that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. In § 522.955, revise paragraph (d)(1)(i)(B) and in paragraph (d)(1)(i)(C), in the first sentence, remove ''last'' to read as follows:

§ 522.955 Florfenicol.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(B) *Indications for use.* For treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis* in beef and non-lactating dairy cattle.

* * * * *

Dated: December 10, 2009.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E9–29875 Filed 12–15–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 260

Outer Continental Shelf Oil and Gas Leasing

CFR Correction

In Title 30 of the Code of Federal Regulations, Parts 200 to 699, revised as of July 1, 2009, on page 549, in § 260.122, reinstate paragraphs (b)(2) and (b)(3) to read as follows:

§ 260.122 How long will a royalty suspension volume be effective for a lease issued in a sale held after November 2000?

* * * * *

(b) * * *

(2) You must pay any royalty due under this paragraph, plus late payment interest under § 218.54 of this title, no later than 90 days after the end of the period for which royalty is owed.

(3) Any production on which you must pay royalty under this paragraph will count toward the production volume determined under §§ 260.120 through 260.124.

* * * * *

[FR Doc. E9–30016 Filed 12–15–09; 8:45 am]

BILLING CODE 1505–01–D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0802; FRL–8798–5]

2,6-Diisopropylnaphthalene (2,6-DIPN); Time-Limited Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of 2,6-diisopropylnaphthalene (2,6-DIPN), including its metabolites and degradates, resulting from post-harvest applications to potatoes, in or on various commodities. Loveland Products, Incorporated requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). The tolerances will expire on May 18, 2012.

DATES: This regulation is effective December 16, 2009. Objections and requests for hearings must be received on or before February 16, 2010, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0802. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Leonard Cole, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5412; e-mail address: *cole.leonard@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. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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–2009–0802 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before February 16, 2010.

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 that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2009–0802, by one of the following methods.

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of October 21, 2009 (74 FR 54043) (FRL–8795–7), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F7626) by Loveland Products, Inc., 7251 W. 4th Street, Greeley, CO 80634. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the biochemical pesticide 2,6-DIPN in or on the following food commodities: Cattle, fat at 0.8 ppm; cattle, liver at 0.3 ppm; cattle, meat at 0.1 ppm; cattle, meat byproducts at 0.1 ppm; goat, fat at 0.8 ppm; goat, liver at 0.3 ppm; goat, meat at 0.1 ppm; goat, meat byproducts at 0.1 ppm; hog, fat at 0.8 ppm; hog, liver at 0.3 ppm; hog, meat at 0.1 ppm; hog, meat byproducts at 0.1 ppm; horse, fat at 0.8 ppm; horse, liver at 0.3 ppm; horse, meat at 0.1 ppm; horse, meat byproducts at 0.1 ppm; milk at 0.1 ppm; potato at 2.0 ppm; potato, wet peel at 6.0 ppm; sheep, fat at 0.8 ppm; sheep, liver at 0.3 ppm; sheep, meat at 0.1 ppm; and sheep, meat byproducts at 0.1 ppm. The proposed tolerance levels were based on results of studies on the magnitude of 2,6-DIPN in potatoes and processed potatoes and in livestock edible commodities.

The Agency failed to include a summary of the petition prepared by Loveland Products, Incorporated, the petitioner, in the docket; therefore, the Agency placed the summary of the petition in the docket and reopened the comment period (74 FR 57467; November 6, 2009) (FRL–8798–4).

One comment was received in response to the October 21, 2009 notice. In general, a private citizen expressed opposition to the establishment of the numeric tolerances sought by the petitioner.

Comment: The commenter objected to the manufacture, sale, and use of pesticide products containing 2,6-DIPN in the United States (U.S.) and asserted that EPA does not possess sufficient data to ascertain whether 2,6-DIPN products are truly harmful to human health. Furthermore, the commenter articulated the following opinions: ''It is also clear that our waters are being deluged with toxic chemicals courtesy of this Agency approving 100% of all toxic chemicals that come before it. This Agency is harmfully impacting the people of the United States and this Agency needs to have fired many of its employees. Bush put lobbyists in charge of it and those guys just sank down to their knees for toxic chemical polluters. The situation is bad and desperately needs correction.''

