Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-10-0102; NOP-10-10]

RIN 0581-AD10

National Organic Program; Periodic Residue Testing

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would clarify a provision of the Organic Foods Production Act of 1990 and the regulations issued thereunder that require periodic residue testing of organically produced agricultural products by accredited certifying agents. The proposed rule would amend the U.S. Department of Agriculture's (USDA) National Organic Program (NOP) regulations to make clear that accredited certifying agents must conduct periodic residue testing of agricultural products that are to be sold, labeled, or represented as "100 percent organic," organic," or "made with organic (specified ingredients or food group(s))." The proposed rule would expand the amount of residue testing of organically produced agricultural products by clarifying that sampling and testing are required on a regular basis. The proposed rule would require that certifying agents, on an annual basis, sample and conduct residue testing from a minimum of five percent of the operations that they certify. This action would help further ensure the integrity of products produced and handled under the NOP regulations.

DATES: Comments must be received by June 28, 2011. Pursuant to the Paperwork Reduction Act, comments on the information collection burden that would result from this action must be received by June 28, 2011.

ADDRESSES: Interested parties may submit written comments on this

proposed rule using one of the following methods:

- Federal eRulemaking Portal: http:// www.regulations.gov. Follow the instructions for submitting comments.
- Mail: Lisa M. Brines, Agricultural Marketing Specialist, National Organic Program, USDA-AMS-NOP, Room 2646-So., Ag Stop 0268, 1400 Independence Ave., SW., Washington, DC 20250-0268.

Instructions: All submissions received must include the docket number AMS-NOP-10-0102; NOP-10-10, and/or Regulatory Information Number (RIN) 0581–AD11 for this rulemaking. You should identify the topic and section number of this proposed rule to which your comment refers. You should clearly indicate whether or not you support the action being proposed for any or all of the items in this proposed rule. You should clearly indicate the reason(s) for your position. You should also offer any recommended language changes that would be appropriate for your position. Please include relevant information and data to support your position (e.g. scientific, environmental, manufacturing, industry impact information, etc.). All comments received will be posted without change to http://www.regulations.gov.

Docket: For access to the docket to read background documents or comments received, go to http:// www.regulations.gov. Comments submitted in response to this proposed rule will also be available for viewing in person at USDA-AMS, National Organic Program, Room 2646—South Building, 1400 Independence Ave., SW., Washington, DC, from 9 a.m. to 12 noon and from 1 p.m. to 4 p.m., Monday through Friday (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this proposed rule are requested to make an appointment in advance by calling (202) 720-3252.

Pursuant to the Paperwork Reduction Act, interested persons may comment on the information collection and recordkeeping requirements required by this proposed rule using one of the following methods:

• Mail: Comments should be sent to above address and to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, New

Executive Office Building, 725 17th Street, NW., Room 725, Washington, DC

- Written comments should be identified with the docket number AMS-NOP-10-0102; NOP-10-10 and should reference the date and page number of this issue of the Federal **Register** and indicate that the comment is regarding the information collection and recordkeeping requirements.
- Comments are specifically invited on: (1) The accuracy of the Agency's burden estimate of the proposed collection of information; (2) ways to minimize the burden of the collection of information on those affected; (3) whether the proposed collection of information is sufficient or necessary to demonstrate compliance with the requirement that certifying agents report all analyses and tests performed to the Administrator, applicable State organic program's governing State official, and to health agencies in accordance with the proposed amendments to § 205.670; and (4) ways to enhance the quality, utility, and clarity of the information to be collected.

All comments on the information collection and recordkeeping requirements required by the proposed amendments to § 205.670 will become a matter of public record and will be available for public viewing at the above referenced location.

FOR FURTHER INFORMATION CONTACT:

Melissa Bailey, Ph.D., Director, Standards Division, Telephone: (202) 720–3252; Fax: (202) 205–7808.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Organic Foods Production Act (OFPA) of 1990 (7 U.S.C. 6511), the National Organic Program (NOP) is authorized to implement regulations that require accredited certifying agents to conduct residue testing of organically produced agricultural products. The OFPA (7 U.S.C. 6506) also requires that the NOP include provisions for periodic residue testing by certifying agents of agricultural products produced or handled in accordance with the NOP.

