EPA-APPROVED MISSOURI REGULATIONS—Continued

Missouri citation	Title	State effective date	EPA approval date	Explanation
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10–6.400	*Restriction of Emission of Particulate Matter from Industrial Processes.*	02/28/11	02/20/13 [*insert* FEDERAL REGISTER *page number where the document begins*].	
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[FR Doc. 2013–03769 Filed 2–19–13; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0065; FRL–9378–1]

3-decen-2-one; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the biochemical pesticide, 3-decen-2-one, in or on potatoes when applied as a postharvest potato sprout inhibitor and used in accordance with label directions and good agricultural practices. On behalf of AMVAC Chemical Corporation (AMVAC), Technology Sciences Group, Inc. (TSG) submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of 3-decen-2-one under the FFDCA.

DATES: This regulation is effective February 20, 2013. Objections and requests for hearings must be received on or before April 22, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2010–0065, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Colin G. Walsh, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–0298; email address: *walsh.colin@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0065 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 22, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0065, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Background and Statutory Findings

In the **Federal Register** of March 10, 2010 (75 FR 11171) (FRL–8810–8), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 9F7670) by TSG, 1150 18th Street NW., Suite 1000, Washington, DC 20036, on behalf of AMVAC, 4695 MacArthur Court, Suite 1250, Newport Beach, CA 90660. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of 3-decen-2-one. This notice referenced a summary of the petition prepared by the petitioner, TSG (on behalf of AMVAC), which is available in the docket via *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit VII.C.

During the initial review of the petition, EPA determined that the data and/or information submitted was insufficient to support the use of the active ingredient, 3-decen-2-one, in or on all food commodities. The petitioner submitted additional data and filed a revised petition (PP 9F7670), proposing to establish an exemption from the requirement of a tolerance for residues of 3-decen-2-one in or on stored potatoes only. A Notice of Filing, allowing for a 30-day comment period, was published in the **Federal Register** of March 14, 2012 (77 FR 15012) (FRL–9335–9). No comments were received following this publication.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(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. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance exemption 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. * * *'' Additionally, FFDCA section 408(b)(2)(D) requires that EPA consider ''available information concerning the cumulative effects of [a particular pesticide's] * * * residues and other substances that have a common mechanism of toxicity.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability, and the relationship of this information to human risk. EPA also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

A. Overview

3-decen-2-one is a naturally occurring biochemical substance, as defined in 40 CFR 158.2000(a)(1), with a history of unremarkable human exposure. 3-decen-2-one functions as a plant growth regulator, affecting plant growth by increasing tuber respiration. Data on file indicate that 3-decen-2-one interferes with membrane integrity, which results in increased oxidative stress, desiccation, and rapid necrosis of the meristems and surrounding sprout tissues. Thus, 3-decen-2-one inhibits sprouting with no observed effects on the potato, potato sweetening, or processing quality. Based on this information, EPA considers the mode of action to be non-toxic (Ref. 1).

3-decen-2-one is approved by the U.S. Food and Drug Administration (FDA) as a synthetic flavoring agent and adjuvant that may be directly added to food (21 CFR 172.515). A report by an independent panel of experts retained by the Flavor and Extract Manufacturer's Association (FEMA) states 3-decen-2-one is considered safe for its intended use when added at an average maximum level of 19 ppm in baked goods, 7.8 ppm in soft candy, 5.8 ppm in frozen dairy products, 4.8 ppm in gelatins and puddings, 4.3 ppm in non-alcoholic beverages, and 4.0 ppm in alcoholic beverages (Oser & Ford, 1978) (Ref. 2).

3-decen-2-one has been well characterized and studied with respect to its metabolism and, more importantly, its natural occurrence in many foods that are common in the human diet including yogurt, skipjack tuna, edible porcini mushrooms and Iberian ham (Ref. 2). Additionally, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) has reported that 3-decen-2-one, a structural class II flavoring agent, is one in a group of compounds that have been identified in fruits, vegetables, spices, cocoa, coffee and tea. JECFA concluded that there are no safety concerns at current intake levels when 3-decen-2-one is used as a flavoring agent (Ref. 2).

