



United States Department of Agriculture
Office of Inspector General





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AUDIT
NUMBER: 01601-0001-Te

TO: Robert Keeney
Acting Administrator
Agricultural Marketing Service

ATTN: Frank Woods
Chief
Internal Controls and Audits Branch

FROM: Gil H. Harden
Assistant Inspector General
for Audit

SUBJECT: National Organic Program – Organic Milk

This report presents the results of the subject audit. Your written response to the official draft, dated February 16, 2012, is included in its entirety at the end of the report. Excerpts from your response and the Office of Inspector General's position are incorporated in the relevant Findings and Recommendations sections of the report. Based on your response, we were able to accept management decision on all recommendations in the report, and no further response to us is necessary.

In accordance with Departmental Regulation 1720-1, final action is required to be taken within 1 year of each management decision to prevent being listed in the Department's annual Performance and Accountability Report. Please follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer, Director, Planning and Accountability Division.

We appreciate the courtesies and cooperation extended to us by members of your staff during our audit fieldwork and subsequent discussion.

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National Organic Program – Organic Milk Report

Executive Summary

The United States Department of Agriculture’s (USDA) Agricultural Marketing Service (AMS) operates the National Organic Program (NOP) to develop, implement, and administer national standards governing the marketing of organic agricultural products and to assure consumers that such products meet consistent standards. Trade in agricultural commodities marked with USDA’s organic seal is growing rapidly—organic dairy products, in particular, have experienced average annual sales growth of over 23 percent from 2000 to 2008, and in 2010 totaled approximately \$3.9 billion in sales.¹ Given the economic importance of AMS’ oversight of organic agricultural commodities, the Office of Inspector General (OIG) initiated this audit to determine whether milk marketed as organic meets NOP’s standards.

Based on our review of NOP’s national operations, as well as our reviews of certifying agents, certified organic milk producers, processors, handlers, and transporters in Texas, we found that NOP can take steps to better ensure that consumers who choose to pay a premium for organic milk are receiving the high-quality product they wish to purchase. Specifically, NOP needs to develop guidance for certifying agents regarding detection of genetically modified (GM) material, provide greater transparency in its yearly list of USDA certified organic operations, ensure certifying agents are adequately addressing milk transporter responsibilities in organic system plans, and develop guidance for certifying agents on conducting unannounced inspections.

For example, NOP needs to conduct an analysis of GM detection methods and protocols then develop guidance for certifying agents – the organizations that verify that production and handling practices meet established organic standards – regarding detection of GM material in organic feed and forage. The Organic Foods Production Act (the Act) requires that certifying agents test organic products periodically to determine whether they contain pesticides, nonorganic residue, or natural toxicants,² but does not explicitly require certifying agents to test for GM material. NOP officials explained that the use of GM feed and forage is prohibited under the excluded methods provisions of NOP regulations and noted that the organic certification process of identity preservation, audit trails, and inspections provide verification that the feed and forage is organic and not genetically modified. NOP officials believe that it is better to allow the certifying agents to decide what they should test for, based on local agricultural conditions, proximity to conventional farming operations, and the product being inspected. However, unless certifying agents utilize GM detection to identify potential violations, there cannot be reasonable assurance that certifiers are identifying and ensuring that GM material is not contaminating organic feed and forage.

The Act also requires that the NOP provide for public access to certification documents and laboratory analyses that pertain to certification.³ In response, NOP publishes a yearly list of

¹ Organic Trade Association, “OTA’s 2011 Organic Industry Survey,” dated April 2011.

² As amended by Public Law 109-97, section 2107(a)(6), dated November 16, 2005.

³ As amended by Public Law 109-97, section 2107(a)(9), dated November 16, 2005.

USDA certified organic operations. We found, however, that NOP's list is an annual snapshot in time and, given the current annual posting schedule, does not contain the organic certificates that have been newly issued, suspended, surrendered, or revoked. As NOP officials explained, these problems occurred because the list of USDA certified organic operations is a work in progress, and needs to be revised to make it more user-friendly. Due to the current limitations of the list of certified organic operations, certifying agents and inspectors bypass NOP's list and instead rely on each other for validation of organic certificates. This should not be the case; NOP's list of USDA certified organic operations should be authoritative, transparent, and publicly accessible.

OIG also found that because the sanitation of organic milk transport tankers is not NOP certified, there is a risk that organic milk can come into contact with prohibited substances as it is being transported from the producer to the processing facility. While organic milk production and processing take place under NOP-certified organic system plans, milk transport tanker sanitation falls outside these plans and is instead governed by the Food and Drug Administration's (FDA) Grade "A" Pasteurized Milk Ordinance. We found that the pasteurized milk ordinance permits the use of FDA-approved sanitizers, not NOP-approved sanitizers. This gap in the organic milk regulatory system occurred because the dairy industry and NOP have interpreted the provision relating to the transportation of organic products as excluding milk transporters when the regulations include no such exclusion.⁴ Because milk transporters are not NOP certified, certifying agents can only validate that the milk transportation processes, including the sanitation of milk transport tankers, is included in the responsible parties' organic system plan. As a result, consumers purchasing organic milk have reduced assurance that their milk will not come into contact with prohibited substances during the transportation process.

Finally, we found that the certifying agents we interviewed are not performing unannounced inspections of organic dairy operations. While unannounced inspections are not required by regulations, they are permitted,⁵ and provide a useful control for ensuring that dairy operations are complying with the rules of organic production. Although NOP has undertaken preliminary steps to address this issue, they have not yet provided certifying agents with additional guidance for conducting unannounced inspections of certified dairy operations.

OIG concluded that NOP can take a number of steps to promote greater consumer confidence in milk labeled as "USDA Organic."

⁴ *Federal Register*, "National Organic Program," volume 65, page 80555, dated December 21, 2000.

⁵ Title 7, *Code of Federal Regulation* 5 (CFR), § 205.403(a)(2)(i) and (iii).

Recommendation Summary

Conduct an analysis of GM detection methods and protocols. Based on the analysis results, determine whether to develop and issue guidance for certifying agents on the utilization of GM detection to identify potential violations of the USDA organic regulations.

Improve NOP's list of certified organic operations so that it is up-to-date, authoritative, and comprehensive.

