VHF–FM marine band radio channels 13 and 16.

(4) The operator of any vessel within or in the immediate vicinity of this safety zone shall:

(i) Stop the vessel immediately upon being directed to do so by any commissioned, warrant or petty officer on board a vessel displaying a Coast Guard Ensign, and

(ii) Proceed as directed by any commissioned, warrant or petty officer on board a vessel displaying a Coast Guard Ensign.

(c) *Definitions. Captain of the Port Baltimore* means the Commander, Coast Guard Sector Baltimore or any Coast Guard commissioned, warrant or petty officer who has been authorized by the Captain of the Port to act on his behalf.

Designated representative means any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port Baltimore to assist in enforcing the safety zone described in paragraph (a) of this section.

(d) *Enforcement.* The U.S. Coast Guard may be assisted by Federal, State and local agencies in the patrol and enforcement of the zone.

(e) *Enforcement periods.* This section will be enforced from 6 p.m. through 11 p.m. on September 1, 2010, September 21, 2010, October 1, 2010, October 9, 2010 and November 18, 2010, and if necessary due to inclement weather, from 6 p.m. through 11 p.m. on November 19, 2010.

Dated: August 16, 2010.

Mark P. O'Malley,

Captain, U.S. Coast Guard, Captain of the Port Baltimore.

[FR Doc. 2010–21781 Filed 8–31–10; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0233; FRL–8841–6]

Choline hydroxide; 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 choline hydroxide (CAS Reg. No. 123–41–1) when used as an inert ingredient that acts as a neutralizer in food use, acidic, preharvest herbicide products. The Dow AgroSciences, LLC, has submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of choline hydroxide.

DATES: This regulation is effective September 1, 2010. Objections and requests for hearings must be received on or before November 1, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0233. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Mark Dow, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5533; e-mail address: *dow.mark@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I 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.gpoaccess.gov/ecfr*.

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–2010–0233 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 November 1, 2010. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0233, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One

Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Exemption

In the **Federal Register** of May 19, 2010 (75 FR 28009)(FRL–9153–1), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 0E7686)(75 FR 28012) by Dow AgroSciences, LLC, 9330 Zionsville Road, Indianapolis, IN, 46268. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of choline hydroxide (CAS Reg. No. 123–41–1) when used as an inert ingredient (a neutralizer) in acidic herbicide formulations applied preharvest. That notice referenced a summary of the petition prepared by Dow AgroSciences, the petitioner, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the exemption requested to pesticide formulations rather than herbicide formulations.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

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 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...."

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with section 408(c)(2)(A) of FFDCA, and the factors specified in FFDCA section 408(c)(2)(B), 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 choline hydroxide including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with choline hydroxide follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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. Specific information on the studies received and the nature of the adverse effects caused by choline hydroxide as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

No toxicity data are available for choline hydroxide. Upon contact with water, choline hydroxide is expected to dissociate into the cationic form (choline) and the anionic form (hydroxide ions). Choline hydroxide added to an acidic herbicide, forms an herbicide-choline salt product which will be sold in concentrate form. When the concentrate is mixed with water prior to application, the salt dissociates to the cationic form (choline). Choline cation therefore, is the moiety of interest. Since no toxicological studies are available in the literature, studies on choline chloride and other salts were used for evaluating the risk from exposure to choline hydroxide.

According to the Organisation for Economic Co-operation and Development (OECD) due to its caustic nature (pH 14), acute toxicity testing of choline hydroxide would not be appropriate (OECD Guidelines for the Testing of Chemicals, Procedure 404 (2002); OECD Guideline for testing of Chemicals, Procedure, 405, 2002). Choline hydroxide is known as a skin, eye and respiratory irritant. It should be noted here that there will be essentially no contact with choline hydroxide in an end-use product.

