



United States Department of Agriculture  
Office of Inspector General





## Evaluation of USDA's Process Verified Programs

Audit Report 50601-0002-23

### What Were OIG's Objectives

OIG reviewed AMS' and FSIS' controls over USDA's PVP to evaluate the approval and proper use of the PVP shield and that the claims approved by the agencies were truthful.

### What OIG Reviewed

OIG sampled 8 of the 54 companies that represented 78 of the 189 PVP process points verified by AMS. These verified process points included "cage-free" and "tenderness guaranteed" for chickens, and "never fed animal protein" for livestock.

### What OIG Recommends

OIG recommended that AMS implement a single agency policy that documents the standards for the types of claims allowed to carry the PVP shield; provide a clear definition for the Never Ever 3 program; implement the procedures necessary to ensure a well-defined approval and denial process for PVP process points and claims; and review AMS' official listing of approved PVP certificates to ensure all process points and claims posted on its website are accurate.

## OIG reviewed how AMS verifies marketing-based claims that companies use to market their food and livestock products.

### What OIG Found

The Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) designed its Process Verified Program (PVP) to facilitate the marketing of agricultural products. Companies with AMS-approved PVP programs are able to make marketing claims associated with their products, such as age, source, feeding practices, or processing claims.

We found that AMS used a segmented process and did not clearly define which companies' claims may use the USDA name and PVP shield in marketing their products. AMS issued a PVP certificate for the "tenderness guaranteed" claim even though it was not reviewed by AMS staff. AMS also issued a PVP certificate for the "cage-free" claim, used by two poultry companies, even though it did not meet agency policy since it is a common industry practice to allow broiler chickens to grow without cages. We also found AMS developed the Never Ever 3 claim, which is important in the marketing of cattle, without sufficient evidence to ensure that feed did not include animal protein. Finally, we found that AMS did not maintain documentation to support the decisions it made to approve approximately 189 PVP process points in addition to an unknown number of denied PVP applications.

Both AMS and Food Safety and Inspection Service (FSIS) were mentioned in both a private industry complaint and a lawsuit related to the "cage-free" claim that placed the reliability of the USDA name and PVP shield at risk. Our audit did not disclose any issues with FSIS controls approving the use of the PVP name or shield on consumer products.

AMS generally agreed with our findings and we accepted management decision on all 10 recommendations.





United States Department of Agriculture  
Office of Inspector General  
Washington, D.C. 20250



DATE: December 9, 2015

AUDIT  
NUMBER: 50601-0002-23

TO: Anne L. Alonzo  
Administrator  
Agricultural Marketing Service

Alfred V. Almanza  
Administrator  
Food Safety and Inspection Service

ATTN: Frank Woods  
Chief, Internal Audits Branch  
AMS Compliance & Analysis Program

Michael Erickson  
Deputy CFO  
FSIS Office of the Chief Financial Officer

FROM: Gil H. Harden  
Assistant Inspector General for Audit

SUBJECT: Evaluation of USDA's Process Verified Programs

This report presents the results of the subject review. Your written response to the official draft report, dated November 13, 2015, 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 into the relevant sections of the report.

Based on your written response, we accept management decision for all 10 audit recommendations in the report and no further response to us is necessary. In accordance with Departmental Regulation 1720-1, final action on the management decision should be completed within 1 year of the date of the management decisions to preclude being listed in the Department's annual Performance and Accountability Report.

We appreciate the courtesies and cooperation extended to us by members of your staff during our audit fieldwork and subsequent discussions. This report contains publically available information and will be posted in its entirety to our website (<http://www.usda.gov/oig>) in the near future.



## **Table of Contents**

---

<b>Background and Objectives</b> .....	<b>1</b>
<b>Section 1: Approval, Verification, and Monitoring of PVP</b> .....	<b>5</b>
<b>Finding 1: AMS Approved PVP Process Points That Did Not Meet Agency Policy</b> .....	<b>5</b>
<b>Recommendation 1</b> .....	<b>8</b>
<b>Recommendation 2</b> .....	<b>8</b>
<b>Recommendation 3</b> .....	<b>9</b>
<b>Recommendation 4</b> .....	<b>9</b>
<b>Finding 2: AMS' Verification Procedures Did Not Ensure a PVP Claim Was Supported</b> .....	<b>10</b>
<b>Recommendation 5</b> .....	<b>12</b>
<b>Recommendation 6</b> .....	<b>12</b>
<b>Recommendation 7</b> .....	<b>13</b>
<b>Finding 3: AMS Did Not Sufficiently Document its Approval and Denial of PVP Process Points</b> .....	<b>14</b>
<b>Recommendation 8</b> .....	<b>16</b>
<b>Recommendation 9</b> .....	<b>17</b>
<b>Recommendation 10</b> .....	<b>17</b>
<b>Scope and Methodology</b> .....	<b>18</b>
<b>Abbreviations</b> .....	<b>20</b>
<b>Exhibit A: Fieldwork Sites</b> .....	<b>21</b>
<b>Agency's Response</b> .....	<b>22</b>



