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RIN 0581–AD10

National Organic Program; Periodic Residue Testing

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule clarifies a provision of the Organic Foods Production Act of 1990 and the regulations issued thereunder that requires periodic residue testing of organically produced agricultural products by accredited certifying agents. The final rule amends 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 final rule expands the amount of residue testing of organically produced agricultural products by clarifying that sampling and testing are required on a regular basis. The final rule requires 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 will help further ensure the integrity of products produced and handled under the NOP regulations.

DATES: *Effective Date:* This final rule is effective January 1, 2013.

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SUPPLEMENTARY INFORMATION:

I. Background

Under section 6511 of the Organic Foods Production Act of 1990 (OFPA), as amended, (7 U.S.C. 6501–6522), the National Organic Program (NOP) is authorized to implement regulations that require accredited certifying agents to conduct residue testing of organically produced agricultural products. Section 6506 of the OFPA 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 section 205.670 of the NOP regulations (7 CFR part 205). This section provides that the Secretary, State organic programs, and certifying agents 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.

The Agricultural Marketing Service (AMS) is issuing this final 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 residue testing to be required by the regulations only under certain circumstances.

AMS conducted a review of this issue in response to the OIG audit. AMS concluded that, under section 6506 of the OFPA, accredited certifying agents are required to conduct residue testing of organic products on a regular and reoccurring basis, as well as when there is reason to believe contamination has occurred, and that the regulations be revised as provided for in this rulemaking.

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 agents 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 final rule.

On April 29, 2011, AMS published a proposed rule for periodic residue testing (76 FR 23914). The rule proposed that certifying agents, on an annual basis, must sample and conduct residue testing from a minimum of five percent of the operations that they certify. The proposed rule included a 60 day comment period. Comments were also specifically requested on the information collection burden that would result from the proposed action. The NOP received over 30 written comments in response to the proposed rule.

II. Comments on Proposed Rule

Comments in response to the proposed rule were received from certified organic operations, certifying agents, consumers, trade associations, organic associations, and various industry groups.

The majority of commenters supported residue testing in general, and offered comments regarding the role of the National Organic Standards Board (NOSB), sampling rates, sample selection, costs and costs estimates, testing methodology, data collection, and reporting requirements.

Four comments specifically addressed the information collection and recordkeeping requirements of this action pursuant to the Paperwork Reduction Act (44 U.S.C. 3501–3520) (PRA).

[1] U.S. Department of Agriculture, Office of Inspector General, Audit Report 01601–03-Hy, March 2010. Available at *http://www.usda.gov/oig/webdocs/01601-03-HY.pdf.*

AMS received one comment from a certifying agent requesting an extension of the comment period. Since the proposed rule included a 60 day comment period and because the NOP previously conducted two webinar trainings with certifying agents on periodic residue testing on June 23 and June 24, 2010, we did not agree that an extension of the comment period was warranted.

Authority To Issue Rule

Seven commenters indicated that they did not believe that AMS has the authority to issue a rule on residue testing under the OFPA without a recommendation from the NOSB.

The NOSB is a federal advisory committee established by the Secretary of Agriculture under section 6518 of the OFPA to assist in the development of standards for substances to be used in organic production and to advise the Secretary on other aspects of the implementation of the NOP.

The commenters cited section 6518 of the OFPA which states ''the Board shall advise the Secretary concerning the testing of organically produced agricultural products for residues caused by unavoidable residual environmental contamination.''

Additionally, two commenters cited a 1990 report of the U.S. Senate Committee on Agriculture, Nutrition, and Forestry, which indicates that the NOSB would be most knowledgeable on the subject of levels of acceptable residues of prohibited materials for organic food, and that the Committee intends that the NOSB shall advise the Secretary concerning appropriate residue levels and testing methods for organic products.[2]

AMS disagrees with the commenters' claims that AMS does not have the authority to issue a rule in this area. This final rule is issued under the authority of the OFPA at section 6506(a)(6) which requires periodic residue testing by certifying agents. This rule does not amend any provisions or thresholds related to the maximum allowable pesticide residue for organic food or thresholds related to unavoidable residual environmental contamination (UREC). The existing NOP regulations regarding UREC at section 205.671 were based on a recommendation adopted by the NOSB at its meeting June 1–4, 1994 in Santa Fe, New Mexico.[3] UREC is defined under section 205.2 of the NOP regulations as background levels of naturally occurring or synthetic chemicals that are present in the soil or present in organically produced agricultural products that are below established tolerances. This rule does not amend this existing definition.

Number of Samples

AMS received twelve comments on the issue of the amount of sampling or number of samples. The proposed rule indicated that certifying agents would be required, on an annual basis, to sample and conduct residue testing from a minimum of five percent of the operations that they certify. The proposed rule indicated that residue testing conducted for causative reasons, such as complaint-driven testing, or testing when there was reason to suspect contamination, would not be counted towards the minimum percentage required.

Based on the comments received, AMS believes that using a percentage of certified operations to determine sample selection offers the simplest implementation for certifying agents and ensures that all certifying agents conduct a minimal level of residue testing. Further discussion of the comments received is provided below.

Number of Samples—Changes Based on Comments

AMS received five comments requesting that all residue testing conducted by a certifying agent be counted towards the five percent minimum requirement, including compliance testing, investigative testing, risk-based sampling, and random sampling. One commenter indicated that establishing random testing at five percent would make it more difficult to do other types of testing (e.g. risk-based, compliance testing) because of the costs involved. Several commenters indicated that compliance, investigative, and risk-based testing would yield more meaningful results than random testing.

One comment from a certifying agent indicated that it did not support revising the rule to include compliance or investigative testing as part of the five percent requirement. Based on experience in taking samples for both purposes, the commenter indicated that the concern from certifying agents that the proposed rule would be a disincentive to conduct compliance or investigative testing was unfounded.

The NOP accepts the majority of the commenters' suggestions to include all testing towards the minimum requirement. Any residue testing performed by a certifying agent may be counted towards the minimum requirement for residue testing, provided that the certifying agent samples and tests from a minimum of five percent of the operations it certifies on an annual basis.

AMS received two comments requesting a phase-in period for the testing requirements. One commenter suggested testing a portion of the five percent minimum percentage of operations in 2012, and the full percentage of operations in 2013. The commenter noted that a phase-in would enable certification agents to plan budgets, develop office procedures, and train staff and inspectors. The commenter also noted that a phase-in would enable the NOP to assess the effectiveness of the testing program. AMS received one comment requesting a phase-in of three percent for the first two years, which could be reevaluated and adjusted accordingly in the future.

