SUPPLEMENTARY INFORMATION:
FOR FURTHER INFORMATION CONTACT:
DATES:
SUMMARY:
Agency (EPA) is providing notice of preliminary calculations for the first-round 2016 NUSA allowance allocations. EPA also described the process for submitting any objections to the preliminary calculations.
In response to the May 27 NODA, EPA received one written objection addressing CSAPR NOx annual and NOx ozone season allowance recordations for 2016 to Missouri’s existing CSAPR units, and the number of allowances shown as available for allocation to Missouri’s new units in 2016 in the May 27 NODA under those programs. Due to an allowance recordation error, two facilities in Missouri with existing units did not receive the CSAPR NOx annual and ozone season existing unit allowance allocations specified in Missouri’s approved 2016 CSAPR State Implementation Plan (SIP). This error in turn impacted the number of NUSA allowances shown in the May 27 NODA as available for allocation to Missouri’s new units for 2016 under those programs. EPA corrected the recordation error to the existing units by recording a total of four additional CSAPR NOx Annual allowances and two additional CSAPR NOx Ozone Season allowances to two facilities in Missouri, consistent with the allocations for those facilities specified by Missouri in their 2016 CSAPR SIP. EPA in turn adjusted downward the number of allowances available for allocation in Missouri’s 2016 CSAPR NOx Annual and CSAPR NOx Ozone Season NUSA’s by four and two allowances, respectively. Since the downward correction to the number of allowances available in Missouri’s 2016 NUSAs was relatively small, the number of allowances allocated to new units in Missouri in the first round was not affected.
The final unit-by-unit data and allowance allocation calculations are set forth in Excel spreadsheets titled “CSAPR_NUSA_2016_NOx_Annual_1st_Round_Final_Data”, “CSAPR_NUSA_2016_NOx_O3_1st_Round_Final_Data”, and “CSAPR_NUSA_2016_SO2_1st_Round_Final_Data”, available on EPA’s Web site at http://www.epa.gov/crossstaterule/actions.html. The three spreadsheets show EPA’s final determinations of first-round 2016 NUSA allocations under the CSAPR NOx annual, NOx ozone season, and SO2 (Group 1 and Group 2) trading programs, respectively.
Pursuant to CSAPR’s allowance recordation timing requirements, the allocated NUSA allowances will be recorded in sources’ AMS accounts by August 1, 2016. EPA notes that an allocation or lack of allocation of allowances to a given unit does not constitute a determination that CSAPR does or does not apply to the unit. EPA also notes that NUSA allocations are subject to potential correction if a unit to which NUSA allowances have been allocated for a given compliance year is not actually an affected unit as of January 1 (or May 1 in the case of the NOx ozone season program) of the compliance year.1

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1 See 40 CFR 97.411(c), 97.511(b), 97.611(b), and 97.711(b).

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EPA-APPROVED FLORIDA NON-REGULATORY PROVISIONS

<table>
<thead>
<tr>
<th>Provision</th>
<th>State effective date</th>
<th>EPA approval date</th>
<th>Federal Register notice</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 2015 Regional Haze Progress Report</td>
<td>3/10/2015</td>
<td>8/2/2016</td>
<td>Insert citation of publication</td>
<td></td>
</tr>
</tbody>
</table>
Dow AgroSciences, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 2, 2016. Objections and requests for hearings must be received on or before October 3, 2016, 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–2012–0843, 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: RDRFNNotices@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?