# Background and Objectives

---

## Background

The Department of Agriculture (USDA), through the Agricultural Marketing Act of 1946 (hereafter referred to as “the Act”) was directed to facilitate the marketing and trade of U.S. agricultural products, and allow consumers to obtain the quality product they desire.<sup>1</sup> The Act provided USDA the authority to provide services that facilitate the marketing of agricultural products from two perspectives: (1) the companies that manufacture and sell those products, and (2) the consumers who buy them. The Agricultural Marketing Service (AMS) has several user fee programs designed to facilitate the standards and marketing of agricultural products, one of which is the Process Verified Program (PVP).<sup>2</sup> PVP is a voluntary, user-fee, audit-based program that is available to companies that supply agricultural products and services (hereafter referred to as products) in wholesale or retail markets.<sup>3</sup>

Companies that participate in PVP are able to identify and make marketing claims associated with their approved process points—such as age, source, feeding practices, or other animal husbandry and processing acts.<sup>4,5</sup> AMS verifies a company’s process points and issues a PVP certificate, which allows the company to market its claim to other companies and consumers under the “USDA Process Verified” shield. Both the company’s processes and related claims are defined by the company, but we identified two exceptions, one of which included AMS’ Never Ever 3 claim, discussed in Finding 2.<sup>6</sup>

A company that decides to market its product under PVP must first apply for AMS’ verification services by describing the process and claim it plans to use in marketing its agricultural product. Since AMS’ PVP is a voluntary value-added marketing program, AMS requires that a company’s process must go beyond the requirements of regulations or a standard under which clients in the same industry generally operate.<sup>7</sup> An AMS Program (Livestock, Poultry, or Seed) Manager, or designee, reviews a company’s application and decides whether to move it forward in the review process. AMS’ review process provides that a company’s PVP application can be: (1) sent to a review committee,<sup>8</sup> (2) approved, (3) denied, or (4) returned to the client for additional information. If a review committee is used, the members vote to recommend approval

---

<sup>1</sup> Agricultural Marketing Act of 1946 (as amended), Section 203 (c), (e), and (h).

<sup>2</sup> AMS was established in 1939 to provide timely, high quality, and unbiased service to facilitate the orderly marketing and distribution of agricultural commodities while simultaneously fostering goodwill in the global marketplace.

<sup>3</sup> There are about 15 AMS staff that perform PVP audits generating approximately \$260,000 in revenue annually.

<sup>4</sup> AMS verifies these points during the animal production or food manufacturing process.

<sup>5</sup> As of May 2014, AMS verified approximately 189 different claims for program participants.

<sup>6</sup> The second exception is the “USDA Animal Protein Free Verification Program” listed in the Poultry Audit Management Program 104.0, dated March 7, 2012. We did not identify any issues with AMS’ implementation of this program.

<sup>7</sup> Grading and Verification Division (GVD) 1001A Section 4.2, dated July 12, 2013.

<sup>8</sup> According to AMS procedure GVD 1115 Section 6.1, referral to the review committee is not required, but is available as needed to facilitate the timely review of new applications, assessment results, requests for extension of scope of an approved program, submission of standards, and requests for extension of accreditation activities. The review committee was made up of AMS personnel based on availability of staff.

or denial of a company's process and claim.<sup>9</sup> The final decision to approve or deny a company's claim rests with the Deputy Director for AMS' GVD.<sup>10</sup>

However, if a company desires to use the PVP shield on a meat or poultry product sold to consumers, it must also apply to USDA's Food Safety and Inspection Service (FSIS) for label approval. FSIS' approval is needed because it has the regulatory authority to approve labels placed on meat and poultry products sold to consumers, including those with the "USDA Process Verified" shield on them. As a point of reference, FSIS approved labels for less than 5 percent of all PVP process points verified by AMS in Fiscal Year (FY) 2014. The Food and Drug Administration (FDA) is also indirectly involved with PVP, as it regulates feed mills that supply animal feed to PVP participants using AMS' Never Ever 3 claim.<sup>11</sup> AMS relies on letters of assurance from those feed mills that FDA guidelines were met. Regardless of whether a company's claim is used in the retail or wholesale market, participation in AMS' PVP does not relieve that company of meeting other regulatory requirements issued by USDA agencies or Federal departments.<sup>12</sup>