Residue testing plays an important role in organic certification by providing a means for monitoring compliance with the NOP and by discouraging the mislabeling of agricultural products. Testing of organically produced agricultural products is promulgated in

§ 205.670(b) of the NOP regulations. This section provides that the Secretary, State organic programs, and certifying agents may require pre-harvest or post-harvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods.

The proposed rule would clarify the requirement for residue testing under the NOP by requiring residue testing by certifying agents on a regularly occurring basis, in addition to residue testing when there is reason to suspect contamination with a prohibited substance.

The Agricultural Marketing Service (AMS) is issuing this proposed rule in response to an audit of the NOP which was conducted in March 2010 by the USDA Office of Inspector General (OIG).¹ As part of the audit, the OIG visited four certifying agents accredited by the NOP. The audit found that none of the four certifying agents visited conducted periodic residue testing. The OIG indicated that these certifying agents noted that they considered periodic residue testing to be required by the regulations only under certain circumstances.

In response, the AMS conducted a legal review of this issue. The AMS has concluded that, under 7 U.S.C. 6506 of the OFPA, accredited certifying agents are required to conduct residue testing of organic products on a regular and random basis, as well as when there is reason to believe contamination has occurred.

Accordingly, the AMS has issued this proposed rule, which would amend § 205.670 of the NOP regulations to clarify that certifying agents conduct periodic testing of agricultural products that are to be sold, labeled or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))." The OFPA requires periodic residue testing by certifying agents of organic products to determine if the products contain any pesticide, other nonorganic residue, or natural toxicants (7 U.S.C. 6506). This action will clarify the amount and frequency of testing and will ensure consistency across all certifying agents in their inspection and testing of agricultural products certified to the NOP regulations. The proposed rule specifies that certifying agents

would be required, on an annual basis, to randomly sample and test agricultural products from a minimum of five percent of the operations they certify.

On June 23 and June 24, 2010, the NOP conducted two Webinar trainings with certifying agents on periodic residue testing under the NOP. The objective of the webinar was to present an overview of requirements for periodic residue testing under the OFPA and the NOP. The NOP also solicited feedback from the certifying agents who participated in the webinar. Of the certifying agencies accredited at that time, 55 individuals registered to participate in the webinar. Ten participants in the webinar provided written feedback to the NOP in response to the information provided. These comments were considered in the development of this proposed rule.

While the proposed action would expand the amount of testing of organically produced agricultural products to include a requirement that is regular and random in scope, certifying agents are already required, under § 205.504(b)(6), to have procedures in place for sampling and residue testing pursuant to § 205.670. Certifying agents should already be conducting sampling and laboratory testing in instances where contamination is suspected under § 205.403(c)(3) and § 205.670(b).

II. Overview of Proposed Amendments

Requirement for Periodic Residue Testing

This proposed rule would amend § 205.670 of the NOP regulations to require accredited certifying agents to conduct random, periodic testing of agricultural products that are to be sold, labeled or represented as "100 percent organic," organic," or "made with organic (specified ingredients or food group(s))."

The proposed rule would amend the title of § 205.670 to reflect the scope of products currently listed under § 205.670(a) and (b). The amended title would read as follows: § 205.670 Inspection and testing of agricultural product to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))."

Number of Samples

The proposed rule would require that all certifying agents conduct a minimum level of periodic residue testing. Under the proposed rule, the minimum number of operations to be sampled for periodic residue testing would be at least five percent of the operations that

the certifying agency certifies on an annual basis, rounded to the nearest whole number. Certifying agents that certify fewer than 30 operations on an annual basis would be required to sample from at least one operation annually. For example, a certifying agency that certifies 29 operations would be required to sample a minimum of 1 operation annually (i.e., $0.05 \times 29 = 1.45$, which rounds to 1 operation). A certifying agency that certifies 30 operations would be required to sample a minimum of 2 operations annually (i.e., $0.05 \times 30 =$ 1.50, which rounds to 2 operations). The minimum number of samples required would be calculated based on the overall number of certified operations. Certifying agents may collect more than one sample per operation for residue testing; however, a minimum of five percent of all its certified operations must be sampled annually, regardless of the number of samples collected per

The proposed five percent minimum for periodic residue testing would be in addition to any testing that certifying agents conduct when there is reason to believe that the agricultural product has come into contact with a prohibited substance. Testing of products when there is reason to believe a violation has occurred, e.g. complaint-driven testing, would not be considered to be random, periodic testing, and must continue to be conducted in addition to the proposed five percent requirement for periodic residue testing.