EPA Response: The toxicity of 2,6-DIPN has been examined thoroughly by the Agency, and the data show that when 2,6-DIPN is used in accordance with EPA-approved labeling and good agricultural practices, there is a reasonable certainty of no harm to human health. Given the available data, the Agency has established numeric tolerances for 2,6-DIPN that are safe.

Based upon review of the data supporting the petition, EPA has increased the petitioned-for tolerance levels for all of the livestock commodities and added two new tolerances for ''milk, fat'' and ''potatoes, granules/flakes.'' EPA also revised commodity terms, as necessary, to agree with the Agency's Food and Feed Commodity Vocabulary. The Agency is also issuing time-limited tolerances at this time instead of permanent tolerances. The reasons for these changes are explained in Unit IV.E.

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. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

Consistent with section 408(b)(2)(D) of FFDCA, 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, consistent with section 408(b)(2) of FFDCA, for time-limited tolerances for residues of 2,6-DIPN, including its metabolites and degradates, in or on cattle, fat at 1.0 ppm; cattle, liver at 0.5 ppm; cattle, meat at 0.2 ppm; cattle, meat byproducts (except liver) at 0.4 ppm; goat, fat at 1.0 ppm; goat, liver at 0.5 ppm; goat, meat at 0.2 ppm; goat, meat byproducts (except liver) at 0.4 ppm; hog, fat at 1.0 ppm; hog, liver at 0.5 ppm; hog, meat at 0.2 ppm; hog, meat byproducts (except liver) at 0.4

ppm; horse, fat at 1.0 ppm; horse, liver at 0.5 ppm; horse, meat at 0.2 ppm; horse, meat byproducts (except liver) at 0.4 ppm; milk at 0.2 ppm; milk, fat at 0.5 ppm; potato at 2.0 ppm; potato, wet peel at 6.0 ppm; potato, granules/flakes at 5.5 ppm; sheep, fat at 1.0 ppm; sheep, liver at 0.5 ppm; sheep, meat at 0.2 ppm; and sheep, meat byproducts (except liver) at 0.4 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the time-limited tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by 2,6-DIPN are discussed in this unit.

Time-limited tolerances for 2,6-DIPN expired on August 1, 2009 (40 CFR 180.590). To evaluate the tolerances requested in the subject petition, EPA reviewed data unavailable for the previous, time-limited tolerances. In support of this rule, EPA is providing a discussion of the toxicity of 2,6-DIPN in light of the newly submitted data. Evaluation of these data indicates that the toxicity profile of 2,6-DIPN has not been affected. Based on this finding, the Agency can make a determination of reasonable certainty of no harm to human health when residues of 2,6-DIPN, including its metabolites and degradates, within the tolerance levels established by this final rule are consumed from the aforementioned commodities.

2,6-DIPN is classified as a biochemical-like active ingredient, primarily based upon its structural and functional similarities to the following naturally occurring plant growth regulators: 1-Isopropyl-4,6-dimethylnaphthalene; 1-methyl-7-isopropylnaphthalene; and 4-isopropyl-1,6-dimethylnaphthalene. 2,6-DIPN behaves as a sprout inhibitor; therefore, the Agency considers this mode of action to be non-toxic. With regard to the toxicity of 2,6-DIPN to humans (including infants and children), as a result of consumption of potatoes treated with this active ingredient after harvest, the Agency has, since 2,6-DIPN's initial registration in 2003, continued to evaluate this active ingredient for its toxicity and safety to the general population. EPA's discussion and analysis of the toxicological profile of 2,6-DIPN can be found in the **Federal Register** of September 1, 2006 (71 FR 52003) (FRL–8081–9), and August 8, 2003 (68 FR 47246) (FRL–7321–6).