Develop and implement controls to ensure certifying agents have adequate oversight over the transportation of bulk raw organic milk so that NOP-prohibited substances do not come into contact with bulk raw organic milk and to ensure that the transportation process is included in the responsible parties' organic system plan.

Develop and issue guidance instructing certifying agents concerning the minimum amount and frequency of unannounced inspections of NOP-certified milk operations, and how they should select milk operations for such inspections.

Agency Response

In its written response to the official draft, dated February 16, 2012, AMS generally concurred with the audit findings and recommendations. Excerpts from the response and OIG's position have been incorporated in the relevant Findings and Recommendations sections. The written response is included in its entirety at the end of the report.

OIG Position

Based on AMS' written response, OIG accepts management decision on all 8 recommendations.

Background and Objectives

Background

The Organic Foods Production Act (the Act), adopted as part of the 1990 Farm Bill, required the U.S. Department of Agriculture (USDA) to establish national standards for the production and handling of organic products to assure consumers that agricultural products marketed as organic meet consistent, uniform standards. The Act also required the establishment of an organic certification program based on recommendations of a National Organic Standards Board.⁶ The National Organic Standards Board is appointed by the Secretary of Agriculture and is comprised of representatives from the following categories: farmer/grower, handler/processor, retailer, consumer/public interest, environmentalist, scientist, and certifying agent. During implementation, the Secretary delegated the functions of the Act to the Agricultural Marketing Service (AMS), the agency tasked with setting marketing standards.

Through regulations finalized in December 2000,⁷ USDA established the National Organic Program (NOP) as a marketing program within AMS. NOP's mission is to develop, implement, and administer national standards governing the marketing of agricultural products as organically produced, to facilitate commerce in fresh and processed food that is organically produced, and to assure consumers that such products meet consistent standards.

Based on the National Organic Standards Board's recommendations, NOP developed national organic standards, established an organic certification program, and maintains a national list of allowed and prohibited substances in organic production and handling. To ensure that producers and handlers of organic products meet applicable requirements for products that are intended to be sold, labeled, or represented as organic, NOP accredits State, private and foreign organizations or persons to become certifying agents. Certifying agents verify that production and handling practices meet established standards. As of December 31, 2010, there were 93 certifying agents (52 domestic, 41 foreign) that certify approximately 30,000 organic operations worldwide.⁸

An operation seeking certification can apply with any of these 93 certifying agents. Organic operations must maintain an organic system plan that is agreed to by the operation and the certifying agent. The organic system plan describes in detail how the operation will achieve, document, and sustain compliance with NOP regulations. Certifying agents will conduct an onsite inspection of the operation to verify that the documents submitted reflect the actual practices employed by the operation. An organic certification will be issued by the certifying agents based on the results of the onsite inspection.

Once certified, the organic operation is responsible for notifying the certifying agent of any updates to the organic system plan. The certifying agent conducts annual inspections of the organic operations and issues updated organic certificates. The organic certification continues in

⁶ As amended through Public Law 109-97, sections 2102 and 2104, dated November 16, 2005.

⁷ *Federal Register*, "National Organic Program," volume 65, page 80548, dated December 21, 2000.

⁸ AMS website, National Organic Program, List of Accredited Certifying Agents.

effect until surrendered by the organic operation or suspended or revoked by the certifying agent, the State organic program's governing State official, or the Administrator. A certified operation whose certification has been suspended may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations.

Organic dairy sales have been one of the fastest growing segments of the U.S. organic industry in recent years. Sales of organic dairy products in 2010 were approximately \$3.9 billion, up 9 percent from 2009 sales of \$3.5 billion. From 2000 to 2008, organic dairy sales grew at an average annual growth rate of over 23 percent.⁹

Like most organic products, organic milk is sold at a premium versus nonorganic milk. According to AMS reports on average milk retail prices for January to December 2010, nonorganic whole milk averaged \$3.24 per gallon while organic whole milk averaged \$7.38 per gallon.¹⁰

In March 2010, we reported in a followup audit that further improvements are needed to ensure effective oversight of the program. We found that NOP officials did not have adequate procedures for tracking the receipt, review, and disposition of complaints and any subsequent enforcement actions. We also found that the California State Organic Program was not equipped to properly enforce the requirements of NOP due to a lack of documented compliance and enforcement procedures. Despite being required to periodically conduct residue testing of organic products under the Act, NOP did not incorporate this provision into its regulations. NOP officials did not assemble a peer review panel to evaluate their accreditation procedures, did not ensure consistent oversight of organic operations by certifying agents, and did not always provide adequate guidance to the agents. Finally, NOP did not complete required onsite reviews of foreign certifying agents in a timely manner.¹¹

We found that AMS has implemented corrective actions in response to all of these findings, except for removing the Federal Advisory Committee Act requirement for the peer review panel from the NOP regulations. This action is scheduled for completion in September 2012. As an agreed-to alternative to the peer review panel, the National Institute of Standards and Technology completed the initial national voluntary conformity assessment evaluation in July 2011. NOP developed and implemented a program handbook to provide those who manage or certify organic operations with guidance and instruction that can assist them in complying with NOP regulations. NOP has also implemented a complaints database to track the full life cycle of complaints received by the program, developed a quality management system, and expanded its communications program to increase transparency and outreach. The California State Organic Program has taken corrective actions to comply with the NOP regulations, and NOP completed followup actions to confirm ongoing compliance. In addition, the NOP

⁹ Organic Trade Association, "OTA's 2011 Organic Industry Survey," dated April 2011.

¹⁰ AMS website, Marketing Orders, Retail Milk Prices, "Whole Milk Monthly Reports - 2010" and "Organic Whole Milk Monthly Reports - 2010."

¹¹ Oversight of the National Organic Program (Audit Report 01601-0003-Hy, dated March 2010).

completed audits of all foreign certifying agents and strengthened enforcement actions including utilizing civil penalties for willful violations of the USDA organic regulations.

Although AMS initiated the rule-making process to amend NOP regulations to clarify the amount and frequency of testing needed to comply with the Act in an effort to ensure consistency across all certifying agents in their testing of agricultural products certified to NOP, the proposed regulation does not incorporate the specific types of residues to be tested for (see Finding 1).