AMS has considered the commenters' suggestion for a phase-in of the implementation and compliance date of the final rule and has issued this final rule with an effective date of January 1, 2013. Certifying agents must be fully compliant with the five percent requirement for the 2013 calendar year. The NOP understands that a minority of accredited certifying agents currently conduct residue testing on a regular, periodic basis. However, the NOP notes that certifying agents are already required, under section 205.504(b)(6) of the NOP regulations, to have procedures and trained staff in place for investigations of pesticide drift, complaints, or when reason to believe a product has come into contact with a prohibited substances. As evidence of their expertise and ability, certifying agents are also already required to submit a copy of the procedures to be used for sampling and residue testing pursuant to section 205.670 as an accreditation requirement.

Number of Samples—Changes Requested But Not Made

One commenter noted that the number of operations that would be sampled under the proposed rule was small relative to the total number of operations. The commenter noted that sampling based on the number of operations does not account for differences in sizes of the operations, and suggested that sampling be based upon size and quantity, rather than the number of operations. The commenter

[2] U.S. Senate, Committee on Agriculture, Nutrition, and Forestry. *Food, Agriculture, Conservation, and Trade Act of 1990,* S. Rpt. 101–357 to accompany S. 2830, July 6, 1990.

[3] National Organic Standards Board, Final Recommendations, Residue Testing, 1994. Available on the NOP Web site at *http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=stelprdc5058863.*

suggested that AMS have an unbiased group determine sampling methodology using proper scientific and statistical techniques. The commenter noted that, unless AMS uses a sound basis in choosing the number, size, and site of the samples, any conclusions drawn from the testing would be invalid.

Another commenter suggested that AMS should require sampling based on a percentage of products, rather than a percentage of operations.

Two comments indicated that the five percent number was arbitrary and not statistically valid, but did not offer an alternative method for determining sampling size.

AMS disagrees. Basing sampling on a percentage of operations reduces the burden on the certifying agents by providing a clear and simple formula for how to comply with the regulations. The five percent requirement satisfies AMS's intent to discourage the mislabeling of agricultural products and provide a means for monitoring compliance with the NOP.

Under the final rule, certifying agents have the discretion to select operations for residue testing based on criteria such as size of operation, quantity of products produced, previous compliance issues, or other risk factors. Certifying agents are knowledgeable about the risk factors affecting the operations it certifies; therefore, it is appropriate for a certifying agent to determine what operations should be tested under this action.

AMS received three comments requesting that AMS lower the minimum percentage of operations to be tested from five percent to three percent due to costs. One of the commenters stated that the costs of testing would be passed on indirectly to farmers and processors in the form of higher certification fees. Another commenter stated that requiring three percent, rather than five percent, would allow the certifying agent more latitude for doing risk-based and compliance sampling.

In the final rule, AMS allows for both periodic testing and compliance sampling to be counted towards the minimum requirement, but has retained the minimum percentage of operations to be tested at five percent annually.

AMS has considered the comment that this action may indirectly increase costs to certified operations if certifying agents increase their certification fees to recover costs from increased residue testing. This action implements periodic residue testing in a way that should minimize the direct costs to certifying agents and any indirect costs to certified operations while still meeting the objectives of implementing periodic residue testing as required by OFPA. Additional details on the costs, benefits, and alternatives considered are discussed in the section titled *Executive Order 12866 and Executive Order 13563.*

AMS notes that lowering the percentage below five percent does not have an impact on the smallest quartile of certifying agents that certify fewer than thirty operations to the NOP per year, since they are required to sample a minimum of one operation under either scenario.

One comment from a consumer group indicated that AMS should reserve the right to raise the percentage for a specific certifying agent if residue testing shows that a certifying agent has an unusually high number of positive results. AMS believes that the regulations provide sufficient flexibility for the NOP to address issues that may arise on a case-by-case basis, and therefore, no modifications are necessary to the regulations.

One commenter requested that AMS review the residue testing data in five years to see if the percentage of operations tested could be reduced. AMS notes that the final rule does not prohibit AMS from reconsidering the percentage of operations required for compliance at a later date based on new information, but this would be under a separate rulemaking action.

AMS received one comment from a certifying agent regarding the role of State organic programs under the proposed rule. AMS currently has one State organic program in California. The commenter requested that testing conducted by a State program should offset the certifying agents' requirement in that State. AMS disagrees. Under the OFPA, certifying agents are required to conduct residue testing. AMS believes that requiring certifying agents to test from five percent of certified operations on an annual basis is reasonable, and that testing conducted by other organizations, including State organic programs or other private testing programs, should not offset this requirement under the OFPA.

Operation Selection and Conflict of Interest—Changes Requested But Not Made

AMS received nine comments regarding the selection of operations for residue testing. Several commenters requested clarification on selection of operations and whether it is AMS' intent to have certifying agents select operations at random or use other criteria. It is not AMS' intent for this final rule to require certifying agents to select operations at random. AMS is not specifying how certifying agents should select operations for residue testing in order to provide flexibility to the certifying agency. Instead, AMS is providing discretion to the certifying agent to select operations. Operation selection for residue testing may include risk factors such as number of products produced, split operations, size of the operation, high-value or high-risk crops, or other criteria deemed appropriate by the certifying agent.

Three commenters indicated that certifying agents should not select the operations for residue testing since this may be an inherent conflict of interest. Commenters suggested that the NOP or other third-party groups select the operations. AMS disagrees. Certifying agents are already required to implement procedures to prevent conflict of interests as a condition of accreditation under the NOP regulations (§ 205.501(a)(11)). AMS also conducts regular audits of certifying agents to ensure compliance with NOP accreditation requirements including preventing conflicts of interest. AMS does not have reason to believe that selection of operations for purposes of periodic residue testing would be different from any other certification work carried out by certifying agents with respect to conflict of interest.

Several commenters suggested utilizing a system of statistical sampling methods for operation selection, such as that used by the AMS Pesticide Data Program. AMS disagrees. It is not AMS' intent to assemble data and draw conclusions based on statistical sampling techniques, as the sampling performed by certifying agents will vary considerably due to the worldwide diversity of operations which are certified to the NOP. Certifying agents have the discretion to sample from higher risk operations, which may yield results that are not representative of all organic operations.

Types of Samples—Changes Based on Comments

AMS received eight comments regarding the selection of samples for residue testing. The commenters requested changes in the rule to clarify that residue sampling may be performed on samples which are not finished products, such as soil samples, tissue samples, or water.

Commenters noted that preharvest sampling may be more meaningful when sampling is risk-based or for investigative testing (e.g., when use of a prohibited substance is suspected). In addition, commenters suggested that preharvest testing of tissue samples,

soil, or water may be more appropriate at certain times during the growing season.