After AMS approves a company's application, it performs two types of audits. The first is an AMS desk audit,<sup>13</sup> which includes a review of a company's quality management system (QMS)<sup>14</sup> manual along with the required supporting documentation. A company's QMS is a key document in AMS' verification of the company's process, since it describes the details that support the company's process and claim. The second type of audit is an onsite audit, performed either bi-annually or annually, which AMS uses to verify whether a company's QMS controls are in place and functioning as intended.<sup>15</sup> AMS issues an audit report to the company describing any noncompliance issues and the need for corrective actions.<sup>16</sup>

If AMS' onsite audit does not find any noncompliance issues, it will issue a PVP certificate to a company that is valid for 1 year or 3 years, depending on the industry. AMS then posts each company's name, certificate number, and verified process points<sup>17</sup> on its official listing maintained on the agency's website.<sup>18</sup> FSIS will check AMS' official listing on that website before it approves a company's use of the "USDA Process Verified" label on a meat or poultry product. AMS' list includes those companies that will use the PVP shield for their own products.

---

<sup>9</sup> The decision to use the review committee is left to the AMS PVP program official's professional judgement.

<sup>10</sup> AMS officials informed us at the exit conference that the Grading and Verification Division's Deputy Director has a new title. The new title is Quality Assessment Division Director, Livestock, Poultry, and Seed Program.

<sup>11</sup> This claim allows companies to prove that they have "never ever" given their livestock any of the following three items: (1) antibiotics, (2) growth promotants, or (3) animal by-products.

<sup>12</sup> Most of the companies that are a part of the PVP program do not market to the consumer. Companies use the PVP program as third party verification for other reasons such as; verification for trade, another level of control, or customer request.

<sup>13</sup> A desk audit is performed to ensure that all program requirements, as outlined in the individual program procedure, are fully addressed. GVD 1000 Procedure Section 8, dated July 20, 2012.

<sup>14</sup> AMS requires that a QMS be established, documented, implemented, and maintained by all companies enrolled in PVP. A QMS is a system of documented controls which provides companies with the processes needed to ensure that their products consistently meet the specified requirements and related claims.

<sup>15</sup> These inspections are completed once every 3 years for seed companies.

<sup>16</sup> AMS does not maintain proprietary documentation received from companies during the audits.

<sup>17</sup> AMS officials stated that the term verified process points is listed as "claims verified" on the agency's website.

<sup>18</sup> The official PVP listing can be found at <http://www.ams.usda.gov/AMSV1.0/processverified>.

The list also includes umbrella companies that provide similar verification activities to other smaller operations, like an individual farmer or rancher, to use in marketing their animals to other companies for further processing.<sup>19</sup> Umbrella companies are private companies that audit other companies for PVP on behalf of AMS. AMS audits the umbrella companies' activities and a judgmental sample of their clients to ensure the umbrella companies are following AMS guidance.

AMS started using umbrella companies after an animal disease was found in cattle of United States origin in 2003, which triggered the closure of most export markets for U.S. beef.<sup>20</sup> AMS' Livestock Program was charged with developing a verification program, which followed the International Organization for Standardization (ISO) 9001 QMS-Requirements,<sup>21</sup> to ensure products exported to Japan were derived from animals that were 20 months of age or younger.<sup>22</sup> AMS verification procedures included checking birth records, which officials described as a monumental task.<sup>23</sup> The Livestock Program decided to enlist the assistance of a PVP-accredited umbrella company, adding the "age verified" process point to its service model.

Currently, there are approximately 2,300 farms, ranches, and feedlots approved by PVP umbrella companies through their verification activities. These umbrella companies will, for a fee, set up an individual farmer, rancher, or feedlot owner with the QMS controls and audits that clients need in order to comply with AMS' PVP regulations. While the clients of an umbrella company cannot use the PVP shield to independently market their own products, they can use their participation in the PVP program as verification that they met one or more process points (i.e., non-hormone treated cattle).<sup>24</sup> The use of the USDA name and PVP shield is not transferrable from the umbrella company to its clients for marketing purposes. The client would need to be approved and audited by AMS to use the PVP name and shield.

AMS' PVP exists for a wide range of process points and industries. AMS' PVP has evolved over the years from the performance of specific verification services, such as age or source claims for cattle on farms and feedlots, to include the auditing of QMS controls for multi-million dollar poultry operations. Although AMS' PVP is a single program, Poultry and Livestock Division officials followed different processes for oversight of PVP.<sup>25</sup> For example, the Poultry Division requires companies to be audited twice a year, while the Livestock Division requires annual audits.

AMS' PVP program is used by about 50 companies, including some with multi-million dollar sales and those that deal in international trade. Those companies have applied to AMS' PVP in order to have their processes audited and PVP certified, use that certification as a marketing tool, obtain a compliance review needed for international trade, provide a company's consumers with

---

<sup>19</sup> This list contains all certificate holdings including umbrella companies but not their clients.

<sup>20</sup> This was a fatal neurological disease of adult cattle linked to feed containing animal protein.