As stated previously in this unit, 3-decen-2-one is a substance that exhibits a non-toxic mode of action. In humans, this substance readily metabolizes into innocuous compounds (Ref. 1). Based on information submitted in support of this petition (summarized in Unit III.B.) and the comprehensive risk assessment conducted by the Agency, EPA concludes that there is a reasonable certainty of no harm from aggregate exposures to 3-decen-2-one, including the consumption of potatoes treated with this active ingredient in accordance with label directions and good agricultural practices. EPA has made this determination for the following reasons:

1. Available toxicology data and information indicate that the active ingredient is of low acute toxicity (with the exception that it is an eye and skin irritant) and is not a developmental toxicant, a mutagen, or toxic via repeat oral exposure;

2. Available information from the scientific literature indicate humans are already exposed to 3-decen-2-one in the diet from foods that naturally contain the chemical and from foods to which the chemical has been added as a food additive at levels higher than what will occur from pesticide use;

3. Metabolism data and information on the chemical indicate that it is metabolized into innocuous substances in humans that present no toxicological or dietary concern; and

4. Deterministic exposure analyses suggest that dietary exposure to the chemical as a pesticide is likely to be less than dietary exposure to the chemical as a food additive, thus as a natural constituent in foods, the pesticidal use of 3-decen-2-one is not likely to result in a significant increase in overall dietary exposure (Ref. 2).

B. Toxicity

The following is a summary of EPA's review of the toxicity profile of this biochemical.

1. *Acute toxicity (OCSPP Guideline Nos. 870.1100, 870.1200, 870.1300, 870.2400, 870.2500, and 870.2600; Master Record Identification (MRID) Nos. 47942609, 47942610, 47942611, 47942612, 47942613, and 47942614).* The petitioner submitted acute toxicity studies conducted on the technical grade material to EPA. Results of the acute toxicity testing indicate that 3-decen-2-one is of low acute toxicity with the exception that the substance is an eye and skin irritant. Acute oral toxicity (rat): LD_{50} > 5,000mg/kg; Acute dermal toxicity (rat): LD_{50} > 5,000mg/kg; Acute inhalation toxicity (rat): LC_{50} = 0.52–2.04 mg/L (male) and LC_{50} > 2.04 mg/L (female); Primary eye irritation (rabbit): moderately irritating; Primary dermal irritation (rabbit): Severely irritating; Dermal sensitization (guinea pig): not a dermal sensitizer (Ref. 3).

2. *90-day oral toxicity (OCSPP Guideline No. 870.3100; MRID Nos. 47942617 and 48422301).* A subchronic 90-day oral toxicity study on the technical grade material was not conducted. In lieu of the study, EPA used a weight-of-the-evidence (WOE) approach to estimate the likelihood of potential of toxicity from repeat oral exposure to this substance (Ref. 2). EPA considered the following evidence:

i. Lack of toxicological endpoints;

ii. Metabolic pathways;

iii. Lack of incidents associated with naturally occurring levels of 3-decen-2-one in foods; and

iv. FDA's approval of this biochemical as a direct food additive.

First, using an expert system computer program (DEREK Nexus), EPA identified two potential toxicological endpoints for 3-decen-2-one (potential dermal sensitization and *in vitro* chromosome damage); however, follow-up studies did not support these as toxicological endpoints. Second, the metabolic pathways of 3-decen-2-one have been characterized and demonstrate that the biochemical is metabolized into innocuous compounds that are either excreted or further metabolized in the fatty acid pathway or citric acid cycle. Third, 3-decen-2-one occurs naturally in some foods and has been used as a food additive without specific reports of adverse effects. Finally, as noted in this unit, FDA has approved the use of 3-decen-2-one as a synthetic flavoring agent and adjuvant that may be directly added to food. Based on this evidence, EPA concludes that 3-decen-2-one has relatively low toxicity.