AMS agrees with the commenters' suggestions and has amended the regulatory text accordingly to clarify that testing may be conducted preharvest or postharvest, and that residue testing is not limited to salable products only. The final rule specifies the types of materials for sampling that are currently listed in section 205.403(c)(3) for on-site inspections. This may include collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. AMS notes that, in the case of pesticide residue testing, tolerances are established by the Environmental Protection Agency (EPA) for specific harvested commodities. These tolerances enable the certifying agent to take appropriate enforcement action, if warranted, for the harvested commodity. If a prohibited residue is detected in a sample where there is not an established tolerance, such as soil, water, or other plant tissues, follow-up testing of the harvestable product may be needed for the certifying agent to determine the appropriate enforcement action.

Additionally, AMS notes that certifying agents currently have the authority to collect samples under section 205.403(c) which states that ''The on-site inspection of an operation must verify: (3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.''

Types of Samples—Changes Requested But Not Made

AMS received one comment requesting that processed products which are to be sold or labeled as ''organic'' or ''made with organic (specified ingredients or food group(s))'' be excluded from residue testing requirements. The commenter states that testing would not pinpoint the source of contaminants in processed, multi-ingredient products. In certain cases, the source of a residue detected in a multi-ingredient processed product may be more difficult to identify; however, we have retained the allowance for testing processed products to allow certifying agents the flexibility of sampling processed products when it may be useful to determine compliance with the regulations.

Reporting Requirements

AMS received eight comments regarding reporting requirements. Several commenters requested clarification on the use of the term ''promptly'' in reporting results to the AMS Administrator (Administrator). The proposed rule did not specify a reporting time period and retained the term ''promptly'' from the existing NOP requirements at section 205.670.

Several commenters also requested a distinction between reporting violative versus non-violative sample results. The commenters suggested that violative samples (i.e., samples with residues detected) could be reported to the Administrator as the information was received, but requested that non-violative samples (i.e., where no residues are detected) be reported on a more infrequent basis, such as quarterly or annually. One commenter requested that reporting be required on at least an annual basis, but not more than twice annually. Two commenters requested that the NOP require all results to be reported and incorporated into a dataset that would be available to the public.

After further consideration, AMS has amended the reporting requirements required under section 205.670 in order to reduce the reporting burden on certifying agents. This rule eliminates the requirement that certifying agents must submit all residue testing results to the Administrator or State organic program's governing State official. AMS does not intend to consolidate residue testing data from certifying agents and does not need reporting of residue testing results as the mechanism to ensure that certifying agents are meeting the requirement periodic residue testing.

AMS intends to verify compliance of certifying agents with the requirements for periodic residue testing as part of the existing accreditation process. Accreditation requirements at section 205.504(b)(6) require certifying agents to have administrative policies and procedures, including procedures to be used for sampling and residue testing pursuant to § 205.670. Certifying agents are also required to submit an annual report to the Administrator on or before the anniversary date of the issuance of notification of accreditation which includes a complete and accurate update of information submitted pursuant to §§ 205.503 and 205.504. In order to verify that certifying agents are implementing this rule in advance of regularly scheduled on-site audits, AMS intends to require, as authorized under section 205.510(a)(3), certifying agents to submit in their next annual report a description of the measures implemented in the previous year and any measures to be implemented in the coming years to meet the requirements in this rule for periodic residue testing. In addition, AMS notes that certifying agents should continue to maintain the complete results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and three preceding calendar years, as required by section 205.504(b)(5)(iii).

The final rule also clarifies 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 (FDA) or EPA's regulatory tolerances. Under section 6506 of the OFPA, 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 section 205.670(e), amended by this final rule at 205.670(g), of the NOP regulations, which requires reporting to the Federal health agency whose regulatory tolerance or action level has been exceeded. The NOP issued a policy memo on reporting health and safety violations to stakeholders and interested parties.[4] This final rule clarifies the reporting requirements at 205.670(g), but does not change the responsibility for reporting by certifying agents when residues are found in excess of federal regulatory tolerances established by EPA or FDA. The final rule indicates that certain residue testing results that are in violation of EPA or FDA requirements must be reported to the appropriate State health agency or foreign equivalent. This change in the regulations is intended to recognize the role of State agencies, or their foreign equivalents, in responding to residues in violation of tolerance requirements.

One comment from a certifying agent that operates outside of the United States indicated that reporting test results that exceed federal regulatory tolerances is under the operator's responsibility. The commenter indicated that, as a certifying agent, it would check to make sure reporting was done correctly by the operation, and that the certifying agent would inform the NOP. AMS disagrees. Under the OFPA (7 U.S.C. 6506), certifying agents, to the extent that they are aware of a

[4] NOP Policy Memo 11–6, Reporting Health & Safety Violations, revised October 31, 2011. Available at *http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5088951.*

violation of applicable laws relating to food safety, are required to report such violation to the appropriate health agencies. This requirement is promulgated at section 205.670 of the regulations. This final rule clarifies the reporting requirements, but does not change the responsibility for reporting by certifying agents.

In addition to the reporting requirements outlined in the final rule, the NOP published, on June 13, 2011 in the **Federal Register** (76 FR 34180), the availability of draft guidance entitled, NOP 5028—Responding to Results from Pesticide Residue Testing, that outlines 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. The notice included a 60-day comment period, which closed on August 12, 2011. After review of the comments received, the NOP intends to publish final guidance on this issue in the NOP Handbook, as described under *Related Documents.* Under section 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 final rule does not change this existing requirement. The draft guidance document provides information to certifying agents on how to respond to results that indicate residues of prohibited substances and how to report results that are in violation of FDA or EPA's regulatory tolerances as required by section 205.670(g).

Wild Crops—Changes Requested But Not Made

AMS received one comment from a certified operation regarding the testing of wild crops. The commenter requested an exemption from the requirement for periodic residue testing for wild crops on the basis that EPA tolerances are not established for most herbs in commerce. The commenter suggests that the absence of established tolerances places wild crops at disproportionate risk of enforcement actions as a result of the detection of trace amounts of unavoidable contamination (e.g., drift) of unknown origin. AMS disagrees. One of the purposes of periodic residue testing is to provide a means for monitoring compliance with the NOP by discouraging the mislabeling of agricultural products. AMS has determined that all crops should be included within the scope of periodic residue testing to serve as a deterrent for mislabeling (e.g., to deter substitution of conventionally produced herbs for organic wild-crop harvested herbs).

