PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for Part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add a new § 165.T0286 to read as follows:

§ 165.T0286 Safety Zone for the Fall River Grand Prix, Mt. Hope Bay and Taunton River, Fall River, MA.

(a) *Location.* The following area is a safety zone: Mt. Hope Bay and the Taunton River navigation channel from approximately Mt. Hope Bay buoy R10 southwest of Brayton Point channel, and extending approximately two miles to the northeast up to and including Mt. Hope Bay buoy C17 north of the Braga Bridge. The safety zone is encompassed by the following coordinates:

Corner	Latitude	Longitude
SW	41°41.40′ N.	71°11.15′ W.
NW	41°41.48′ N.	71°11.15′ W.
SE	41°42.33′ N.	71°09.40′ W.
NE	41°42.42′ N.	71°09.47′ W.

(b) *Enforcement Period.* Vessels will be prohibited from entering this safety zone, when enforced, during the Fall River Grand Prix marine event between 9 a.m. and 5 p.m. from Friday, August 14, 2015 to Sunday, August 16, 2015.

(c) *Definitions.* The following definitions apply to this section:

(1) *Designated Representative.* A ''designated representative'' is any Coast Guard commissioned, warrant or petty officer of the U.S. Coast Guard who has been designated by the Captain of the Port, Sector Southeastern New England (COTP), to act on his or her behalf. The designated representative may be on an official patrol vessel or may be on shore and will communicate with vessels via VHF–FM radio or loudhailer. In addition, members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation.

(2) *Official Patrol Vessels.* Official patrol vessels may consist of any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the COTP.

(3) *Patrol Commander.* The Coast Guard may patrol each safety zone under the direction of a designated Coast Guard Patrol Commander. The Patrol Commander may be contacted on Channel 16 VHF–FM (156.8 MHz) by the call sign ''PATCOM.''

(4) *Spectators.* All persons and vessels not registered with the event sponsor as participants or official patrol vessels.

(d) *Regulations.* (1) The general regulations contained in 33 CFR 165.23 as well as the following regulations apply to the safety zone established in conjunction with the Fall River Grand Prix, Taunton River, vicinity of Fall River, MA. These regulations may be enforced for the duration of the event.

(2) No later than 8 a.m. each day of the event, the Coast Guard will announce via Safety Marine Information Broadcasts and local media the times and duration of each race scheduled for that day, and the precise area(s) of the safety zone that will be enforced.

(3) Vessels may not transit through or within the safety zone during periods of enforcement without Patrol Commander approval. Vessels permitted to transit must operate at a no-wake speed, in a manner which will not endanger participants or other crafts in the event.

(4) Spectators or other vessels shall not anchor, block, loiter, or impede the movement of event participants or official patrol vessels in the safety zone unless authorized by an official patrol vessel.

(5) The Patrol Commander may control the movement of all vessels in the safety zone. When hailed or signaled by an official patrol vessel, a vessel shall come to an immediate stop and comply with the lawful directions issued. Failure to comply with a lawful direction may result in expulsion from the area, citation for failure to comply, or both.

(6) The Patrol Commander may delay or terminate the Fall River Grand Prix at any time to ensure safety. Such action may be justified as a result of weather, traffic density, spectator operation or participant behavior.

Dated: May 8, 2015.

J.T. Kondratowicz,

Captain, U.S. Coast Guard, Captain of the Port Southeastern New England.

[FR Doc. 2015–12736 Filed 5–28–15; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0230; FRL–9927–02]

RIN 2070–ZA16

Banda de Lupinus albus doce BLAD; Proposed Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to revoke the current exemption from the requirement for a tolerance for residues of banda de *Lupinus albus* doce (BLAD) in or on all food commodities. In its place, EPA proposes to establish a tolerance limiting residues of BLAD to 0.005 parts per million (ppm) in or on almonds, grapes, strawberries and tomatoes. The Agency is undertaking this action under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: Comments must be received on or before July 28, 2015.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2015–0230, 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 Confidential Business Information (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.*

FOR FURTHER INFORMATION CONTACT: Robert McNally, Director, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@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. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition, to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html*.

II. This Proposal

A. What is the authority for this action?

EPA is taking this action under section 408(e) the FFDCA, 21 U.S.C. 346a(e), which allows EPA to initiate a tolerance action under FFDCA section 408, 21 U.S.C. 346a *et seq.* 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.'' FFDCA section 408(b)(2)(A)(ii) 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.