3. *Prenatal developmental toxicity (OCSPP Guideline No. 870.3700; MRID No. 48970303).* An acceptable prenatal developmental toxicity study was submitted. In the study, Crl:CD Sprague-Dawley rats were administered doses of AMV–1018 (99.81% purity 3-decen-2-one) by gavage at 0, 100, 300 or 1,000 mg/kg/day from day 6 to day 19 of gestation. Each treatment group consisted of 24 female rats:

i. The control group which received corn oil and

ii. The test substance vehicle group.

No maternal deaths or clinical signs related to treatment were observed in the study. Salivation was observed in all animals in the intermediate- and high-dose groups during the treatment period. Chin rubbing, which is associated with salivation, was observed in some animals in the high-dose group. These observations were considered to be attributable to the palatability of the test substance and not toxicologically significant. Bodyweight gain in the low- and intermediate-dose groups was not affected by treatment. When compared to the control group, overall mean bodyweight gain in the high-dose group was slightly low during gestation, which was associated with slightly lower food consumption in the high-dose group. The bodyweight gain effect is considered to be attributable to the palatability of the test substance and not toxicologically significant. Food consumption in the low- and intermediate-dose groups was unaffected by treatment. Gravid uterine weights were not affected by treatment in any group. There were no maternal treatment-related macroscopic effects. All females in each test group were pregnant. Mean corpora lutea, implantations, early, late and total resorption counts, live young, sex ratio, pre- and post-implantation loss, litter weight, placental weight, male and female fetal weight and overall fetal weight were all considered to be unaffected by treatment at all doses. In all dose groups, no relationship to treatment was observed in the incidence of major and minor fetal abnormalities and skeletal variants. There was a slight increase in the percentage of incidences of fetuses with 13/14 and 14/14 ribs in all dose groups when compared to the control group, but the incidences were similar to historical control data, and in the absence of other related findings in the study, the observations were not considered to be treatment related. Based on the lack of systemic maternal and fetal toxicity, the no-observed-adverse-effect-level (NOAEL) for maternal and fetal (developmental) toxicity is 1,000 mg/kg/day (Ref. 2).

4. *Mutagenicity (OCSPP Guideline Nos. 870.5100, 870.5300, and 870.5395; MRID Nos. 47942616, 47942615, and 48412402).* Three mutagenicity studies were submitted. In a reverse mutation assay, AMV–1018, containing 98% of the active ingredient 3-decen-2-one, was investigated for its potential to induce gene mutations via a plate incorporation test and a pre-incubation test. Each experiment was conducted with five tester strains of *Salmonella typhimurium,* six different test substance concentrations (0.0316, 0.100, 0.316, 1.0, 2.5 and 5.0 µL/plate, and control scenario), and with and without metabolic activation. According to the results of this study, no biologically relevant increases in revertant colony numbers of any of the five tester strains were observed following treatment with AMV–1018 at any concentration level, neither in the presence or absence of metabolic activation, in either experiment. In the pre-incubation experiments, cytotoxicity was noted in all five tester strains at a dose concentration of 5.0 µL/plate without metabolic activation and in tester strain TA 102 at a dose concentration of 5.0 µL/plate with metabolic activation. The reference mutagens employed in the control scenarios induced a distinct increase in revertant colonies, indicating the validity of the experiments. Therefore, the test substance is considered to be non-mutagenic in this bacterial reverse mutation assay (Ref. 3).