In support of these current time-limited tolerances, EPA did not assess any new toxicity data on 2,6-DIPN. EPA has previously conducted comprehensive evaluations of the potential human health and dietary toxicity of 2,6-DIPN. As mentioned above (see Unit III.A.2.), EPA reviewed newly submitted nature of residue data conducted on plants and livestock (For a detailed discussion of these data, see Unit IV.A.). These data are required by the Agency to demonstrate the fate and distribution of the active ingredient and its metabolites in plants and livestock. These data enable the Agency to better understand if any metabolites of the active ingredient contribute to the toxicity of the active ingredient being evaluated and require an increase or decrease in proposed tolerance levels. Moreover, this information ultimately may or may not impact the Agency's risk assessment. In the case of the evaluation of these newly submitted data in support of these time-limited tolerances and a reevaluation of field trial data on file (Master Record Identification Number (MRID No.) 451632–02), the Agency has concluded that the toxicity profile of 2,6-DIPN has not changed, nor does the original risk assessment for this active ingredient change. In further support of this assertion, the Agency also considered potato processing data, which demonstrates that residues of 2,6-DIPN were found not to concentrate in baked potatoes, boiled potatoes, and french fries (MRID No. 448660–01). In consideration of all of the previously explained information, EPA concludes that residues of 2,6-DIPN, including its metabolites and degradates within the tolerance limits established by this final rule will present no harm to human health when used in accordance with EPA-approved labeling and good agricultural practices. Included in this document is a summary of the toxicity findings to date from both acute and chronic perspectives (see Unit III.B.).

Additionally, EPA concludes that the analytical methods submitted to enforce the time-limited tolerance levels established for 2,6-DIPN residues in potato and potato peels (MRID Nos. 464749–01 and 464749–02, respectively) are adequate for the purpose of establishing these tolerances for 2,6-DIPN. But, a revised analytical method for the analysis of 2,6-DIPN and its metabolites in livestock commodities remains inadequate. Data reviewed in support of these time-limited tolerances support validation of the analytical method for the parent compound in livestock commodities only, while an independent laboratory validation demonstrating the suitability of the analytical method for the metabolites and degradates in livestock commodities and a radiovalidation are still required. The need for these data will be set as conditions of registration.

B. Toxicological Endpoints

1. *Acute toxicity*. While EPA's discussion and analysis of acute toxicity of 2,6-DIPN can be found in the **Federal Register** of August 8, 2003 (68 FR 47246), in summary, 2,6-DIPN is classified as Toxicity Category IV for the oral route of exposure (lethal dose $(LD)_{50}$ >5,000 milligrams/kilogram (mg/kg)).

2. *Short- and intermediate-term toxicity*. While EPA's complete discussion and analysis of short- and intermediate-term toxicity of 2,6-DIPN can be found in the **Federal Register** of August 8, 2003 (68 FR 47246), a summary is provided here. The subchronic toxicity study submitted and reviewed suggests the endpoint selection (value/dose at which an effect was observed) is the 104 milligrams/kilogram/day (mg/kg/day) no observable adverse effects level (NOAEL) based on reduced body weight, weight gain, and food consumption. Although the developmental toxicity study indicated a lower NOAEL (50 mg/kg/day) for the same toxicity, the maternal lowest observable adverse effects level (LOAEL) of 150 mg/kg/day is between the subchronic NOAEL of 104–121 mg/kg/day and the LOAEL of 208–245 mg/kg/day. The NOAEL of 50 mg/kg/day may have been appropriate for use in characterization of risks for the subpopulation of women of childbearing age; however, the response at 50 mg/kg/day in the developmental study was minimal and the observations for toxic effects were more thoroughly documented in the subchronic study.

3. *Chronic toxicity*. EPA has established the Reference Dose (RfD) for 2,6-DIPN at 1 mg/kg/day. This RfD is based on results from the subchronic and developmental toxicity studies described in the **Federal Register** of September 1, 2006 (71 FR 52003) (FRL–8081–9). In support of these tolerances, the RfD remains unchanged.

4. *Carcinogenicity*. No new study results suggest that 2,6-DIPN is carcinogenic. See EPA's discussion and analysis in the **Federal Register** of August 8, 2003 (68 FR 47246).

C. Exposures and Risks

1. *From food and feed uses.* The Agency is establishing time-limited tolerances for the residues of 2,6-DIPN, including its metabolites and degradates, in or on cattle, fat at 1.0 ppm; cattle, liver at 0.5 ppm; cattle, meat at 0.2 ppm; cattle, meat byproducts (except liver) at 0.4 ppm; goat, fat at 1.0 ppm; goat, liver at 0.5 ppm; goat, meat at 0.2 ppm; goat, meat byproducts (except liver) at 0.4 ppm; hog, fat at 1.0 ppm; hog liver at 0.5 ppm; hog, meat at 0.2 ppm; hog, meat byproducts (except liver) at 0.4 ppm; horse, fat at 1.0 ppm; horse, liver at 0.5 ppm; horse, meat at 0.2 ppm; horse, meat byproducts (except liver) at 0.4 ppm; milk at 0.2 ppm; milk, fat at 0.5 ppm; potato at 2.0 ppm; potato, granules/flakes at 5.5 ppm; potato, wet peel at 6.0 ppm; sheep, fat at 1.0 ppm; sheep, liver at 0.5 ppm; sheep, meat at 0.2 ppm; and sheep, meat byproducts (except liver) at 0.4 ppm.