FFDCA section 408(b)(2)(C) 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 . . .''

Section 408(c)(2)(A)(ii) contains the same safety standard for establishing or leaving in effect an exemption from the requirement of a tolerance. Section 408(c)(2)(A)(i) requires the Agency to modify or revoke an exemption if the Agency determines it is not safe.

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of FFDCA section 408 and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/regulating/tolerances.htm*.

B. What action is the Agency taking?

EPA, on its own initiative under FFDCA section 408(c)(1)(B), is proposing to revoke the existing exemption from the requirement of a tolerance for residues of the fungicide BLAD in or on all food commodities as established in the **Federal Register** of March 22, 2013 (78 FR 17600) (FRL–9380–6). In addition, EPA is proposing to establish a tolerance under FFDCA section 408(e) for residues of the fungicide BLAD, in or on almonds, grapes, strawberries, and tomatoes at the level of detection of 0.005 ppm.

EPA is taking this action in response to concerns that were raised by the Federal Drug Administration (FDA) about the potential allergenicity of BLAD for peanut-sensitive individuals following EPA's promulgation of the tolerance exemption of BLAD on all food commodities. Based on the potential uncertainty raised by those concerns, EPA sought additional data from the petitioner and reexamined the safety of the BLAD tolerance exemption. Following an assessment of the additional data that was provided, EPA has concluded that the available data supports establishing a more limited tolerance at the level of detection on specific commodities.

III. Regulatory Background

In the **Federal Register** of March 22, 2013, EPA established a tolerance exemption for residues of BLAD in or on all food commodities when applied as a fungicide and used in accordance with label directions and good agricultural practices. EPA established this tolerance exemption following the receipt of a petition from Consumo Em Verde S.A, Biotecnologia De Plantas, Parque Technologico de Cantanhede (CEV) in 2012. All of the data requirements to support the exemption from the requirement of a tolerance were fulfilled, and following an assessment of all available data, EPA concluded that there was a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of BLAD.

Following EPA's establishment of a tolerance exemption for residues of BLAD on all food commodities, FDA raised concerns about the potential allergenicity of the BLAD protein for peanut-sensitive individuals. EPA's original review of the data in support of the establishment of a tolerance exemption had considered BLAD's potential allergenicity and concluded that the use of BLAD as pesticide would not result in any meaningful exposure to human health and the environment based on the following considerations. First, because lupines are commonly used in human and animal nutrition as a food and feed, EPA concluded that any dietary contribution from use of BLAD as a pesticide would be relatively limited. Second, the weight of evidence regarding the BLAD protein suggested low risk for allergenicity concerns upon application of the criteria set by the Codex Alimentarius (2003) and the Food and Agricultural Organizations of the United Nations/World Health Organization (FAO/WHO) (2001):

• Amino acid homology: Having an amino acid residue similarity of greater than 35% over a sequence of 80 amino acids of a known allergenic protein (*Ara h 1*). Residues 5 to 169 in BLAD exhibit a 58% sequence homology when compared to residues 148 to 312 in *Ara h 1,* which is similar to other legume seed storage proteins;

• Having one or more sets of more than 6 contiguous amino acid residues that are identical to amino acids of a known allergenic protein. BLAD contains only one stretch of contiguous amino acid residues identical to *Ara h 1;* as a comparison there are 2 in lupine and bean vicilin, 3 in pea and broad bean vicilin, and 5 in soybeans. This observation suggests a more likely presence of IgE recognition epitopes on the vicilins rather than on BLAD;

• Serum cross-reactivity to known allergens: Moneret-Vautrin *et al.,* 1999 found that although peanut-lupine cross-reactivity allergenic potential is high, it presumably corresponds to lupine γ-conglutin and not to lupine β-conglutin, the precursor of BLAD;

• Pepsin resistance: BLAD is readily degraded by proteolytic enzymes and

• Expression levels: Using immunological methods, residual levels of BLAD were not detectable 18 hours after application to tomatoes, relative to controls.

This information was used by the EPA to conclude that BLAD is not likely to be an allergen.