<sup>21</sup> ISO is an independent, non-governmental membership organization and the developer of voluntary international standards that provide specifications for products, services, and systems, to ensure quality, safety, and efficiency.

<sup>22</sup> This is the critical age when certain animal disease can form in cattle.

<sup>23</sup> AMS white paper, *Accredited Umbrella Company Involvement in the USDA Process Verified Program*, prepared in February 2015.

<sup>24</sup> The process points an umbrella company can verify are limited to those that AMS has approved for that company.

<sup>25</sup> Grain and Seed industries are regulated under the Livestock Division.

some assurances of their products' consistency, or provide assurances that they have processes that go beyond government and industry standards.

## **Objectives**

We evaluated AMS' and FSIS' controls over USDA's process verified program to determine the approval and proper use of the PVP shield and that the claims approved by the agencies, in regards to PVP, represent "truth in labeling."

FSIS has the regulatory authority to approve the use of meat and poultry labels on consumer products; however, it relies on AMS' internal controls to determine whether to allow companies to use PVP on their labels. FSIS is responsible for assuring "truth in labeling" for all claims, including those relating to PVP. Our audit did not disclose any issues with FSIS' controls approving the use of the PVP name or shield on consumer products.

## Section 1: Approval, Verification, and Monitoring of PVP

---

### Finding 1: AMS Approved PVP Process Points That Did Not Meet Agency Policy

AMS issued PVP certificates for process verified points<sup>26</sup> that were either not reviewed or not allowed by agency policy.<sup>27</sup> For example, AMS issued a PVP certificate for the “tenderness guaranteed” process point to a poultry company, even though AMS had not audited that claim in over 6 months to ensure it was still supported. These problems occurred because AMS implemented the PVP program without developing the necessary controls to ensure that the process points met program requirements and were fully supported prior to issuance of certificates. In addition, AMS had not fully developed a control structure to ensure consistency among AMS divisions in their review and approval of PVP certificates. As a result, AMS compromised the reliability of the USDA name and PVP shield, since it could not support the basis for its approval of at least one processed verified point or the recertification of the company’s use of “tenderness guaranteed.”

At the time of our audit, AMS’ policy<sup>28</sup> stated that process verified points must add value and not be the requirements of regulations or a standard under which clients in the same industry generally operate.<sup>29</sup> In addition, AMS’ procedure requires a bi-annual audit of a company’s processes that support the related marketing claims.<sup>30</sup> AMS’ policy and procedure supports, in part, some of AMS’ stated values such as (1) acting independently and objectively to create trust in its programs and services for individuals and businesses and (2) being accountable to its customers and treating everyone with fairness. However, we determined that AMS did not ensure each division consistently applies this guidance.

We assessed AMS’ review and approval process for issuing certificates for the approximately 189 different process points verified under PVP.<sup>31</sup> We found that AMS’ Poultry Division issued a PVP certificate to a poultry company approving a process point called, “tenderness guaranteed,” even though AMS had not audited that process in over 6 months to ensure it was still supported.<sup>32</sup> These bi-annual audits are intended to ensure that the company conforms to its written quality management program that supports the process point. However, while accompanying AMS officials during an onsite audit, the officials pointed out that the company

---

<sup>26</sup> AMS verifies these points during the animal production or food manufacturing process.

<sup>27</sup> FSIS requires a PVP certificate before approving a company’s request to associate the PVP shield with a claim shown on consumer packaging.

<sup>28</sup> GVD 1001A, Section 4, dated July 12, 2013.

<sup>29</sup> During our August 11, 2015 exit conference, AMS officials stated that they are in the process of better defining PVP. They also provided revised guidance, dated July 31, 2015, that would allow AMS to verify process points that are equivalent to standards under which clients in the same industry generally operate. We did not audit these new processes; therefore, we are unable to provide any conclusions on the control environment in relation to this change.

<sup>30</sup> Poultry programs require bi-annual audits. Poultry Audit Management Program 100.1, Section 7, dated March 14, 2011. Livestock programs require annual audits, GVD 1001, Section 5, dated April 16, 2004. Seed programs require audits every 3 years, GVD 1005, Section 4.1, dated January 9, 2009.

<sup>31</sup> These data are as of May 2014. We conducted onsite reviews for 77 of the 189 process points.

<sup>32</sup> AMS did not define the “tenderness guaranteed” claim or the related processes to be verified, both are defined by the company.

was not utilizing the process related to the “tenderness guaranteed” process point. We noted the process point was still on the certificate and asked the AMS auditor if he would review that process, and he said no. The auditor explained that the company still had the means and equipment to produce chicken under the “tenderness guaranteed” process point, but it had suspended the process for over 1 year due to a lack of product demand. However, the Poultry Division’s review of the auditor’s report did not identify that this process was not reviewed. As a result, AMS continued to issue the “tenderness guaranteed” PVP certificate to the company. This practice differed from what we observed with the Livestock Division, which would review a process point, regardless of whether a company was actively utilizing that process. After discussions between Office of Inspector General (OIG) and AMS officials, AMS removed the process point from its website and the company’s PVP certificate.

