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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1250

[Doc. No. AMS-LPS-15-0042]

Amendment to the Egg Research and Promotion Rules and Regulations To Update Patents, Copyrights, Trademarks, and Information Provisions

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends the Patents, Copyrights, Trademarks, Publications, and Product Formulations (IP) language of the Egg Research and Promotion Rules and Regulations (Regulations) to conform with commodity research and promotion program orders created under the Commodity Promotion, Research, and Information Act of 1996 (1996 Act).

DATES: Effective January 13, 2017.

FOR FURTHER INFORMATION CONTACT: Kenneth R. Payne, Research and Promotion Division; Livestock, Poultry, and Seed Program; AMS, USDA; 1400 Independence Avenue SW., Room 2610-S; Washington, DC 20250; telephone (202) 720-5705; fax (202) 720-1125; or email *Kenneth.Payne@ams.usda.gov*.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

The Office of Management and Budget (OMB) has waived the review process required by Executive Order 12866 for this action.

Executive Order 12988

This rule was reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have a retroactive effect. This action will not

preempt any state or local laws, regulations, or policies unless they present an irreconcilable conflict with this rule. The Egg Research and Consumer Information Act (Act) [7 U.S.C. 2701 *et seq.*] provides that administrative proceedings be filed before parties may consider suit in court. Under section 14 of the Act [7 U.S.C. 2713], a person subject to the Egg Promotion and Research Order (Order) may file a petition with the Department of Agriculture (USDA) stating that the Order, any provision of the Order, or any obligation imposed in connection with the Order, is not in accordance with the law and request a modification of the Order or an exemption from the Order. The petitioner is afforded the opportunity for a hearing on the petition. After a hearing, USDA would rule on the petition. The Act provides that district courts of the U.S. in any district in which such person is an inhabitant, or has their principal place of business, has jurisdiction to review USDA's ruling on the petition, if a complaint for this purpose is filed within 20 days after the date of the entry of the ruling.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (RFA) [5 U.S.C. 601-612], the Agricultural Marketing Service (AMS) has determined that this rule will not have a significant economic impact on a substantial number of small entities as defined by RFA. The purpose of RFA is to fit regulatory action to scale on businesses subject to such action so that small businesses will not be disproportionately burdened. As such, these changes will not impose a significant impact on persons subject to the program.

According to the American Egg Board (Board), in 2015, approximately 181 egg producers were subject to the provisions of the Order, including paying assessments. Under the current Order, producers in the 48 contiguous States of the U.S. and the District of Columbia who own more than 75,000 laying hens currently pay a mandatory assessment of 10 cents per 30-dozen case of eggs sold. Egg handlers are responsible for collecting and remitting assessments to the Board. According to the Board, of those 181 egg producers, about 138 egg handlers collect assessments. Assessments under the program are

used by the Board to finance promotion, research, and consumer information programs designed to increase consumer demand for eggs in domestic and international markets.

In 13 CFR part 121, the Small Business Administration (SBA) defines small agricultural producers as those having annual receipts of no more than \$750,000 and small agricultural service firms as those having annual receipts of no more than \$7 million. Under this definition, the vast majority of egg producers that would be affected by this rule would not be considered small entities. Producers owning 75,000 or fewer laying hens are eligible to be exempt from this program. This rule does not impose additional recordkeeping requirements on egg producers or handlers. There are no Federal rules that duplicate, overlap, or conflict with this rule.

Paperwork Reduction Act

In accordance with OMB regulation 5 CFR part 1320, which implements the Paperwork Reduction Act of 1995 [44 U.S.C. Chapter 35], the information collection and recordkeeping requirements that are imposed by the Order and Rules and Regulations have been approved previously under OMB control number 0581-0093. This rule does not result in a change to those information collection and recordkeeping requirements.

Background

The Act established a national egg research and promotion program—administered by the Board—that is financed through industry assessments and subject to oversight by USDA's AMS. This program of promotion, research, and consumer information is designed to strengthen the position of eggs in the marketplace and to establish, maintain, and expand markets for eggs.

