provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: August 25, 2006.

Anne E. Lindsay,

Acting Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.618 is added to read as follows:

§ 180.618 Benthiavalicarb-isopropyl; tolerance for residues.

(a) *General*. Tolerances are established for the combined residues of benthiavalicarb-isopropyl, isopropyl[(S)-1-[[[(1R)-1-(6-fluoro-2-benzothiazolyl)ethyl]amino] carbonyl]-2-methylpropyl]carbamate and isopropyl[(S)-1-[[[(1S)-1-(6-fluoro-2-benzothiazolyl)ethyl]amino] carbonyl]-2-methylpropyl]carbamate, in or on the following raw agricultural commodities:

Commodity	Parts per million
Grape, imported	0.25
Grape, raisin	1.0
Tomato	0.45

Note: There are no U.S. registrations as of July 30, 2006.

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

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

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

[FR Doc. 06–7313 Filed 8–31–06; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0373; FRL–8081–9]

2, 6-Diisopropylnaphthalene; 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, resulting from post-harvest applications to potato, in or on fat (cattle, goat, hog, horse, and sheep) at 0.8 part per million (ppm); liver (cattle, goat, hog, horse, and sheep) at 0.3 ppm; meat (cattle, goat, hog, horse, and sheep) at 0.1 ppm; meat byproducts (cattle, goat, hog, horse, and sheep) at 0.1 ppm; milk at 0.1 ppm; potato at 2.0 ppm; and potato, wet peel at 6.0 ppm. Loveland Products, Inc. had requested permanent tolerances (in or on whole potato and potato peels at 2 and 6 ppm, respectively) under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The time-limited tolerances will expire on August 1, 2009.

DATES: This regulation is effective September 1, 2006. Objections and requests for hearings must be received on or before October 31, 2006, 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–2006–0373. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Denise Greenway, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8263; e-mail *address:greenway.denise@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 an electronic copy of this **Federal Register** document through the electronic docket 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 pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm/*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, as amended by the FQPA, 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–2006–0373 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 October 31, 2006.

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–2006–0373, 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 Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket'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 telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of December 9, 2005 (70 FR 73234) (FRL–7748–5), 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 1F6338), originated by Platte Chemical Company, now Loveland Products, Inc., 7251 W. 4th Street, Greely, CO 80634. The petition requested that 40 CFR 180.590 be amended by establishing permanent tolerances for residues of the biochemical pesticide 2, 6-diisopropylnaphthalene (2, 6-DIPN), resulting from post-harvest applications to potato, in or on whole potato and potato peels at 2 and 6 parts per million (ppm), respectively. The electronic docket (EPA–HQ–OPP–2005–0318) for this notice included a summary of the petition prepared by Loveland Products, Inc., the registrant. In submitting this petition, Loveland Products, Inc. (formerly Platte Chemical Company) is relying on new data summarized in the cited summary, and also on information previously submitted by Platte Chemical Company, which was summarized in a previous notice of filing published in the **Federal Register** on September 21, 2001 (66 FR 48677) (FRL–6798–3). New data submitted to the Agency by Loveland Products, Inc. on February 8, 2005 and summarized by the company in the current petition are a magnitude of the residue in livestock study, which was a condition of registration for the subject active ingredient when the end-use product, EPA Registration Number 34704–843, was registered on July 31, 2003. Other new data summarized in the electronic docket for the December 9, 2005 notice were analytical enforcement methods to determine residues in potato, potato peels (submitted by Loveland Products, Inc. on February 15, 2005), and livestock commodities (submitted by Loveland Products, Inc. on February 8, 2005); and a magnitude of the residue study which presented recalculations of previously submitted data to support proposed label amendments (submitted by Loveland Products, Inc. on July 20, 2005). As explained in this final rule, the Agency is not granting the two permanent tolerances sought in Loveland Products, Inc.'s current petition, but rather is establishing several time-limited tolerances that will expire on August 1, 2009.

One comment was received from a private citizen opposing the establishment of the permanent numeric tolerances sought by the petitioner.

1. *Comment*. One commenter objected to the use of 2, 6-DIPN on potato in storage, citing information from 60 references on naphthalene, which is a structurally related chemical. There were 24 citations containing information on human health hazards and 36 describing animal studies. The hazards of concern associated with naphthalene exposure included hemolytic anemia, cataracts, and respiratory tract toxicity. Reported no-observed-adverse-effect levels (NOAEL) for naphthalene ranged from 50 milligrams/kilogram/day (mg/kg/day) (an oral chronic toxicity study in the rat) to 200 mg/kg/day (administered by gavage 5 days/week for 13 weeks in mice).

EPA response. Toxicity data on 2, 6-DIPN indicate a NOAEL of approximately 100 mg/kg/day based on decreased body weights in a 13-week feeding study in rats with supporting evidence from a developmental toxicity study in rats. This NOAEL is in the range of NOAELs described by the commenter for general toxicity of naphthalene (i.e., decreased body weight). However, one of the commenter's references in particular indicated that 2, 6-DIPN may be less toxic than naphthalene since the plant regulator was the least toxic of the four compounds tested for respiratory tract toxicity by the investigators (the other three were naphthalene, 2-methylnaphthalene, and 2-isopropylnaphthalene; Honda, T., et al. *Chem Pharm Bull* 38 (11):3130–5 (1990)). This study suggests that alkyl substituted naphthalenes such as 2, 6-DIPN are not as likely to form toxic epoxides in epoxidase-rich lung tissues.