We also found inconsistencies in AMS’ application of its policy on whether to approve a company’s process verified point. For example, one poultry company applied for a PVP certificate for its “cage free” process point to be used on packages of broiler-type<sup>33</sup> chicken sold to consumers.<sup>34</sup> AMS’ policy stated that “process verified” points must add value to the product or service, and be substantive, verifiable, repeatable, auditable, feasible, factual, and within the scope of the Livestock, Poultry, and Seed Program. In addition, it stated that process verified points must not be requirements of regulations or the USDA PVP or a standard under which clients in the same industry generally operate.<sup>35</sup> AMS reviewed the company’s application and determined that, even though other companies in the industry do not generally cage broiler-type chickens, it would issue a PVP certificate for that process point anyway.<sup>36</sup>

This occurred because AMS’ controls over the PVP process allowed its Poultry Division to independently approve the claim without the use of an objective panel, like a review committee, which could have ensured that verifying this process point complied with AMS policy. We found that Poultry Division officials followed an undocumented process in which many of these decisions were made by either one official (e.g., the branch chief) or an informal group of senior program officials. While AMS had established a review committee made up of various program officials, it did not establish a requirement that its various divisions use that committee for all new applications. We concluded that a review committee is important, since it could include officials from different AMS divisions that may provide a more objective analysis of a company’s application. AMS’ routine use of a review committee would better ensure the consistent treatment of companies in approving their applications and prevent complaints of unfair marketing practices.

After AMS issued the PVP certificate for the “cage-free” process point, it was cited in both a written petition (complaint) from another poultry company and in a lawsuit brought forth by a

---

<sup>33</sup> These are chickens raised specifically for their meat.

<sup>34</sup> AMS did not define the claim “cage-free” or the related processes to be verified, both of which are defined by the individual companies.

<sup>35</sup> GVD 1001A, Section 4, dated July 12, 2013.

<sup>36</sup> According to current AMS officials, there is no documentation for the approval of the “cage free” process point and the officials that were involved are no longer with the agency.

private organization.<sup>37</sup> A poultry company that was not using the PVP “cage-free” claim asserted that the claim was deceptive and saw it as an attempt by another poultry company to mislead consumers. In the lawsuit, USDA PVP was cited as endorsing a company’s claim for “cage-free” and alleged that the practice of advertising chicken products as “raised cage-free” was “meaningless and misleading” because broiler chickens in the United States are virtually never raised in cages. In response to the petition, AMS and FSIS officials stated that their labels, including the “cage-free” PVP claim, are truthful and not misleading. Further, their response noted that AMS’ PVP is a voluntary, user-fee program that is open to all companies. However, their response did not address the fact that approving the PVP certificate for the “cage-free” process point for that company contradicted AMS’ documented policy of not approving a practice under which clients in the same industry generally operate. AMS officials did agree that their review and approval process was an area that could be strengthened, and they agreed that they had additional work to do on unifying the review and approval processes for PVP.

While the Act gives AMS the authority to develop marketing programs and define the rules for those programs, the agency needs to consider the impact of those changes from the companies’ and consumers’ perspectives.<sup>38</sup> AMS’ proposal to change its policy to allow “cage-free” as an approved PVP process point may help some companies to better market their products, but it does not take into account the consumers of those products. We believe AMS’ programs should inform consumers of the processes involved in the production (i.e., cage-free) of products, so they can obtain the quality product they desire. Allowing a PVP process point for an established industry practice may mislead the consumer to believe that only products with the PVP cage-free claim were raised without cages, even though nearly all poultry companies produce broiler chickens in the same manner. We conclude that AMS should provide the highest level of transparency possible regarding process points verified under the PVP.

We commend AMS for taking prompt action to rescind the “tenderness guaranteed” process point from its website and the participant’s certificate when it became aware of the issue. We recommend that AMS officials continue in their efforts to merge the various aspects of PVP and develop the necessary controls to ensure that the review and approval process is consistent for all PVP certificates. AMS should also review all existing process points and document how each one meets AMS’ standards, and immediately rescind the use of the USDA shield for PVP process points that do not meet AMS standards or schedule audits to verify that those process points are still valid. Finally, AMS needs to implement the controls and oversight necessary to ensure it does not approve PVP process points until they have passed an AMS audit. AMS’ implementation of a unified process for PVP will help ensure the long-standing reliability of the USDA name and public trust in the PVP shield.