The commenter also requested written clarification as to how unavoidable pesticide residue contamination of wild crops would be addressed under the regulation in the absence of EPA-established tolerances for most plant species. A clarification is included in the draft guidance NOP 5028—Responding to Results from Pesticide Residue Testing, as described below under *Related Documents.*

International Trade

AMS received one comment from an organic industry group in Canada which opposed the proposed rule. The commenter stated that the United States and Canada are currently signatories to an equivalency determination for organic products, and that the imposition of a costly measure on the United States' side, without a corresponding rule in Canada, could lead the identification of this regulatory change as a critical variance which would impede trade. Residue testing is required under the European Union's (EU) organic standards and, in 2011, Canada and the EU signed an organic equivalency determination that does not include any critical variances related to residue testing. In addition, certifying agents accredited under the NOP must already conduct sampling and laboratory testing in instances where contamination is suspected under sections 205.403(c)(3) and 205.670(b). AMS does not anticipate that this requirement for periodic residue testing will impact the United States' equivalency determination with Canada.

Costs and Cost Estimates—Changes Requested But Not Made

AMS received eighteen comments regarding estimates of the costs of testing. In the proposed rule, AMS had estimated the cost at $500 per sample, and estimated that the costs may represent approximately 1% of a certifying agent's operating budget.

Several commenters stated their belief that residue testing at the certifying agent's own expense was a disincentive to residue testing, and that the OFPA did not directly address who must pay for testing. A comment from a certifying agent who certifies operations to the organic standards of the EU, the Japanese Agricultural Standard (JAS), and the NOP, indicated that the regulations of the EU and JAS do not oblige the certifying agent to pay for pesticide analyses; instead, the cost is directly passed on to the operator. The commenter suggested that the NOP adopt this same approach and indicated that it encourages certifying agents to take the amount of samples which is necessary, and not just what is required by the regulations. Another commenter expressed support for this model. Section 205.670(b) currently provides that preharvest and postharvest testing is conducted at a certifying agent's expense. Similar to that provision, it is reasonable that periodic residue testing also be conducted at the certifying agent's expense, and therefore no changes are made to the final rule based on these comments.

Several commenters requested a more thorough analysis of the costs of implementing periodic residue testing. A more detailed analysis of the costs associated with this action is provided under the section titled *Executive Order 12866 and Executive Order 13563.* AMS notes that a minority of certifying agents currently conduct periodic residue testing at or above the minimum levels established by this final rule and there would be no additional costs associated with this action for those certifying agents. The majority of certifying agents, however, would need to allocate additional resources for the costs associated with periodic residue testing. AMS received one comment from a certifying agent operating outside of the United States which indicates that it currently tests 20–25% of its certified operations, which is above the minimum level specified in this final rule.

One comment from a laboratory indicated that AMS' estimated $500 cost for analysis was high by a factor of two or more, and that it may be able to perform this analysis for certifying agents at $250 per sample or less. The commenter's estimate appears to be limited to the direct laboratory costs of residue analysis, and does not include the additional related costs that AMS has included in the estimated costs per sample.

Several commenters indicated that the costs may disproportionally affect smaller certifying agents, since they would not be able to receive quantity discounts. Some laboratories may offer discounts to its higher-volume clients, including certifying agents. However, AMS also notes that lowering the percentage below five percent does not have an impact on the smallest quartile of certifying agents that certify fewer than thirty operations per year, since they are required to sample a minimum of one operation annually.

One commenter suggested an alternative funding mechanism, such as having pesticide manufacturers and producers of genetically modified seed

pay for the costs of testing. AMS does not have the statutory authority to institute this type of third-party funding model.

Purpose of Testing—Changes Requested But Not Made

AMS received several comments requesting clarification on the purpose of residue testing.

AMS is publishing this final rule to implement the requirements of the OFPA for periodic residue testing by certifying agents. Residue testing plays an important role in organic certification by providing a means for monitoring compliance with the NOP regulations and by discouraging the mislabeling of agricultural products.

AMS does not intend to integrate results into a single dataset, as was requested by some commenters. To minimize the reporting burden for certifying agents, this final rule does not require that certifying agents submit copies of test results to the Administrator; however, certifying agents continue to be required to report certain test results that are found in excess of federal regulatory tolerances or action levels for pesticide residues or environmental contaminants to the appropriate health agency under the section 205.670(g). This final rule does not require reporting of testing data to the Administrator since this action is not intended as a data collection mechanism to draw conclusions about residues in organic products in general. AMS will verify compliance of certifying agents with this rule under the existing requirements for accreditation as discussed in the response to comments on *Reporting Requirements.*

The NOP also notes that this final rule does not amend the existing requirement that results of all analyses and tests performed under section 205.670 be made available for public access, unless the testing is part of an ongoing compliance investigation. The public may access sampling results obtained by certifying agents under the existing regulations.

Types of Residues—Changes Requested But Not Made

AMS received four comments regarding types of residues that would be considered acceptable targets for testing under the rule.

On February 2, 2011, the NOP published NOP 2611–1, Prohibited Pesticides for NOP Residue Testing, on the NOP Web site in the NOP Handbook. This document provides a list of target pesticides to certifying agents that conduct pesticide residue testing of organically produced agricultural products. This document is available at the NOP Web site at *http://www.ams.usda.gov/nop* and is discussed below under *Related Documents.* AMS has not included a specific list of pesticide residues that could be tested for in the regulations. This is intended to allow flexibility in revising the list of target pesticide residues as new pesticides enter the market. In addition, this flexibility allows the NOP to respond more quickly to observed trends in detection of residues on specific commodities.

The NOP does not intend for certifying agents to test every sample for all residues on the list of target pesticides. Instead, the list is provided as a reference for a number of pesticides which are prohibited under the NOP regulations, and that may be detected by a laboratory that conducts multi-residue analysis of agricultural products.

AMS received one comment that indicated that this list would serve as a ''cheat sheet'' for operations seeking to willfully violate the NOP regulations. AMS disagrees. The document provides a list of pesticide residues most commonly found on conventional commodities, based on data obtained from the AMS Pesticide Data Program. This list is intended to instruct certifying agents and laboratories on which residues would be the most useful targets for multi-residue analysis of agricultural products. The regulations and guidance documents do not prohibit a certifying agent from testing for other residues if the presence of a specific pesticide is suspected.

Four commenters requested clarification on testing for genetically modified organisms (GMOs). AMS does not intend for the testing conducted under section 205.670 to be limited to pesticides residues. Under the existing provisions at section 205.670, certifying agents have the flexibility to test for a range of prohibited materials and excluded methods, including, but not limited to, pesticides, hormones, antibiotics, and GMOs. AMS notes that, under section 205.671, thresholds for unavoidable residual environmental contamination are established only for pesticides residues.

Testing Methodology

The final rule maintains the current requirement under section 205.670 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* [5] 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 further described below under *Related Documents* and are available on the NOP Web site at *http://www.ams.usda.gov/nop.* AMS anticipates that these instructions will change over time in response to advances in testing methodology, analytical instrumentation, and residue detection techniques.