Acute dietary 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 the case of 2,6-DIPN, the toxicity data base did not indicate an acute endpoint, but the 100 mg/kg/day NOAEL from the subchronic toxicity study (rounded from 104 mg/kg/day) was used to evaluate potential acute dietary exposure as a conservative basis for risk characterization. Also, if the 50 mg/kg/day NOAEL from the developmental toxicity study had been used to establish an acute RfD, this choice would have been inconsistent with the use of the 100 mg/kg/day NOAEL since it implies that exposure to repeated daily doses at 100 mg/kg/day is potentially less hazardous than a single dose at 50 mg/kg/day. Given the minimal nature of the responses in the subchronic and developmental toxicity studies, and the fact that the NOAEL from the developmental study is only appropriate to the subgroup of females 13–49 years of age, using the 100 mg/kg/day RfD for the acute and chronic dietary assessments is more appropriate for assessing risk for other subgroups and the general population. Therefore, a conservative interpretation of these endpoints indicated the need for an acute dietary exposure assessment. The 100 mg/kg/day endpoint was also interpreted as requiring a chronic dietary exposure assessment.

Acute and chronic dietary exposure assessments for 2,6-DIPN were conducted using the Dietary Exposure Evaluation Model software (DEEM™ version 1.30), which incorporates consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII, 1994–1996/1998).

For acute exposure assessments, individual 1–day food consumption data define an exposure distribution, which is expressed as a percentage of the acute population adjusted dose (aPAD) (for 2,6-DIPN, aPAD = 0.1 mg/kg/day). For chronic exposure and risk assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the commodity residue list is multiplied by the average daily consumption estimate for the food or food-form. The resulting residue consumption estimate for each food or food-form is summed with the residue consumption estimate for all other food or food-forms on the commodity residue list to arrive at the total estimated exposure. Exposure estimates are expressed as mg/kg body weight/day and as a percent of the 2,6-DIPN chronic population adjusted dose (cPAD) (0.1 mg/kg/day). These procedures are performed for each population subgroup.

2. *From drinking water.* Because 2,6-DIPN treatment of stored (i.e., post-harvest) potato occurs inside (in warehouses, for example), no concern from exposure through water is expected regarding acute and chronic dietary risk assessment. For this reason, the dietary risk assessment did not include drinking water values.

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). 2,6-DIPN is not registered for use on any sites that would result in residential exposure. Furthermore, because the registered use involves applications via a closed system, no exposure of consequence is expected to mixers or loaders.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the 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.''

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 2,6-DIPN and any other substances. In this case, 2,6-DIPN, as well as the three functionally and structurally similar substances, all act as plant regulators by a ''mode of action'' that is specific to plants, and therefore, their common mode of action is unlikely to be relevant to a mechanism of toxicity in animals or humans. The comparison of 2,6-DIPN with three naturally occurring, alkyl-substituted naphthalenes is made to demonstrate biological activity (plant regulation, in this case), which the Agency has characterized as a non-toxic mode of action with respect to pesticidal activity. For the purposes of this tolerance action, therefore, EPA has not assumed that 2,6-DIPN has 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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Aggregate Risks and Determination of Safety for U.S. Population and for Infants and Children

1. *Acute risk.* Acute dietary exposure estimates were based on the tolerances (i.e., the tolerance levels as established in this final rule supported by the residue trial results) and worst-case assumptions.

As reported in the **Federal Register** of August 8, 2003 (68 FR 47246), EPA established a RfD of 1 mg/kg/day, and an aPAD and cPAD of 0.1 mg/kg/day.