In a mammalian cell gene mutation assay, mouse lymphoma cells cultured *in vitro* were exposed to AMV–1018 (3-decen-2-one; 98.57% active ingredient) in dimethyl sulfoxide (DMSO) at the various concentrations for 4 and 24 hours with and without metabolic activation. The S9 fraction (for metabolic activation) was derived from the livers of male Wistar rats induced with phenobarbital (80 mg/kg bw) and β-Naphthoflavone (100 mg/kg bw). The solvent DMSO served as a negative control in the presence and absence of S9. Benzo(α)pyrene (BP) served as a positive control in the presence of S9. Ethylmethanesulfonate (EMS) and methylmethanesulfonate (MMS) served as positive controls in the absence of S9. Selection of test substance concentrations were based on a pre-experiment for cytotoxicity. No precipitation of the test substance was noted in the experiments. Growth inhibition was noted in all experiments (+/− S9), with marked cytotoxicity seen in several cases (one incident less than 10%, several less than 20%). The pH values for the highest concentrations

tested were within the physiological range. The osmolality for the solvent controls as well as for the highest test concentrations was found to be 465 mosmol/kg. Thus, the osmolality was above the physiological range. Test substance was positive for mutagenicity in the 24 hour exposure without metabolic activation and equivocal results with metabolic activation. The mouse lymphoma results are considered equivocal because it is not clear whether the positive results would translate into an *in vivo* system based on the increased osmotic pressure and marked cytotoxicity noted during the experiment (Ref. 3).

A Tier II *in vivo* mammalian erythrocyte micronucleus test guideline study was submitted due to the equivocal results found in the mouse lymphoma assay. The test substance for the study was AMV–1018, containing 98.0% 3-decen-2-one. The test substance was prepared with cottonseed oil and the volume administered intraperitoneal to the 5 male and 5 female mice was 10 mL/kg bw. A range finding study was performed prior to the experiment to determine the maximum tolerable dose (MTD). The MTD was determined to be 50%/kg bw, which is equivalent to an application of 10 mL/kg bw of 5% v/v test item solution. The three dose levels used in the experiment were 1 MTD, 0.5 MTD, and 0.2 MTD, which is equivalent to 50%/kg bw, 25%/kg bw, and 10%/kg bw, respectively. The animals treated with a dose of 0.2 MTD showed no signs of systemic toxicity after treatment, whereas the animals at 1 MTD and 0.5 MTD showed signs of toxicity including reduction of spontaneous activity, prone position, clonic convulsion, ataxia, constricted abdomen, piloerection, half eyelid closure, diarrhea, cramps, and loss of weight. Peripheral blood samples were taken at 44 and 68 hours after a single application of the test item solution for micronuclei analysis. All mean values of micronuclei were within range or decreased compared to the corresponding negative control in all dose groups. The positive control used cyclophosphamide (40 mg/kg bw), which showed significant increase in micronucleus frequency and was used to validate the assay. A nonparametric Mann-Whitney Test was performed and showed no statistically significant increase ($p<0.05$) of micronuclei cells in any dose group. The test material, AMV–1018 (98% 3-decen-2-one), is considered non-mutagenic with respect to clastogenicity and aneugenicity based on the test item material showing no signs of induction of structural or numerical chromosomal damage in the immature erythrocytes of the mice (Ref. 1).

IV. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

In addition to the natural presence and the deliberate addition of 3-decen-2-one in other foods, people will be exposed 3-decen-2-one through the consumption of treated potatoes. A qualitative risk assessment was conducted for the chemical to assess potential risks (if any) from dietary exposure.

1. *Food.* Dietary exposure to 3-decen-2-one is already occurring, given that this substance is a component of and/or is used as a flavoring agent in many foods that are commonly consumed by humans. When 3-decen-2-one is applied as a potato sprout inhibitor and used in accordance with good agricultural practices and label directions, the aforementioned dietary exposure is not likely to be substantially increased.

A deterministic quantitative evaluation of potential dietary exposure to children (1 to 2 years) from consumption of pesticide-treated potatoes was conducted and compared to estimated dietary exposure to 3-decen-2-one as a natural constituent of food and as a food additive. Based on the results of the analysis, EPA has concluded that dietary exposure to residues of 3-decen-2-one when used as a pesticide will be considerably less than dietary exposure to the chemical as a naturally occurring constituent in food and/or as a food additive. This conclusion is supported by data obtained from the residue study specifically on baked potatoes, which demonstrated that residues of 3-decen-2-one decline over time and are reduced when potatoes are cooked (Ref. 2).