The NOP understands that a minority of accredited certifying agents currently conduct residue testing on a regular, periodic basis. Any additional costs for residue testing under this proposed rule will need to be provided by the applicable certifying agent and are considered a cost of doing business. The additional costs of residue testing will be borne by the applicable certifying agent, as previously discussed in the preamble to the December 21, 2000 final rule (65 FR 80548).

Testing Methodology

The proposed rule maintains the current requirement under § 205.670(c) that chemical analysis must be made in accordance with the methods described in the most current edition of the Official Methods of Analysis of the AOAC International or other current applicable validated methodology for determining the presence of contaminants in agricultural products. On February 2, 2011, the NOP provided instructions on laboratory selection criteria for pesticide residue testing to certifying agents. These instructions are

¹ Audit Report 01601-03-Hy, March 2010.

further described below under *Related Documents* and are available on the NOP Web site at *http://www.ams.usda.gov/nop*. The AMS anticipates that these instructions will change over time in response to advances in testing methodology, analytical instrumentation, and residue detection techniques.

Analytes for Pesticide Residue Testing

On February 2, 2011, the NOP published a list of target pesticides that are suggested for certifying agents that conduct pesticide residue testing of organically produced agricultural products. This list is available at the NOP Web site at http:// www.ams.usda.gov/nop and is discussed below under Related Documents. The AMS does not intend to amend the NOP regulations to include a specific list of pesticide residues to allow flexibility in revising the list of target pesticide residues as new pesticides enter the market. In addition, this flexibility will allow the NOP to respond more quickly to observed trends in detection of residues on specific commodities.

Reporting Requirements

The proposed rule would maintain the current reporting requirements for submitting results of all analyses and tests performed under § 205.670. Certifying agents would continue to be required to submit results promptly to the Administrator; except, that, where a State organic program exists, all results shall be provided to the State organic program's governing State official. Required reporting would include copies of original laboratory results, including analyses where residues are not detected or are not in violation of the NOP standards. Submission of copies of original test results, rather than requiring that results be provided in a specific format, is intended to minimize the reporting burden on certifying agents.

The proposed rule would amend § 205.670 to clarify the reporting requirements when test results indicate that a specific agricultural product contains pesticide residues or environmental contaminates that exceed the Food and Drug Administration's or Environmental Protection Agency's regulatory tolerances. Under the OFPA (7 U.S.C. 6506), certifying agents, to the extent that they are aware of a violation of applicable laws relating to food safety, are required to report such violation to the appropriate health agencies. This is promulgated in § 205.670(e) of the NOP regulations, which requires reporting to the Federal

health agency whose regulatory tolerance or action level has been exceeded. The NOP has previously provided additional information on reporting health and safety violations to stakeholders and interested parties and is available on the NOP Web site at http://www.ams.usda.gov/nop. 2 The proposed rule would amend § 205.670(e) to clarify that these results must also be reported to the appropriate State health agency or foreign equivalent. This change is proposed to acknowledge the role of State agencies, or their foreign equivalents, in responding to residues in violation of food safety requirements.

The proposed rule would not change the requirement that certifying agents provide copies of test results, including results when residues are not detected, to certified operations in accordance with § 205.403(e)(2).

In addition to the reporting requirements outlined in the proposed rule, the NOP plans to publish a guidance document that will outline the actions to be taken by accredited certifying agents if test results from residue analysis show evidence of prohibited substance(s) in or on the product. This document will be published in the NOP Program Handbook, as described under Related Documents. Under § 205.671, when residue testing detects prohibited substances that are greater than five percent of the EPA's tolerance for the specific residue detected or unavoidable residual environmental contamination, the agricultural product must not be sold, labeled, or represented as organically produced. This proposed rule would not change this requirement. The guidance document will provide information to certifying agents on how to respond to results that indicate residues of prohibited substances and report results to the Administrator, or State organic program, under §§ 205.670 and 205.671.

