Dated: April 22, 2015.

Jack Housenger,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 174—[AMENDED]

■ 1. The authority citation for part 174 continues to read as follows:

Authority: 7 U.S.C. 136–136y; 21 U.S.C. 346a and 371.

■ 2. In § 174.502, revise paragraph (b) to read as follows:

§ 174.502 *Bacillus thuringiensis* Cry1A.105 protein; exemption from the requirement of a tolerance.

* * * * *

(b) Residues of *Bacillus thuringiensis* Cry1A.105 protein in or on soybean are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in the food and feed commodities of soybean.

[FR Doc. 2015–10624 Filed 5–5–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0353; FRL–9924–81]

1-Octanol; 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 1-octanol in or on root and tuber vegetables. D–I–1–4, Inc., a division of 1,4-Group, Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an amendment to the exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of 1-octanol in or on root and tuber vegetables.

DATES: This regulation is effective May 6, 2015. Objections and requests for hearings must be received on or before July 6, 2015, 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–2014–0353, 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), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

B. 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 Publishing 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, 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–2014–0353 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 July 6, 2015. 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–2014–0353, 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.html.*

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

II. Background and Statutory Findings

In the **Federal Register** of August 1, 2014 (79 FR 44729) (FRL–9911–67), 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 3F8195) by D–I–1–4, Inc., a division of 1,4-Group, Inc. (the Petitioner), P.O. Box 860, Meridian, ID 83360. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of 1-octanol, applied post-harvest to stored potatoes and other sprouting root and tuber crops. That document referenced a summary of the

petition prepared by the Petitioner, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

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 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, EPA is required to take into account the factors set forth in FFDCA section 408(b)(2)(D).

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

A. Overview of 1-Octanol

1-Octanol, or octyl alcohol, is a linear saturated aliphatic alcohol containing eight carbons. It is classified as a biochemical pesticide and functions as a plant growth regulator (PGR) by inhibiting sprout growth on stored potatoes and other sprouting root and tuber crops when applied after harvesting.

There is a significant history of human dietary exposure to 1-octanol. 1-Octanol occurs naturally in the essential oils of green tea, grapefruit, California orange, bitter orange, Turkish rose and Bulgarian rose. 1-Octanol has also been identified as a component of fried bacon, roasted filberts, raw and roasted earth almonds, mutton, chicken, pork, raw beef, frankfurters, nectarines, apple juice, common guava, Gruyere cheese and in foods processed from cassava root. The amount of 1-octanol has been quantified in some foods: Fermented soybean curds were found to contain 164.8 to 337.1 micrograms per kilogram (ug/kg) of 1-octanol, and duck meat and duck fat were found to contain 1-octanol as a volatile component at 8.88 parts per billion (ppb) and 12.69 ppb, respectively. 1-Octanol is approved by the FDA for use as a direct food additive under 21 CFR 172.230 in microcapsules for flavoring substances and under 21 CFR 172.515 as a synthetic flavoring substance and adjuvant.

EPA has already determined under the FFDCA that there is a reasonable certainty that no harm will result from aggregate exposures to 1-octanol, when 1-octanol is used as an inert ingredient (specifically as a solvent or co-solvent) in pesticide products applied to food. In addition, 1-octanol has been registered for use as an active ingredient to control tobacco sucker and as an inert ingredient for nonfood and fragrance uses.

For a summary of the data upon which EPA relied, and its human health risk assessment based on that data, please refer to the March 13, 2015 document entitled: ''Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for 1-Octanol'' available in the docket for this action.

B. Biochemical Pesticide Toxicology Data Requirements

All applicable mammalian toxicology data requirements supporting the petition to establish an exemption from the requirement of a tolerance for the use of 1-octanol as an active ingredient, post-harvest, on root and tuber vegetables have been fulfilled. No significant toxicological effects were observed in any of the acute toxicity studies and no toxic endpoints were established as a result of these studies. In addition, data and information submitted indicate that 1-octanol is not genotoxic. A developmental toxicity study (subchronic) revealed increased salivation (maternal) at 1,000 milligrams 1-octanol per kilogram body weight (mg/kg); however, the Agency does not consider this to be an adverse effect because the effect occurs at a very high dose, much higher dose than the level at which humans are likely to be exposed, given the half-life of this substance and the classification of the pesticide: A plant growth regulator intended for use before long-term storage. EPA concludes that 1-octanol has no subchronic toxic effects and is not a developmental toxicant. There are no known effects of 1-octanol on endocrine systems via oral, dermal, or inhalation routes of exposure.