Based on the information in this unit, which includes an estimation of potential dietary exposure to 3-decen-2-one from the consumption of treated potatoes, the Agency concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from dietary exposure to the pesticidal residues of 3-decen-2-one in food.

2. *Drinking water exposure.* Based on the proposed use pattern of the active ingredient as a potato sprout inhibitor used in indoor settings, residues in drinking water are not anticipated if products are used according to good agricultural practices and label instructions. Products containing the active ingredient will be used in indoor commercial settings only; therefore, 3-decen-2-one residues in drinking water are highly unlikely. In the unlikely event that exposure via drinking water does occur, the health risk would be expected to be minimal based on the low acute oral toxicity of 3-decen-2-one.

B. Other Non-Occupational Exposure

Non-occupational exposure is not expected from the postharvest use of 3-decen-2-one on stored potatoes via a closed system. Any exposure is expected to be occupational in nature.

V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance exemption, EPA consider ''available information concerning the cumulative effects of [a particular pesticide's] * * * residues and other substances that have a common mechanism of toxicity.''

EPA has not found 3-decen-2-one to share a common mechanism of toxicity with any other substances, and 3-decen-2-one does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 3-decen-2-one does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine chemicals that have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

VI. Determination of Safety for U.S. Population, Infants and Children

FFDCA section 408(b)(2)(C) provides that, in considering the establishment of a tolerance or tolerance exemption for a pesticide chemical residue, EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an

additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure, unless EPA determines that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor. In applying this provision, EPA either retains the default value of 10X, or uses a different additional or no safety factor when reliable data are available to support a different additional or no safety factor.

Because there are no threshold effects associated with this biochemical, an additional margin of safety for infants and children is not necessary.

EPA has determined that there are no foreseeable dietary risks to the U.S. population, including infants and children, from the use of 3-decen-2-one as a pesticide on stored potatoes when label instructions and good agricultural practices are followed. The available data and information indicate that the chemical:

1. Is of low toxicity and is not a developmental toxicant;

2. Naturally occurs in the human diet;

3. Has been approved by FDA for use in foods as a food additive without limitation; and

4. Is metabolized into innocuous substances.

Additionally, basic exposure analyses that were specifically conducted for children aged 1–2 years suggest that dietary exposure from ingestion of the chemical as a pesticide is likely to be less than dietary exposure from ingestion of the chemical as a food additive and/or as a constituent that naturally occurs in foods (Ref. 2). When compared to the amount of 3-decen-2-one that is likely already consumed in the human diet, dietary exposure from pesticidal use is not anticipated to significantly increase overall dietary exposure of infants and children.

Therefore, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the residues of 3-decen-2-one when it is used as labeled and in accordance with good agricultural practices. Such exposure includes all anticipated dietary exposures and all other exposures for which there is reliable information. EPA has arrived at this conclusion because the data and information available on 3-decen-2-one do not demonstrate significant toxic potential to mammals, including infants and children.

VII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes for the reasons stated in Unit VI. and because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

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

The Codex has not established a MRL for 3-decen-2-one.

C. Response to Comments

In response to a Notice of Filing that published in the **Federal Register** of March 10, 2010, EPA received a comment from Michael J. Keim (Keim Aerosol Technologies) in docket ID number EPA–HQ–OPP–2010–0065. Mr. Keim believes that EPA has not been adequately informed [by the petitioner] with respect to the use of chemicals for the postharvest treatment of stored potatoes and that such use poses a risk to humans and the environment. His conclusion is based on his experience with the use of chlorpropham (CIPC), a conventional chemical that is applied (via thermal fog generator) in the same manner as the proposed product. Mr. Keim states that half of CIPC applied to stored potatoes does not deposit on the potatoes and, therefore, is expelled to the outside environment. As a result of this application method, Mr. Keim contends that EPA has not adequately assessed the risks to non-target organisms and worker/handlers.

