ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0073; FRL–9914–18]

Sulfuric Acid; 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 sulfuric acid (CAS Reg. No. 7664–93–9), when used as an inert ingredient, in antimicrobial formulations, on food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils. Exponent, Inc., on behalf of Ecolab, Inc., 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 sulfuric acid.

DATES: This regulation is effective September 5, 2014. Objections and requests for hearings must be received on or before November 4, 2014 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2014–0073, 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: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

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

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2014–0073 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 4, 2014. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2014–0073, by one of the following methods:

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

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

II. Petition for Exemption

In the **Federal Register** of February 25, 2014 (79 FR 10458) (FRL–9906–77), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–10654) by Exponent, Inc. (1150 Connecticut Ave. NW., Washington, DC 20036), on behalf of Ecolab, Inc., 370 N. Wasbasha St., St. Paul, MN 55102. The petition requested that 40 CFR 180.940 be amended by establishing an exemption from the requirement of a tolerance for residues of sulfuric acid (CAS Reg. No. 7664–93–9) when used as an inert ingredient in antimicrobial formulations applied on food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils up to 600 parts per million (ppm) in end use formulations. That document referenced a summary of the petition prepared by Exponent, Inc., on behalf of Ecolab, Inc., the petitioner, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

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 FFDCA section 408(c)(2)(A), 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 sulfuric acid including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with sulfuric acid 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 sulfuric acid 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.

In formulating a pesticide product, an acidic chemical such as sulfuric acid serves a specific purpose, that of a neutralizing agent or a pH adjuster. During the manufacture of a pesticide product (or, in fact, many industrial chemicals), it may be necessary to adjust the pH of the product. An acid functions as a neutralizing agent when the hydrogen ion (H+ 1) combines with the hydroxy (OH-) in a basic solution to form a molecule of water. Small amounts of the hydrogen ion would be added to the solution to lower the pH until a neutral pH is reached. After the pH adjustment is performed and the neutralization reaction occurs, sulfuric acid is no longer present. The reaction products that are then present are the sulfate (II) negatively charged ion and water.

Alternatively, it might be necessary to have a pesticide product maintain an acidic pH; thus, the sulfuric acid would be added during the manufacturing process to deliberately lower the pH, which would mean an excess of the hydrogen ion. Such products are not likely to be sold to the residential market.

As a chemical class, acids are significantly different from many of the chemicals regulated as inert ingredients in pesticide products. First, acids are highly corrosive. Due to this property, toxicity testing can only be performed on very diluted solutions. Therefore, toxicity studies performed with undiluted (concentrated) sulfuric acid are not available. Second, acids are highly reactive, and therefore are not expected to be persistent in the food supply, the environment, or in water resources. Sulfuric acid would be expected to dissociate and immediately react with both plant and animal materials.

Chemically, an acid is a substance that yields a hydrogen (H+1) ion when dissolved in water. The increase of the concentration of the H+ 1 ion reduces the pH. It is the hydrogen ion that is highly reactive, thus displaying the corrosive characteristic. The consequences of acute exposure to acids are well understood; they are corrosive to the eyes, the skin, and the respiratory tract. The hazard of any acidic chemical derives directly from and is due to these irritation and acidic effects.

Sulfuric acid is a strong acid. It is also a commonly used chemical. It has been used for years, and therefore, there is a significant body of existing publicly available information.

- Solutions of sulfuric acid greater than 10% are severely corrosive by all routes of exposure.
- Solutions of sulfuric acid of less than 10% are strong irritants.
- There is sufficient evidence that occupational exposure to strong-inorganic-acid mists containing sulfuric acid is carcinogenic (International Agency for Research on Cancer).
- There were no significant developmental or reproductive effects in mice or rabbits exposed to 20 milligram/cubic meter (mg/m3) sulfuric acid aerosols 7 hours per day on gestation days 6 to 15 (Agency for Toxic Substances and Disease (ATSDR)).

In fact, available data for sulfuric acid indicates that the acute oral and dermal toxicity of sulfuric acid is moderate; the acute inhalation lethal concentration (LC_{50}) is 18 mg/m3 in guinea pigs; and that sulfuric acid is corrosive to the eyes and skin in rabbits.

However, as noted above, exposure to sulfuric acid in pesticide products as an inert ingredient would be in the role of a pH adjuster, that is, a liquid form, not a mist. As an inert ingredient small amounts of sulfuric acid are incorporated in a pesticide product to lower the pH. After the pH adjustment is performed, the sulfuric acid would be neutralized, and therefore no longer present. It is recognized that sulfuric acid must be used and applied according to good manufacturing or good agricultural practices.

There are no available information on sulfuric acid indicative of a human health hazard from the ingestion of food directly treated with sulfuric acid. In fact, sulfuric acid would not be present in consumed foods. The small amounts of acids that might be added to a food during processing react rapidly with a food substance. Thus, the exposure is actually to sulfate residues.