The 12 citations describing studies of respiratory tract toxicity indicated that most investigators chose injection (an unlikely route of exposure for pesticides), or dose levels much higher than those used to define dose-response

relationships (including NOAELS) for general toxicity, or both, to characterize toxicity in the lung. Therefore, use of the NOAELs based on decreased body weight are assumed to be an adequate basis for determining a reference dose for 2, 6-DIPN's risk assessment since body weight decreases occurred at lower doses than those causing respiratory toxicity.

The Agency's Integrated Risk Information System (IRIS) contains a report entitled ''Toxicological Review of Naphthalene'' dated August, 1998 (available at *http://www.epa.gov/iris/toxreviews/* as of May 4, 2006), which includes the citations found in the comment in a comprehensive review and assessment of the literature on naphthalene. That report notes (at page 41), ''the limited subchronic oral animal data identify decreased body weight in rats as the most appropriate critical effect for deriving a chronic oral RfD (reference dose) for naphthalene.''

The IRIS report further indicates (page 41) that an RfD of 0.02 mg/kg/day ''...was derived by dividing a duration-adjusted NOAEL, 71 mg/kg/day, for mean terminal body weight decrease (> 10% of control) in male rats... by an uncertainty factor of 3,000 (10 to extrapolate from rats to humans; 10 to protect sensitive humans; 10 to extrapolate from subchronic to chronic exposure; and 3 for database deficiencies,...).'' A similar derivation of RfDs for 2, 6-DIPN (described as acute or chronic population adjusted doses; aPAD and cPAD, respectively) is accomplished by dividing the 100 mg/kg/day NOAEL by a thousandfold uncertainty factor (10 for intraspecies variability, 10 for interspecies extrapolation, and an additional 10 to consider sensitivity of infants and children as required by the Food Quality Protection Act (FQPA)). Application of an additional threefold uncertainty factor based on data deficiencies was not done for 2, 6-DIPN, because the plant regulator is classified as ''biochemical-like'' based on its structural similarity to 1-isopropyl-4,6-dimethylnaphthalene, 1-methyl-7-isopropylnaphthalene, and 4-isopropyl-1,6-dimethylnaphthalene which are naturally occurring plant regulators. Based on the functional and structural similarities between these naturally occurring alkyl substituted naphthalene plant regulators, their plant-specific modes of action, and the decreased toxicity associated with these compounds, 2, 6-DIPN's classification as ''biochemical-like'' requires less data for registration (i.e., the data set required by 40 CFR 158.690 to support registration of biochemical or biochemical-like pesticides is reduced compared to that required for conventional chemical pesticides). In addition, using the 3,000-fold uncertainty factor for the reasons described in the IRIS assessment would triple the dietary risks described below, but those risks still do not exceed the level of concern for 2, 6-DIPN (i.e., dietary exposure remains <100% of the acute population adjusted dose/chronic population adjusted dose (aPAD/cPAD)).

A late, ten-point comment was received from 1,4Group, Inc. Each of the ten points raised by this comment is summarized individually below, followed by EPA's response.

2. *Comment 1*. It is requested that the Agency address whether the three (unregistered) chemicals (1-isopropyl-4, 6-dimethylnaphthalene; 1-methyl-7-isopropylnaphthalene; 4-isopropyl-1, 6-dimethylnaphthalene) to which 2, 6-DIPN is functionally/structurally similar, share a common mechanism of toxicity.

EPA Response. A ''common mechanism of toxicity'' in the context of cumulative effects relates to the safety evaluation undertaken by EPA in connection with related pesticides (e.g., organophosphates with the common mechanism of toxicity such as cholinesterase inhibition). In this case, 2, 6-DIPN and 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 the four chemicals 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.

3. *Comment 2*. This comment identifies a statement from the Agency's 2, 6-Diisopropylnaphthalene Biopesticide Registration Action Document (BRAD), where on page one 2, 6-DIPN was incorrectly said to be ''...functionally and structurally identical to the naturally occurring plant regulator in potato.''

EPA response. The Agency recognizes the error; potato naturally contain *more than one* plant regulator, and the synthetic 2, 6-DIPN is *similar* in function and structure to 1-isopropyl-4, 6-dimethylnaphthalene; 1-methyl-7-isopropylnaphthalene; and 4-isopropyl-1, 6-dimethylnaphthalene, which are naturally-occurring compounds in plant tissues, including those of potato.

4. *Comment 3*. This comment is a request that the Agency provide documentation of the natural occurrence of the three substances (1-isopropyl-4, 6-dimethylnaphthalene; 1-methyl-7-isopropylnaphthalene; and 4-isopropyl-1, 6-dimethylnaphthalene) to which 2, 6-DIPN is similar.

EPA response. 2, 6-Diisopropylnaphthalene is functionally and structurally similar to the three referenced compounds, which are naturally-occurring in plants. 1-isopropyl-4, 6-dimethylnaphthalene (CAS No. 4545–23–7) is also known as daucalene or isocadalene and is found in roots and plant oils:

- Bicchi *et al.*, 1983. *Journal of High Resolution Chromatography and Chromatographic Communications* 6(4): 213–215.
- Van Dooren *et al.*, 1981. *Planta Medica* 42(4): 385–389.