During the exit conference, AMS provided us with its revised policy<sup>39</sup> that now allows it to approve process points for practices under which clients in the same industry generally operate. AMS implemented their revised policy subsequent to the issuance of our draft report and,

---

<sup>37</sup> FSIS was also named in that petition because it has the regulatory authority to approve the company’s use of the claim “cage free” on consumer products. However, since the company’s claim also included AMS’ PVP shield, it would need AMS’ prior approval of the “cage free” process point.

<sup>38</sup> Agricultural Marketing Act of 1946 (as amended).

<sup>39</sup> GVD 1001A, Section 4, dated July 31, 2015.

therefore, we did not consider that policy in our audit work or our conclusions reached in this finding.

## **Recommendation 1**

Develop and implement a single agency policy that not only documents that policy but also identifies the standards for the types (e.g., age, source, cage-free, etc.) of claims AMS will allow to carry the PVP shield.

### **Agency Response**

In its November 13, 2015 response, AMS officials stated that it is committed to increasing transparency of the USDA PVP. The audit services are now managed through a single set of revised audit procedures and overseen by a single organizational unit. AMS updated the Quality Assurance Division (QAD) 1001 Procedure to clarify the parameters of the USDA PVP and will update the Official Listing (Business Directory) by December 31, 2015, providing additional information on process points and linking those points to available standards and definitions.

### **OIG Position**

We accept AMS' management decision for this recommendation.

## **Recommendation 2**

Develop and implement a process that requires an independent review committee to approve or deny all new PVP process point applications.

### **Agency Response**

In its November 13, 2015 response, AMS officials stated that, at the time of the audit, a Program Committee Review procedure was in place for both the Poultry Program and the Livestock and Seed Program, but they were not yet combined, leading to each Program using different methodologies to arrive at a decision. Even though there were two documents, each Program's procedures required it to maintain records of decisions. Since Program Review Committee decisions depended on receiving the request in the form of a manual for new applicants or an expansion of scope request for existing applicants, discussions with potential and existing applicants about potential process points were not vetted using the Program Review Committee Procedure (because it was not required by the procedure).

To remedy this gap and provide greater transparency to the process point vetting process, AMS now operates the PVP under a single Program Committee Review Procedure, QAD 1115, which was updated on October 26, 2015, to incorporate a formalized decision-making process regardless of when or how an inquiry is received by the Program. AMS also tracks Program Review Committee decisions through the QAD 1115D - Form Process Point Inquiry Log, dated November 10, 2015, and uses the QAD 1115E - Decision Matrix, dated September 9, 2015, to illustrate the process for reviewing new process verified points.

## **OIG Position**

We accept AMS' management decision for this recommendation.

## **Recommendation 3**

Review all existing PVP certificates to ensure documentation exists on how each one (e.g., raised cage free) meets AMS' revised policy, and immediately rescind the use of the PVP shield for process points that do not meet that policy or schedule audits to verify that the process points are still valid.

## **Agency Response**

In its November 13, 2015 response, AMS stated that while the PVP previously allowed companies to process verify points that were only "beyond the requirements of regulations or a standard under which clients in the same industry generally operate," the QAD 1001 Procedure was updated, on October 26, 2015, to remove this requirement. AMS has reviewed the Official Listing, PVP Certificates of Conformance, and related audit reports to ensure the approved process point(s) meet the current requirements as outlined in the QAD 1001 Procedure.

## **OIG Position**

We accept AMS' management decision for this recommendation.

## **Recommendation 4**

Implement the controls and oversight necessary to ensure that AMS does not approve or renew PVP certificates until they have passed AMS audits for each year those claims are marketable.<sup>40</sup>

## **Agency Response**

In its November 13, 2015, response, AMS agreed with this recommendation. AMS stated that it has reviewed the processes used to ensure proper control and oversight of the PVP. It updated the QAD 1001 Procedure on October 26, 2015, to ensure all process points are verified during a company's annual PVP audit. Any process point not verified during a company's annual audit will be identified in the official report and subsequently removed from the Official Listing and Certificate of Conformance. Companies are audited at least annually and may be audited more frequently. AMS further stated that in October 2015, it provided additional training to all audit staff on audit procedures and management of process points when an applicant is not actively producing during an onsite audit.

## **OIG Position**

We accept AMS' management decision for this recommendation.

---

<sup>40</sup> While poultry companies are audited bi-annually, AMS issues the certificates annually.

## Finding 2: AMS' Verification Procedures Did Not Ensure a PVP Claim Was Supported

AMS approved companies to use the USDA name and PVP shield for the Never Ever 3 claim without sufficient evidence that the claim was verifiable.<sup>41</sup> At the two umbrella<sup>42</sup> companies we visited that verified the claim, we found that there were over 400 auction houses, farms, and livestock yards approved for the Never Ever 3 designation. For the 18 feedlots we visited, we found that the feedlots did not maintain adequate documentation to show that no residue of animal protein was in their feed or feed supplements.<sup>43</sup> This occurred because AMS assumed that FDA<sup>44</sup> officials would report to AMS if a feed mill, which supplies animal feed to PVP participants, did not pass FDA's inspection regarding restricted animal feed, even though AMS had not coordinated with FDA concerning that notification. AMS also did not require PVP participants that use private feed mills to provide adequate documentation to show that animal feed was totally free from animal protein. As a result, AMS weakened the reliability of its Never Ever 3 claim since it could not guarantee that animal feed was completely protein free.