Nonetheless, FDA expressed concerns about the potential allergenicity of BLAD because lupine is known to incite food allergy in sensitive individuals and because of reports of cross-reactivity to lupine protein in peanut sensitive

individuals. In response to these newly raised concerns, EPA decided to investigate further the issues raised by FDA and seek additional data, including a skin prick (*in vivo*) test on *Ara h 1* peanut/lupine sensitive individuals and an *in vitro* immunological testing on serum from *Ara h 1* peanut/lupine sensitive individuals. The focus on *Ara h 1* sensitive individuals is due to the similarity of the β-conglutin parent molecule of BLAD to the *Ara h 1* allergen and reports of cross reactivity in peanut-sensitive individuals to lupine protein.

In addition, EPA required residue chemistry field trials conducted on crops listed on the proposed pesticide label using PROBLAD PLUS, the end-use pesticide containing the BLAD protein, at label rates and exaggerated application rates (5X) to establish a rate of decline and residue levels of BLAD on crops tested. Upon receipt of all the new information, EPA reexamined the safety of BLAD.

IV. Aggregate Risk Assessment and Determination of Safety

A. EPA's Safety Determination

EPA has evaluated the available toxicity and exposure data and considered its validity, completeness, and reliability, as well as the relationship of the results of the studies to human risk. Based upon that evaluation, 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 BLAD residues under the tolerance proposed in this action.

EPA's assessment of exposures and risks associated with BLAD is discussed in this unit of the document.

B. 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.

BLAD is a naturally occurring 20 kilo Dalton (kDa) polypeptide fragment of β-conglutin, a main storage protein in the flowering plant sweet lupines (*Lupinus albus*). BLAD protein is produced by breakdown of β-conglutin during day 4 to 12 of the germination process of the sweet lupines. Data submitted and reviewed by the Agency demonstrate that BLAD operates in a non-toxic manner. BLAD, which is used as a fungicide, degrades chitin by catalyzing and successfully removing the N-acetyl-D-glucosamine terminal monomers, resulting in the destruction of the fungal cells. There is a history of safe use in human and livestock consumption; however, there may be a potential for allergenicity with some sensitive populations.

All of the toxicity data requirements have been fulfilled. EPA has concluded that the data are acceptable and no additional data are required. Data on the end-use product, PROBLAD PLUS, containing BLAD as its active ingredient, did not indicate toxicity endpoints. The toxicological information showed that PROBLAD PLUS has a low toxicity profile as noted in the test results for the following studies: Acute Oral Lowest Dose $(LD)_{50}$ > 5,000 milligram/kilogram (mg/kg); Acute Dermal LD_{50} > 2,000 mg/kg; Acute Inhalation LC_{50} > 5.34 milligram/Liter (mg/L); Primary Eye Irritation was slight; Primary Dermal Irritation was mild to slight; and PROBLAD PLUS is not a contact dermal sensitizer. Moreover, there are no known effects on endocrine systems via oral, dermal, or inhalation exposure. Therefore, the Agency concludes that there are no toxicity risks with BLAD.

As noted in Unit III., EPA re-examined the potential allergenicity of BLAD because of the concern raised about potential sensitivity of peanut-sensitive individuals. The following observations raised new questions about the potential for BLAD to pose an allergenicity concern:

1. BLAD comprises an internal segment of β-conglutin;

2. β-conglutin exhibits a relatively strong homology to the other members of the vicillin family, including well-known allergens contained in peanuts and soybeans (specifically *Ara h 1*); and

3. There are a considerable number of studies concerning the allergenicity of lupine-derived products.

EPA then evaluated the reactivity to BLAD in sensitive individuals.

A Skin Prick Test (SPT) with lupine or peanut extracts in order to establish a sampling population that was sensitive to lupines and/or peanuts was submitted to the Agency. The serum from a sensitive population that tested positive to lupine/peanut exposure through a SPT was used to evaluate the capacity of cross-reactivity to BLAD in these sensitive individuals. Negative results to BLAD in IgE-specific *in vitro* immunoblot (ELISA) testing on serum from sensitive individuals, suggest that the compound is non-allergenic to lupine and/or peanut-sensitive individuals.