1-methyl-7-isopropylnaphthalene (CAS No. 490–65–3) is also known as eudalene and is present in plant oils:

- Abegaz and Yohannes, 1982. *Phytochemistry* 21(7): 1791–1793).

4-isopropyl-1, 6-dimethylnaphthalene (CAS No. 483–78–3) is also known as cadalin or cadelene, and is found in the foliage and wood of trees, flowers, seeds, berries, hops and ferns:

- Chalchat *et al.*, 1994. *Journal of Essential Oil Research* 6(3): 323–325.
- Dodd *et al.*, 1994. *Biochemical Systematics and Ecology* 22(4): 393–400.
- El-Seedi *et al.*, 1994. *Phytochemistry* 35(6): 1495–1497.
- Omata *et al.*, 1990. *Agricultural and Biological Chemistry* 54(4): 1029–1033.
- Ekundayo and Hammerschmidt, 1988. *Fitoterapia* 59(1): 52–54.
- Lawerance, 1984. *Perfume and Flavor* 9(5): 65–69.
- Tressel *et al.*, 1983. *Journal of Agricultural and Food Chemistry* 31(4): 892–897.
- Konecny *et al.*, 1982. *Collect. Czech. Chemistry Communications* 47(11): 3164–3169).

5. *Comment 4*. In the fourth comment, the correspondent points out that a rat metabolism study discussed in the 2, 6-Diisopropylnaphthalene BRAD did not explain the ''fate of the remaining 77% of the administered dose,'' and asks if the conditional livestock feeding study could account for it.

EPA response. Although the submitted magnitude of the residue study in livestock was conducted in a reasonable manner, it was designed to determine the magnitude of 2, 6-DIPN residues (not residues from 2, 6-DIPN metabolites) in cattle fed at up to 5.64 times the normal application rate, and only in milk and edible tissues. It did not, therefore, account for the fate of the remaining 77% of the administered dose from the earlier rat metabolism study. The rat metabolism study was also

designed to identify residues/metabolites of toxicological concern, and the absence of a complete accounting of the administered dose was a factor in determining the need for the livestock feeding study. Furthermore, the cattle feeding study cannot be expected to resolve metabolism questions arising from the rat data because the two species may metabolize 2, 6-DIPN differently. The Agency is therefore requiring, as a condition of registration, submission of a nature of the residue study to determine the fate of the dose (i.e., to determine the distribution of 2, 6-DIPN metabolites in livestock commodities), and a laboratory-validated multi-residue analytical method. However, because worst case (conservative) estimates were used to support the time-limited tolerances established in this rule, EPA has concluded that there is a reasonable certainty of no harm from the use of 2, 6-DIPN during the short period while these studies are conducted.

6. *Comment 5*. In this comment the correspondent observes from the notice of filing (December 9, 2005 (70 FR 73234) (FRL–7748–5)) that the petitioner is seeking use rates/tolerance levels higher than those actually tested in the submitted residue trials.

EPA response. The cited notice includes a discussion of information and magnitude of the residue data previously submitted by the petitioner to support a related request to amend the label of the 2, 6-DIPN end-use product, EPA Registration No. 34704–843. That data, on whole potato and potato peel, have been reviewed by the Agency and found to adequately demonstrate that 2, 6-DIPN residues in both commodities declined over time. Recalculations based on these storage stability data for analytical samples, the increased application rate, and more refined residue chemistry data including information on secondary residues in cattle fed 2, 6-DIPN treated potato waste resulted in significantly reduced risk (see discussion below and the previous notice of filing of December 9, 2005, cited above). The Agency's assessment of the new information (to project the residue levels expected to result from an increased application rate) supports the amended maximum yearly application rate of 1.5 (increased from 1.0) pounds of active ingredient per 600 hundred weight of potato. Although the petitioner in their summary of PP 1F6338 referred to the proposed application rate as 1.5 pounds of product per 600 hundredweight of potato, any future references in this document to the application rate will be expressed as pounds of active ingredient per 600 hundredweight of potato because (a) the end-use product is 99.7% pure active ingredient, and (b) the subject of this rule is the active ingredient. Available residue data also provide adequate support to reduce the required period for holding treated stored potato from 30 to zero days because in its analysis the Agency considered data from samples collected on the day of treatment. The adequacy of all of this data will be re-evaluated upon review of a nature of the residue study for potato, which the Agency is requiring as another condition of registration.

7. *Comment 6*. Comment six cites the 2, 6-Diisopropylnaphthalene BRAD (page 10) as stating that a developmental toxicity study in a second species and a reproduction toxicity study were not available to ''...fully determine age-related differences in response.'' The correspondent requests we address this lack of data, and states in this comment, ''Since 2, 6-DIPN does not occur in nature, requirement of a reproduction study would be appropriate.''