EPA notes that the comment from Mr. Keim pertains mainly to the application equipment used on the proposed label, which would be more applicable to the Notice of Receipt (see the **Federal Register** of March 10, 2010 (75 FR 11175) (FRL–8811–6)) for 3-decen-2-one, and to the conventional chemical, CIPC, which, from a toxicological perspective, is quite different from 3-decen-2-one. Nonetheless, EPA will address Mr. Keim's comment in this document.

EPA would first direct the commenter to the documents in the docket for the Registration Review of CIPC (docket ID number EPA–HQ–OPP–2010–0923) as the Agency's Health Effects Division (HED) and Environmental Fate and Effects Division (EFED) have already responded to Mr. Keim's comments regarding the application equipment used for CIPC products and the potential for exposure based on the displacement and degradation of CIPC.

As stated in the EPA memoranda listed in Unit IX., the Agency received and reviewed product chemistry, residue, mammalian toxicity, and non-target organism data and/or information for this new active ingredient, 3-decen-2-one, as outlined in 40 CFR 158.2030, 158.2040, 158.2050, and 158.2060. The data and information submitted to EPA indicate that 3-decen-2-one is of low toxicity (with the exception that it is an eye and dermal irritant), no developmental effects were found at the highest dose tested (NOAEL = 1,000 mg/kg/day), and 3-decen-2-one is not mutagenic. With regard to worker exposure, the thermal fogging application method on the proposed product label used for stored potatoes is an automated system and, as such, EPA considers this method a closed-delivery system and does not expect occupational handler exposure. The only occupational exposure expected is the handling of the product prior to application, which is mitigated by appropriate precautionary statements and personal protective equipment (PPE) requirements listed on the label. EPA has not identified any toxic endpoints for non-target mammals, birds, plants, aquatic, or soil organisms and has no concerns for any non-target organisms exposed to 3-decen-2-one when used in accordance with approved label directions. The petitioner did submit information that estimated the physical and chemical properties for 3-decen-2-one by using QSAR modeling based on the Estimation Programs Interface Model (EPI Suite™ 4.0). Using Henry's Law, which states that the solubility of a gas in a liquid is directly proportional to the partial pressure of the gas above the liquid, 3-decen-2-one is estimated to be 5.4×10^{-4} atm·m^3/mol and indicates that the active ingredient has a potential for volatility from water or moist soil. In soil, the estimated K_{oc} of 165.2–860.9 L/kg

indicates that 3-decen-2-one would have medium to low mobility in soil. In water, an estimated log K_{ow} of 3.28 and an estimated bioconcentration factor (BCF) of 67.41 L/kg wet-wt indicate that bioaccumulation in aquatic organisms is unlikely. In the air, atmospheric oxidation by hydroxyl radicals' reaction is expected to occur with estimated half-lives of 1.9–2.2 hours. The probability of biodegradation of 3-decen-2-one was evaluated using EPI Suite™ 4.0 in the BIOWIN module. Various models in the BIOWIN module predicted rapid biodegradation of 3-decen-2-one. Based on a total air volume in a potato warehouse of 1,910 m^3 and the total applied 3-decen-2-one of 122,475 g calculated by the petitioner, the maximum air concentration of 3-decen-2-one in a potato warehouse was estimated to be 64.14 mg/L of air. With an estimated ventilation rate of 825 m^3 of air/min, the air volume in a potato warehouse will be exchanged within 2.5 minutes when the vents to the outdoors are opened. Thus, the concentration emitted will be rapidly diluted in the outside air, which further demonstrates insignificant exposure to non-target organisms. In summary, given that 3-decen-2-one is applied indoors in a closed system, has low toxicity, is naturally occurring in foods that are common in the human diet, and presents little, if any, risk to non-target organisms, EPA concludes that pesticide products containing this new active ingredient, 3-decen-2-one, are not expected to cause unreasonable adverse effects on the environment (includes consideration of risks to workers/handlers and non-target organisms).