AMS requires that all PVP process points be verifiable, auditable, factual, and within the scope of the Livestock, Poultry, and Seed Program.<sup>45</sup> AMS developed specific guidance for the Never Ever 3 program that prohibits feeding *any* animal proteins, animal fats, or animal by-products to animals in those programs.<sup>46</sup> The Never Ever 3 program was developed to offer an alternative to the commonly used practice of industry-providing affidavits to support the "natural" claim.<sup>47</sup> The Never Ever 3 claim allows companies to state that AMS has verified that the livestock they are selling have never been fed *any* animal proteins or animal byproducts, providing producers a marketing advantage.

Our observations at the two umbrella companies disclosed that AMS auditors accepted letters of assurance and feed labels from either the feedlot itself or a feed mill as assurance of no animal protein in the feed. However, our review of that documentation disclosed that it did not include such statements as the feed "did not include any animal protein," or any assurance that the animal feed was free of all animal protein.<sup>48</sup> We found that AMS auditors requested proof from PVP program participants that no animal protein was in the feed, but they did not assess whether that documentation was sufficient to determine that the feed did not contain any animal protein. When we asked about the validity of the letters of assurance they reviewed from feed mills,

---

<sup>41</sup> The Never Ever 3 claim is one of two claims AMS defined. Normally, a private company will define the claim and related processes.

<sup>42</sup> Umbrella companies are private companies that audit other companies for PVP on behalf of AMS.

<sup>43</sup> These were clients of the two umbrella companies. The umbrella companies are the holders of the official USDA PVP certificate.

<sup>44</sup> FDA has regulatory authority of feed mills that supply animal feeds or supplements to the livestock industry.

<sup>45</sup> AMS Policy GVD 1001A, Section 4.1, dated July 12, 2013.

<sup>46</sup> The Never Ever 3 program prohibits the use of hormones, antibiotics, and the feeding of animal proteins, animal fats, or animal by-products to animals in the program. GVD 1006, Section 5, dated April 6, 2009.

<sup>47</sup> The term "natural" may be applied only to products that contain no artificial ingredients, coloring ingredients, or chemical preservatives. Livestock companies that use that label have elected to raise their animals without the use of sub-therapeutic levels of antibiotics, growth stimulants, etc.

<sup>48</sup> At the two umbrella companies we visited as part of our fieldwork, over 400 auction houses, farms, and livestock yards are approved for the Never Ever 3 designation.

AMS auditors deferred to FDA, which regulates that industry. AMS officials admitted they have not coordinated with FDA in this area.

At 18 feedlots we visited,<sup>49</sup> we observed AMS auditors accept letters of assurance from private feed mills and the ingredient list as proof that the animal feed did not contain animal protein. We found that those letters stated that the supplement [animal feed] was manufactured within the FDA regulations and that it contained no prohibited ruminant proteins.<sup>50</sup> Although the letter specifically stated that there was no ruminant protein in the feed, it did not state whether other animal protein (i.e., non-mammalian) was included in the feed. We asked an AMS auditor if those letters were sufficient proof that there was no animal protein in the feed, and he replied that FDA regulated the feed mills and AMS does not audit the feed mills. We found that none of the feedlots we visited maintained official letters from FDA, which could have provided assurance that the feed products contained no animal proteins. We conclude that AMS should either require PVP participants to obtain documentation from the feed mill that specifically states the feed “does not contain any animal protein” or change the definition and criteria for AMS’ Never Ever 3 program.

We spoke with FDA officials about the steps they take to verify the ingredients in animal feed. An FDA official stated that, using State partners, FDA requires inspections of feed mills, every 1 to 4 years, depending on the level of risk at the particular feed mill.<sup>51</sup> FDA officials also stated that the focus of their inspections relates to preventing animal disease and determining whether animal feed contains ruminant protein. The agency does not have a policy on non-ruminant protein residues used in animal feed. However, it considers any animal protein residues present to be a contractual issue between the purchaser (i.e., PVP participant) and the feed mill.<sup>52</sup> During our discussion with FDA officials, they stated they had feed mills that did not pass inspections and the agency was required to take enforcement action for major deficiencies.<sup>53</sup> They have also had feed mills with minor issues where corrective action was required, but no enforcement action was needed. However, FDA does not have a policy or memorandum of understanding that requires them to notify AMS about deficiencies found at feed mills, and FDA did not notify AMS of any feed mills that did not pass inspection.