EPA response. As indicated in the response to comment 1 above, 2, 6-DIPN was classified as a biochemical-like pesticide based on functional and structural similarity to certain plant regulators, thus qualifying for a reduced data set for registration (i.e., the data set required by 40 CFR 158.690 to support registration of biochemical or biochemical-like pesticides is reduced compared to that required for conventional chemical pesticides). In the absence of the full complement of developmental (in two species) and reproduction toxicity studies, an added 10x uncertainty factor was retained for the reference doses selected for dietary risk characterization. In addition, the developmental toxicity study of 2, 6-DIPN considered by the Agency did not indicate differences in sensitivity of maternal animals and their offspring. Given these circumstances, the Agency has adequately assessed age-related differences in responses to 2, 6-DIPN exposure by retaining the 10x uncertainty factor in lieu of the second developmental and reproduction toxicity studies.

8. *Comment 7*. In this comment, the correspondent states that 2, 6-DIPN is a pesticide for which pork may be tested under the U.S. Department of Agriculture's Pesticide Data Program, which was developed in coordination with the Agency's Health Effects Division, and asks (a) if 2, 6-DIPN residues in pork have been found, and (b) why the required livestock feeding study was limited to cattle.

EPA response. No 2, 6-DIPN residues were found in pork because a study with swine was not requested by the Agency. The conditionally-required livestock feeding study was limited to cattle in alignment with OPPTS Harmonized Guideline 860.1480, which states that, ''...in most cases the results of the cattle feeding study will be used to establish tolerances on goat, hog, horse, and sheep....'' This is because the overall percentage of the potato commodities in the diet of cattle is much higher than in the diet of swine (Table 1 of OPPTS Harmonized Guideline 860.1000). Furthermore, of those potato commodities utilized as feedstuffs, processed potato waste (i.e., potato, wet peel), where the majority of 2, 6-DIPN residue is expected to occur, can represent a high percentage of the diet for cattle, but is either not used, or used at less than 10%, in the diet for swine. Testing of cattle rather than swine, therefore, represents the more conservative, ''worst-case,'' scenario. Nonetheless, dietary contributions of residues from swine fed 2, 6-DIPN treated potato were factored into the Agency's dietary assessment by conservatively assuming the same levels in pork commodities as those found in cattle.

9. *Comment 8*. In this comment the correspondent observes from the notice of filing (December 9, 2005 (70 FR 73234) (FRL–7748–5)) that, except at the highest dose level, the petitioner reported 2, 6-DIPN residues were not located in cow liver, an organ that usually concentrates exogenous chemicals as it metabolizes them. The Agency is asked to address if 2, 6-DIPN was radio-labeled for use in the cited livestock feeding study.

EPA response. Unless their purpose is to determine the nature of the residue, feeding trials are conducted with standard analytical methods without radio-labeled test material for determining the presence of pesticide residues in meat, meat byproducts, milk, etc., to establish the need for tolerances in those commodities and to develop appropriate enforcement analytical methods. Radio-labeled test material is used to evaluate absorption, distribution, metabolism (nature of the residue), and excretion of an administered dose. Based on physical and chemical properties, 2, 6-DIPN is soluble in non-polar solvents (e.g., fat), making it unlikely that 2, 6-DIPN will accumulate in the liver of cattle fed treated potato waste. Also, in the livestock magnitude of the residue study, 2, 6-DIPN residues were found in higher levels in ruminant fat than liver. Tolerance levels in livestock

commodities were set accordingly. Should the conditionally-required metabolism (nature of the residue in livestock) study be submitted, if residues of 2, 6-DIPN and its metabolite(s) are found at some higher level in cow liver, the Agency will re-evaluate its tolerance decision based upon a new risk assessment revised to incorporate data on such increased residues in cow liver. However, the existing residue data do not indicate that 2, 6-DIPN accumulates in livestock liver.

10. *Comment 9*. In this comment, the Agency is requested to assess risk and exposure to 2, 6-DIPN using both a ''local milkshed'' and a national average scenario (to account for the feeding of potato waste containing pesticide residues to local cattle, from which meat/milk is locally distributed), as was done in the Reregistration Eligibility Document (page 25) for the conventional chemical, chlorpropham.

EPA response. The ''local milkshed'' scenario assumes that finite residues may be expected in milk and liver consumed by individuals living in a highly localized area where cattle may be fed processed potato waste from nearby potato processing plants (i.e., higher exposure may be expected in rural communities where cattle are fed peelings from treated potato). In the case of 2, 6-DIPN, since the national average scenario is already based on a very conservative, ''worst case,'' scenario (that all potato nationwide are treated), there is no need to duplicatively use a ''local milkshed'' scenario, which also represents the worst case.

11. *Comment 10*. In this comment, the correspondent states that diisopropylnaphthalenes have commercial uses (primarily paper production) in the U.S., and asks the Agency to address whether aggregate exposure is likely and if the non-pesticidal commercial uses of 2, 6-DIPN are likely to contribute to consumer exposure.

EPA response. Section 408 (b)(2)(A)(ii) explicitly requires the Agency to find that ''there is a reasonable certainty that no harm will result from aggregate exposures, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' As discussed below, EPA has considered all available information on non-dietary and non-occupational exposures in establishing these time-limited tolerances. There is no potential for exposure to residues of 2, 6-DIPN in drinking and ground water as a result of application to potato stored in warehouses, where the pesticide remains until the storage area is ventilated and 2, 6-DIPN has degraded somewhat or evaporated. The FQPA requires conduct of an aggregate risk assessment, considering all non-occupational sources, including exposure from water, food, and residential use. But since there are no registered residential or water uses, an aggregate assessment for 2, 6-DIPN is not required. Pesticidal uses only are aggregated; non-pesticide uses (i.e., the commercial uses identified in the comment) are not part of this analysis.