In aqueous environments, sulfuric acid will rapidly dissociate into sulfate ions and hydrogen protons. The sulfate

anion, which is a normal constituent in the body, predominantly resulting from the body's metabolism of sulfur-containing food sources such as foods containing the essential amino acids cysteine and methionine, will enter the body electrolyte pool. Sulfate anions are vital components in a number of human biosynthetic pathways such as cartilage production and the formation of pancreatic digestive enzymes. Additionally, the sulfate anion is also an important conjugate in the Phase II conjugation/elimination of oxidized (OH) aromatic ring metabolites and for hydroxyl steroid hormones, such as estrogen, where it acts as a transport agent to target organ tissue receptors. Following ingestion, sulfate anions are predominantly not absorbed from the gastrointestinal tract and are excreted unchanged in urine. Therefore, the sulfate anion is unlikely to pose significant toxicity.

The sulfate residues (resulting from the use of sulfuric acid) are of minimal toxicity. In fact, calcium, sodium, magnesium, and potassium sulfates have been previously classified as List 4A, chemical substances of minimal risk. Various sulfate chemicals have uses as direct food additives. The human body metabolizes sulfate through well-understood pathways. It is a necessary human nutrient. There are no significant adverse effects, to the general public or any population subgroup from consumption of residues of sulfuric acid (actually the neutralized form which is the sulfate ion in solution) resulting from pesticide product uses.

Sulfuric acid was not mutagenic in the Ames Test. It caused chromosomal aberrations in a non-bacterial test *in vitro.* However, it is well known that the aberrations were a consequence of reduced pH.

Neither a neurotoxicity nor an immunotoxicity study was available for review. However, any sulfuric acid absorbed into the body would be in the form of inorganic sulfate, which is indistinguishable from endogenous sulfate. As a normal body constituent, sulfate is unlikely to be neurotoxic or immunotoxic.

B. Toxicological Points of Departure/ Levels of Concern

Based on the low potential hazard, toxicological endpoints of concern have not been identified for sulfuric acid. Thus, due to its low potential hazard and lack of hazard endpoint, the Agency has determined that a quantitative risk assessment using safety factors applied to a point of departure protective of an identified hazard endpoint is not appropriate.

C. Exposure Assessment

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

Dietary exposure (food and drinking water) to sulfuric acid can occur following ingestion of foods with residues from food-contact surface sanitizing solutions for public eating places, treated dairy- and food-processing equipment and utensils; pre- and post-harvest crop uses and as a direct food additives. However, a quantitative dietary exposure assessment was not conducted since an endpoint for risk assessment was not identified.

2. *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).

Residential (dermal and inhalation) exposure are not expected from the current requested use pattern. However, residential (dermal and inhalation) exposure can occur from the use of consumer products containing sulfuric acid (i.e., stain remover, drain solutions). Since an endpoint for risk assessment was not identified, a quantitative residential exposure assessment for sulfuric acid was not conducted.

3. *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 sulfuric acid to share a common mechanism of toxicity with any other substances, and sulfuric acid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that sulfuric acid 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

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10×) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines 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 Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10×, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

As part of its qualitative assessment, the Agency did not use SFs for assessing risk, and no additional SF is needed for assessing risk to infants and children. Based on an assessment of sulfuric acid and its chemical properties, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children.

E. Aggregate Risks and Determination of Safety

In examining aggregate exposure, EPA takes into account the available and reliable information concerning exposures to pesticide residues in food and drinking water, and non-occupational pesticide exposures. Dietary (food and drinking water) and non-dietary (residential) exposures of concern are not anticipated for sulfuric acid because it dissociates to ions in water, these ions are essential components in the human metabolic processes and there are no toxicity issues. In addition, it is currently exempted from the requirement of a tolerance (with limitations) under 40 CFR 180.940(b) and (c); 40 CFR 180.910 and 40 CFR 180.1019. Further, the Food and Drug Administration (FDA) considers sulfuric acid as generally recognized as safe (GRAS) for use in foods and drinking water. Taking into consideration all available information on sulfuric acid up to 600 ppm, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to sulfuric acid under reasonable foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR

180.940 for residues of sulfuric acid when used as an inert ingredient in pesticide formulations on food contact surfaces in public eating places, dairy processing equipment and food processing equipment and utensils up to 600 ppm in antimicrobial formulations, is safe under FFDCA section 408.

V. Other Considerations

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.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.940 for sulfuric acid (CAS Reg. No. 7664–93–9) when used as an inert ingredient in microbial formulations applied on food-contact surfaces in public eating places, dairy-processing equipment and food-processing equipment and utensils up to 600 ppm.