Technical Correction

The proposed rule would amend § 205.670(e) by changing "tolerences" to "tolerances" to correct the spelling of this term.

III. Related Documents

Documents related to this proposed rule include the Organic Foods Production Act (OFPA), as amended (7 U.S.C. 6501 *et seq.*) and its implementing regulations (7 CFR part 205). The March 2010 USDA Office of Inspector General audit report of the

National Organic Program is available as Audit Report 01601–03–Hy.

The NOP has also published three instruction documents related to residue testing as part of the NOP Program Handbook: (1) Sampling Procedures for Residue Testing (NOP 2610), (2) Laboratory Selection Criteria for Pesticide Residue Testing (NOP 2611), and (3) NOP Target Pesticide List (NOP 2611–1). The goal of the NOP Program Handbook is to provide those who own, manage, or certify organic operations with guidance, instructions, and policy memos that can assist them in complying with the NOP regulations. The most recent edition of the NOP Program Handbook is available for viewing and downloading through the NOP Web site at http:// www.ams.usda.gov/nop.

The three instruction documents are meant to inform certifying agents about best practices for conducting residue testing of organically produced agricultural products. NOP 2610, Sampling Procedures for Residue Testing, contains recommended procedures for product sampling, including documentation, recommended sample sizes, shipping conditions to the laboratory, and chain of custody requirements. NOP 2611, Laboratory Selection Criteria for Pesticide Residue Testing, contains instructions for certifying agents in selecting a qualified laboratory for pesticide residue testing, including accreditation, quality assurance, proficiency testing, and reporting guidelines. NOP 2611-1, NOP Target Pesticide List, is a list of pesticide residues that certifying agencies can provide to laboratories which conduct pesticide residue testing of agricultural products. The three instruction documents were effective immediately upon their issuance and publication on February 2, 2011.

Members of the public who wish to request that the agency issue, reconsider, modify, or rescind a guidance or instruction document, or to complain that the agency is not following the procedures in the Office of Management and Budget's Bulletin on Good Guidance Practices published January 25, 2007 (72 FR 3432), or is improperly treating a guidance document as a binding requirement, may do so by sending an email to NOP.Guidance@ams.usda.gov or by mailing a letter to Standards Division, National Organic Program, U.S. Department of Agriculture, Room 2646-So. (Stop 0268), 1400 Independence Ave SW., Washington, DC 20250-0268.

² NOP Policy Memo 11-6.

IV. Statutory and Regulatory Authority

The Organic Foods Production Act of 1990 (OFPA), as amended (7 U.S.C. 6501 et seq.), authorizes the Agricultural Marketing Service (AMS) to administer to the NOP. Under the NOP, AMS oversees national standards for the production and handling of organically produced agricultural products.

Section 2107(a)(6) of the OFPA (7 U.S.C. 2107) requires periodic residue testing by certifying agents of agricultural products that have been produced on certified organic farms and handled through certified organic handling operations to determine whether such products contain any pesticide or other nonorganic residue or natural toxicants. This section also requires certifying agents to report violations of applicable laws relating to food safety (e.g. pesticide residues in excess of FDA action levels or EPA tolerances) to the appropriate health agencies. Additional information on reporting health and safety violations has been previously provided by the NOP to stakeholders and interested parties.3 This information is available on the NOP Web site at http:// www.ams.usda.gov/nop.

Section 2112(a) of the OFPA (7 U.S.C. 6511) requires the Secretary, the applicable governing State official, and the certifying agent to utilize a system of residue testing to test products sold or labeled as organically produced.

Section 2112(b) of the OFPA (7 U.S.C. 6511) allows the Secretary, the applicable governing State official, or the certifying agent to require preharvest tissue testing of any crop grown on soil suspected of harboring contaminants.

A. Executive Order 12866

This action has been determined nonsignificant for purposes of Executive Order 12866, and therefore, has not been reviewed by the Office of Management and Budget.

B. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This proposed rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a

certifying agent, as described in § 2115(b) of the OFPA (7 U.S.C. 6514(b)). States are also preempted under §§ 2104 through 2108 of the OFPA (7 U.S.C. 6503 through 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to § 2108(b)(2) of the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) Further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to § 2120(f) of the OFPA (7 U.S.C. 6519(f)), this proposed rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspections Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), nor the authority of the Administrator of the EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 et seq.).