Section 408(b)(2)(A)(i) of the 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 the 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 the 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*.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the 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 the FFDCA, for time-limited tolerances for residues of 2, 6-DIPN, resulting from post-harvest applications to potato, in or on fat (cattle, goat, hog, horse, sheep) at 0.8 ppm; liver (cattle, goat, hog, horse, sheep) at 0.3 ppm; meat (cattle, goat, hog, horse, sheep) at 0.1 ppm; meat byproducts (cattle, goat, hog, horse, sheep) at 0.1 ppm; milk at 0.1 ppm; potato at 2.0 ppm; and potato, wet peel at 6.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the time-limited tolerances follows.

A. Toxicological Profile

EPA has previously 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 health risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

In the **Federal Register** of August 8, 2003 (68 FR 47246) (FRL–7321–61), EPA established time-limited tolerances (which were throughout that final rule erroneously referred to as temporary tolerances) for residues of the plant regulator 2, 6-diisopropylnaphthalene (2, 6-DIPN) in or on the food commodities meat, meat byproducts, milk, potato (peel) and potato (whole) at 1.35, 1.35, 0.7, 3, and 0.5 ppm, respectively. Although not explicitly noted in the tolerance expression (40 CFR 180.590) that these time-limited tolerances were limited to 2, 6-DIPN residues resulting from post-harvest application to potato, that fact was implicitly noted throughout the final rule itself. Nonetheless, this oversight is explicitly corrected in the new tolerance expression for 2, 6-DIPN set forth in this final rule.

The August 8, 2003 final rule included a summary of the Agency's assessment of the health effects data submitted by the applicant, who was seeking an exemption from the requirement of a tolerance, as opposed to the time-limited numeric tolerances that the Agency ultimately granted. Although the toxicity data do not indicate extra sensitivity of offspring when compared with that of adult animals, due to the application of uncertainty factors the data base does represent a conservative FQPA assessment of potential age-related sensitivity or acute effects other than lethality, notwithstanding the absence of a developmental toxicity study in a second species, a multi-generation reproduction toxicity study, or a range of doses adequate to induce a full range of toxic responses (especially, potential acute effects in any of the available studies). However, because 2, 6-DIPN has been classified by the Agency as a biochemical-like active ingredient, it is subject to a reduced data set which does not include the cited developmental and reproductive toxicity data. Instead, the FQPA criteria concerning the potential extra sensitivity of infants and children

may be met by the application of a safety factor. Therefore, the August 8, 2003 final rule also announced that, in considering the sensitivity of infants and children, the thousandfold safety factor (10x for interspecies extrapolation, 10x for intraspecies variability and the 10x default safety factor) includes the retention of the FQPA default tenfold uncertainty factor, which (in lieu of the cited data) adequately accounts for age-related sensitivity for the subpopulations of infants and children. The expiration date of the time-limited tolerances was May 31, 2006.

Summaries of the toxicological profile and other relevant health effects data, in compliance with the requirements of the FFDCA, as amended by the FQPA of 1996, were reported in the August 8, 2003, **Federal Register** publication of the final rule establishing the time-limited tolerances. Although the petitioner has not submitted the conditionally-required independent laboratory validation of the enforcement analytical methods and there is a newly-identified data gap (nature of the residue in plants and livestock), based on (1) the previously submitted data outlined in the August 8, 2003 **Federal Register** final rule, and the rationale included therein, and (2) the Agency's assessment of results from the new magnitude of the residue in livestock study; the analytical enforcement methods to determine residue in potato, potato peels and livestock commodities; and the magnitude of the residue submission which presented recalculations of previously submitted data to support proposed label amendments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to 2, 6-DIPN, during the time period for which these time-limited tolerances are established. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

The conditionally-required magnitude of the residue study in livestock (MRID 464650–01) involved testing at three dose levels in dairy cattle. The dose levels were multiples (1x, 3x, and 10x) of the 9 ppm maximum theoretical dietary burden (MTDB) for dairy cattle which was based on the original time-limited tolerances of 0.5 and 3 ppm in/on whole potato and potato peels, respectively. Since the proposed tolerances are 2.0 ppm in or on potato and 6.0 ppm in or on potato, wet peel, the multiples of the revised MTDB (16 ppm) are 0.56x, 1.59x, and 5.64x. The highest residue levels were found in fat (0.095 ppm at 0.56x, 0.2 ppm at 1.59x and 0.74 ppm at 5.64x). The second highest residue levels were found in milk cream (0.17 ppm at 5.64x). Whole milk residue levels plateaued at approximately 0.025 ppm after 4 days' feeding of the 5.64x test diet. At the end of the 29–day feeding study, the residue levels of 2, 6-DIPN were at 0.033, 0.035, and 0.23 ppm in milk, kidney, and liver, respectively at the 5.64x feeding level. Although the highest multiple of the MTDB tested was fivefold to sixfold, rather than the tenfold recommended in OPPTS Harmonized Guideline 860.1480, the trial itself was conducted in a reasonable manner. In the end, residues were found at levels below the proposed time-limited tolerance levels for those matrices at an application rate similar to the proposed new rate of 1.5 pounds of active ingredient per 600 hundredweight of potato. The assumption of 100% crop treated and the use of the results from the 5.64x dietary level provides an adequate basis for estimating dietary exposures in the assessment of potential risks associated with the normal (i.e., in accordance with good agricultural practices) post-harvest use of 2, 6-DIPN on stored potato as directed on the product label.