The Acute Dietary Exposure Analysis was based on the following tolerance levels for the residues of 2,6-DIPN, including its metabolites and degradates: in or on cattle, fat at 1.0 ppm; cattle, liver at 0.5 ppm; cattle, meat at 0.2 ppm; cattle, meat byproducts (except liver) at 0.4 ppm; goat, fat at 1.0 ppm; goat, liver at 0.5 ppm; goat, meat at 0.2 ppm; goat, meat byproducts (except liver) at 0.4 ppm; hog, fat at 1.0 ppm; hog, liver at 0.5 ppm; hog, meat at 0.2 ppm; hog, meat byproducts (except liver) at 0.4 ppm; horse, fat at 1.0 ppm; horse, liver at 0.5 ppm; horse, meat at 0.2 ppm; horse, meat byproducts (except liver) at 0.4 ppm; milk at 0.2 ppm; milk, fat at 0.5 ppm; potato at 2.0 ppm; potato, granules/flakes at 5.5 ppm; potato, wet peel at 6.0 ppm; sheep, fat at 1.0 ppm; sheep, liver at 0.5 ppm; sheep, meat at 0.2 ppm; and sheep, meat byproducts (except liver) at 0.4 ppm;

For the U.S. population, acute dietary exposure was estimated to be 0.011459 mg/kg/day. This value represented

11.46% of the aPAD. The subpopulation with the highest acute dietary exposure estimate was children 1–2 years old (0.029362 mg/kg/day, 29.36% of the aPAD). Therefore, the acute dietary exposures to all the subpopulations in the analysis did not exceed EPA's level of concern (i.e., they did not exceed 100% of the aPAD).

2. *Chronic risk*. The chronic dietary risk estimates do not exceed EPA's level of concern (i.e., they do not exceed 100% of the cPAD). For the U.S. population, chronic dietary exposure was estimated to be 0.003516 mg/kg/day. This value represented 3.5% of the cPAD. The subpopulation with the highest chronic dietary exposure estimate was children 1–2 years old (0.012173 mg/kg/day, 12.2% of the cPAD).

3. *Determination of safety*. Based on these risk assessments and in consideration of new residue data, 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 residues of 2,6-DIPN and its metabolites and degradates within the established tolerance limits resulting from post-harvest applications, undertaken in accordance with good agricultural practices and EPA-approved labeling, to potatoes. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. In arriving at this conclusion, the Agency has retained the tenfold margin of safety in order to adequately account for potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children, pursuant to FFDCA section 408(b)(2)(C).

IV. Other Considerations

A. Metabolism in Plants and Animals

The metabolism study for stored potatoes treated with [^{14}C-]-DIPN is ACCEPTABLE. The results indicate that significant amounts of [^{14}C-]-DIPN were lost during storage. Total Radioactive Residues (TRR) of 2,6-DIPN decreased from 94.1% to 26.3% in whole potatoes from day 0 to 178 days. The percentages of the TRR identified in the whole potato samples ranged from 70.2% to 95.3% (70.6% to 95.3% for potato peels).

The four metabolites detected, which reached or exceeded 10% of the TRR in potato peels and whole potatoes, were M29, M22, M19, and M18. The metabolic pathway of 2,6-DIPN in potatoes demonstrates that these four metabolites are adequately understood. M29, a monohydroxy derivative of 2,6-DIPN, appeared first as a significant residue. The other major metabolites (M22, M19, and M18) were formed by metabolism of M29, which indicated that M29 was formed continuously throughout the study. However, based on residue declined data, these metabolites (M29, M22, M19, and M18) will not be included in tolerance setting because they showed an insignificant amount at day 0.

The nature of the residue study in a lactating goat indicated that residues of 2,6-DIPN and its metabolites were distributed in muscle loin, muscle flank, fat renal, fat omental, fat subcutaneous, liver, kidney, blood, skim milk, and milk fat. The Agency has considered this information in evaluating the levels of 2,6-DIPN in livestock commodities and has incorporated residues of metabolites that exceed 10% of the TRR in its risk assessment.

The qualitative nature of the 2,6-DIPN residues in livestock commodities is adequately understood, based on a metabolism study. The four major metabolites (i.e., M14, M19, M27, and M29) were identified by high performance liquid chromatography/mass spectrometry (HPLC/MS) from samples of milk, muscles, fat, liver, and kidney.