Allergenicity relates to both a sensitizing exposure (sensitization leading to allergy cannot occur to a protein without a prior exposure) and a subsequent acute effect if allergy develops (a single exposure in a sensitive individual will cause a response). The difficulty with assessing allergenicity relates to determining a threshold level of exposure below which there is no reasonable expectation of eliciting a reaction in a sensitive individual. Although the new allergenicity data suggest that BLAD is not an allergen, the existing exemption from the requirement of a tolerance allows any amount of residue that might result from reasonably foreseeable uses of BLAD as a fungicide. In light of the similarity of BLAD to peanut allergens and documented allergies to lupines in the literature, the Agency believes the safety of BLAD also depends on demonstrating no detectable residues, in the absence of a demonstrated threshold level.

Specific information on the studies received and EPA's assessment of them can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2015–0230.

C. Toxicological Points of Departure/Levels of Concern

Based on the available toxicity and allergenicity data, the Agency did not identify any toxicological points of departure or levels of concern. Nevertheless, due the potential for allergenicity that might arise under the current exemption due to potentially unlimited exposure to residues of BLAD, the Agency is relying on data supporting a lack of exposure to BLAD residues on certain crops. Therefore, the Agency is conducting a qualitative assessment based on a lack of residues.

D. Exposure Assessment

1. *Dietary exposure from food and feed uses.* The dietary exposure to residues of BLAD via pesticidal use is expected to be negligible as, based on available residue data, the residues are below the level of detection.

Due to the potential for allergenicity, field trials using PROBLAD PLUS at the product-labeled application rate and an exaggerated application rate (5X) were submitted in order to determine levels of potential exposure and the rate of BLAD residue degradation. Those studies, conducted on grapes, tomatoes and strawberries, showed that even with multiple consecutive applications at exaggerated application rates, the residue levels of BLAD will be negligible or non-existent. Both studies (involving label and exaggerated

application rates) showed similar residue measurements and a similar pattern with a half-life of about 2 days.

At label application rates, grape and strawberry samples showed no detectable residues (< limit of detection (LOD), 0.005 ppm) of BLAD on day zero; tomato samples showed BLAD residues < limit of quantitation (LOQ) (0.0062 ppm) on day zero but declined to < LOD levels one day after application. To ensure the reduction of any available residues, a one-day pre-harvest interval on PROBLAD PLUS labeling is being required.

Additionally, due to the presence of an almond husk and the subsequent processing of almond nut meats, the pre-harvest use of BLAD on almonds following good agricultural practices does not represent any reasonable possibility of resulting in detectable residues on the edible nut.

2. *Dietary exposure from drinking water.* Pesticide residues in drinking water are not expected because BLAD residues degrade rapidly in the environment. Specific information on the studies received and EPA's assessment of them can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2015–0230.

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). BLAD 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 BLAD to share a common mechanism of toxicity with any other substances, and BLAD does not appear to degrade into any toxic metabolite or other substance of concern. For the purposes of this tolerance action, therefore, EPA has assumed that BLAD 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

FFDCA section 408(b)(2)(C) provides that, in considering the establishment of a tolerance or tolerance exemption for a pesticide chemical residue, 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 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 are available to support the choice of a different safety factor.

As part of its qualitative assessment, the Agency did not use safety factors for assessing risk; therefore, no additional safety factor is needed for assessing risk to infants and children. The available data indicate that BLAD has minimal or no toxicity and is not an allergen, especially in combination with the data demonstrating a lack of exposure from application as a pesticide. EPA therefore concludes that there are no threshold effects of concern to infants, children, or adults when BLAD is applied as a fungicide and used in accordance with label directions and good agricultural practices.

E. Aggregate Risks and Determination of Safety

Taking into consideration all available information on BLAD, EPA concludes that the potential for allergenicity of BLAD introduces a reasonable uncertainty concerning the potential for harm to peanut-sensitive individuals in light of the possibility for unlimited exposure to BLAD that might be permitted under an unlimited exemption from the requirement of a tolerance. To address that potential uncertainty, EPA is proposing to revoke the current tolerance exemption for BLAD in 40 CFR 180.1319. In its place, and in consideration of these potential concerns, EPA is proposing to establish a more limited tolerance of 0.005 ppm for residues of BLAD in or on almonds, grapes, strawberries, and tomatoes. This is based on crop-specific residue data on grapes, strawberries, and tomatoes that demonstrates a lack of residues on those specific crops. Additionally, due to the presence of an almond husk and the subsequent processing of almond nut meats, the pre-harvest use of BLAD on almonds following good agricultural practices does not represent any reasonable possibility of resulting in detectable residues on the edible nut.