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

The proposed use patterns may result in dietary exposure to 1-octanol, however, dietary exposure as a result of the application of 1-octanol to post-harvest potatoes and other root tubers is expected to be insignificant. 1-Octanol is volatile and is expected to degrade in the atmosphere by reaction with photochemically-produced hydroxyl radicals; its half-life is estimated to be from 3.5 minutes to 1.3 days. The typical length of time between application of the pesticide and consumption of the potatoes will exceed this half-life. Therefore, residues of 1-octanol are unlikely to occur at the time of consumption. No significant exposure via drinking water is expected from its use as an active ingredient in this pesticide as 1-octanol is applied indoors only. Some dietary exposure is expected from the use of 1-octanol as an inert ingredient in pesticide formulations.

Some dietary exposure to 1-octanol might occur through other nonpesticidal sources as a result of its natural presence in other foods or from its use as a food additive and flavoring substance. Should exposure occur, however, minimal to no risk is expected for the general population, including infants and children, due to the low toxicity of 1-octanol.

B. Other Non-Occupational Exposure

Other non-occupational exposure to 1-octanol from pesticidal use may occur in tobacco products from its use on

tobacco or in or on other food and non-food commodities, as a result of its use as a pesticide inert ingredient. However, minimal to no risk is expected for the general population, including infants and children, due to the low toxicity of this chemical as demonstrated in the data submitted and evaluated by the Agency, as fully explained in the March 13, 2015 document entitled: ''Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for 1-Octanol'' available in the docket for this action.

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, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found 1-octanol to share a common mechanism of toxicity with any other substances, and 1-octanol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 1-octanol does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

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 (FQPA)(SF). 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.

As part of its qualitative assessment, EPA evaluated the available toxicity and exposure data on 1-octanol and considered its validity, completeness, and reliability, as well as the relationship of this information to human risk. EPA considers the toxicity database to be complete and has identified no residual uncertainty with regard to prenatal and postnatal toxicity or exposure. No hazard was identified based on the available studies; therefore, EPA concludes that there are no threshold effects of concern to infants, children, or adults from 1-octanol. As a result, EPA concludes that no additional margin of exposure (safety) is necessary.

VII. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

VIII. Conclusion

Based on its assessment of 1-octanol, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to 1-octanol. Therefore, an amendment to the exemption of a tolerance is established for residues of 1-octanol in or on root and tuber vegetables.

The Agency is issuing the exemption for residues on root and tuber vegetables instead of limiting this exemption to post-harvest indoor applications to root and tuber vegetables because these restrictions are not relevant to the FFDCA safety finding for 1-octanol. Those limitations are related to the use of the pesticide and regulated under FIFRA.

IX. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this 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 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, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this 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 Agency 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).

X. 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: April 10, 2015.

Robert McNally,

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. Add § 180.1330 to subpart D to read as follows:

§ 180.1330 1-Octanol; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of 1-octanol in or on root and tuber vegetables when applied as a plant growth regulator in accordance with label directions and good agricultural practices.

[FR Doc. 2015–10364 Filed 5–5–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0075; FRL–9925–97]

Fenazaquin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenazaquin in or on almonds and cherries. Gowan Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 6, 2015. Objections and requests for hearings must be received on or before July 6, 2015, 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–2006–0075, 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), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2006–0075 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 July 6, 2015. 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–2006–0075, 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.
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- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of April 20, 2011 (76 FR 22067) (FRL–8869–7), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F7825) by Gowan Company, P.O. Box 5569, Yuma, AZ 85366. The petition requested that 40 CFR 180.632 be amended by establishing tolerances for residues of the insecticide fenazaquin, 4-[2-[4-(1,1-dimethylethyl)phenyl] ethoxy]quinazoline, in or on fruit, pome group at 0.35 parts per million (ppm); cucurbit group at 0.25 ppm; almond, hulls at 4.5 ppm; apple, wet pomace at 0.6 ppm; berry fruit group at 0.6 ppm;