AMS received several comments regarding ISO 17025 accreditation of laboratories. This accreditation is mentioned in NOP 2611, Laboratory Selection Criteria for Pesticide Residue Testing, which is further discussed under *Related Documents* and is available on the NOP Web site at *http://www.ams.usda.gov/nop.* No comments requested the incorporation of ISO 17025 accreditation into the regulatory text. The comments are under consideration for future revision of the instruction documents and are not impacted by this rulemaking action.

Information Collection Burden

The proposed rule requested comments on the information collection and recordkeeping requirements required by the proposed amendments to section 205.670. Comments were specifically 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.

AMS received four comments specifically on the issue of information collection burden. Two comments indicated that they were unclear whether the estimated time is accurate and that more data and analysis was needed. One commenter suggested that the NOSB should hear from the various stakeholders in public forums before AMS considers the accuracy of the estimate. One commenter indicated that the estimate of 1.74 hours appears to be

[5] *http://www.aoac.org/.*

low, especially when foreign operations and imported products are considered, but did not offer an alternative estimate for the number of hours or data to support a different estimate.

Two comments indicated that submission of report copies, or laboratory summaries of test results, should be sufficient to demonstrate compliance with the requirement. In order to reduce the information collection burden on certifying agents, AMS has removed the requirement that test results be reported to the Administrator. AMS has retained the requirement that test results that 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 be reported to the appropriate health agency.

AMS intends to verify compliance of certifying agents with the requirements for periodic residue testing as part of the existing accreditation process, rather than by requiring submission of residue testing results. Accreditation requirements at section 205.504(b)(6) require certifying agents to have administrative policies and procedures, including procedures to be used for sampling and residue testing pursuant to § 205.670. Certifying agents are also required to submit an annual report to the Administrator on or before the anniversary date of the issuance of notification of accreditation which includes a complete and accurate update of information submitted pursuant to §§ 205.503 and 205.504. In order to verify that certifying agents are implementing this rule in advance of regularly scheduled on-site audit of certifying agents, AMS intends to require, as authorized under section 205.510(a)(3), certifying agents to submit in their next annual report a description of the measures implemented in the previous year and any measures to be implemented in the coming years to meet the requirements in this rule for periodic residue testing.

AMS received one comment that indicated that the proposed rule did not identify what would be done with the information collected. A response is provided above under the section, *Purpose of Testing—Changes Requested But Not Made.*

One comment suggested that existing testing programs, such as the AMS Pesticide Data Program, should be used to the extent possible. The commenter also suggested that AMS should partner with the FDA and various State agencies that currently conduct residue testing programs. AMS notes that testing conducted by other third-parties does not eliminate the requirement under OFPA for residue testing by certifying agents. AMS believes that requiring certifying agents to conduct residue testing from a minimum of five percent of the operations they certify is a reasonable number which ensures that all certifying agents, regardless of the number of operations they certify, are responsible for some level of regular testing at reasonable cost.

One comment indicated that certifying agents would prefer to submit test results on a quarterly basis. In this final rule, AMS has removed the requirement for reporting results of residue testing, with the exception of results that exceed certain federal regulatory requirements established by EPA or FDA. AMS notes that certifying agents should maintain the complete results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and three preceding calendar years, as required by section 205.504(b)(5)(iii).

Comments on Instruction Documents

AMS received four comments on instruction documents that the NOP has published in the NOP Handbook regarding residue testing. The instruction documents are discussed under *Related Documents.* These comments are beyond the scope of this rulemaking; however, they are under consideration for future revision of the instruction documents through a separate action.

III. Related Documents

A proposed rule was published in the **Federal Register** on April 29, 2011 (76 FR 23914). Additional documents related to this final rule include the Organic Foods Production Act (OFPA), as amended (7 U.S.C. 6501–6522) 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.[6]

The NOP has also published three instruction documents related to residue testing as part of the NOP Handbook: (1) Sampling Procedures for Residue Testing (NOP 2610), (2) Laboratory Selection Criteria for Pesticide Residue Testing (NOP 2611), and (3) Prohibited Pesticides for NOP Residue Testing (NOP 2611–1). The goal of the NOP 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 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, Prohibited Pesticides for NOP Residue Testing, is a list of pesticide residues that certifying agents 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.

On June 13, 2011, the NOP published draft guidance, NOP 5028—Responding to Results from Pesticide Residue Testing, that outlines 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. A notice on the availability of draft guidance was published in the **Federal Register** (76 FR 34180) with a 60 day comment period. The comment period closed on August 12, 2011, and comments are under review by the NOP. After review of the comments received, the NOP intends to publish the final guidance in the NOP Handbook.

Members of the public who wish to request that the agency issue, reconsider, modify, or rescind a guidance or instruction document 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.

IV. Statutory and Regulatory Authority

OFPA authorizes AMS to administer the NOP. Under the NOP, AMS oversees national standards for the production

[6] U.S. Department of Agriculture, Office of Inspector General, Audit Report 01601–03–Hy, March 2010. Available at *http://www.usda.gov/oig/webdocs/01601-03-HY.pdf.*

and handling of organically produced agricultural products.

Section 6506 of the OFPA 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 other federal tolerance requirements (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.[7] This information is available on the NOP Web site at *http://www.ams.usda.gov/nop.*

Section 6511 of the OFPA 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 6511 of the OFPA also 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 and Executive Order 13563

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This action has been determined not significant for purposes of Executive Order 12866, and therefore, has not been reviewed by the Office of Management and Budget.

Need for the Rule

NOP is authorized to implement regulations that require accredited certifying agents to conduct residue testing of organically produced agricultural products (7 U.S.C. 6511). In addition, section 6506 of the OFPA requires that the NOP include provisions for periodic residue testing by certifying agents of agricultural products produced or handled in accordance with the NOP. This final rule ensures that all certifying agents conduct a minimal level of residue testing.

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 section 205.670 of the NOP regulations. This section provides that the Secretary, State organic programs, and certifying agents 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.

AMS is issuing this final rule in response to an audit of the NOP which was conducted in March 2010 by the USDA's OIG.[8] As part of the audit, the OIG visited four certifying agents accredited by the NOP. The OIG indicated that these certifying agents noted that they considered residue testing to be required by the regulations only under certain circumstances.

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

Regulatory Objective

The primary objective of this rule is to align the NOP regulations with the requirement for residue testing of organic products under OFPA. This final rule ensures that all certifying agents conduct a minimum level of residue testing.