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–2012–0843 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 October 3, 2016. 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–2012–0843, by one of the following methods:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments.
• 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. Summary of Petitioned-For Tolerance

In the Federal Register of December 19, 2012 (77 FR 75082) (FRL–9372–6), 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 2F8085) by Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The petition requested that 40 CFR 180.560 be amended by expanding the tolerances therein to cover residues of the inert ingredient (herbicide safener) cloquintocet-mexyl (acetic acid [(5-chloro-8-quinolinoxyacetic) acid] when used in pesticide formulations containing the new active ingredient halaluxifen-methyl (XDE-729 methyl), in or on barley grain, barley hay, barley straw, wheat forage, wheat grain, wheat hay, and wheat straw. No numerical change to the tolerances for the specific commodities was sought. That document referenced a summary of the petition prepared by Dow AgroSciences LLC, the registrant, which is available in the docket, http://www.regulations.gov. There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . .”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), 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 for cloquintocet-mexyl including exposure resulting from the tolerances established by this action. EPA’s assessment of exposures and risks associated with cloquintocet-mexyl follows.

Detailed exposure and risk assessment information is provided in Supporting Information Part I.A. of the supplemental information at http://www.regulations.gov, which is available in the docket, http://www.regulations.gov.
A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Cloquintocet-mexyl has a low order of acute oral, dermal, and inhalation toxicity. It is slightly irritating to the eyes and non-irritating to the skin. Cloquintocet-mexyl is a skin sensitizer. The chemical is not genotoxic and is not a reproductive and developmental toxicant. There is no evidence of neurotoxicity in the available studies. Cloquintocet-mexyl is classified as “not likely to be a human carcinogen.” The main metabolite for cloquintocet-mexyl is 5-chloro-8-quin-linoxyacetic acid, and testing on the metabolite is part of the toxicology database for cloquintocet-mexyl.

Specific information on the studies received and the nature of the adverse effects caused by cloquintocet-mexyl as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at http://www.regulations.gov in document Cloquintocet-Mexyl—Updated Human Health Risk Assessment from Uses of Halauxifen-methyl (PC Code 117501) in docket ID number EPA–HQ–OPP–2012–0843.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see http://www.epa.gov/pesticides/factsheets/riskassess.htm.

A summary of the toxicological endpoints for cloquintocet-mexyl used for human risk assessment is shown in Table 1 of this unit.

<table>
<thead>
<tr>
<th>Exposure/scenario</th>
<th>Point of departure and uncertainty/safety factors</th>
<th>RID, PAD, LOC for risk assessment</th>
<th>Study and toxicological effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute dietary (Females 13–49 years of age).</td>
<td>NOAEL = 100 mg/kg/day. UF_A = 10. UF_H = 10x. FQPA SF = 1x.</td>
<td>Acute RfD = 1 mg/kg/day. aPAD = 1 mg/kg/day.</td>
<td>Developmental toxicity study in rats (MRID 44387429). LOAEL = 400 mg/kg/day based on higher incidence of skeletal variants and decrease in fetal body weights in the high dose group.</td>
</tr>
<tr>
<td>Acute dietary (General population including infants and children).</td>
<td>NOAEL = 4.3 mg/kg/day. UF_A = 10x. UF_H = 10x. FQPA SF = 1x.</td>
<td>Chronic RfD = 0.04 mg/kg/day. cPAD = 0.04 mg/kg/day.</td>
<td>Based on available data, a suitable endpoint was not identified for the general population because there were no effects observed in oral toxicity studies appropriate to this population that could be attributed to a single dose exposure. Chronic/Oncogenicity Toxicity—Rat (MRID 44387431). LOAEL = 41.2 mg/kg/day based on thyroid hyperplasia in females.</td>
</tr>
<tr>
<td>Chronic dietary (All populations).</td>
<td>NOAEL = 4.3 mg/kg/day. UF_A = 10x. UF_H = 10x. FQPA SF = 1x.</td>
<td>Chronic RfD = 0.04 mg/kg/day. cPAD = 0.04 mg/kg/day.</td>
<td>Cloquintocet-mexyl is classified as “not likely to be carcinogenic to humans.”</td>
</tr>
<tr>
<td>Cancer (Oral, dermal, inhalation).</td>
<td>NOAEL = 4.3 mg/kg/day. UF_A = 10x. UF_H = 10x. FQPA SF = 1x.</td>
<td>Chronic RfD = 0.04 mg/kg/day. cPAD = 0.04 mg/kg/day.</td>
<td>Cloquintocet-mexyl is classified as “not likely to be carcinogenic to humans.”</td>
</tr>
</tbody>
</table>