Section 2121 of the OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

C. Regulatory Flexibility Analysis (5 U.S.C. et seq.)

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the

objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

Pursuant to the requirements set forth in the RFA, the AMS performed an economic impact analysis on small entities in the final rule published in the **Federal Register** on December 21, 2000 (65 FR 80548). The AMS has also considered the economic impact of this action on small entities. The AMS has determined that the impact on entities affected by this proposed rule would not be significant.

Small agricultural service firms, which include producers, handlers, and accredited certifying agents, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than \$7,000,000 and small agricultural producers are defined as those having annual receipts of less than \$750,000.

According to Economic Research Service (ERS) data based on information from USDA-accredited certifying agents, the number of certified U.S. organic crop and livestock operations totaled nearly 13,000 and certified organic acreage exceeded 4.8 million acres in 2008.⁴ ERS, based upon the list of certified operations maintained by the NOP, estimated the number of certified handling operations was 3,225 in 2007.⁵ AMS believes that most of these entities would be considered small entities under the criteria established by the SBA.

The U.S. sales of organic food and beverages have grown from \$3.6 billion in 1997 to nearly \$21.1 billion in 2008.⁶ The organic industry is viewed as the fastest growing sector of agriculture, representing over 3% of overall food sales in 2009. Between 1990 and 2008, organic food sales have historically demonstrated a growth rate between 15

³ NOP Policy Memo 11-6.

⁴U.S. Department of Agriculture, Economic Research Service. 2009. Data Sets: U.S. Certified Organic Farmland Acreage, Livestock Numbers and Farm Operations, 1992–2008. http:// www.ers.usda.gov/Data/Organic/.

⁵ U.S. Department of Agriculture, Economic Research Service, 2009. *Data Sets: Procurement and Contracting by Organic Handlers: Documentation.* http://www.ers.usda.gov/Data/OrganicHandlers/Documentation.htm.

⁶Dimitri, C., and L. Oberholtzer. 2009. Marketing U.S. Organic Foods: Recent Trends from Farms to Consumers, Economic Information Bulletin No. 58, U.S. Department of Agriculture, Economic Research Service, http://www.ers.usda.gov/Publications/FIR58

to 24 percent each year. In 2009, organic food sales grew 5.1%.⁷

The USDA has 94 accredited certifying agents (ACAs) who provide certification services to producers and handlers under the NOP. A complete list of names and addresses of ACAs may be found on the AMS NOP Web site at: http://www.ams.usda.gov/nop. The AMS believes that most of those accredited certifying agents would be considered small entities under the criteria established by the SBA. Certifying agents reported approximately twenty-seven thousand certified operations worldwide in 2010.

The AMS is proposing a minimum testing requirement of five percent of certified operations. This level was chosen to ensure that all certifying agents, regardless of the number of operations they certify, are responsible for some level of regular residue testing at reasonable cost. Under § 205.670(b) of the current NOP regulations, certifying agents are responsible for expenses associated with preharvest and postharvest testing; this requirement would also apply to the requirements for periodic residue testing in this proposed rule. To estimate the annual costs associated with instituting periodic residue testing, the NOP conducted a preliminary assessment of costs at different minimum testing requirements (i.e. 3%, 5%, and 10% of certified operations).

Under this new action with a five percent minimum testing requirement, the two certifying agents with the largest number of certified operations (approximately 2,100 operations each for 2009) would be required to collect a minimum of 105 samples. Smaller certifying agents (those certifying fewer than 30 operations) would be required to collect and test at least 1 sample on an annual basis. In 2010, approximately one-third of accredited certifying agents certified fewer than 30 operations.8 Over half of all certifying agents certified fewer than 200 operations in 2010 and would be required to sample 10 or fewer operations annually under this proposal for periodic residue testing.

At a five percent minimum testing requirement, the costs of sample analysis would range from approximately \$500 to \$53,000 per certifying agent per year based on the average cost of \$500 per sample and the range in the number of operations

certified by different certifying agents. Additional costs may be required to follow up on results if prohibited substances are detected.

