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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0202; FRL-9371-6]

Clodinafop-propargyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation reduces the established tolerance for residues of clodinafop-propargyl in or on wheat, grain. Syngenta Crop Protection, LLC requested this tolerance change under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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-2012-0202, 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: Mindy Ondish, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 605-0723; email address: *ondish.mindy@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://ecfr.gpoaccess.gov/cgi/t/text/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-2012-0202 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 [*insert date 60 days after date of publication in the* **Federal Register**]. 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-2012-0202, 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 Confidential Business Information (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. Summary of Petitioned-For Tolerance

In the **Federal Register** of October 17, 2012 (77 FR 63782) (FRL-9366-2), 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 1F7955) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419-8300. The petition requested that 40 CFR 180.559 be amended by lowering the established tolerance for residues of the herbicide clodinafop-propargyl in or on wheat, grain from 0.1 to 0.02 parts per million (ppm). That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket, *http://www.regulations.gov*. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C. Finally, EPA is revising the tolerance expression for the reasons explained in Unit IV.D.

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 clodinafop-propargyl including exposure resulting from the tolerance established by this action. EPA's assessment of exposures and risks associated with clodinafop-propargyl follows.

In the **Federal Register** of June 22, 2000 (65 FR 38765) (FRL-6590-7), EPA published a final rule establishing tolerances for combined residues of the herbicide clodinafop-propargyl and its acid metabolite in or on wheat (forage, grain, hay, and straw) based upon EPA's conclusion that aggregate exposure to clodinafop-propargyl is safe for the general population, including infants and children. Since 2000, there have been no additional tolerance actions for clodinafop-propargyl.

This action decreases the established tolerance for residues of clodinafop-propargyl in or on the commodity wheat, grain from 0.1 to 0.02 ppm, based upon a change to an enforcement method (Method MS 247) with a lower limit of quantitation (LOQ) on

wheat grain than the current methods. Since an established tolerance is being reduced, which is expected to have no significant exposure effect, no new dietary exposure assessment, drinking water exposure assessment, or non-dietary exposure assessment was conducted.

Except as supplemented by the information described in this unit, EPA is relying on the safety finding in the 2000 rulemaking and the risk assessment underlying that action in amending the tolerance for wheat grain. Further information regarding the safety finding for the last rulemaking can be found in the **Federal Register** of June 22, 2000, at *http://www.epa.gov/fedrgstr/EPA-PEST/2000/June/Day-22/p15715.htm*. Although significant new data have been received since the 2000 rulemaking, as discussed in this unit, these data do not indicate that risk from exposure to clodinafop-propargyl were understated. To the contrary, these new data suggest that EPA's prior risk assessment overstated clodinafop-propargyl risks. Further information about EPA's risk assessment and determination of safety for this action can be found at http://*www.regulations.gov* in document "Clodinafop-propargyl. Human Health Risk Assessment for Clodinafop-propargyl to Reduce the Established Tolerance on Wheat Grain" in docket ID number EPA-HQ-OPP-2012-0202.

For the 2000 rulemaking, the toxicity database for clodinafop-propargyl was considered incomplete. Acute neurotoxicity, subchronic neurotoxicity, developmental neurotoxicity, and *in vitro* cytogenetic studies were required. The absence of these studies, along with quantitative and qualitative evidence of increased susceptibility, and evidence of potential endocrine disruption, led EPA to retain an additional safety factor for the protection of infants and children as provided by FFDCA section 408(b)(2)(C) (i.e., 10X for acute risk

for females 13+ and chronic risk; 3X for acute risk for infants and children). With the exception of the cytogenetic studies, the required studies have since been submitted and found acceptable. Studies were submitted which removed mutagenicity concerns and thus the cytogenetic studies were no longer required.

In all likelihood, the submission of these data will lead EPA to remove the additional safety factor for the protection of infants and children when it formally revises the clodinafop-propargyl risk assessment. The absence of these data was the primary reason for retaining that additional factor. Currently, there is a data gap for an immunotoxicity study. In 2007 changes to 40 CFR part 158 imposed new data requirements for immunotoxicity testing (OPPTS Guideline 870.7800) for pesticide registration. This study has not been submitted for clodinafop-propargyl. The absence of this study is unlikely to result in retention of an additional safety factor. EPA has only retained an additional safety factor when there is a data gap for immunotoxicity where the database shows clear evidence of immunotoxicity and immunotoxic effects were seen at the LOAEL that defined the point of departure (POD). For clodinafop-propargyl, there is evidence in the current toxicological database that clodinafop-propargyl may perturb immune function but this evidence is not strong and it did not affect the choice of the POD. In the subchronic oral toxicity study in rats, treatment-related effects were observed (37% decrease in thymus weight and increased thymic atrophy). Thymus effects were observed only in males at the highest treatment-dose (71 mg/kg/day), and were fully reversed after a 4-week recovery period. No thymus effects were observed in the chronic toxicity/carcinogenicity study in rats. No other indicators of structural immunotoxicity were observed in the current database. While an immunotoxicity study

is required to complete the database, the absence of this study is not expected to alter the aRfD or cRfD for clodinafop-propargyl. Hence, by relying on the 2000 risk assessment and the additional safety factors retained in that assessment, EPA has taken a conservative approach that is likely to overstate the estimated risk of clodinafop-propargyl.

The EPA has determined that the results of the neurotoxicity studies adequately elucidate the hazard but do not affect EPA's derivation of clodinafop-propargyl's acute reference dose (aRfD) or chronic reference dose (cRfD). The NOAELs for adverse effects seen in the neurotoxicity studies are well above the NOAELs in the studies used as PODs. Thus, the PODs used in the risk assessment for the 2000 rulemaking for clodinafop-propargyl, as well as the aRfD and the cRfD derived from those PODs, are protective of all effects, including neurotoxicity, observed in the neurotoxicity studies.