C. Exposure Assessment

1. Dietary exposure from food and feed uses. In evaluating dietary exposure to cloquintocet-mexyl, EPA considered exposure under the petitioned-for tolerances as well as all existing cloquintocet-mexyl tolerances in 40 CFR 180.560. EPA assessed dietary exposures from cloquintocet-mexyl in food as follows:
   i. Acute exposure. Quantitative acute dietary exposure and 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. Such effects were identified for cloquintocet-mexyl and are applicable only to females 13–49 years old in order to account for fetal effects (higher incidence of skeletal variants and decrease in fetal body weights) that were seen in the developmental toxicity study in rats. In estimating acute dietary exposure, EPA used food consumption information from the 2003–2008 National Health and Nutrition Examination Surveys (NHANES). As to residue levels in food, EPA assumed tolerance-level residues of cloquintocet-mexyl and cloquintocet acid in all forms of barley, triticale, and wheat, and assumed that all of those crops are treated (i.e., 100% crop treated).
   ii. Chronic exposure. In conducting the chronic dietary exposure assessment
EPA used the food consumption data from the 2003–2008 National Health and Nutrition Examination Surveys (NHANES). As to residue levels in food, EPA assumed tolerance-level residues of cloquintocet-mexyl and cloquintocet acid in all forms of barley, triticale, and wheat, and assumed that all of those crops are treated (i.e., 100% crop treated).

ii. Cancer. Based on the data summarized in Unit III.A., EPA has concluded that cloquintocet-mexyl does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of evaluating cancer risk is unnecessary.

2. Dietary exposure from drinking water. The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for cloquintocet-mexyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of cloquintocet-mexyl. Further regarding EPA drinking water models used in pesticide exposure assessment can be found at http://www.epa.gov/oppfed1/models/water/index.htm.

Based on the First Index Reservoir Screening Tool (FIRST) and the Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of cloquintocet-mexyl for acute exposures are estimated to be 0.186 parts per billion (ppb) for surface water and 0.000061 ppb for ground water. Chronic exposures are estimated to be 0.005 ppb for surface water and 0.000061 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. As a conservatism in the assessment, the acute drinking water estimate (0.186 ppb), rather than the chronic drinking water estimate (0.005 ppb) was used in chronic dietary assessment.

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, termiteicides, and flea and tick control on pets). Cloquintocet-mexyl is not registered for any specific use patterns that would result in residential exposure.

4. Cumulative effects from substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, 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 cloquintocet-mexyl to share a common mechanism of toxicity with any other substances, and cloquintocet-mexyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that cloquintocet-mexyl does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s Web site at http://www.epa.gov/pesticides/cumulative.

D. Safety Factor for Infants and Children

1. In general. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the absence of data sufficient to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. Prenatal and postnatal sensitivity. There was no evidence of increased susceptibility of in utero or post-natal exposure to rats or rabbits in the prenatal developmental studies or in rats in the 2-generation reproduction study. NOAELs for maternal/parental toxicity were either less than or equal to the NOAELs for fetal or reproductive toxicity.

3. Conclusion. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. This decision is based on the following findings:

i. The toxicity database for cloquintocet-mexyl is sufficient for risk assessment.

ii. There is no indication that cloquintocet-mexyl is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UF's to account for neurotoxicity.

iii. There is no evidence that cloquintocet-mexyl results in increased susceptibility in in utero rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to cloquintocet-mexyl in drinking water. These assessments will not underestimate the exposure and risks posed by cloquintocet-mexyl.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute POD (aPOD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. Acute risk. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to cloquintocet-mexyl will occupy <1% of the aPOD for females age 13–49, the population group receiving the greatest exposure.