VIII. Conclusion

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 3-decen-2-one. Therefore, an exemption from the requirement of a tolerance is established for residues of the biochemical pesticide, 3-decen-2-one, in or on potatoes when applied as a postharvest potato sprout inhibitor and used in accordance with label directions and good agricultural practices.

IX. References

The references used in this document are available as ''Supporting & Related Material'' within docket ID EPA–HQ–OPP–2010–0065 at *www.regulations.gov.*

1. U.S. EPA. 2011. Memorandum from Colin G. Walsh thru Angela L. Gonzales to Linda A. Hollis. Joint Science Review with Health Canada Pest Management Regulatory Agency (PMRA) in Support of the Registration of AMV–1018 Technical (EPA File Symbol No. 5481–LAI), a Manufacturing-Use Product (MP), Containing 98.0% of 3-decen-2-one as its Active Ingredient and Tolerance Exemption Petition Review in Support of 3-decen-2-one. U.S. Environmental Protection Agency, Office of Pesticide Programs. December 20, 2011.

2. U.S. EPA. 2013. Memorandum from Angela L. Gonzales thru Felecia A. Fort to Colin G. Walsh. Joint Science Review with Health Canada Pest Management Regulatory Agency (PMRA) in Support of the Registration of AMV–1018 Technical Containing 98.0% of 3-decen-2-one as its Active Ingredient. U.S. Environmental Protection Agency, Office of Pesticide Programs. January 3, 2013.

3. U.S. EPA. 2010. Memorandum from Gina M. Casciano and Colin G. Walsh thru Russell S. Jones to Driss Benmhend. Revised Hazard Assessment for Tier I Human Health Toxicity in Support of the Registration of AMV–1018 Technical, Containing 3-decen-2-one as its Active Ingredient (Amends EPA Memorandum from Gina M. Casciano and Colin G. Walsh through Russell S. Jones to Driss Benmhend dated June 16, 2010). U.S. Environmental Protection Agency, Office of Pesticide Programs. December 7, 2010.

X. Statutory and Executive Order Reviews

This final rule establishes a tolerance exemption under FFDCA section 408(d) in response to a petition submitted to EPA. 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 FFDCA section 408(d), such as the tolerance exemption 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. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA 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, EPA 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) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require EPA consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

XI. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: February 5, 2013.

Steven Bradbury,

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. In subpart D, add § 180.1318 to read as follows:

§ 180.1318 3-decen-2-one; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biochemical pesticide, 3-decen-2-one, in or on potatoes when applied as a potato sprout inhibitor and used in accordance with label directions and good agricultural practices.

[FR Doc. 2013–03758 Filed 2–19–13; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R7–ES–2012–0009; 4500030113]

RIN 1018–AY40

Endangered and Threatened Wildlife and Plants; Special Rule for the Polar Bear Under Section 4(d) of the Endangered Species Act

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule; availability of environmental assessment and Finding of No Significant Impact.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), amends it regulations which implement the Endangered Species Act of 1973, as amended (ESA), to create a special rule under authority of section 4(d) of the ESA that provides measures that are necessary and advisable to provide for the conservation of the polar bear (*Ursus maritimus*), while also including appropriate prohibitions from section 9(a)(1) of the ESA.

DATES: This rule becomes effective on March 22, 2013.

ADDRESSES: *Document Availability:* The final rule, final environmental assessment, and finding of no significant impact are available for viewing on *http://www.regulations.gov* under Docket No. FWS–R7–ES–2012–0009. Supporting documentation we used in preparing this final rule is available for public inspection, by appointment, during normal business hours, at the Marine Mammal Management Office, U.S. Fish and Wildlife Service, 1011 East Tudor Road, Anchorage, AK 99503.