Paragraph (b) of 40 CFR 180.940 contains an entry exempting residues of sulfuric acid in antimicrobial formulations applied to dairy-processing equipment and food-processing equipment and utensils up to 288 ppm, and paragraph (c) of 40 CFR 180.940 contains an entry exempting residues of sulfuric acid in antimicrobial formulations applied to food-processing equipment and utensils at concentrations not to exceed 228 ppm. Because EPA is establishing an exemption for residues of sulfuric acid in paragraph (a) of 40 CFR 180.940, which would exempt residues of sulfuric acid in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at concentrations not to exceed 600 ppm, this exemption supersedes the current exemptions in paragraphs (b) and (c) of 40 CFR 180.940. To avoid confusion caused by inconsistency between the paragraphs and because all residues covered under 40 CFR 180.940(b) and (c) would also be covered under 40 CFR 180.940(a), EPA is removing the entries for sulfuric acid (CAS Reg. No. 7664–93–9) in 40 CFR 180.940(b) and (c).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the 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).

VIII. 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: August 25, 2014.

Lois Rossi,

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 § 180.940:

■ a. Alphabetically add the following inert ingredient to the table in paragraph (a).

■ b. Remove the entries for sulfuric acid (CAS Reg. No. 7664–93–9) from the tables in paragraphs (b) and (c).

The addition reads as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

* * * * *

(a) * * *

Pesticide chemical	CAS Reg. No.	Uses
*	*	*
Sulfuric acid	7664–93–9	Food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils in antimicrobial formulations. Not to exceed 600 ppm.
*	*	*

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[FR Doc. 2014–21109 Filed 9–4–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 146, 147, 148, 155, and 156

[CMS–9941–F]

RIN 0938–AS32

Patient Protection and Affordable Care Act; Annual Eligibility Redeterminations for Exchange Participation and Insurance Affordability Programs; Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule specifies additional options for annual eligibility redeterminations and renewal and re-enrollment notice requirements for qualified health plans offered through the Exchange, beginning with annual redeterminations for coverage for benefit year 2015. This final rule provides additional flexibility for Exchanges, including the ability to propose unique approaches that meet the specific needs of their state, while streamlining the consumer experience.

DATES: These regulations are effective on October 6, 2014.

FOR FURTHER INFORMATION CONTACT: Jacob Ackerman, (301) 492–4179, for questions regarding parts 146 through 148. Christine Hammer, (301) 492–4431, for questions regarding part 155. Spencer Manasse, (301) 492–5141, for questions regarding part 156.

SUPPLEMENTARY INFORMATION: This **Federal Register** document is also available from the **Federal Register** online database through *Federal Digital System (FDsys),* a service of the U.S. Government Printing Office. This database can be accessed via the internet at *http://www.gpo.gov/fdsys.*

Table of Contents

I. Background

A. Legislative Overview

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this final rule, we refer to the two statutes collectively as the ''Affordable Care Act.'' Subtitles A and C of Title I of the Affordable Care Act reorganized, amended, and added to the provisions of part A of Title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets.

Starting on October 1, 2013 for coverage starting as soon as January 1, 2014, qualified individuals and qualified employers have been able to purchase qualified health plans (QHPs)—private health insurance that has been certified as meeting certain standards—through competitive marketplaces called Exchanges or Health Insurance Marketplaces. The word ''Exchanges'' refers to both State Exchanges, also called State-based Exchanges, and Federally-facilitated Exchanges (FFEs). In this final rule, we use the terms ''State Exchange'' or ''FFE'' when we are referring to a particular type of Exchange. When we refer to ''FFEs,'' we are also referring to State Partnership Exchanges, which are a form of FFE.

Section 1411(f)(1)(B) of the Affordable Care Act directs the Secretary of Health and Human Services (the Secretary) to establish procedures to redetermine the eligibility of individuals on a periodic basis in appropriate circumstances. Section 1321(a) of the Affordable Care Act provides authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs and other components of Title I of the Affordable Care Act. Section 2703 of the PHS Act, as added by the Affordable Care Act, and sections 2712 and 2741 of the PHS Act, as added by the Health Insurance Portability and Accountability Act of 1996, require health insurance issuers in the group and individual markets to guarantee the renewability of coverage unless an exception applies.

B. Stakeholder Consultation and Input

The Department of Health and Human Services (HHS) has consulted with stakeholders on a number of policies related to the operation of Exchanges, including eligibility redetermination. HHS has held a number of listening sessions with consumers, providers, employers, health plans, and State representatives to gather public input. HHS consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners (NAIC), regular contact with states through the Exchange grant process, meetings with the CMS Tribal Technical Advisory Group and an All Tribes Call on July 21, 2014 with tribal leaders and representatives, health insurance issuers, trade groups, consumer advocates, employers, and