Objectives

The objective of our audit was to determine whether milk marketed as organic met AMS' NOP standards. In addition, the audit evaluated the adequacy and consistency of NOP's and certifying agents' oversight to ensure that certified organic milk operations comply with all NOP requirements.

Section 1: Oversight of NOP

Finding 1: NOP Needs to Develop Guidance on How to Utilize GM Detection to Identify Potential Violations of USDA Organic Regulations

The Organic Foods Production Act (the Act) requires that certifying agents test organic products periodically to determine whether they contain pesticides, nonorganic residue, or natural toxicants. National Organic Program (NOP) regulations do not explicitly require certifying agents to test for genetically modified (GM) material that could enter into the organic production process, such as GM feed and forage. NOP officials explained that the prohibited use of GM feed and forage is covered under the excluded methods provisions of NOP regulations. NOP officials have not specified that certifying agents test for GM feed and forage, and believe that it is better to allow the certifying agents to decide what they should test for, based on local agricultural conditions, proximity to conventional farming operations, and the product being inspected. However, unless certifying agents utilize GM detection to identify potential violations, there cannot be reasonable assurance that certifiers are identifying and ensuring that GM material is not contaminating organic feed and forage.

The Act requires that certifying agents test organic products periodically to determine whether they contain pesticides, nonorganic residue, or natural toxicants.¹² Based on a prior audit recommendation,¹³ NOP published a proposed rule that clarified that residue sampling and testing would occur on a regular basis, in addition to residue testing when there is reason to suspect contamination with a prohibited substance¹⁴ or has been produced using excluded methods.¹⁵ The proposed rule requires certifying agents, on an annual basis, to randomly sample and test agricultural products from a minimum of 5 percent of the operations they certify.¹⁶ NOP officials explained that the proposed rule for requiring certifying agents to conduct periodic residue tests has been published and that the final rule requiring periodic residue tests will be published in fiscal year 2012. The proposed rule issued allows certifiers to choose the best products to test and the appropriate types of analyses to conduct. It does not explicitly specify that certifying agents are required to test for nonorganic residue or natural toxicants, which would include GM materials in feed and forage.

In February 2011, NOP provided training to the certifying agents. We found that the residue testing training materials refer to NOP regulations for the conditions under which responsible parties should conduct testing of agricultural production. Further, the materials explain that samples should be collected for residue testing under the following conditions: when it is suspected that a prohibited substance has been applied or contamination from GM material may

¹² As amended by Public Law 109-97, section 2107(a)(6), dated November 16, 2005.

¹³ Oversight of the National Organic Program (Audit Report 01601-0003-Hy, dated March 2010).

¹⁴ "Prohibited substance" is defined as a substance the use of which in any aspect of organic production or handling is prohibited or not provided for in the Act or the regulations.

¹⁵ "Excluded methods" is defined as a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production.

¹⁶ *Federal Register*, "National Organic Program; Periodic Residue Testing," volume 76, page 23914, dated April 29, 2011.

have occurred, when pesticide drift may have occurred, to gather evidence as part of an investigation, or as part of a surveillance sampling program.

On April 15, 2011, NOP issued a policy memorandum clarifying existing regulations regarding the use of GM material in organic production and handling.¹⁷ GM feed and forage for organic dairy cattle is prohibited under the “excluded methods” provisions of NOP regulations; however, the presence of GM material in an organic product does not constitute a violation of this regulation if the producer followed the organic system plan agreed to by the producer and the certifying agent. If a test were to detect GM material in feed or forage intended for organic milk-producing dairy cattle, then the certifying agent would need to investigate to determine if the GM material found its way into the feed or forage, either due to an accident or, more seriously, due to a systemic problem with the producer’s organic system plan.

Many different varieties of GM corn, alfalfa, soybeans, and other types of agricultural products are available in the market. Given the widespread availability of GM feed and forage, it is possible that an organic milk producer might inadvertently plant seed that contains GM seed or purchase organic feed and forage that contains GM ingredients. It is also conceivable that an organic milk producer, organic seed supplier, or organic feed supplier may fraudulently substitute GM products for organic products. Dairy producers are allowed to plant nonorganic seed if organic seed is not available, so long as the nonorganic seed has not been treated with NOP-prohibited substances. At the large-scale organic dairy producers we visited, we found that the producers purchase feed for their organic livestock in bulk. The producers’ utilize organic certificates for assurance that the purchased feed is organic and does not contain GM material. Presently, however, there is little likelihood that a certifying agent would test for GM feed and forage, since the organic certification process of identity preservation, audit trails, and inspections provide verification that the feed and forage is organic and not genetically modified.

When we spoke to NOP officials about the possibility of requiring testing of feed or forage destined for organic dairy cattle for GM material, they expressed concerns about the feasibility of such testing. They stated that current rapid tests for GM organisms only detect the presence of GM material and not its level, and that the Food and Drug Administration or NOP may need to set a tolerance level before conducting any testing. They also reiterated that NOP testing is designed to certify a process as being organic.

OIG acknowledges the obstacles to regularly testing for GM feed and forage destined for organic dairy cattle, but notes that consumers expect that organic milk will not come from cattle fed a diet containing GM material. USDA’s Grain Inspection, Packers and Stockyards Administration Federal Grain Inspection Service has already established tests for detecting the presence of biotechnology-derived grains and oilseed and mycotoxins¹⁸ in grains. It administers a program to verify performance claims of qualitative rapid test kits and issues Certificates of Performance for test kits that successfully demonstrate conformance with the manufacturer’s claims. NOP should determine the feasibility of using this program to help establish residue testing for GM feed and forage.

¹⁷ NOP Policy Memo 11-13, “GMOs,” initially issued April 15, 2011, and reissued October 31, 2011.

¹⁸ Mycotoxins are byproducts of the growth of mold and can be frequently found as aflatoxin in grain. They have very real toxic effects to other plants, animals, and humans.

Because the audit was not designed to perform residue testing, OIG did not find any evidence of feed and forage contaminated with GM material. Based on our interview with one certifying agent, we found that the certifying agent had received training on residue testing but was not performing residue testing for GM material. The certifying agent stated that they conduct residue testing for pesticides, herbicides, and fertilizers on soil and plant tissue samples as part of the initial application inspections and on plant tissue samples as part of the annual inspections.