Alternatives Considered

Alternatives to this final rule that were considered include (1) maintaining the status quo; (2) distinguishing periodic residue testing from risk-based testing for purposes of calculating the percentage of operations to be tested annually; (3) requiring testing at an alternate level of 25% of the operations certified by a certifying agent; and (4) testing all certified operations annually.

In addition, proposals for testing at a reduced sampling rate, and testing scaled to the size of operation or to the number of certified organic products were suggested by commenters and are discussed under the above section, *Number of Samples—Changes Requested But Not Made.* AMS believes that calculating the samples based on a percentage of operations reduces the burden on the certifying agents by providing a clear and simple formula for how to comply with the regulations. AMS has not specified how certifying agents must select operations for residue testing to provide flexibility and discretion to the certifying agent in how to most efficiency and effectively implement the minimum testing required under the rule. Operation selection for residue testing may include risk factors such as number of products produced, split operations, size of the operation, split operations (i.e., operations that produce or handle both organic and nonorganic agricultural products), previous non-compliances, high-value or high-risk crops, or other criteria deemed appropriate by the certifying agent.

The first alternative of maintaining the status quo was not considered feasible due to a finding identified in an audit report issued by USDA's OIG in March 2010.[9] In response to the OIG audit, AMS conducted a review of the residue testing requirements in OFPA and the NOP regulations. AMS concluded that, under section 6506 of the OFPA, accredited certifying agents are required to conduct residue testing of organic products on a regular and reoccurring basis, as well as when there is reason to believe contamination has occurred, and that the regulations be revised as provided for in this rulemaking.

The second alternative distinguishes between periodic residue testing and risk-based testing for purposes of calculating the percentage of operations to be tested annually. This alternative was discussed in the proposed rule published April 29, 2011 (76 FR 23914). The proposed rule indicated that certifying agents would need to sample a minimum of five percent of their certified operations annually, and that such testing would be in addition to any testing conducted when there was

[7] NOP Policy Memo 11–6, Reporting Health & Safety Violations, revised October 31, 2011. Available at *http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5088951.*

[8] U.S. Department of Agriculture, Office of Inspector General, Audit Report 01601–03-Hy, March 2010. Available at *http://www.usda.gov/oig/webdocs/01601-03-HY.pdf.*

[9] U.S. Department of Agriculture, Office of Inspector General, Audit Report 01601–03-Hy, March 2010. Available at *http://www.usda.gov/oig/webdocs/01601-03-HY.pdf.*

reason to believe that the agricultural product had come into contact with a prohibited substance (e.g., investigative or complaint-driven testing). This alternative would result in higher costs to the certifying agent, since costs associated with other types of testing would be in addition to costs for periodic testing. After consideration of the comments received, AMS believes that the final rule offers more flexibility by allowing both complaint-driven and periodic residue testing to count toward the sample minimum. This final rule should also minimize the burden on certifying agents by removing the need to distinguish between different types of testing.

The third alternative of requiring certifying agents to test 25% of the operations they certify annually was also considered. This target is based a statistically based sample size based upon the rate of detection of residues in organic products sampled through the AMS Pesticide Data Program (PDP). The costs associated with this alternative and that would be imposed on certifying agents are estimated at $3.70 million annually, based on an estimated $492 in costs to the certifying agent per operation tested across 7,530 certified operations (25% of 30,118). The costs associated with testing 25% of operations are significantly higher than the costs of sampling 5% of operations under the final rule. AMS determined that using a statistically based sample size is not necessary to achieve the regulatory objective of this action and would impose unnecessary additional direct costs to certifying agents.

The fourth alternative of sampling all operations annually was also considered as an alternative to the five percent minimum requirement. The costs associated with this alternative are estimated at $14.82 million annually, based on an estimated $492 in costs per operation for 30,118 certified operations. The objectives for periodic residue testing can be met by sampling a subset of operations annually, and therefore, the additional costs that would be required to test all operations are unnecessary.

Baseline

AMS is aware that a minority of accredited certifying agents are currently conducting periodic residue testing at or above the minimum levels established by this final rule. In 2011, the NOP received pesticide residue results from 13 accredited certifying agents. Seven of the certifying agents that reported results to the NOP were based in the United States and six were based internationally. The NOP also understands that there may be additional certifying agents that are currently conducting residue testing that do not report results to the NOP, or that submit results only when a prohibited residue is detected.

The number of results reported to the NOP in 2011 represents a sampling rate of less than 1% of certified operations. The majority of results reported to the NOP in 2011 were received from certifying agents which are headquartered outside of the United States, where periodic residue testing is a requirement under international organic standards (e.g., the EU). AMS received one comment on the proposed rule from a certifying agent operating outside of the United States which indicates that it currently tests 20–25% of its certified operations.

AMS received one comment from a certifying agent that indicated that it has a history of sampling and testing products for more than 20 years. This commenter supported the five percent testing requirement as outlined in the proposed rule and did not support revising the rule to include compliance or investigative testing as part of the five percent. AMS also received one comment from a certifying agent that had increased their testing program for residues within the last two years and requested that the proposed rule be revised to allow sampling from sources other than the agricultural product (e.g. samples of soil, water, seeds) to be counted towards the minimum testing requirement. Under this final rule, sampling from a range of sources as indicated in sections 205.670(b) and (c) may be counted towards the minimum testing requirement.

Benefits to the Final Rule

This final rule clarifies a provision of OFPA and the regulations issued thereunder that requires periodic residue testing of organically produced agricultural products by accredited certifying agents. The rule ensures consistency of the regulations with OFPA by ensuring that all certifying agents are conducting residue testing of organic products on a regular reoccurring basis. 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. This action further ensures the integrity of products produced and handled under the NOP regulations.

Costs of the Final Rule

This final rule increases the amount of residue testing currently conducted by most accredited certifying agents. Direct costs to the certifying agents include the cost of sample analysis (i.e., laboratory costs), sample packaging and shipping costs, and the staff costs associated with sample collection by an inspector, review and maintenance of sample results, and reporting costs. In addition, some certifying agents indicated that the proposed action would also increase their training costs for review staff and field inspectors. AMS is unable to ascertain how certification fees may shift in response to this action because of the diversity of fee structures used by certifying agents.

The total direct cost of this action is estimated to be $741,000 annually. This estimate is based on a sampling rate of five percent of certified operations. There were an estimated 30,118 operations certified under the NOP in 2011. The five percent sampling requirement would result in sample collection from approximately 1,506 operations per year. AMS has estimated the total costs to the certifying agent at $492 per sample as detailed in Table 1.