Under the current Regulations initially established in 1976, any IP financed by assessment funds or other revenues of the Board shall become property of the U.S. Government as represented by the Board. The language does not allow for alternative ownership arrangements. In addition, there is no explicit allowance for alternative ownership arrangements in cases where the Board is not providing all of the funding for a project. According to the Board, the current language in the Order has made negotiating contracts for

shared ownership of IP rights with research entities difficult and in some cases impossible. Specifically, a majority of university policies typically reflect a requirement for the university to own any IP created under research projects they conduct, even if the project is funded with outside money. These university policies have made it difficult for the Board to contract with universities for research due to the IP ownership requirements contained in the Order.

As a result, USDA is amending § 1250.542 of the Regulations to incorporate language utilized by research and promotion boards created under the 1996 Act that would provide the Board with flexibility in negotiating over the ownership of IP rights. The research and promotion boards created under the 1996 Act have utilized this language to negotiate ownership rights over IP to effectively expend assessment funds to promote agricultural commodities.

Summary of Comments

AMS published the notice of proposed rulemaking in the **Federal Register** on March 16, 2016 [81 FR 14021]. The comment period ended on May 16, 2016. AMS received one timely comment from a university. The commenter expressed that it is the policy of the university to retain ownership of intellectual property generated through research funded by external parties and encouraged AMS to adopt policies and rules that closely follow the standard approaches articulated in Federal Government grants. However, the egg research and promotion program is not a grant program and is not subject to Federal grants policy. In addition, the Board does not receive Federal funding. All funds are received from egg producers required under the enabling legislation to pay an assessment to the Board to fund programs designed to increase demand for eggs and egg products both domestically and internationally. Accordingly, AMS did not incorporate the Federal grants policy into the final rule.

List of Subjects in 7 CFR Part 1250

Administrative practice and procedure, Advertising, Agricultural research, Eggs and egg products, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 1250 is amended as follows:

PART 1250—EGG RESEARCH AND PROMOTION

- 1. The authority citation of 7 CFR part 1250 continues to read as follows:

Authority: 7 U.S.C. 2701–2718; 7 U.S.C. 7401.

- 2. Revise § 1250.542 to read as follows:

§ 1250.542 Patents, Copyrights, Inventions, Trademarks, Information, Publications, and Product Formulations.

(a) Except as provided in paragraph (b) of this section, any patents, copyrights, inventions, trademarks, information, publications, or product formulations developed through the use of funds collected by the Board under the provisions of this subpart shall be the property of the U.S. Government, as represented by the Board, and shall, along with any rents, royalties, residual payments, or other income from the rental, sales, leasing, franchising, or other uses of such patents, copyrights, inventions, trademarks, information, publications, or product formulations, inure to the benefit of the Board; shall be considered income subject to the same fiscal, budget, and audit controls as other funds of the Board; and may be licensed subject to approval by the Secretary. Upon termination of this subpart, § 1250.358 shall apply to determine disposition of all such property.

(b) Should patents, copyrights, inventions, trademarks, information, publications, or product formulations be developed through the use of funds collected by the Board under this subpart and funds contributed by another organization or person, the ownership and related rights to such patents, copyrights, inventions, trademarks, information, publications, or product formulations shall be determined by an agreement between the Board and the party contributing funds towards the development of such patents, copyrights, inventions, trademarks, information, publications, or product formulations in a manner consistent with paragraph (a) of this section.

Dated: December 8, 2016.

Elanor Starmer,

Administrator, Agricultural Marketing Service.

[FR Doc. 2016–29988 Filed 12–13–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2011–N–0146]

RIN 0910–AH23

Amendments to Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications To Provide for the User Fee Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is amending its regulations on accreditation of third-party certification bodies to conduct food safety audits and to issue certifications to provide for a reimbursement (user fee) program to assess fees for the work FDA performs to establish and administer the third-party certification program under the FDA Food Safety Modernization Act (FSMA).

DATES: This rule is effective January 13, 2017.

FOR FURTHER INFORMATION CONTACT: Sylvia Kim, Office of Foods and Veterinary Medicine, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3212, Silver Spring, MD 20993–0002, 301–796–7599.

SUPPLEMENTARY INFORMATION:

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