The analytical methods submitted to enforce the time-limited tolerance levels established for 2, 6-DIPN residues in potato, potato peels, and in livestock commodities (MRIDs 464749–01, 464749–02, and 464650–02, respectively) are adequate for the purpose of this extension and amendment of the time-limited tolerances for 2, 6-DIPN. Validation of these methods by an independent laboratory remains a condition of registration and must be submitted to the Agency for review in advance of the new time-limited tolerance expiration date of August 1, 2009. Furthermore, should the newly-imposed conditional data (nature of the residue in plants and livestock) be performed, an independently validated multi-residue laboratory method must be submitted to the Agency for review in advance of the expiration date of August 1, 2009 for the new time-limited tolerances.

The study in which previously submitted magnitude of the residue data were recalculated (MRID 466005–01) to project residue levels for the proposed increased application rate (from 1.0 to 1.5 lbs of active ingredient per 600 hundredweight of potato) adequately supports the new maximum yearly application rate (which may be applied via multiple treatments). Also acceptable is a proposal to reduce from 30 to zero days the required period for holding treated stored potato. The highest residues of 2, 6-DIPN are 1.59 ppm for potato and 5.06 ppm for potato peel at the zero day sampling. Since the proposed tolerance levels exceed the extrapolated maximum residue values for the increased application rate, the estimated risk characterization does not exceed our level of concern.

B. Toxicological Endpoints

1. *Acute toxicity*. 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) (FRL–7321–61).

2. *Short- and intermediate-term toxicity*. EPA's 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) (FRL–7321–61). Based on the information summarized in that final rule, the 104 mg/kg/day NOAEL is selected as the endpoint for this assessment.

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 above.

4. *Carcinogenicity*. No study results suggest that 2, 6-DIPN is carcinogenic. See the EPA's discussion and analysis in the **Federal Register** of August 8, 2003 (68 FR 47246) (FRL–7321–61).

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.590) for the residues of 2, 6-DIPN, resulting from post-harvest applications to potato, in or on a variety of food commodities: fat (cattle, goat, hog, horse, and sheep) at 0.8 ppm; liver (cattle, goat, hog, horse, and sheep) at 0.3 ppm; meat (cattle, goat, hog, horse, and sheep) at 0.1 ppm; meat byproducts (cattle, goat, hog, horse, and sheep) at 0.1 ppm; milk at 0.1 ppm; potato at 2.0 ppm; and potato, wet peel at 6.0 ppm. Risk assessments were conducted by EPA to assess dietary exposures from 2, 6-DIPN. These assessments were based on 100% crop treated, maximum label application rate, and used the tolerance levels (which exceeded reported residue levels).

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 limited 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 USDA'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 (for 2, 6-DIPN, aPAD = 0.1 mg/kg). 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 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 and 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 Web site 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 (supported by the residue trial results, i.e. the tolerance levels as established in this final rule) and worst-case assumptions.

As reported in the **Federal Register** of August 8, 2003 (68 FR 47246) (FRL–7321–61), EPA established a RfD of 1 mg/kg/day, and the aPAD and cPAD at 0.1 mg/kg/day.

For the U.S. population, acute dietary exposure was estimated to be 0.009167 mg/kg/day. This value represented 9.17% of the aPAD (27.5% if the aPAD is calculated using the same uncertainty factor of 3,000 as that described above for the IRIS assessment of naphthalene; aPAD = 0.033 mg/kg). The subpopulation with the highest acute dietary exposure estimate was children 1 to 2 years of age (0.022197 mg/kg/day, 22.20% of the aPAD; 66.6% when using the IRIS adjustment). If the 50 mg/kg/day NOAEL from the developmental toxicity study is used to derive an aPAD, the exposure for the subgroup females 13 to 49 years of age (0.006701 mg/kg/day) represented 6.7% of the subgroup-specific aPAD (0.05 mg/kg); this subgroup's exposure represented 13.4% of the 0.05 mg/kg aPAD. Therefore, the acute dietary exposures to all the subpopulations in the analysis did not exceed EPA's level of concern (>100% of the aPAD).

These dietary exposure estimates based on the 0.1 mg/kg/day aPAD are less than previously described by the Agency. For example, the previous estimated dietary exposure for the general U.S. population was 0.023113 mg/kg/day which is slightly more than twice the current estimate. Residue data have been refined and, accordingly, support revised tolerances (meat, meat byproducts and milk tolerances decrease and new livestock commodities liver and fat are added based upon the low or undetected residues from the livestock feeding trial; potato and potato, wet peel tolerances increase based upon the residue data and increased application rate) as follows: the previous tolerance on potato (0.5 ppm) increases to 2.0 ppm; the 3 ppm tolerance on potato, wet peel, increases to 6.0 ppm; the 1.35 ppm tolerances for meat and meat byproducts decrease to 0.1 ppm; the milk tolerance of 0.7 ppm drops to 0.1 ppm; and tolerances for liver (0.3 ppm) and fat (0.8 ppm) are added. Overall, these revised tolerances have significantly reduced estimated dietary exposures and the associated potential risks when calculations are based on the 0.1 mg/kg/day aPAD.

2. *Chronic risk*. EPA has concluded that the chronic dietary exposure estimates based on the 0.1 mg/kg/day cPAD are also less than previously described. For example, the previous

chronic dietary exposure estimate for the general population was 0.006939 mg/kg/day, which is more than twice the current estimate of 0.002718 mg/kg/day (2.7% of the cPAD). The subpopulation with the highest chronic dietary exposure estimate was children 1 to 2 years of age, with estimated exposures of 0.008068 mg/kg/day, which constitutes 8.1% of the cPAD. The previous chronic exposure estimates were more than twice the values determined in the current exposure assessment for the same reasons (refinements due to the availability of additional data, and increased application rate) as for the dietary exposure estimates described above. The chronic dietary exposures to all the subpopulations, as estimated in 2003, and the current, even lower, values estimated herein, do not exceed the Agency's level of concern.

3. *Determination of safety*. Based on these risk assessments, 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 resulting from post-harvest applications, undertaken in accordance with good agricultural practices and label directions, to potato. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. In arriving at this conclusion, and as stated earlier in Unit III.A. of this preamble, it is important to re-emphasize that EPA, pursuant to FFDCA section 408(b)(2)(C), has retained the tenfold margin of exposure 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.

IV. Other Considerations

A. Metabolism in Plants and Animals

The nature of the residue in stored potato is not adequately understood for the purpose of establishing non-time-limited/permanent tolerances. The regulation at 40 CFR 158.690(a) requires that nature of the residue data be submitted for plants when the application rate of the product exceeds a level determined to be comparable to 0.7 ounces active ingredient per application (when the application rate is not expressed in terms of ounces per acre per application). Calculations based on *Agriculture Statistics 2005* indicate that the new maximum single application rate of 1.5 pounds active ingredient per 600 hundredweight of potato is approximately equal to 14 ounces of active ingredient per acre per application, thus triggering the data requirement. A study conducted in accordance with OPPTS Harmonized Guideline 860.1300 is conditionally required to determine the residue(s) of concern in or on stored potato treated with 2, 6-DIPN, and must be submitted so as to permit an Agency decision on its adequacy in advance of the August 1, 2009 expiration date for the time-limited tolerances.

The nature of the residue in livestock is not adequately understood for the purpose of establishing non-time-limited/permanent tolerances. The submitted metabolism study showed the total urinary excretion of 2, 6-DIPN metabolites to be about 23% of the administered dose, while the fate of the the remaining 60% or 77% of the administered dose was unexplained. Submission of a nature of the residue study in livestock is conditionally required based on the same application rate criteria discussed above for the nature of the residue in plants requirement. A study conducted in accordance with OPPTS Harmonized Guideline 860.1300 is conditionally required to determine the distributions of residue(s) of 2, 6-DIPN and its metabolites in livestock commodities, and must be submitted so as to permit an Agency decision on its adequacy in advance of the August 1, 2009 expiration date for the time-limited tolerances.

Any multi-residue methods developed in conjunction with these conditionally required nature of the residue studies (in plants and livestock) must be validated by an independent laboratory and also be submitted so as to permit an Agency decision on adequacy in advance of the August 1, 2009 expiration date for the time-limited tolerances.

Notwithstanding these data gaps and conditions of registration, the EPA has determined, based on the available toxicological data, the thousandfold uncertainty factor, and the levels of exposure, 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 pesticide (2, 6-DIPN) and its residues during the period of the time-limited tolerances.

B. Analytical Enforcement Methodology

High Performance Liquid Chromatography (HPLC)/ Ultraviolet(UV) and gas chromatography (GC)/Mass Spectroscopy (MS) methods were used to measure the levels of 2, 6-DIPN in the residue studies. However, as a condition of the registration granted for 2, 6-DIPN on July 31, 2003, the petitioner was required to submit an independent laboratory validation (ILV) of the analytical enforcement method(s) used to detect residues of 2, 6-DIPN in potato and livestock food commodities. Because these data have not been submitted, the ILV remains a condition of registration for 2, 6-DIPN. Furthermore, a newly-imposed condition of registration is the submission of nature of the residue data for plants and livestock, and the Agency is placing a 3–year time-limitation on the established numeric tolerances. Multi-residue method(s) associated with those conditional data are required, and also must be validated by an independent laboratory. During this 3–year time period the petitioner must supply all the required ILV, allowing adequate time from its submission to permit the Agency's review and decision in advance of the August 1, 2009 expiration date for the time-limited tolerances.

C. International Residue Limits

There are no Codex Alimentarius Commission (Codex) Maximum Residue Levels (MRLs) for residues of 2, 6-DIPN.