Sample collection costs (inspector costs) are estimated at $20.36 per sample. This estimate is based on an estimated 1.0 labor hour per sample at $20.36 per hour. The hourly rate is estimated based on the mean hourly wage for agricultural inspectors as published by the Bureau of Labor Statistics.[10] This classification was selected as an occupation with similar duties and responsibilities to that of an organic inspector. Such duties and responsibilities include inspection of agricultural commodities, processing equipment, and facilities, to ensure compliance with regulations and laws governing health, quality, and safety.

Sample shipping boxes and supplies are estimated at $40 per sample, based on a costs associated with a pilot project for pesticide residue sampling conducted by the NOP in conjunction with the AMS Pesticide Data Program. Shipping costs are estimated at $25 per sample. AMS notes that these costs are an average and may vary depending on the sample type and shipping distance to laboratory.

Labor costs associated with review of sample results are estimated at $16.21 per sample. This estimate is based on an estimated 0.5 labor hour per sample at $32.42 per hour. The hourly rate is estimated based on the mean hourly wage for auditors as published by the

[10] Mean Hourly Wage for Agricultural Inspector, U.S. Department of Labor, Bureau of Labor Statistics, *Occupational Employment and Wages,* May 2010. *http://bls.gov/oes/current/oes452011.htm.*

Bureau of Labor Statistics.[11] 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.

If certifying agents receive sample results which are in excess of EPA or FDA regulatory tolerances, the certifying agent must promptly report such data to the Federal health agency (i.e., EPA or FDA) 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. This requirement is clarified in this final rule under § 205.670(g); however, this is not a new requirement under this action and additional costs not expected from this clarification. AMS expects that the majority of tested organic products will not have detectable residues of prohibited pesticide substances, based on historical data from the AMS Pesticide Data Program.

AMS believes that this rate of testing provides the benefits at reasonable cost to certifying agents. AMS recognizes that a minority of certifying agents conduct residue testing on a regular basis, and that certifying agents not currently conducting testing will need to account for these costs as a cost of doing business.

In consideration of training costs, the NOP notes that, while this action expands the amount of testing of organically produced agricultural products to include a requirement that is regular and periodic in scope, certifying agents are already required, under section 205.504(b)(6), to have procedures in place for sampling and residue testing pursuant to section 205.670. Certifying agents must already be conducting sampling and laboratory testing in instances where contamination is suspected under section 205.403(c)(3) and section 205.670(b). Therefore, AMS does not believe that additional training costs are imposed by this final rule.

TABLE 1—ESTIMATED COSTS PER SAMPLE COLLECTED

Item	Estimated cost per sample	Basis for estimate
Sample collection (inspector time)	$20.36	1 hour @ $20.36 per hour.
Sample shipping boxes and supplies	40.00	AMS Pesticide Data Program.
Shipping costs	25.00	Estimate for in-state shipping of 5 pound sample.
Laboratory costs for multi-residue analysis.	390.00	AMS Pesticide Data Program.
Review of Sample Results—Labor Costs	16.21	0.5 hour @ $32.42 per hour.
Total costs per sample	491.57	

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 final 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 section 6514(b) of the OFPA. States are also preempted under sections 6503 through 6507 of the OFPA 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 section 6507 of the OFPA, 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 section 6519 of the OFPA, this final rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601–624), the Poultry Products Inspection Act (21 U.S.C. 451–471), or the Egg Products Inspection Act (21 U.S.C. 1031–1056), 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. 301–392), nor the authority of the Administrator of the EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136–136(y)).

Section 6520 of the OFPA 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. Executive Order 13175

This final rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) 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

[11] U.S. Department of Labor, Bureau of Labor Statistics, *Occupational Employment and Wages,* May 2009. *http://www.bls.gov/oes/2009/may/oes132011.htm.*

barriers that would restrict their ability to compete in the market. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small business will not be unduly or disproportionately burdened. 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 force in the RFA, 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). AMS has also considered the economic impact of this final rule on small entities. AMS certifies that this rule would not have a significant economic impact on a substantial number of small entities.

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.[12] ERS, based upon the list of certified operations maintained by the NOP, estimated the number of certified handling operations was 3,225 in 2007.[13] AMS estimates that there were 30,118 operations certified to the NOP in 2011. USDA has 93 accredited certifying agents that provide certification services to producers and handlers under the NOP. A complete list of names and addresses of certifying agents may be found on the AMS NOP Web site at: *http://www.ams.usda.gov/nop*. AMS believes that most of these entities would be considered small entities under the criteria established by the SBA.

This final rule will affect all certifying agents by requiring that each agent conduct residue testing from a minimum of five percent of the operations they certify on an annual basis. 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 section 205.670, certifying agents have been responsible for expenses associated with preharvest and postharvest testing; this requirement also applies to expenses for periodic residue testing in this final 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., 5%, 25%, and 100% 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 in 2009) are required to collect a minimum of 105 samples. Smaller certifying agents (those certifying fewer than 30 operations) are 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 to the NOP.[14] Over half of all certifying agents certified fewer than 200 operations in 2010 and are required to sample 10 or fewer operations annually under this final rule.

At a five percent minimum testing requirement, the costs of sampling are estimated from approximately $492 to 51,106 per certifying agent per year based on the average cost of $492 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. AMS expects that the majority of results will be for samples with no prohibited residues detected, based on historical data from the AMS Pesticide Data Program.

AMS is establishing a five percent testing level in this final rule because this level is expected to be, in most cases, no more than two 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 is consistent with the amount of residue sampling already being conducted by some certifying agents. As a percentage of a certifying agent's total operating costs, this estimate was revised upward from one percent to two percent, based on public comment received in response to the proposed rule. Comments included a summary of data from an association representing certifying agents, and included data from 25 certifying agents. The range of costs was reported at between 1% and 11% of a certifying agent's overall operating budget, with one certifying agent reporting that the cost of one sample would account for 11% of their total operating costs for the year and one certifying agent reporting that the cost for three samples would account for 1% of their total operating costs. The majority of these certifying agents estimated the costs associated with this action to account for no more than 2% of their operating budget annually.

Alternatives to this final rule that were considered include (1) maintaining the status quo; (2) distinguishing periodic residue testing from risk-based testing for purposes of calculating the percentage of operations to be tested annually; (3) requiring testing at an alternate level of 25% of the operations certified by a certifying agent; and (4) testing all certified operations annually.

These are discussed in detail above under *Alternatives Considered*. AMS determined that the alternatives of a statistically based sample size (i.e., 25% of operations annually) or testing all operations annually were not practical due to the costs and the uneven burden that could be placed upon smaller certifying agents in either scenario.