As was discussed above, the hydroxy moiety dissociates and essentially ceases to exist upon mixing with water in preparation for application and in the body. The choline cation is what is left to be considered. The Agency has extensively assessed the effects of choline upon human systems and the environment. A summary of the Agency's findings are recorded in: Final Rule, Choline Chloride; Exemption from the Requirement of a Tolerance, EPA–HQ–OPP–2008–0671; FRL–8802–4 (75 FR 760, January 6, 2010). Details of the Agency's assessment are found in: Decision Document for Petition Number 8E7387; Choline Chloride, CAS Reg. No 67–48–1; Memorandum, D. Sunderland, RD/OPP, 16 OCT 2009.

Choline is an essential component of the human diet and acts as a precursor to acetylcholine, phospholipids, and the methyl donor betaine. It is important for the structural integrity of cell membranes, cholinergic

neurotransmission, transmembrane signaling, methyl metabolism, and lipid and cholesterol transport and metabolism.

Choline was officially made an "essential nutrient" in 1998 and adequate intake (AI) levels were established (women - 425 milligrams/day (mg/day), pregnant women - 450 mg/day, men and lactating women - 550 mg/day). The Daily Upper Intake Level for choline is 3.5 grams (g) for adults. Research indicates that many individuals are not getting enough choline, with daily intake levels far below the AI.

One study in mice evaluated the impact of 200 milligram/kilogram/day (mg/kg/day) choline chloride given orally or intranasally for 28 days. No adverse effects were observed with regards to body weight, food and water consumption, hematology, clinical biochemistry, or histopathology of various organs (lung, heart, liver, spleen, and kidney). Results from intranasal exposure to choline chloride were comparable with their respective controls and to other treatment groups. The no-observed-adverse-effect-level (NOAEL) for oral and intranasally administered choline chloride is ≥ 200 mg/kg/day.

A 72–week feeding study was conducted in rats administered 500 mg/kg/day of choline chloride; the animals were observed for 30 weeks post exposure. There were no significant differences between the control and treated group in relation to body weights, relative liver weight, survival rates, and the number of neoplastic liver nodules, hepatocellular carcinomas, lung tumors, leukemia, or other tumors. This study resulted in a NOAEL of 500 mg/kg/day (the highest dose tested).

Choline is a precursor to the vital neurotransmitter acetylcholine. Studies show that choline has beneficial effects on the nervous system and memory. Choline is necessary to promote proper development in the fetus and infant and prevent cognitive problems. Choline chloride is not expected to cause neurotoxicity and it is not a known endocrine disruptor nor are its metabolites related to any class of known endocrine disruptors. Based on the results of the *in vitro* and *in vivo* studies the Agency concluded that choline chloride is not expected to be carcinogenic or mutagenic.

Since the 1930's choline chloride has been used as a widespread nutrient in animal feed without adverse effects reported on fertility or teratogenicity. The Food and Drug Administration (FDA) requires choline be added to non-milk based infant formulas at a minimum concentration of 7 mg for every 100 kilocalories (21 CFR 107.100). Although one study did show developmental effects, they were only seen at very high doses (≥ 4,160 mg/kg/day) and only in the presence of maternal toxicity. There were no observed adverse effects for both mothers and pups exposed to 1,250 mg/kg/day. Based on this information the Agency concluded that choline chloride, when used as an inert ingredient, will not cause reproductive or developmental toxicity and therefore, does not anticipate an increased risk to infants and children.

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 the NOAEL and the LOAEL of concern are identified. 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*.

No toxicological endpoints have been identified in the available toxicological database. Considering the low toxicity of choline chloride, its natural occurrence, the body's ability to synthesize the nutrient, and the relatively small amount in the formulation, it is not necessary to conduct a quantitative risk assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to choline hydroxide, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from choline hydroxide in food as follows:

Choline is a natural component of a variety of commonly consumed foods (e.g. (per 100 g food) - eggs (251 mg), wheat germ (152 mg), bacon (125 mg), dried soybeans (116 mg), pork (103 mg), cod (83 mg), beef (80 mg), chicken (70 mg), and salmon (65 mg)) United States Department of Agriculture (USDA, 2004). It has been added as a supplement to infant formula in the United States for decades (Politizer Shronts, 1997). In addition to dietary consumption, choline is made endogenously in the human body.