2. Chronic risk. Using the exposure assumptions described in this unit for chronic exposure. EPA has concluded that chronic exposure to cloquintocet-mexyl from food and water will utilize <1% of the cPAD for all subpopulations. There are no residential uses for cloquintocet-mexyl.

3. Short-term and intermediate-term risk. Because cloquintocet-mexyl is not registered for use in pesticide formulations that will result in residential exposure, EPA concludes that cloquintocet-mexyl will not pose a short-term or intermediate-term risk.

4. Aggregate cancer risk for U.S. population. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, cloquintocet-mexyl is not expected to pose a cancer risk to humans.

5. Determination of safety. Based on these risk assessments, 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 cloquintocet-mexyl residues.
IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: residualmethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for cloquintocet-mexyl.

V. Conclusion

The residue data indicate that combined residues of cloquintocet-mexyl and cloquintocet acid are unlikely to exceed the existing tolerances for residues in barley, triticale, and wheat commodities, therefore, the existing tolerance levels remain unchanged. However, the active ingredient, halauxifen-methyl, will be added to the list of active ingredients addressed in the tolerance expression for cloquintocet-mexyl as a result of this tolerance amendment for cloquintocet-mexyl.

Therefore, 40 CFR 180.560 is amended by establishing a tolerance for the combined residues of cloquintocet-mexyl (acetic acid [5-chloro-8-quinoliny] oxyxl, 1-methylhexyl ester; CAS Reg. No. 99607–70–2) and its acid metabolite (5-chloro-8-quinolinoyacetic acid) when used as an inert ingredient (safener) in pesticide formulations containing the active ingredients clodinafop-propargyl (wheat only), dicamba (wheat only), flucarbazone-sodium (wheat only), halauxifen-methyl (wheat or barley), pinoxaden (wheat or barley), or pyroxsulam (wheat only) at 0.1 ppm in/on barley commodities (grain, hay, and straw), wheat grain, and wheat straw; at 0.2 ppm in/on wheat forage; and at 0.5 ppm in/on wheat hay.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has completed these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.), 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 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 action 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 with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (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 (NTTAA) (15 U.S.C. 272 note).

VII. 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: June 28, 2016.

Susan Lewis,
Director, Registration 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:


2. In § 180.560, revise the introductory text of paragraph (a) to read as follows:

§ 180.560 Cloquintocet-mexyl; tolerances for residues.

(a) General. Tolerances are established for residues of the inert ingredient cloquintocet-mexyl, including its metabolites and degradates, in or on the commodities in the following table when used as a safener in pesticide formulations containing the active ingredients clodinafop-propargyl (wheat only), dicamba (wheat only), flucarbazone-sodium (wheat only), halauxifen-methyl (wheat or barley), pinoxaden (wheat or barley), or pyroxsulam (wheat only). Compliance with the tolerance levels specified is to be determined by measuring the combined residues of cloquintocet-mexyl, (acetic acid [(5-
chloro-8-quinolinyl)oxy]-, 1-
methylhexyl ester; CAS Reg. No. 99607–
70–2) and its acid metabolite (5-chloro-
8-quinolinoxaycetic acid), expressed as
cloquintocet-mexyl, in or on the following commodities:
* * * * *

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 202, 212, 242, 246, and 252

[Docket DARS–2015–0038]

RIN 0750–A158

Defense Federal Acquisition Regulation Supplement: Detection and Avoidance of Counterfeit Electronic Parts—Further Implementation

(DFARS Case 2014–D005)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.


DATES: Effective August 2, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Amy G. Williams, telephone 571–372–6106.

SUPPLEMENTARY INFORMATION:

I. Background


In accordance with section 818, this rule requires DoD contractors and subcontractors, except in limited circumstances, acquire electronic parts from trusted suppliers in order to further address the avoidance of counterfeit electronic parts. DoD contractors and subcontractors that are not the original component manufacturer are required by this rule to notify the contracting officer if it is not possible to obtain an electronic part from a trusted supplier. For those instances where the contractor obtains electronic parts from sources other than a trusted supplier, the contractor is responsible for inspection, test, and authentication in accordance with existing applicable industry standards.