B. Analytical Enforcement Methodology

Loveland Products, Incorporated has proposed a liquid chromatographic/ultraviolet (LC/UV) detection analytical method for enforcement of tolerances for residues of 2,6-DIPN in potatoes and potato peels. The method (entitled, ''Liquid Chromatographic Analysis for the Determination of 2,6-Diisopropylnaphthalene (DIPN) in Potatoes and ''Liquid Chromatographic Analysis for the Determination of 2,6-Diisopropylnaphthalene (DIPN) in Potato Peels'' (Platte Report Number CARDC–1298–DIPN)) was used for the determination of residues of 2,6-DIPN in potatoes and potato peels.

The method includes instructions and chromatograms for analysis of samples of potatoes and potato peels. Briefly, samples are extracted with acetonitrile. The extracts are partitioned with hexane. The acetonitrile part is discarded. The hexane part is roto-evaporated to dryness. The residues are reconstituted in hexane and purified using a Florisil column. The residues are roto-evaporated to dryness and reconstituted in acetonitrile. The samples are filtered through Acrodisc® LC polyvinylidene difluoride (PVDF) 0.45 micrometer (µm) filters and analyzed by high performance liquid chromatography (HPLC) with ultraviolet (UV) detection at 254 nanometers (nm) using a Zorbax ODS column.

The validated limit of quantitation (LOQ) is 0.01 ppm for 2,6-DIPN in potatoes and 0.02 ppm in potato peels. The reported limits of detection (LODs) were 0.001 ppm for 2,6-DIPN in potatoes and potato peels. The method does not include instructions for confirmatory analysis. Method validation data for the LC/UV method demonstrated adequate method recoveries of residues of 2,6-DIPN. Potato samples were fortified with 2,6-DIPN at levels of 0.01 ppm, 0.02 ppm, 0.05 ppm, and 50 ppm. Samples were analyzed at the limit of quantitation of 0.01 ppm. Overall, recovery ranges (and CVs) from these matrices were 77.9–123.2 (13.9%) for 2,6-DIPN. Potato peel samples were fortified with 2,6-DIPN at levels of 0.02 ppm, 0.05 ppm, and 0.2 ppm. Samples were analyzed at the limit of quantitation of 0.02 ppm. Overall, recovery ranges (and CVs) from these matrices were 83.2–96.1 (5.3%) for 2,6-DIPN.

Acceptable independent laboratory validation is available for this method using potato and potato peel samples.

As described above, an adequate enforcement methodology (liquid chromatographic/ultraviolet detection analytical method) is available to enforce the tolerance expression for potatoes and potato peels only.

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; e-mail address: *residuemethods@epa.gov*. As conditions of registration, the Agency is requesting a revised analytical method for the analysis of the metabolites of 2,6-DIPN in livestock commodities, an associated independent laboratory validation, and radiovalidation of this method. As stated Unit III.A., the Agency is requesting these data since the study analyzed the parent compound only.

C. International Residue Limits

There are currently no established Codex Alimentarius Commission, Canadian, or Mexican Maximum Residue Levels (MRLs) for residues of 2,6-DIPN in/on plant or livestock commodities. Therefore, no compatibility issues exist with regard to the proposed U.S. tolerances.

D. Rotational Crop Restrictions

The rotational crop restrictions are not applicable for this petition because the commodity is for stored potatoes.

E. Revisions to the Requested Tolerances

Based upon review of the data supporting the petition, EPA has slightly increased the tolerance levels requested in the petition for all of the livestock commodities and added two new tolerances for ''milk, fat'' and ''potatoes, granules/flakes.'' EPA also revised commodity terms, as necessary, to agree with the Agency's Food and Feed Commodity Vocabulary.

In light of review of the submitted nature of the residue data (lactating goat), the Agency slightly increased all of the livestock commodity tolerance levels to fully account for metabolites that exceeded 10% of the TRR. Additionally, EPA has set tolerance levels for milk, fat and potatoes, granules/flakes because residues of 2,6-DIPN would normally be expected to be present in these byproducts.

While the petitioner requested permanent tolerances for residues of 2,6 DIPN in or on the food commodities listed in this document, the Agency has determined that time-limited tolerances with an expiration date is appropriate in the absence of an analytical method for metabolites of 2,6-DIPN in livestock.