Recommendation 1

Conduct an analysis of GM detection methods and protocols. Based on the analysis results, determine whether to develop and issue guidance for certifying agents on the utilization of GM detection to identify potential violations of the USDA organic regulations.

Agency Response

AMS accepts this recommendation. Conducting an analysis of GM detection methods and protocols will be a necessary prerequisite in the development of any potential draft guidance related to GM testing. The analysis will examine the reliability and utility of various testing protocols with respect to determining the likelihood that GM was intentionally used (violation of standard) or was unavoidably present (not a violation), which is an essential distinction for enforcement purposes. AMS will complete this analysis by February 13, 2013.

OIG Position

We accept AMS' management decision on this recommendation.

Finding 2: NOP Needs to Improve List of Certified Organic Operations

NOP publishes a yearly list of USDA-certified organic operations. The list is posted as an annual snapshot, and includes a core set of identifying information about each certified operation. Given the current annual posting schedule, the list does not contain organic certificates that have been newly issued, suspended, surrendered, or revoked. The list also does not currently identify the organic industry (e.g. dairy, meat, frozen foods) in which the operation does business. As NOP officials explained, the list of certified operations is a work in progress, and needs to be revised to make it more user-friendly. Due to the current limitations of the list of certified operations, certifying agents and inspectors bypass NOP's list and instead rely on each other for validating organic certificates.

The Act requires that NOP provide for public access to documents and laboratory analyses that pertain to certification.¹⁹ Certifying agents are required to submit to NOP, by January 2nd, a list of their operations granted certification during the preceding year.²⁰ Certifying agents are also required to submit to NOP, on an ongoing basis, notifications of suspension and revocation

¹⁹ As amended by Public Law 109-97, section. 2107(a)(9), dated November 16, 2005.

²⁰ 7 CFR § 205.501(a)(15)(ii).

actions,²¹ but they are not required to submit notifications of new certifications until their annual updates.

Although NOP consolidates the lists submitted by certifying agents and annually publishes a list of certified operations on the NOP website, we found that the list could be improved to make it a more useful tool for certifying agents, inspectors, operations doing business in organic foods, and the general public.

The list of certified operations is not updated throughout the year with newly issued organic certificates or with certifying agents' notifications of surrendered, suspended, revoked, or reinstated certificates. Essentially, the list of certified operations is a snapshot in time and is out-of-date on the day it is published. Lists of suspended, revoked, and reinstated organic certificates are maintained by NOP separately and are updated monthly. Anyone accessing the list of certified operations to determine the validity of an organic certificate would be looking at outdated information and would have to contact the certifying agent directly for more accurate information. As a result, certifying agents and inspectors rely on each other to confirm that an NOP certificate is authentic and has not been surrendered, suspended, or revoked.

The list of certified operations also does not include comprehensive, consistent information concerning the organic products that a farmer may be certified to produce. NOP instructions to certifying agents for submission of the yearly list allow for the input of a primary and secondary scope²² using one of four types of scope issued (Crop, Wild Crop, Livestock, and Handling).²³ After conducting an analysis of the NOP list of certified organic operations (for the calendar year ended December 31, 2010) we found certifying agents were not following NOP's instructions for inputting primary and secondary scopes and used over 200 scope types that were not on NOP's list of allowed types. The list does not include a data entry field for the type of business or industry that the certified operation is in (e.g., dairy, meat, frozen foods). Instead, certifying agents are allowed to enter up to five products that the certified operation produces into a data entry field that is free-form text. We found that the certifying agents do not use this free-form field consistently when we attempted to use the list of certified operations to identify all domestic NOP-certified organic dairy operations. To select dairy operations to review, we relied on a certifying agent to provide us with a list of their certified organic dairy operations. Because certifying agents are not given an NOP-provided standardized spreadsheet that includes data entry validation fields, certifying agents submit their own in-house created spreadsheets or lists to NOP with data entry fields whose data are not consistent with other certifying agents' data.

When we spoke to NOP officials regarding the limitations in the design of the list of certified operations and how those limitations might hamper those doing business in organic products, as well as members of the public attempting to use the list to look up certifications of organic producers, they acknowledged that the list of certified organic operations is a work in progress, and stated their intent to make the list more user-friendly and up-to-date. In order to be

²¹ 7 CFR § 205.501(a)(15)(i).

²² Each certified operation will have at least one and up to four types of organic operations. The types of organic operations are entered in the primary and secondary scope fields in the spreadsheet. If there are more than two scopes listed on a certificate, then a separate entry is made in the spreadsheet for the additional scopes.

²³ NOP 2026 Instruction, "Submitting Annual Lists of Certified Operations," dated December 12, 2007.

transparent and publicly accessible, NOP needs to take steps to improve the list and ensure that the information it contains is comprehensive and up-to-date. This should include an indepth analysis of what should be included on the list and how it will be maintained.

Recommendation 2

Conduct an analysis of the NOP list of certified operations to develop and implement a plan to ensure the information is comprehensive and up-to-date. To meet the needs of all stakeholders, consider fields for the type of industry, the type of certificate, and the certificate status.

Agency Response

AMS concurs with this recommendation. Developing a list of certified operations that is timely, of interest to the public, and of high quality and consistency is a high priority for the program. Building on a previous NOP business process mapping project, the NOP plans to develop a Needs Assessment and Business Requirements Analysis to describe both the current and target business rules and workflow associated with updating and maintaining the list of certified operations. This Needs Assessment and Business Requirements Analysis is planned for completion by October 2012, and will guide subsequent technology design and development efforts.

OIG Position

We accept AMS' management decision on this recommendation.

Recommendation 3

Require certifying agents to timely notify NOP when they issue new certifications for inclusion on the NOP list of certified operations.

Agency Response

AMS concurs with this recommendation. The current NOP regulations require certifying agents to submit to the AMS Administrator, "A list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year." NOP Instruction 2024 "Information Submission Requirements for Certifying Agents" contains requirements for how this information is to be submitted to the NOP. Changing the frequency for this notification requirement would be a change in current requirements and processes, but may be feasible if the associated work burden for both certifiers and the NOP is managed appropriately. The Needs Assessment and Business Requirements Analysis planned for completion by October 2012 will inform how the current Instruction 2024 would need to be updated to result in an approach that achieves more timely reporting, without significant added burden from certifiers. This update to Instruction NOP 2024 will be completed by November 2012, in order to guide the 2013 submittal of information from certifiers.