Therefore, under this more limited scenario, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the residues of BLAD when it is applied as fungicide to the specifically noted crops and used in accordance with label directions and good agricultural practices. Such exposure includes all anticipated dietary exposures and all other exposures for which there is reliable information. Based on this information, EPA expects that, when used according to the proposed label directions, the tolerance for residues of BLAD on the listed commodities is safe, and no adverse effects such as allergenic reactions are expected to occur.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Enzyme-Linked Immunosorbent Assay (ELISA: EASI Method No: RA029 and RA031) is available to enforce the tolerance expression.

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

B. International Residue Limits

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

The Codex has not established a MRL for BLAD.

C. Trade Considerations

The revocation of the existing tolerance exemption and establishment of tolerances for four commodities is a reduction in allowable residues of BLAD on food. Therefore, EPA intends to provide notice to the World Trade Organization (WTO) of this proposal in accordance with its obligations under the WTO's Sanitary and Phytosanitary Measures Agreement.

VI. Conclusion

EPA proposes to revoke the existing tolerance exemption for residues of BLAD in or on all food commodities as established in the **Federal Register** of March 22, 2013 under section 408 of the FFDCA due to potential allergenicity concerns. In its stead, the Agency proposes to establish a tolerance for residues of BLAD in or on almonds, grapes, strawberries, and tomatoes at the level of detection of 0.005 ppm based on BLAD's low toxicity profile, testing that indicated that BLAD is non-allergenic, and residue data that demonstrated a rapid decline of BLAD following application at an exaggerated rate. Therefore, EPA is proposing to establish a tolerance level at the limit of detection for the analytical method to prevent any exposure to sensitive individuals from potential residues of BLAD on the treated crops.

VII. Statutory and Executive Order Reviews

This proposed action would revoke an existing exemption from the requirement of a tolerance and establish new tolerances under FFDCA section 408(e). The Office of Management and Budget (OMB) has exempted tolerance actions from review under Executive Orders 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), and 13563, entitled *Improving Regulation and Regulatory Review* (76 FR 3821, January 21, 2011). As a result, 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). Nor does it require OMB review or any Agency action under 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.*); 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); and 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).

This action directly regulates growers, food processors, food handlers, and food retailers, but it does not regulate State or tribal governments. Nor does this action alter the relationships or distribution of power and responsibilities established in the preemption provisions of FFDCA section 408(n)(4). Therefore, the Agency has determined that Executive Orders 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and 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, contain any unfunded mandate, or otherwise significantly or uniquely affect small governments as described in the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

Under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), I certify that this action will not have significant economic impact on a substantial number of small entities. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the action will not impose any requirements on small entities. There are not a substantial number of small entities affected by this rule. BLAD, which is currently manufactured only by CEV, is not being used as a pesticide on food at this time. Therefore, this action will not impose any requirements or have a significant impact on a substantial number of small entities. We have therefore concluded that this action will not impact small entities.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 13, 2015.

Jack Housenger,

Director, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be 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.

■ 3. Section 180.683 is added to read as follows:

§ 180.683 Banda de Lupinus albus doce; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide banda de *Lupinus albus* doce (BLAD), including its metabolites and degradates, in or on the commodities in the table below as a result of the application of BLAD. Compliance with the tolerance levels specified below is to be determined by measuring only BLAD in or on the following commodities.

Commodity	Parts per million
Almonds	0.005
Grapes	0.005
Strawberries	0.005
Tomatoes	0.005

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

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

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

§ 180.1319 [Removed and Reserved]

■ 3. Remove and reserve § 180.1319.

[FR Doc. 2015–12530 Filed 5–28–15; 8:45 am]

BILLING CODE P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Chapter I

[EPA–HQ–OPP–2014–0818; FRL–9927–36]

Proposal To Mitigate Exposure to Bees From Acutely Toxic Pesticide Products; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is seeking comment on a proposal to adopt mandatory pesticide label restrictions to protect managed bees under contract pollination services from foliar application of pesticides that are acutely toxic to bees on a contact exposure basis. These label restrictions would prohibit applications of pesticide products, which are acutely toxic to bees, during bloom when bees are known to be present under contract. EPA is also seeking comment on a proposal to rely on efforts made by states and tribes to reduce pesticide