The U.S. sales of organic food and beverages have grown from $3.6 billion in 1997 to nearly $21.1 billion in 2008.[15] Between 1990 and 2008, organic food sales have historically demonstrated a growth rate between 15 to 24 percent each year. In 2010, organic food sales grew 7.7%.[16]

The NOP is authorized under OFPA to implement regulations that require accredited certifying agents to conduct residue testing of organically produced agricultural products (7 U.S.C. § 6511). In addition, the OFPA requires that the NOP include provisions for periodic residue testing by certifying agents of agricultural products produced or handled in accordance with the NOP (7

[12] U.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/*.

[13] 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*.

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

[15] Dimitri, C.; Oberholtzer, L. 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/EIB58*.

[16] Organic Trade Association's *2011 Organic Industry Survey, http://www.ota.com*.

U.S.C. § 6506). This final rule ensures that all certifying agents conduct a minimal level of residue testing.

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 section 205.670 of the NOP regulations. This section provides that the Secretary, State organic programs, and certifying agents 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.

However, 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 reoccurring basis, as well as when there is reason to believe contamination has occurred.

The final rule is necessary to clarify a requirement of OFPA that certifying agents conduct periodic residue testing of organic products. The final rule will increase the amount of residue testing that certifying agents must conduct when compared to the current regulations. This final rule ensures that certifying agents are conducting a minimal level of residue testing on a regular and reoccurring basis.

The cost of testing is to be borne by the applicable certifying agent and is considered a cost of doing business.

The population that is directly impacted by this final rule is accredited certifying agents. The USDA has 93 certifying agents who provide certification services to producers and handlers under the NOP. A complete list of names and addresses of certifying agents may be found on the AMS NOP Web site at: *http://www.ams.usda.gov/nop.* AMS believes that most accredited certifying agents would be considered small entities under the criteria established by the SBA. Approximately 30,118 operations worldwide were certified to the NOP standard in 2011; certified operations may be indirectly impacted by this action as additional operations will be subject to residue testing by certifying agents.

For certifying agents who are not currently conducting residue testing at the minimum levels specified in the final rule, this action will increase costs. AMS has estimated costs at $492 per sample. At an estimated cost of $492 per sample and a sampling rate of 5% of certified operations, certifying agents would need to budget an estimated $25 per certified operation for testing costs. The total costs of residue testing are estimated at approximately $492 to $51,106 per certifying agent per year based on the average cost of $492 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 portion of the total estimated costs would be considered new or additional costs as a result of this action is not known, as a minority of certifying agents are already conducting residue testing of organic products and have budgeted for these costs under their existing fee structures. If these costs have not been previously budgeted for by the certifying agent, it will need to account for these costs as part of their cost of business.

To reduce additional inspector costs associated with sample collection, AMS has not specified which operations must be sampled annually or when the samples must be collected. This is intended to provide flexibility to the certifying agent implement a schedule for sample collection in the most efficient manner.

The final rule will increase costs for certifying agents who are not currently performing residue testing at the minimal levels specified in this rule. Some certifying agents may increase their certification fees for its clients to pay for additional costs associated with residue testing. At an estimated cost of $492 per sample and a sampling rate of 5% of certified operations, certifying agents would need to budget approximately $25 per operation for testing costs.

This final rule clarifies a provision of OFPA and the regulations issued thereunder that requires periodic residue testing of organically produced agricultural products by accredited certifying agents. The final rule expands the amount of residue testing of organically produced agricultural products by clarifying that sampling and testing are required on a regular basis. The final rule requires that certifying agents, on an annual basis, sample and conduct residue testing from a minimum of five percent of the operations that they certify.

AMS believes that the benefits of residue testing in protecting organic integrity and ensuring compliance with the regulations outweigh the estimated costs.

E. 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 was submitted to OMB at the proposed rule stage for approval of 776 hours in total burden hours to cover this new collection and recordkeeping burden of the amendments to section 205.670 of this final rule. Between the proposed rule and this final rule, there is a reduction of 350 hours based on comments received. Upon OMB's approval of this new information collection, the NOP intends to merge this collection into currently approved OMB Control Number 0581–0191.

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.

F. Civil Rights Impact Analysis

AMS has reviewed this rule in accordance with the Department Regulation 4300–4, Civil Rights Impact Analysis (CRIA), to address any major civil rights impacts the rule might have on minorities, women, and persons with disabilities. After a careful review of the rule's intent and provisions, AMS has determined that this rule has no potential for affecting certified operations or certifying agents in protected groups differently than the general population of certified operations and certifying agents. This rulemaking was initiated to clarify a regulatory requirement and enable consistent implementation and enforcement.

Protected individuals have the same opportunity to participate in the NOP as non-protected individuals. The NOP regulations prohibit discrimination by certifying agents. Specifically, section 205.501(d) of the current regulations for accreditation of certifying agents provides that ''No private or governmental entity accredited as a certifying agent under this subpart shall exclude from participation in or deny the benefits of the NOP to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status.'' Section 205.501(a)(2) requires

''certifying agents to demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart'' including the prohibition on discrimination. The granting of accreditation to certifying agents under section 205.506 requires the review of information submitted by the certifying agent and an on-site review of the certifying agent's operation. Further, if certification is denied, section 205.405(d) requires that the certifying agent notify the applicant of their right to file an appeal to the AMS Administrator in accordance with section 205.681. These regulations provide protections against discrimination, thereby permitting all handlers, regardless of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status, who voluntarily choose to adhere to the final rule and qualify, to be certified as meeting NOP requirements by an accredited certifying agent. This final rule in no way changes any of these protections against discrimination.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, 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 is 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 products 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. Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. 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)).'' Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. Such tests must be conducted by the certifying agent at the certifying agent's own expense.

(d) 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. Tests conducted under paragraphs (b) and (c) of this section will apply to the minimum percentage of operations.

(e) 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.

(f) Results of all analyses and tests performed under this section will be available for public access, unless the testing is part of an ongoing compliance investigation.

(g) 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: November 5, 2012.

David R. Shipman,

Administrator, Agricultural Marketing Service.

[FR Doc. 2012–27378 Filed 11–8–12; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2012–1194; Special Conditions No. 25–472–SC]

Special Conditions: Boeing Model 757 Series Airplanes; Seats with Non-Traditional, Large, Non-Metallic Panels

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special condition; request for comments.

SUMMARY: These special conditions are issued for the Boeing Model 757 series airplanes. These airplanes as modified by Flight Structures, Inc. will have novel or unusual design features associated with seats that include non-traditional, large, non-metallic panels that would affect survivability during a post-crash fire event. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: The effective date of these special conditions is November 5, 2012. We must receive your comments by December 24, 2012.

ADDRESSES: Send comments identified by docket number [FAA–2012–1194] using any of the following methods:

• *Federal eRegulations Portal:* Go to *http://www.regulations.gov/* and follow the online instructions for sending your comments electronically.

Mail: Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey