,

maternal animals exhibited clinical signs indicative of neurobehavioral

effects as previously discussed. In the range-finding acute

neurotoxicity study with mefenoxam, females exhibited abnormal FOB

findings at doses lower than in males. In the subchronic neurotoxicity

study with mefenoxam, there were no indications of neurotoxicity up to

the HDT. In metalaxyl and mefenoxam treated adult animals, clinical

signs and abnormal FOB findings were noted. However, a developmental

neurotoxicity (DNT) study is not required for metalaxyl or mefenoxam

because (1) there are no indications of increased susceptibility for

infants or children; (2) the convulsions observed in the rat prenatal

developmental toxicity study occurred in the maternal animals with no

effects being observed in the young; (3) the convulsions occurred only

after a bolus dose; (4) the available developmental and range-finding

acute neurotoxicity studies provided clear NOAELs and LOAELs for

evaluating effects; (5) the current POD is below the level at which any

effects were seen in either study, and (6) there were no other

indications of neurotoxicity in the mefenoxam or metalaxyl databases,

which include a subchronic (adult rat) neurotoxicity study for

mefenoxam. Therefore, there is no need for a developmental

neurotoxicity study or additional UFs to account for neurotoxicity. See

``Metalaxyl, Mefenoxam (metalaxyl-m) Human Health Draft Risk Assessment

for Registration Review'' docket ID number EPA-HQ-OPP-2009-0863-0023.

 iii. As discussed above in Unit III.D.2., there is no evidence that

metalaxyl results in increased susceptibility in the developmental or

reproductive toxicity studies; and

 iv. There are no residual uncertainties in the exposure database.

Dietary exposure analysis was performed incorporating all existing and

proposed uses using tolerance level values to estimate residues in food

commodities and anticipated residues in livestock commodities. Drinking

water estimates were generated based upon conservative inputs and

modeling. Similarly, potential residential post application exposures

are based upon conservative, default assumptions. EPA made conservative

(protective) assumptions in the ground and surface water modeling used

to assess exposure to metalaxyl 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 are not expected to underestimate the exposure to

metalaxyl.

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. Using the exposure assumptions described in this unit

for acute exposure, EPA has concluded that acute exposure to metalaxyl

from food and water will utilize 52% of the aPAD for children 1 to 2

years old, the population subgroup with the highest exposure estimate.

 2. Chronic risk. There is no increase in hazard from repeat

exposures to metalaxyl/mefenoxam; therefore, a chronic dietary POD was

not selected. Due to the lack of a chronic endpoint, a chronic dietary

risk is not expected. The acute endpoint and dietary exposure

assessment are protective of potential effects from chronic duration

dietary exposures.

 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). Mefenoxam and

metalaxyl are currently registered 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 mefenoxam and metalaxyl. 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 an aggregate MOE of 270 for children. Because EPA's

level of concern for mefenoxam is a MOE of 100 or below, this MOE is

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,

metalaxyl and mefenoxam are not registered for any use patterns that

would result in intermediate-term residential exposure.

 5. Aggregate cancer risk for U.S. population. Metalaxyl is

classified as ``Not Likely to Be Carcinogenic to Humans''; therefore,

EPA does not expect metalaxyl exposures to pose an aggregate cancer

risk.

 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 metalaxyl residues.

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IV. Other Considerations

A. Analytical Enforcement Methodology

 There are adequate residue analytical methods for enforcing

tolerances for metalaxyl residues of concern in/on the registered plant

and livestock commodities. These several methods include gas

chromatography equipped with an alkali flame ionization detector (GC/

AFID), gas chromatography equipped with a nitrogen/phosphorus detector

(GC/NPD), the multiresidue method in PAM, Vol. I section 302 (Protocol

D) in the nitrogen-specific mode, and gas-liquid chromatography/mass

spectrometry in the chemical ionization mode with selected ion

monitoring (SIM) of the M+1 ion at m/z 268 for determining residues in/

on black pepper and livestock.

 The method may be requested from: Chief, Analytical Chemistry

Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD

20755-5350; telephone number: (410) 305-2905; email address:

residuemethods@epa.gov.

B. International Residue Limits

 In making its tolerance decisions, EPA seeks to harmonize U.S.

tolerances with international standards whenever possible, consistent

with U.S. food safety standards and agricultural practices. EPA

considers the international maximum residue limits (MRLs) established

by the Codex Alimentarius Commission (Codex), as required by FFDCA

section 408(b)(4). The Codex Alimentarius is a joint United Nations

Food and Agriculture Organization/World Health Organization food

standards program, and it is recognized as an international food safety

standards-setting organization in trade agreements to which the United

States is a party. EPA may establish a tolerance that is different from

a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain

the reasons for departing from the Codex level. The Codex has not

established a MRL for metalaxyl in or on black pepper.

C. Response to Comments

 Two comments were received in response to the notice of filing. One

of the comments was not germane to the petition for metalaxyl

tolerances.

 The second comment argued against the use metalaxyl on black pepper

and expressed concern about the overall toxicity of pesticides.

Although the Agency recognizes that some individuals believe that

pesticides should be banned on agricultural crops, the existing legal

framework provided by FFDCA section 408 authorizes EPA to establish

tolerances when it determines that the tolerance is safe. Upon

consideration of the validity, completeness, and reliability of the

available data as well as other factors the FFDCA requires EPA to

consider, EPA has determined that these metalaxyl tolerances are safe.

The commenter has provided no information supporting a contrary

conclusion.

D. Revisions to Petitioned-For Tolerances

 EPA is establishing the tolerance at 0.3 ppm rather than at the

petitioned-for tolerance level of 1.0 ppm. EPA's analysis of the

monitoring data that was submitted to support the tolerance level

concludes that 0.3 ppm is sufficient to cover residues in imported

black pepper.

V. Conclusion

 Therefore, tolerances are established for residues of metalaxyl,

methyl N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-DL-alaninate, in or on

pepper, black at 0.3 ppm.

VI. Statutory and Executive Order Reviews

 This action establishes a tolerance under FFDCA section 408(d) in

response to a petition submitted to the Agency. The Office of

Management and Budget (OMB) has exempted these types of actions from

review under Executive Order 12866, entitled ``Regulatory Planning and

Review'' (58 FR 51735, October 4, 1993). Because this action has been

exempted from review under Executive Order 12866, this action is not

subject to Executive Order 13211, entitled ``Actions Concerning

Regulations That Significantly Affect Energy Supply, Distribution, or

Use'' (66 FR 28355, May 22, 2001) or 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 (CRA)

 Pursuant to the CRA (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 3, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

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

40 CFR chapter I as follows:

[[Page 53009]]

PART 180--TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES

IN FOOD

0

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

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

0

2. In Sec. 180.408, amend the table in paragraph (a) by:

0

i. Designating the table as Table 1 to Paragraph (a).

0

ii. Adding in alphabetical order an entry for ``Pepper, black''.

0

iii. Add footnote 1.

 The additions read as follows:

Sec. 180.408 Metalaxyl; tolerances for residues.

\* \* \* \* \*

 Table 1 to Paragraph (a)

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 Parts per

 Commodity million

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 \* \* \* \* \*

Pepper, black \1\.......................................... 0.3

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\1\ There are no U.S. registrations for use of this pesticide on this

 commodity as of September 24, 2021.

\* \* \* \* \*

[FR Doc. 2021-20743 Filed 9-23-21; 8:45 am]

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