OIG Position

We accept AMS' management decision on this recommendation.

Recommendation 4

Develop and implement a process to timely update the NOP list of certified operations when certification actions, such as suspensions or revocations, are reported to NOP.

Agency Response

AMS concurs with this recommendation. The current NOP regulations require certifying agents to submit to the AMS Administrator, "...notification of suspension or revocation....simultaneously with its issuance." The NOP uses this information to post a monthly update to the list of suspended and revoked operations on its website. The Needs Assessment and Business Requirements Analysis for an improved list of certified operations planned for completion by October 2012 will include a consideration for how suspensions and revocations could be reported within the comprehensive list, rather than as a separate posting, as well as business rules and processes for how it would be updated. The NOP will develop instructions and implement procedures for timely updating the list of suspensions and revocation by November 2012.

OIG Position

We accept AMS' management decision on this recommendation.

Recommendation 5

Revise the instructions given to certifying agents for submitting the annual list of certified operations, to include clarifying how to consistently and comprehensively update the primary scope, secondary scope, and products produced data fields of the list.

Agency Response

AMS concurs with this recommendation. As an initial step in this effort, in November 2011, NOP sent its data call to all certifying agents requesting their lists of 2011 certified operations. This data call introduced data structure and quality improvements in the data collection process, and NOP accreditation managers are currently working with certifying agents to review their submissions to improve data quality. Transitioning to a more real-time database of certified operations, with increased consistency in how scope and products are reported by certifying agents is a priority. As with the other recommendations here, implementing these recommendations will require a combination of internal and external business process changes and technology development. NOP will complete its Needs Assessment and Business Requirements Analysis for the overall improvement to the list of certified operations by October 2012, and will revise the instructions to certifying agents for submitting the annual list of certified operations by November 2012.

OIG Position

We accept AMS' management decision on this recommendation.

Finding 3: NOP Needs to Ensure Organic Milk is not Coming Into Contact With Prohibited Substances While Being Transported

While organic milk production and processing take place under NOP-certified organic system plans, the way that milk transport tankers are sanitized falls outside these plans. We found that the workers responsible for sanitizing organic milk transportation tankers were following a pasteurized milk ordinance which permits the use of FDA-approved sanitizers without making any provisions for using NOP-approved sanitizers when sanitizing the milk transport tankers used in transporting organic milk. This gap in the organic milk regulatory system occurred because the dairy industry and NOP have interpreted the provision relating to the transportation of organic products as excluding milk transporters, because they do not handle or process the organic product being transported. However, those regulations include no such exclusion.²⁴ Because milk transporters are not NOP certified, the certifying agents can only validate that the milk transport procedures, which include the sanitation of the milk transport tankers, are included in the responsible party's organic system plan. As a result, consumers purchasing organic milk have reduced assurance that their milk will not come into contact with NOP-prohibited substances during the transportation phase in the chain of custody.

NOP regulations require producers and handlers to develop an organic system plan that includes a description of the management practices and physical barriers established to prevent commingling of organic and nonorganic products and to prevent contact with prohibited substances.²⁵ Certifying agents are responsible for evaluating these management practices to ensure they are adequate and organic milk does not come into direct contact with prohibited substances during transportation (as is the case with a milk tanker).

Once the raw organic milk arrives at the processing plant, it is transferred to the plant's storage tanks, and the milk transportation vehicle is cleaned and sanitized in an enclosed washing facility at the plant. We found that the sanitation of milk transportation vehicles followed the FDA's Grade "A" pasteurized milk ordinance.²⁶ The pasteurized milk ordinance requires that the interior of the milk transporters be cleaned and sanitized, using FDA-approved sanitizers, after each unloading and that it must be cleaned and resanitized if not refilled within 96 hours.

²⁴ *Federal Register*, dated December 21, 2000, published the Final Rule establishing NOP and its related organic regulations and mentioned specific circumstances under which transporters would be excluded from the regulatory requirements of NOP. It referenced transporters which would not have any direct physical contact with the organic products, such as when it is bottled and shipped, after processing, to either a wholesaler or retailer. The regulation did not reference excluding transporters which, in the case of raw organic milk, *do* have direct contact with the product being transported (*Federal Register*, "National Organic Program," volume 65, page 80555, dated December 21, 2000).

²⁵ 7 CFR § 205.201(a).

²⁶ Grade "A" Pasteurized Milk Ordinance, appendix B, 2009 revision.

While the pasteurized milk ordinance sanitation procedures are appropriate for nonorganic milk hauling tankers, the procedures do not make special provisions for the sanitation of milk tankers used for hauling organic milk—the procedures do not require that only NOP-approved sanitizers be used. The pasteurized milk ordinance requires the use of 46 different sanitizing compounds, which are listed on the FDA’s list of approved sanitizers.²⁷

We found that measures such as the sanitation of organic milk transportation vehicles were not included in the milk producer’s organic system plan, and that transportation of organic milk did not conform to any specified organic process. When organic milk producers sell their milk to organic milk handlers, the handlers contract with milk hauling companies to pick up the organic milk at the producer site and deliver it to the milk processing plant. The transport companies hauling organic milk we reviewed are not NOP certified, do not maintain an organic system plan, and sanitize their milk transport tankers as if they were hauling nonorganic milk.

When we spoke to NOP officials about this gap in the organic milk production process, they stated that the sanitizers used in the sanitation of organic milk transport tankers should be listed on the national list of approved substances, and organic milk producers, processors, and handlers should address how organic milk is being transported, and how the vehicles involved are being sanitized.

OIG concluded that NOP needs to take steps to ensure that organic milk does not come into contact with prohibited substances during the transportation process, and that the responsibility for ensuring that the transportation process is organic should fall under an organic system plan.

Recommendation 6

Develop and implement controls to ensure certifying agents have adequate oversight over the transportation of bulk raw organic milk so that NOP-prohibited substances do not come into contact with bulk raw organic milk, and so that the transportation process is included in the responsible parties’ organic system plan.

Agency Response

AMS concurs with this recommendation. AMS has begun to implement measures to improve controls over all unpackaged, bulk organic products, including organic milk transported in tankers. On February 3, 2012, the NOP issued draft guidance with request for public comment that outlines the certification requirements and limitations for handlers of bulk organic products. In this draft guidance, the NOP clarifies that, according to NOP regulations, milk tankers are picking up from organic farms and delivering bulk milk to an organic processing plant, are not excluded from certification. The draft guidance proposes that uncertified transporters of unpackaged, bulk products such as organic milk must either be certified or be specifically included by direct reference in the organic system plan of the certified seller or buyer of the organic products, subject to approval and inspection by the certifying agent of the certified

²⁷ CFR § 178.1010.

operation. Either direct certification or certification by reference in the certified seller or buyer's organic system plan would enable certifying agents to verify that product has not come into contact with prohibited substances and that any sanitation measures utilized by a milk transporter comply with the NOP regulations. The NOP is currently taking public comment on this draft guidance; the NOP plans to have final guidance completed by February 2013.

OIG Position

We accept AMS' management decision on this recommendation.

Recommendation 7

During future NOP Audit, Review, and Compliance Branch audits of certifying agents, assess certifying agents' oversight of the requirement that handling operations are adequately addressing milk transportation in organic system plans, and protecting organic products from contact with prohibited substances during transportation.

Agency Response

AMS concurs with this recommendation. Once the NOP guidance on handling unpackaged bulk organic products is finalized, the NOP will conduct training with all NOP Grading and Verification Division (formerly Audit, Review, and Compliance Branch) auditors on this guidance, and incorporate it as appropriate into audit checklists. This training and the changes to the audit checklist will be dependent on the content of the final guidance, planned for completion by December 2012. Given this dependency, the NOP plans to have the training and revised checklists completed by February 2013.

OIG Position

We accept AMS' management decision on this recommendation.

Section 2: Oversight of Certifying Agents

Finding 4: Certifying Agents Are Not Performing Unannounced Inspections of Organic Dairy Operations

Although regulations allow certifying agents to perform unannounced inspections at organic milk operations, we found that the certifying agents that we interviewed were not performing these types of inspections. This occurred because, while guidance on conducting unannounced inspections is planned, NOP has not yet provided certifying agents with these resources. Increasing the use of unannounced inspections would increase confidence that organic dairy operations are complying with their organic system plan and, in particular, the new access to pasture rule.

NOP regulations do not require certifying agents to conduct unannounced inspections to determine if certificate holders, such as dairy operations, are complying with NOP regulations, but the regulations do allow such inspections.²⁸ NOP regulations also allow certifying agents to conduct unannounced inspections without an authorized representative of the operation being present during the inspection.²⁹

Based on our file reviews of three dairy producers and interviews with two certifying agents and one dairy processing plant, we found that, although the certifying agents saw the value of conducting unannounced inspections, they were not performing them. One certifying agent stated that they conduct unannounced inspections when they investigate noncompliance complaints, but we noted that no organic milk-related noncompliance complaints have been filed with that certifying agent. Both certifying agents mistakenly believed that an authorized representative of the operation being inspected must be present during an unannounced inspection.

When we spoke to NOP officials about this, they acknowledged that certifying agents are not conducting as many unannounced inspections as NOP would prefer. NOP is working on increasing the number of unannounced inspections by including discussions on them as part of their training sessions and conferences with certifying agents. We noted, however, that while NOP regulations allow unannounced inspections, the NOP handbook does not provide additional guidance to certifying agents as to how to use a risk-based approach in selecting organic operations for unannounced inspections. The NOP handbook also does not provide additional guidance to certifying agents as to the minimum amount or frequency of unannounced inspections to conduct.

On June 23, 2011, the NOP issued a memorandum to the National Organic Standards Board requesting a proposal from the board on best practices for unannounced inspections. The board's Certification, Accreditation and Compliance Committee reviewed the request and developed a proposal for NOP to issue guidance on unannounced inspections. The committee acknowledged

²⁸ 7 CFR § 205.403(a)(2)(i) and (iii).

²⁹ 7 CFR § 205.403(b)(2).

that unannounced inspections are allowed but not required by NOP regulations. Further, some certifying agents conduct many unannounced inspections while other certifying agents conduct none. The board voted on and passed the committee's proposed recommendations at its meeting on December 2, 2011.

We concluded that unannounced inspections play a critical role in ensuring compliance with NOP rules and regulations. We question whether the current practice of scheduling inspections is an effective tool in monitoring the implementation of the new "access to pasture rule," which requires that organic dairy cattle be able to spend a portion of their time in the open air.³⁰

Unannounced inspections should instead be used to help certifying agents verify that organic milk producers are complying. Moreover, performing more unannounced inspections should strengthen consumer confidence in the organic seal.

Recommendation 8

Develop and issue guidance instructing certifying agents how often they should conduct unannounced inspections of NOP-certified milk operations, and how they should select milk operations based on the risk inherent in each operation.

Agency Response

AMS concurs with this recommendation. Unannounced inspections are an important tool to monitor compliance with NOP regulations. The NOP Accreditation and International Activities Division will issue draft and then, based on public comments, final guidance on conducting unannounced inspections based on the National Organic Standards Board recommendations. The NOP plans to have final guidance completed by February 2013.

OIG Position

We accept AMS' management decision on this recommendation.

³⁰ In February 2010, a final rule was published amending the livestock and related provisions of the "access to pasture" rule and became effective June 17, 2010. Producers are now required to provide livestock with year-round access to the outdoors, recognize pasture as a crop, establish a management plan for pasture, incorporate the pasture management plan into their organic system plan, provide livestock with pasture throughout the grazing season (at least 120 days), and ensure livestock derive no less than 30 percent of their dry matter intake requirement from pasture grazed over the course of the grazing season. The final rule was to be fully implemented by June 17, 2011. (*Federal Register*, "National Organic Program; Access to Pasture (Livestock)," volume 75, page 7154, dated February 17, 2010).

Scope and Methodology

We performed our review at AMS Headquarters in Washington, D.C., and the Texas Department of Agriculture, as well as certified milk operations in Texas. We visited two certified organic milk producers and one certified organic milk processing plant, and conducted interviews with representatives of the Texas Department of Health Services, two certifying agents, one organic milk handler, two truck-washing facilities, and one milk transporter. Our review took place from October 2010 to June 2011.