V. Conclusion

A data gap currently exists for an independent laboratory validation (ILV) of the analytical enforcement method(s) used to detect residues of 2, 6-DIPN in potato and livestock food commodities, because the petitioner failed to submit these data as was required by a condition of the July 31, 2003 registration of 2, 6-DIPN. There is also imposed a new condition of registration; nature of the residue in plants and livestock must be submitted. Any multi-residue method(s) developed in association with these conditionally required data must also be validated by an independent laboratory. All tolerances are time-limited because of these data gaps. The time limitation allows for conduct, submission, and review of the data. Notwithstanding these data gaps and conditions of registration, the EPA has determined, based on the available toxicological data, the thousandfold uncertainty factor, and the levels of exposure, 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 pesticide (2, 6-DIPN) and its residues during the period of the time-limited tolerances.

Based on the information and rationale cited in the final rule of August 8, 2003, plus the results of the new magnitude of the residue in livestock study; the analytical enforcement methods to determine

residue in potato, potato peel and livestock commodities; and the magnitude of the residue submission which presented recalculations of previously submitted data to support proposed label amendments, the Agency has determined that the establishment of the time-limited tolerances by amending 40 CFR 180.590 in the manner set forth in this final rule will be safe.

Therefore, the following time-limited tolerances are established for residues of 2, 6-DIPN in or on the following commodities resulting from post-harvest applications to potato: fat (cattle, goat, hog, horse, and sheep) at 0.8 ppm; liver (cattle, goat, hog, horse, and sheep) at 0.3 ppm; meat (cattle, goat, hog, horse, and sheep) at 0.1 ppm; meat byproducts (cattle, goat, hog, horse, and sheep) at 0.1 ppm; milk at 0.1 ppm; potato at 2.0 ppm; and potato, wet peel at 6.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes time-limited tolerances under section 408(d) of the 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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., or 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). 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); or 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 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). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the time-limited tolerances 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: July 14, 2006.

Janet L. Andersen,

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 revised to read as follows:

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

(a) *General.* Time-limited tolerances are established for residues of 2, 6-DIPN in or on the following commodities resulting from post-harvest applications to potato, when 2, 6-DIPN is used in accordance with good agricultural practices:

Commodity	Parts per million	Expiration/ revocation date
Cattle, fat	0.8	8/1/09
Cattle, liver	0.3	8/1/09
Cattle, meat	0.1	8/1/09
Cattle, meat by-products	0.1	8/1/09
Goat, fat	0.8	8/1/09
Goat, liver	0.3	8/1/09

Commodity	Parts per million	Expiration/ revocation date
Goat, meat	0.1	8/1/09
Goat, meat by-products	0.1	8/1/09
Hog, fat	0.8	8/1/09
Hog, liver	0.3	8/1/09
Hog, meat	0.1	8/1/09
Hog, meat by-products	0.1	8/1/09
Horse, fat	0.8	8/1/09
Horse, liver	0.3	8/1/09
Horse, meat	0.1	8/1/09
Horse, meat by-products	0.1	8/1/09
Milk	0.1	8/1/09
Potato	2.0	8/1/09
Potato, wet peel	6.0	8/1/09
Sheep, fat	0.8	8/1/09
Sheep, liver	0.3	8/1/09
Sheep, meat	0.1	8/1/09
Sheep, meat by-products	0.1	8/1/09

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

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

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

[FR Doc. E6–14545 Filed 8–31–06; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 4100

[WO–220–1020–24 1A]

RIN 1004–AD42

Grazing Administration—Exclusive of Alaska

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rule; correction.

SUMMARY: This document corrects editorial and typographical errors in a final rule published in the **Federal Register** on July 12, 2006, regarding the administration of livestock grazing on public lands managed by the Bureau of Land Management (BLM).

EFFECTIVE DATE: August 11, 2006.

FOR FURTHER INFORMATION CONTACT: Ted Hudson, 202–452–5042. Individuals who use a telecommunications device for the deaf (TDD) may contact him through the Federal Information Relay Service at 1–800/877–8339, 24 hours a day, seven days a week.

SUPPLEMENTARY INFORMATION:

Background

The final rule that is the subject of these corrections amended the regulations on grazing administration, exclusive of Alaska, in 43 CFR part 4100.

Need for Correction

As published, the final rule contained editorial, typographical, and printing errors in the preamble, involving cross-references and CFR citations, which may prove to be misleading and need to be corrected.

In rule FR Doc. 06–5788 published on July 12, 2006 (71 FR 39402), make the following corrections.

1. On page 39437, in the third column, correct the second full paragraph by removing the citation ''1610.0–5(b)'' in the eighth (8th) line, and adding in its place the citation ''1601.0–5(b),'' and by removing the citation ''1610.0–5(c)'' in the 14th line, and adding in its place the citation ''1601.0–5(c).''

2. On page 39446, in the first column, correct the second full paragraph by removing the citation ''1600.0–5'' from the third-to-last line, and adding in its place the citation ''1601.0–5(i)''.

3. On page 39488, in the third column, correct the heading between the third and fourth paragraphs by removing the citation ''4160.37'' and adding in its place the citation ''4160.3.''

Dated: August 28, 2006.

Johnnie Burton,

Acting Assistant Secretary of the Interior.

[FR Doc. 06–7397 Filed 8–31–06 8:45 am]

BILLING CODE 4310–84–P