Humans are currently exposed to choline on a daily basis through commonly eaten foods (both naturally occurring and when added as a nutrient) and through the bodies natural ability to synthesize the nutrient. It is unlikely that the exposure from choline chloride, when used as an inert ingredient applied preharvest to food commodities, will significantly increase the natural concentration of choline present in foods. Because of its high water solubility it is expected that most of the inert will be washed from the plant prior to consumption. Once in water, it will be broken into in a quaternary hydroxyl alkylammonium ion and a chloride ion.

2. *Dietary exposure from drinking water*. A quantitative drinking water assessment was not performed because it is expected that upon contact with water choline chloride will be broken into a quaternary hydroxyl alkylammonium ion and a chloride ion. Therefore, direct contact with choline hydroxide is not expected through drinking water.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Occupational exposure to choline chloride is expected via dermal and inhalation routes of exposure. Since an endpoint for risk assessment was not identified, a quantitative occupational and residential exposure assessment for choline hydroxide was not conducted. Residential (dermal and inhalation) exposures from home garden uses are possible.

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, 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 choline hydroxide to share a common mechanism of toxicity with any other substances, and choline hydroxide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that choline hydroxide 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 website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

There is no evidence of increased susceptibility in the available developmental toxicity study in mice. Choline is a natural component of a variety of commonly consumed foods. It has been added as a supplement to infant formula in the United States for decades. In addition to dietary consumption of choline, choline is made endogenously in the human body. Choline is a precursor to the vital neurotransmitter acetylcholine. Studies show that choline has beneficial effects on the nervous system and memory. Choline is necessary to promote proper development in the fetus and infant and prevent cognitive problems. Choline hydroxide is not expected to cause neurotoxicity. Exposure to choline hydroxide is not expected to significantly increase the pre-existing levels found in commonly eaten foods. Due to the negligible anticipated crop residues and subsequent exposure, the low toxicity of the chemical and its metabolites, and the body's need for choline from a dietary source, EPA has determined that a quantitative risk assessment using safety factors is unnecessary. For the same reason, no additional safety factor for the protection of infants and children is needed.

E. Aggregate Risks and Determination of Safety

Taking into consideration all available information on choline hydroxide, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to choline hydroxide under reasonably foreseeable circumstances.

In addition to its low toxicity, exposure to choline hydroxide will be limited. The expected exposure pathway is via the oral and the dermal routes. Humans are currently exposed to choline on a daily basis through commonly eaten foods (both naturally occurring and when added as a nutrient) and through the bodies natural ability to synthesize the nutrient. It is unlikely that the exposure from choline hydroxide, when used as an inert ingredient applied preharvest to food commodities, will significantly increase the natural concentration of choline and chloride in foods. Choline is also found naturally in the environment.

Taking into consideration all available information on choline hydroxide, it has been determined that there is a reasonable certainty that no harm to any population subgroup, including infants and children, will result from aggregate exposure to this chemical. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.920 for residues of choline hydroxide when used as an inert ingredient in pesticide formulations applied to preharvest applications of pesticides, is safe under FFDCA section 408.

V. Other Considerations

A. 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.

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 U.N. 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 choline hydroxide.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for choline hydroxide (CAS Reg. No. 123–41–1) when used as an inert ingredient (in acidic herbicides to act as a neutralizer]) in pesticide formulations applied to preharvest applications.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this 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 section 408(d) of FFDCA, 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 section 408(n)(4) of FFDCA. 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) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: August 20, 2010.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR part 180 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 §180.920 add alphabetically the following inert ingredient to the table to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

Inert ingredients	Limits	Uses
* * *	* * * *	
Choline hydroxide (CAS Reg No. 123–41–1)	Without limitation	Neutralizer
* * *	* * * *	

[FR Doc. 2010–21544 Filed 8–31–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0682; FRL–8841–9]

Spiromesifen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spiromesifen in or on leaf petioles subgroup 4B, dry pea seed, spearmint tops, and peppermint tops. The Interregional Research Project Number 4 (IR-4) and Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 1, 2010. Objections and requests for hearings must be received on or before November 1, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0682. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Andrew Ertman, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; e-mail address: *ertman.andrew@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I 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.gpoaccess.gov/ecfr*.

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