To accomplish our objectives, we evaluated NOP's and the certifying agents' oversight and monitoring activities to ensure certified organic milk operations comply with all NOP requirements and that milk marketed as organic met AMS' NOP standards.

AMS Headquarters

To evaluate NOP's oversight and monitoring activities, we held discussions with AMS' NOP and Compliance and Analysis Program officials in Washington, D.C. We also held discussions with officials of the AMS Livestock and Seed Program Audit, Review, and Compliance Branch. In addition, we reviewed organic milk complaints filed with NOP and OIG, program directives and guidance to certifying agents, and policies and procedures related to program oversight and administration. We downloaded the NOP list of certified operations and analyzed the data in an effort to determine the universe and select an audit sample of dairy operations to review.

Certifying Agents

We conducted a site visit to the Texas Department of Agriculture in Austin, Texas. We selected this certifying agent because it certified three large-scale organic milk producers in the State of Texas. To evaluate the certifying agent's oversight and monitoring activities, we interviewed Texas Department of Agriculture officials and personnel and reviewed policies and procedures relating to the certifying agent's certification and oversight of organic milk operations. This included obtaining information related to the certifying agent's employee qualifications, conflict-of-interest prevention, processing of complaints, corrective actions on NOP audit findings, communication with NOP officials, certification of organic milk operations, and residue testing programs.

In addition, we contacted two other certifying agents. We contacted these two agents because one agent certified the milk processing plant related to organic milk purchased from an organic milk producer that we visited, and the other agent certified a milk handler who contracted with the milk processing plant we visited. This enabled us to follow the chain of custody from the organic milk producer to the organic milk handler. These two certifying agents were:

- Quality Assurance International, San Diego, California; and
- Oregon Tilth Certified Organic, Corvallis, Oregon.

To evaluate these certifying agents' oversight and monitoring activities, we contacted certifying agent officials and reviewed documents related to the certification and inspection of the organic milk handler and the milk processing plant.

Certified Organic Milk Producers

We visited two of the three organic milk producers certified by the Texas Department of Agriculture. These organic milk producers were selected due to Texas Department of Agriculture's previously scheduled yearly inspections for its Feed and Milk Handling certificate renewals. To evaluate the two organic milk producers' compliance with NOP regulations and standards, we interviewed the milk producers, reviewed the organic system plans, and reviewed supporting documents and computer records. In addition, we toured the operations' facilities including the feed lots, milking barns, storage areas, and grazing pastures in order to validate their written policies and procedures.

Certified Organic Milk Processor

We visited an organic milk processing plant in Austin, Texas. This plant was selected because it processed the milk purchased from one of the two organic milk producers that we visited. To evaluate the milk processing plant's compliance with NOP regulations and standards, we interviewed plant officials and reviewed the organic system plan and supporting documents. In addition, we toured the operation's facilities including the truck washing, milk container manufacturing, milk storage, and milk processing areas in order to validate the operation's written policies and procedures.

Certified Organic Milk Handler

We contacted the certifying agent for an organic milk handler and obtained the handler's organic system plan. We selected this handler because it contracted with the dairy processing plant we visited. This enabled us to follow the chain of custody for organic milk purchased from the organic milk producers. To evaluate the organic milk handler's compliance with NOP regulations and standards, we reviewed the organic milk handler's organic system plan.

Milk Transporters and Truck Washing Facilities

We contacted two milk transporters, one truck washing facility, and the Texas Department of Health Services, which issues permits and conducts inspections. We selected one milk transporter because it hauls organic milk from the milk producers we visited to the dairy processing plant we visited in Austin, Texas. This enabled us to follow the chain of custody for organic milk from the producer to the handler. Using a list of milk hauling and milk tanker cleaning service companies obtained from an internet search engine, we judgmentally selected two companies in order to validate the cleaning and sanitation procedures used for organic milk transporters.

Because organic milk transporters and washing facilities are not NOP certified, we could not evaluate their compliance with NOP regulations and standards. Instead, we evaluated the

process of cleaning and sanitizing the milk transporters in relation to NOP regulations and standards. To accomplish this objective, we interviewed milk transporters, truck washing facilities, and Texas Department of Health Services officials and discussed policies and procedures relating to milk transporter cleaning and sanitation.

Our audit was conducted in accordance with generally accepted Government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions.

Abbreviations

AMS.....	Agriculture Marketing Service
CFR.....	Code of Federal Regulations
FDA.....	Food and Drug Administration
GM.....	Genetically Modified
NOP.....	National Organic Program
OIG	Office of Inspector General
USDA.....	United States Department of Agriculture
the Act.....	The Organic Foods Production Act

**USDA'S
AGRICULTURAL MARKETING SERVICE
RESPONSE TO AUDIT REPORT**



1400 Independence Avenue, SW.
Room 3071-S, STOP 0201
Washington, DC 20250-0201

DATE: February 16, 2012

TO: Gil H. Harden
Assistant Inspector General for Audit
Office of Inspector General

FROM: Robert Keeney /s/
Acting AMS Administrator

SUBJECT: AMS' Response to OIG Audit #01601-1-Te: "National Organic Program – Organic Milk"

We have reviewed the subject audit report and agree with the recommendations. Our detailed response, including actions to be taken to address the recommendations, is attached.

If you have any questions or need further information, please contact Frank Woods, Internal Controls and Audits Branch Chief, at 202-720-8836.

Attachment

**AMS Response to Office of Inspector General (OIG) Audit:
Organic Milk AUDIT REPORT 01601-0001-Te**

Finding 1: NOP Needs to Develop Guidance on How to Utilize GM Detection to Identify Potential Violations of USDA Organic Regulations

Recommendation 1

Conduct an analysis of GM detection methods and protocols. Based on the analysis results, determine whether to develop and issue guidance for certifying agents on the utilization of GM detection to identify potential violations of the USDA organic regulations.

Agency response: AMS accepts this recommendation. Conducting an analysis of GM detection methods and protocols will be a necessary prerequisite in the development of any potential draft guidance related to GM testing. The analysis will examine the reliability and utility of various testing protocols with respect to determining the likelihood that GM was intentionally used (violation of standard) or was unavoidably present (not a violation), which is an essential distinction for enforcement purposes. AMS will plan to complete this analysis by February 2013.