FOR FURTHER INFORMATION CONTACT: Charles Hamilton, Marine Mammals Management Office, U.S. Fish and Wildlife Service, Region 7, 1011 East Tudor Road, Anchorage, AK 99503; telephone 907–786–3309. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, 24 hours a day, 7 days a week.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why We Need To Publish a Final Rule

The Service was challenged via litigation on our December 16, 2008, final special rule under section 4(d) of the ESA (hereafter referred to as 4(d) special rule) (16 U.S.C. 1531 *et al*), for the polar bear. The District Court for the District of Columbia (Court) found that, although the final 4(d) special rule published December 16, 2008 (73 FR 76249) for the polar bear was consistent with the ESA, the Service violated the National Environmental Policy Act (42 U.S.C. 4321 et seq.) (NEPA) and the Administrative Procedure Act (5 U.S.C. 500 et seq.) by failing to conduct a NEPA analysis when it promulgated the final rule. On November 18, 2011, the Court vacated the final 4(d) special rule and ordered that the May 15, 2008, interim 4(d) special rule take effect until superseded by a new final 4(d) special rule. The Service is therefore promulgating a new final 4(d) special rule with appropriate NEPA analysis. Through the NEPA process, the Service fully considered a suite of alternatives for the special rule.

What is the effect of this rule?

The 2008 listing of the polar bear as a threatened species under the ESA is not affected by this final rule. In addition, nothing in this rule affects requirements applicable to polar bears under any other law such as the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 et seq.). On-the-ground conservation management of the polar bear under both the May 15, 2008, interim 4(d) special rule and the December 16, 2008, final 4(d) special rule, were substantively similar; this final 4(d) special rule reinstates the regulatory parameters afforded the polar bear under the December 16, 2008 rule, which was in place until November 18, 2011. Because this rule adopts a regulatory scheme that has governed polar bear management for over 30 years, the requirements placed on individuals, local communities, and industry are not substantively changed.

The Basis for Our Action

Under section 4(d) of the ESA, the Secretary of the Interior (Secretary) has discretion to issue such regulations as he deems necessary and advisable to provide for the conservation of threatened species. The Secretary also has the discretion to prohibit by regulation with respect to a threatened species any act prohibited by section 9(a)(1) of the ESA.

Exercising this discretion, which has been delegated to the Service by the Secretary, the Service has developed general prohibitions that are appropriate for most threatened species in 50 CFR 17.31 and exceptions to those prohibitions in 50 CFR 17.32. But for the polar bear, the Service has determined that a 4(d) special rule is appropriate. This 4(d) special rule adopts the existing conservation regulatory requirements under the MMPA and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES; 27 U.S.T. 1087) as the primary regulatory provisions for the polar bear. If an activity is authorized or exempted under the MMPA or CITES, no additional authorization under the ESA regulations is required, although consultation under section 7 of the ESA will also still be required if there is a Federal nexus. But if the activity is not authorized or exempted under the MMPA or CITES, and that activity would result in an act otherwise prohibited under the general ESA regulatory prohibitions for threatened species, then the general prohibitions at 50 CFR 17.31 would apply, and we would require a permit for the activity as specified in our ESA regulations.

Under this rule, incidental take caused by activities within the United States but outside the current polar bear range would not be subject to the takings prohibition under 50 CFR 17.31 as it is for most threatened species, but would remain subject to the taking prohibition in the MMPA and, if there is a Federal nexus, to the consultation requirement of section 7 of the ESA.

Previous Federal Actions

On May 15, 2008, the Service published a final rule listing the polar bear (*Ursus maritimus*) as a threatened species under the ESA (73 FR 28212). At the same time, the Service also published an interim special rule for the polar bear under authority of section 4(d) of the ESA that provided measures necessary and advisable for the conservation of the polar bear and prohibited certain acts covered in section 9(a)(1) of the ESA (73 FR 28306);