The AMS is proposing a five percent level in this proposed rule because this level is expected to be, in most cases, no more than one percent of a given certifying agent's operating budget, a level that can be considered a reasonable cost to the organic industry given the benefits of residue testing in discouraging the mislabeling of agricultural products. Furthermore, the number of samples required at a five percent level would be consistent with the amount of residue sampling already being conducted by some certifying agents.

The AMS considered two additional alternatives to the 5% proportional requirement: (1) A requirement for certifying agents to sample 25% of all certified operations (a statistically based sample size based upon the rate of detection of residues in organic products sampled through the USDA AMS Pesticide Data Program (PDP)), and (2) a requirement for certifying agents to sample all 27,000 certified operations. The AMS determined that both alternatives are impractical due to the costs and the uneven burden that could be placed upon smaller certifying agents in either scenario.

The proposed rule is necessary to clarify a requirement of OFPA that certifying agents conduct periodic residue testing of organic products. The proposed rule would increase the amount of residue testing that certifying agencies must conduct when compared to the current regulations. The costs of testing will be borne by the applicable certifying agent and is considered a cost of doing business.

D. Paperwork Reduction Act

In accordance with Office of Management and Budget (OMB) regulations (5 CFR part 1320) that implement the Paperwork Reduction Act (44 U.S.C. 3501-3520) (PRA), the information collection requirements associated with the NOP have been previously approved by OMB and assigned OMB control number 0581-0191. A new information collection package is being submitted to OMB for approval of 776 hours in total burden hours to cover this new collection and recordkeeping burden of the amendments proposed to § 205.670 in this proposed rule. Upon OMB's approval of this new information collection, the NOP intends to merge this collection into currently approved OMB Control Number 0581-0191. In accordance with 5 CFR Part 1320, we

have included below a description of the collection and recordkeeping requirements and an estimate of the annual burden on certifying agents who would be required to maintain information under this proposed rule. Authority for this action is the Organic Foods Production Act of 1990 (7 U.S.C. 6501 et seq.), as amended.

Title: National Organic Program; Periodic Residue Testing.

OMB Control Number: 0581–NEW. Expiration Date of Approval: 3 years from OMB date of approval.

Type of Request: New collection. Abstract: The information collection and recordkeeping necessitated by amendments to § 205.670 are essential to ensure that certifying agents conduct periodic residue testing of agricultural products produced or handled as required by OFPA (7 U.S.C. 6506). Based on available information, AMS estimates that there are 94 certifying agents, both foreign and domestic, who will be subject to the amendments at § 205.670. The proposed rule would expand the amount of residue testing of organically produced agricultural products by clarifying that sampling and testing are required on a regular, random basis. As a result of this action and per § 205.670(e)(1), certifying agents would be required to report more test results to the AMS Administrator or, if applicable, State organic program's governing State official. To meet this requirement, certifying agents would need to submit a copy of each test result to the Administrator or State organic program upon receiving these results from an accredited laboratory. Allowing the submission of copies of test results, rather than requiring that results are provided in a specific format to the Administrator or State organic program, should minimize the reporting burden on certifying agents. The frequency of this reporting would be dependent upon when, during the course of a year, the certifying agent conducts their testing (i.e. certifying agents may choose to complete their testing and reporting all in the same month or may choose to spread their testing and reporting throughout the year). The expansion of testing may also lead, under certain circumstances, to an increase in the reporting to a Federal health agency, State health agency, or foreign equivalent as required by § 205.670(f) of the proposed amendment. The frequency of this reporting would vary with the number of times that test results exceed a regulatory tolerance as specified at § 205.670(f).

The PRA also requires AMS to measure the recordkeeping burden. While certifying agents are already

⁷ Organic Trade Association's 2010 Organic Industry Survey, http://www.ota.com.

⁸ As reported by certifying agents during the 2010 certification year and available at http://apps.ams.usda.gov/nop/.

required to maintain records under § 205.510(b) of the NOP regulations as part of accreditation, this action would increase the volume of records that certifying agents would need to maintain. Maintaining copies of laboratory results would be necessary for certifying agents to demonstrate compliance with the proposed requirement at § 205.670(c). This requirement would specify that certifying agents must annually conduct residue testing of agricultural products from at least five percent of the operations they certify. Certifying agents would also need to document correspondence that demonstrates their reporting to a Federal health agency, State health agency, or foreign equivalent, for results with residues that exceed the regulatory tolerance as specified at § 205.670(f) as proposed.