Finding 2: NOP Needs to Improve the List of USDA-Certified Organic Operations

Recommendation 2

Conduct an analysis of the NOP list of certified operations to develop and implement a plan to ensure the information is comprehensive and up-to-date. To meet the needs of all stakeholders, consider fields for the type of industry, the type of certificate, and the certificate status.

Agency response: AMS concurs with this recommendation. Developing a list of certified operations that is timely, of interest to the public, and of high quality and consistency is a high priority for the program. Building on a previous NOP business process mapping project, the NOP plans to develop a Needs Assessment and Business Requirements Analysis to describe both the current and target business rules and workflow associated with updating and maintaining the list of certified operations. This Needs Assessment and Business Requirements Analysis is planned for completion by October 2012, and will guide subsequent technology design and development efforts.

Recommendation 3

Require certifying agents to timely notify NOP when they issue new certifications for inclusion on the NOP list of certified operations.

Agency response: AMS concurs with this recommendation. The current National Organic Program regulations require accredited certifying agents to submit to the AMS Administrator, “A list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year.” NOP Instruction 2024 “Information Submission Requirements for Certifying Agents” contains requirements for how this information is to be submitted to the NOP. Changing the frequency of this notification requirement would be a change in current requirements and processes, but may be feasible if the associated work burden for both certifiers and the NOP is managed appropriately. The Needs Assessment and

Business Requirements Analysis planned for completion by October 2012 will inform how the current Instruction 2024 would need to be updated to result in an approach that achieves more timely reporting, without significant added burden from certifiers. This update to NOP 2024 will be completed by November 2012, in order to guide the 2013 submittal of information from certifiers.

Recommendation 4

Develop and implement a process to timely update the NOP list of certified operations when certification actions, such as suspensions or revocations, are reported to NOP.

Agency response: AMS concurs with this recommendation. The current National Organic Program regulations require accredited certifying agents to submit to the AMS Administrator, "...notification of suspension or revocation...simultaneously with its issuance." The NOP uses this information to post a monthly update to the list of suspended and revoked operations on its website. The Needs Assessment and Business Requirements Analysis for an improved list of certified operations planned for completion by October 2012 will include a consideration of how suspensions and revocations could be reported within the comprehensive list, rather than as a separate posting, as well as the business rules and processes for how it would be updated. The NOP will develop instructions and implement procedures for timely updating the list of suspensions and revocations by November 2012.

Recommendation 5

Revise the instructions given to certifying agents for submitting the annual list of certified operations, to include clarifying how to consistently and comprehensively update the primary scope, secondary scope, and products produced data fields of the list.

Agency response: AMS concurs with these recommendations. As an initial step in this effort, in November 2011, NOP sent its data call to all certifying agents requesting their lists of 2011 certified operators. This data call introduced data structure and quality improvements into the data collection process, and NOP accreditation managers are currently working with certifying agents to review their submissions to improve data quality. Transitioning to a more real-time database of certified operations, with increased consistency in how scope and products are reported by certifying agents is a priority. As with the other recommendations here, implementing these recommendations will require a combination of internal and external business process changes and technology development. NOP will complete its Needs Assessment and Business Requirements Analysis for the overall improvement to the list of certified operations by October 2012, and will revise the instructions to certifying agents for submitting the annual list of certified operations by November 2012.

Finding 3: NOP Needs to Ensure that Organic Milk is not Coming into Contact with Prohibited Substances While Being Transported

Recommendation 6

Develop and implement controls to ensure certifying agents have adequate oversight over the transportation of bulk raw organic milk so that NOP-prohibited substances do not come into

contact with bulk raw organic milk, and so that the transportation process is included in the responsible parties' organic system plan.

Agency response: AMS concurs with this recommendation. AMS has begun to implement measures to improve controls over all unpackaged, bulk organic products, including organic milk transported in tankers. On February 3, 2012, the NOP issued draft guidance (NOP 5031) with request for public comment that outlines the certification requirements and limitations for handlers of bulk organic products. In this draft guidance, the NOP clarifies that, under § 205.101(b) of the NOP regulations, milk tankers picking up from organic farms and delivering bulk milk to an organic processing plant, are not excluded from certification. The draft guidance proposes that uncertified transporters of unpackaged, bulk products such as organic milk must either be certified or be specifically included by direct reference in the Organic System Plan (OSP) of the certified seller or buyer of the organic products, subject to approval and inspection by the certifying agent of the certified operation. Either direct certification or certification by reference in the certified seller or buyer's OSP would enable certifying agents to verify that product has not come into contact with prohibited substances and that any sanitation measures utilized by a milk transporter comply with the NOP regulations. The NOP is currently taking public comment on this draft guidance; the NOP plans to have final guidance completed by February 2013.

Recommendation 7

During future NOP Audit, Review and Compliance Branch audits of certifying agents, assess certifying agents' oversight of the requirement that handling operations are adequately addressing milk transportation in organic system plans, and protecting organic products from contact with prohibited substances during transportation.

Agency response: AMS concurs with this recommendation. Once the NOP guidance on handling unpackaged bulk organic products is finalized, the NOP will conduct training with all NOP Grading and Verification Division (GVD, formerly ARC Branch) auditors on this guidance, and incorporate it as appropriate into audit checklists. This training and the changes to the audit checklist will be dependent on the content of the final guidance, planned for completion by December 2012. Given this dependency, the NOP plans to have the training and revised checklists completed by February 2013.

Finding 4: Certifying Agents Are Not Performing Unannounced Inspections of Organic Dairy Operations

Recommendation 8

Develop and issue guidance instructing certifying agents how often they should conduct unannounced inspections of NOP-certified milk operations, and how they should select milk operations based on the risk inherent in each operation.

Agency Response: AMS concurs with this recommendation. Unannounced inspections are an important tool to monitor compliance with NOP regulations. The NOP Accreditation and International Activities Division will issue draft and then, based on public comments, final

guidance on conducting unannounced inspections based on the National Organic Standards Board recommendations. The NOP plans to have final guidance completed by February 2013.

Informational copies of this report have been distributed to:

Administrator, Agricultural Marketing Service (2)

Attn: Agency Liaison Officer

Government Accountability Office (1)

Office of Management and Budget (1)

Office of the Chief Financial Officer (1)

Attn: Director, Planning and Accountability Division

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