Previously, EPA considered clodinafop-propargyl as likely to be carcinogenic to humans based on increased incidences of prostate tumors in male rats, ovarian adenomas in female rats, liver tumors in male and female mice, and blood vessel tumors in female mice and estimated cancer risk using a linear (non-threshold) approach. Since that time, additional data have been submitted, including a re-evaluation of the proliferative lesions in the rat ovary and prostate as well as mode of action data for mouse liver tumors. In 2006, EPA revised its cancer determination on clodinafop-propargyl concluding that the evidence was no greater than suggestive of carcinogenic potential and thus did not support the finding that clodinafop-propargyl was likely to be carcinogenic to humans. That conclusion was based on the following:

1. Prostate tumors (driven mainly by adenomas) were seen in one sex (male) of one species (rat) at the high dose only.

2. There is no mutagenicity concern for clodinafop-propargyl.

3. The weight-of-evidence supports activation of peroxisome proliferator-activated receptor alpha (PPAR") as the mode of action for clodinafop-induced hepatocarcinogenesis in mice. While the PPAR mode of action for liver tumors in mice is theoretically plausible in humans, hepatocarcinogenesis by this mode of action is quantitatively implausible and unlikely to take place in humans based on quantitative species differences in PPAR" activation and toxicokinetics.

4. Ovarian tumors in the rat and vascular tumors in the mouse were not considered to be treatment-related in the Second Report of the Cancer Assessment Review Committee.

Given this limited evidence of carcinogenic effects in animals or effects unlikely to be relevant to humans, the use of a linear (non-threshold) approach for assessing cancer risk is no longer appropriate. Instead, EPA has determined that the chronic threshold-based risk assessment (i.e., the cRfD approach) will be protective of any cancer risk.

Based upon the 2000 rulemaking and the other information discussed in this unit, EPA concludes that there is a reasonable certainty that no harm will result to the general population and to infants and children from aggregate exposure to clodinafop residues. EPA relies upon those risk assessments and the findings made in the **Federal Register** document in support of this action.

IV. Other Considerations

A. Analytical Enforcement Methodology

An analytical method using high-performance liquid chromatography with tandem mass spectrometry detection (LC/MS/MS), Enviro-Test Laboratories Report No. MS 247 (Method MS 247) was submitted in support of reducing the tolerance for wheat grain. This LC/MS/MS method has a lower LOQ than the current HPLC-UV methods (REM 138.01 for clodinafop-propargyl and REM 138.10 for clodinafop) for the determination of residues of clodinafop-propargyl (CGA-184927) and its metabolite clodinafop (CGA-193469) in or on wheat commodities. Method MS 247 was adequately validated using fortified samples of wheat grain, forage, and straw.

The current enforcement methods (REM 138.01 for clodinafop-propargyl and REM 138.10 for clodinafop) can serve as confirmatory methods for Method MS 247 on wheat grain since they use a different detection system. Therefore, the LC/MS/MS Method MS 247 is adequate as an enforcement analytical method for determination of residues of clodinafop-propargyl and its metabolite clodinafop in wheat grain at 0.02 ppm (0.01 ppm for each analyte). The methods referenced in this unit 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: *residuemethods@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 MRLs for clodinafop-propargyl in or on any commodities.

C. Response to Comments

EPA received an anonymous comment in response to the Notice of Filing that objected to the proposed tolerance petition. The commenter stated that the objection was to the "Syngenta application to increase [the tolerance] from .01 to .02 ppm". Because this action is to decrease the tolerance from 0.1 to 0.02 ppm, it is assumed that the commenter misinterpreted the proposed petition and would have no objections otherwise. The commenter made additional comments proposing to eliminate tolerances and pesticides altogether. The Agency understands the commenter's concerns and recognizes that some individuals believe that certain pesticide chemicals should not be permitted in our food. However, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. When new or amended tolerances are requested for residues of a pesticide in food or feed, the Agency, as is required by section 408 of the FFDCA, estimates the risk of the potential exposure to these residues. The Agency has concluded after this assessment that there is a reasonable certainty that no harm will result from aggregate human exposure to clodinafop-propargyl.

EPA received a second anonymous comment in response to the Notice of Filing which urged that regulations in general be stopped because they are killing small businesses. This comment is considered irrelevant to this action because the safety standard for approving tolerances under section 408 of FFDCA focuses on potential harm to human health and does not permit consideration of effects on any type of businesses.

D. Revisions to Petitioned-For Tolerances

Finally, the EPA is revising the tolerance expression to:

1. Clarify that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of clodinafop-propargyl not specifically mentioned; and

2. Clarify that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, the established tolerance for residues of clodinafop-propargyl in or on wheat, grain is reduced from 0.1 to 0.02 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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 tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of 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).

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: November 27, 2012.

G. Jeffrey Herndon,

Acting 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:

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

2. In § 180.559, in paragraph (a), revise the introductory text; and in the table, revise the entry for "Wheat, grain" to read as follows:

§ 180.559 Clodinafop-propargyl; tolerances for residues.

(a) *General.* Tolerances are established for clodinafop-propargyl, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only clodinafop-propargyl [(2*R*)-2-[4-[(5-chloro-3-fluoro-2-pyridinyl)oxy]phenoxy]propanoic acid, 2-propynyl ester] and its metabolite clodinafop [(2*R*)-2-[4-[(5-chloro-3-fluoro-2- pyridinyl)oxy]phenoxy]propanoic acid].

Commodity	**Parts per million**
* * * * *	
Wheat, grain	0.02
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