V. Conclusion

Therefore, time-limited tolerances are established for residues of 2,6-DIPN, including its metabolites and degradates, when applied post-harvest to potatoes, in or on cattle, fat at 1.0 ppm; cattle, liver at 0.5 ppm; cattle, meat at 0.2 ppm; cattle, meat byproducts (except liver) at 0.4 ppm; goat, fat at 1.0 ppm; goat, liver at 0.5 ppm; goat, meat at 0.2 ppm; goat, meat byproducts (except liver) at 0.4 ppm; hog, fat at 1.0 ppm; hog, liver at 0.5 ppm; hog, meat at 0.2 ppm; hog, meat byproducts (except liver) at 0.4 ppm; horse, fat at 1.0 ppm; horse, liver at 0.5 ppm; horse, meat at 0.2 ppm; horse, meat byproducts (except liver) at 0.4 ppm; milk at 0.2 ppm; milk, fat at 0.5 ppm; potato at 2.0 ppm; potato, granules/flakes at 5.5 ppm; potato, wet peel at 6.0 ppm; sheep, fat at 1.0 ppm; sheep, liver at 0.5 ppm; sheep, meat at 0.2 ppm; and sheep, meat byproducts (except liver) at 0.4 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 section 408(d) of FFDCA, 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 final rule 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 section 408(n)(4) of FFDCA. 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

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 of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: November 18, 2009.

Keith A. Matthews,

Acting Director, Biopesticides and Pollution Prevention Division, 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. Section 180.590 is amended by revising paragraph (a) to read as follows:

§ 180.590 2,6-Diisopropylnaphthalene (2,6-DIPN); tolerances for residues.

(a) *General.* (1) Time-limited tolerances are established for combined residues of 2,6-DIPN, including its metabolites and degradates, in or on the commodities in the table below as a result of the post-harvest application of 2,6-DIPN to potatoes, when 2,6-DIPN is used in accordance with good agricultural practices. Compliance with the tolerance levels specified below is to be determined by measuring only 2,6-DIPN in or on the commodities.

Commodity	Parts per million	Expiration/ revocation date
Potato, granules/ flakes	5.5	5/18/12
Potato, wet peel	6.0	5/18/12
Potato, whole	2.0	5/18/12

(2) Time-limited tolerances are established for combined residues of 2,6-DIPN, including its metabolites and degradates, in or on the commodities in

the table below as a result of the post-harvest application of 2,6-DIPN to potatoes, when 2,6-DIPN is used in accordance with good agricultural practices. Compliance with the tolerance levels specified below is to be determined by measuring only 2,6-DIPN and the metabolites M14, M19, M27, and M29 in or on the commodities.

Commodity	Parts per million	Revocation/ expiration date
Cattle, fat	1.0	5/18/12
Cattle, liver	0.5	5/18/12
Cattle, meat	0.2	5/18/12
Cattle, meat by-products	0.4	5/18/12
Goat, fat	1.0	5/18/12
Goat, liver	0.5	5/18/12
Goat, meat	0.2	5/18/12
Goat, meat by-products	0.4	5/18/12
Hog, fat	1.0	5/18/12
Hog, liver	0.5	5/18/12
Hog, meat	0.2	5/18/12
Hog, meat by-products	0.4	5/18/12
Horse, fat	1.0	5/18/12
Horse, liver	0.5	5/18/12
Horse, meat	0.2	5/18/12
Horse, meat by-products	0.4	5/18/12
Milk, fat	0.5	5/18/12
Sheep, fat	1.0	5/18/12
Sheep, liver	0.5	5/18/12
Sheep, meat	0.2	5/18/12
Sheep, meat by-products	0.4	5/18/12

* * * * *

[FR Doc. E9–29897 Filed 12–15–09; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2008–0020; Internal Agency Docket No. FEMA–8107]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date.

DATES: *Effective Dates:* The effective date of each community's scheduled suspension is the third date (''Susp.'') listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact David Stearrett, Mitigation Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2953.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the NFIP, 42 U.S.C. 4001 *et seq.;* unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. However, some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of the communities will be published in the **Federal Register**.

In addition, FEMA has identified the Special Flood Hazard Areas (SFHAs) in these communities by publishing a Flood Insurance Rate Map (FIRM). The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may legally be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year, on FEMA's initial flood insurance map of the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment under 5 U.S.C. 553(b) are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Considerations. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

Paperwork Reduction Act. This rule does not involve any collection of