This information collection is used by the certifying agent; certified operation; authorized representatives of USDA, including AMS and NOP staff; applicable State organic program; and Federal health agencies, State health agencies, or foreign equivalent. Certifying agents and USDA are the primary users of the information.

Information Collection Burden

Estimate of Burden: Public reporting burden for the collection of information per sample analysis submitted to the Administrator or State organic program is estimated to be 15 minutes. The estimated reporting burden is based upon feedback provided to the NOP by domestic and foreign certifying agents. To meet the requirement to annually test for residues from at least five percent of the operations they certify, certifying agents would, on average, need to conduct and report results on fifteen samples on an annual basis. This estimate is based upon AMS data that the 94 certifying agents provide certification services to approximately 27,000 operations. AMS estimates the annual collection cost per certifying agent to be \$121.58. This estimate is based on an estimated 3.75 labor hours per year (reporting 15 samples per year at 0.25 hour per sample) at \$32.42 per hour for a total salary component of \$121.58 per year. The hourly rate is estimated based on the mean hourly wage for auditors as published by the Bureau of Labor Statistics.⁹ This classification was selected as an occupation with similar duties and responsibilities to that of a certifying agent. Such duties and responsibilities

include conducting reviews of operations against accepted standards and evaluating audit or inspection findings for compliance.

Public reporting burden for information that requires submission to a Federal health agency, state agency, or foreign equivalent is estimated to be a one hour per response. Certifying agents would need to report on results that show residues that exceed regulatory tolerances per proposed § 205.670(f). Based upon the USDA AMS Pesticide Data Program data from calendar year 2008, results from residue testing of conventional commodities showed regulatory tolerances exceeded in approximately 4.2% of samples. 10 While it is expected that organic products would have a lower incidence of samples with residues that exceed regulatory tolerance, the 4.2% estimate provides an upper limit for how often certifying agents might have to report residue testing results to Federal health agencies, appropriate State health agency, or their foreign equivalent. As a result, each certifying agent, on average, would be expected to report less than one response to a Federal health agency, State health agency, or foreign equivalent. AMS estimates the annual collection cost per certifying agent to be \$19.45. This estimate is based on an estimated 0.6 labor hours per year (reporting fewer than one result per year, on average, at one hour per submission) at \$32.42 per hour for a total salary component of \$19.45 per

Respondents: Certifying agents. Estimated Number of Respondents: 94

Estimated Number of Responses per Respondent: 15.6.

Estimated Total Annual Burden on Respondents: 409 hours.

Total Cost: \$13,257.

Recordkeeping Burden

Estimate of Burden: Public recordkeeping burden is estimated to be an annual total of 3.9 hours per respondent at \$32.42 per hour for a total salary component cost of \$126.44. This accounts for both the recordkeeping associated with maintaining copies of test results and documenting any correspondence with a Federal health agency, state health agency, or foreign equivalent.

Respondents: Certifying agents. Estimated Number of Respondents: 94.

Estimated Number of Responses per

Respondent: 15.6. Estimated Total Annual Burden on Respondents: 367 hours.

Total Cost: \$11,898. Comments: AMS is inviting comments from all interested parties concerning the information collection and recordkeeping required as a result of the amendments proposed to § 205.670 in this proposed rule. Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments that specifically pertain to the information collection and recordkeeping requirements of this action should be sent to Lisa M. Brines, Agricultural Marketing Specialist, Standards Division, National Organic Program, USDA-AMS-NOP, Room 2646-So., Ag Stop 0268, 1400 Independence Ave., SW., Washington, DC 20250-0268 and to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, 725 17th Street, NW., Room 725, Washington, DC 20503. Comments on the information collection and recordkeeping requirements should reference the date and page number of this issue of the Federal Register. All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

The comment period for the information collection and recordkeeping requirements contained in this proposed rule is 60 days.