This rule enhances DoD’s ability to strengthen the integrity of the process for acquisition of electronic parts and benefits both the Government and contractors. The careful selection of suppliers and the inspection, testing, and authentication of electronic parts that are not traceable to the original manufacturer are consistent with industry risk-based processes and are steps that a prudent contractor should take notwithstanding this rule. The avoidance of the proliferation of counterfeit electronic parts in the DoD supply chain reduces the risk of critical failure of fielded systems such as aircraft, ships, and other weapon systems, thus protecting troops’ lives and safety.

This rule is part of DoD’s retrospective plan, completed in August 2011, under Executive Order 13563, Improving Regulation and Regulatory Review. DoD’s full plan and updates can be accessed at: http://www.regulations.gov/#!docketDetail;D=DOD-2011-OS-0036. Eighteen respondents submitted public comments in response to the proposed rule.

II. Discussion and Analysis

DoD reviewed the public comments in the development of the final rule. A discussion of the comments and the changes made to the rule as a result of those comments is provided, as follows:

A. Summary of Significant Changes From the Proposed Rule

1. Definitions
   • Replaces the definition of “authorized dealer” with a definition of “authorized supplier.”
   • Replaces the definition of “contract electronics manufacturer” with a definition of “contract manufacturer” and a definition of “authorized aftermarket manufacturer.” This also results in a conforming change to the definition of “original manufacturer.”
   • Deletes the definition of “trusted supplier” and adds a definition of “contractor-approved supplier.”
   • Amends the definition of “obsolete electronic part” to utilize the newly defined term “authorized aftermarket manufacturer.”
   • Makes conforming changes throughout the rule in accordance with the added, revised, or deleted definitions.

2. Amends the following paragraphs of DFARS clause 252.246–7008, Sources of Electronic Parts, with conforming changes to DFARS subpart 246.8, as follows:
   • (b)(1)—Clarifies “in production” and “currently available in stock”.
   • (b)(2) Introductory text—Clarifies “not in production” and “not currently available in stock” and changes “or” to “and” in the condition for use of contractor-approved suppliers, i.e., “Obtain electronic parts that are not in production by the original manufacturer or an authorized aftermarket manufacturer and not currently available in stock from a source listed in paragraph (b)(1) of this clause, from suppliers identified by the Contractor as contractor-approved suppliers . . . .”
   • (b)(2)(i)—For electronic parts not in production and not currently available in stock, adds to the requirement for use of established counterfeit prevention industry standards and processes, the reference to the DoD-adopted standards at https://assist.dla.mil, but allows use of other appropriate standards. Use of DoD-adopted counterfeit prevention industry standards was previously required in the definition of “trusted supplier.”
   • (b)(2)(iii)—Specifies that the contracting officer is the appropriate DoD official to review and audit. This function is also added at DFARS 242.302 as a contract administration function that is delegable to the administrative contracting officer.
   • (b)(3)—Moves former paragraph (d) to paragraph (b)(3), requiring prompt notification in writing, and adds the requirement that the contractor shall make documentation of the inspection, testing, and authentication of such electronic parts available to the contracting officer upon request if the contractor—
     • Obtains an electronic part from a source other than any of the sources identified in paragraph (b)(1) or (b)(2) of the clause due to nonavailability from such sources, or a subcontractor (other than the original manufacturer) that refuses to accept flowdown of the clause; or
     • Cannot confirm that an electronic part is new or that it has not been comingle in supplier new production or stock with used, refurbished, reclaimed, or returned parts.
   • (c)(2)—Deletes contractor consideration of counterfeit parts if the contractor cannot establish traceability from the original manufacturer for a