The AMS is committed to complying with the E-Government Act to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals,

⁹ U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages, May 2009.

¹⁰ U.S. Department of Agriculture, Agricultural Marketing Service, Pesticide Data Program Annual Summary, Calendar Year 2008. http:// www.ams.usda.gov/pdp.

Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205, subpart G is proposed to be amended as follows:

PART 205—NATIONAL ORGANIC PROGRAM

1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501-6522.

2. Section 205.670 is revised to read as follows:

§ 205.670 Inspection and testing of agricultural product to be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))."

(a) All agricultural products that are to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be made accessible by certified organic production or handling operations for examination by the Administrator, the applicable State organic program's governing State official, or the certifying

agent.

(b) The Administrator, applicable State organic program's governing State official, or the certifying agent may require preharvest or postharvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods. Such tests must be conducted by the applicable State organic program's governing State official or the certifying agent at the official's or certifying agent's own expense.

(c) A certifying agent must conduct periodic residue testing of agricultural products to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))." Such tests must be conducted by the certifying agent at the certifying agent's own expense. A certifying agent must, on an annual basis, sample and test from a minimum of five percent of the operations it certifies, rounded to the nearest whole number. A certifying agent that certifies fewer than thirty operations on an annual basis must sample and test from at least one operation annually.

(d) Sample collection pursuant to paragraphs (b) and (c) of this section must be performed by an inspector representing the Administrator, applicable State organic program's governing State official, or certifying agent. Sample integrity must be maintained throughout the chain of custody, and residue testing must be performed in an accredited laboratory. Chemical analysis must be made in accordance with the methods described in the most current edition of the Official Methods of Analysis of the AOAC International or other current applicable validated methodology for determining the presence of contaminants in agricultural products.

- (e) Results of all analyses and tests performed under this section:
- (1) Must be promptly provided to the Administrator; *Except*, That, where a State organic program exists, all test results and analyses shall be provided to the State organic program's governing State official by the applicable certifying party that requested testing; and
- (2) Will be available for public access, unless the testing is part of an ongoing compliance investigation.
- (f) If test results indicate a specific agricultural product contains pesticide residues or environmental contaminants that exceed the Food and Drug Administration's or the Environmental Protection Agency's regulatory tolerances, the certifying agent must promptly report such data to the Federal health agency whose regulatory tolerance or action level has been exceeded. Test results that exceed federal regulatory tolerances must also be reported to the appropriate State health agency or foreign equivalent.

Dated: April 25, 2011.

David R. Shipman,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2011–10415 Filed 4–28–11; 8:45 am]

BILLING CODE 3410-02-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2011-0318; Directorate Identifier 2010-CE-033-AD]

RIN 2120-AA64

Airworthiness Directives; Burl A. Rogers (Type Certificate Previously Held by William Brad Mitchell and Aeronca, Inc.) Models 15AC and S15AC Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM); Extension of the comment period.

SUMMARY: This document extends the period for public comment on the above-referenced NPRM. The proposed AD would require repetitive inspections of the upper and lower main wing spar cap angles for cracks and/or corrosion and installing inspection access panels. The proposed AD would also require replacing the wing spar cap angles if moderate or severe corrosion is found and applying corrosion inhibitor. The proposed AD was prompted by reports of intergranular exfoliation and corrosion of the upper and/or lower wing main spar cap angles found on the affected airplanes. We are proposing this AD to detect and correct cracks, intergranular exfoliation and corrosion in the wing main spar cap angles, which could result in reduced strength of the wing spar and the load carrying capacity of the wing. This could lead to wing failure and consequent loss of control. This extension of the comment period is necessary to assure that all interested persons have ample opportunity to present their views on the proposed requirements of the NPRM.

DATES: We must receive comments on this proposed AD by July 3, 2011. The comment due date is being extended from May 19, 2011.

ADDRESSES: You may send comments by any of the following methods:

- Federal eRulemaking Portal: Go to http://www.regulations.gov. Follow the instructions for submitting comments.
 - Fax: 202-493-2251.
- Mail: U.S. Department of Transportation, Docket Operations, M–30, West Building *Ground* Floor, Room W12–140, 1200 New Jersey Avenue, SE, Washington, DC 20590.
- Hand Delivery: U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590,