For AMS to be able to verify this process, it would need to ensure that there was no residue of animal proteins in the feed or feed supplements given to the animals. AMS’ current policy for the Never Ever 3 program does not allow for even unintentional contamination. However, according to AMS officials, it relied on FDA to report whenever a private feed mill, which supplies animal feed to PVP participants, did not pass FDA’s inspection. AMS officials stated that when they began the protein free programs, they decided not to audit areas that were under the jurisdiction of other agencies, such as feed mills regulated by FDA. However, we found that AMS had not implemented compensating controls to coordinate with FDA concerning feed mills and had not required FDA to notify AMS when a feed mill did not pass inspection.

---

<sup>49</sup> The feedlots were clients of PVP approved umbrella companies.

<sup>50</sup> Ruminant proteins are animal byproducts that come from animals that chew cud, such as cattle. Mammalian proteins are animal byproducts that come from mammals such as swine or cattle.

<sup>51</sup> The risk is related to how likely a particular feed mill could produce cattle feed contaminated with prohibited ruminant proteins.

<sup>52</sup> FDA prohibits ruminant proteins in animal feed destined for cattle.

<sup>53</sup> FDA official enforcement actions can include warning letters, product recalls, fines, or criminal prosecutions.

Based on our fieldwork and our conversations with the AMS auditors and FDA officials, we determined that AMS could not verify that the animals in PVP were never fed any animal proteins. We discussed our concerns about the Never Ever 3 program with AMS officials. Those officials stated that the Never Ever 3 claim was not meant to mean “never” and instead only assured that the animals were not intentionally fed animal proteins. Those same officials stated that the intent of the claim was to allow cattle producers to supply their buyers with a greater assurance for their claims than the unverified affidavit system provided. However, the AMS officials agreed they could require the PVP participants to obtain more assurance from their feed mills, and to better define the animal protein level allowed in the Never Ever 3 claim.

To ensure the reliability of the USDA name and PVP shield, AMS needs to better coordinate with FDA regarding the source of animal feed used in the Never Ever 3 program. AMS also needs to review and amend PVP program definitions to ensure the agency can fully verify and audit those process points.

During the exit conference on August 11, 2015, AMS officials stated that they are considering removing the Never Ever 3 claim from PVP and no longer plan to define process points for their clients.

## **Recommendation 5**

Provide a clear definition or rename the Never Ever 3 program and indicate what, if any, protein levels are acceptable under those PVP certificates.

## **Agency Response**

In its November 13, 2015, response, AMS stated that it acknowledges there were shortcomings in the Never Ever 3 Program. Accordingly, AMS stated that it has contacted Never Ever 3 Program participants and will either allow them to create their own program requirements or remove this process point from their PVP approval. AMS further stated that this will allow program participants to continue to make the three objective claims that underpinned the Never Ever 3 Program, but AMS will no longer offer a standalone AMS Never Ever 3 Program, effective November 13, 2015, underpinned by potentially misleading supply chain prerequisites.

## **OIG Position**

We accept AMS’ management decision for this recommendation.

## **Recommendation 6**

Review and amend the verification requirements for the Never Ever 3 claim to ensure these process points are verifiable.

## **Agency Response**

In its November 13, 2015 response, AMS agreed with this recommendation and referred to its response for recommendation 5, which stated that AMS has contacted Never Ever 3 Program participants and will either allow them to create their own program requirements or remove this process point from their PVP approval. AMS further stated that this will allow program participants to continue to make the three objective claims that underpinned the Never Ever 3 Program, but AMS will no longer offer a standalone AMS Never Ever 3 Program, effective November 13, 2015, underpinned by potentially misleading supply chain prerequisites. AMS also stated that for those clients who wish to utilize a Never Ever 3 type claim, AMS will inform them of the need to consult with FSIS for prior label approval.

## **OIG Position**

We accept AMS' management decision for this recommendation.

## **Recommendation 7**

Coordinate with FDA to routinely obtain a current listing of feed providers that have not passed FDA inspections. Provide this list to AMS auditors and umbrella companies to be used during their annual reviews to ensure PVP participants are not using feed providers that are violating FDA requirements.

## **Agency Response**

In its November 13, 2015, response, AMS agreed with this recommendation and referred to its response for recommendation 5, which stated that AMS has contacted Never Ever 3 Program participants and will either allow them to create their own program requirements or remove this process point from their PVP approval. AMS further stated that this will allow program participants to continue to make the three objective claims that underpinned the Never Ever 3 Program, but AMS will no longer offer a standalone AMS Never Ever 3 Program, effective November 13, 2015, underpinned by potentially misleading supply chain prerequisites. AMS also stated that beyond the Never Ever 3 program, it will ensure that for any PVP process point that relies upon FDA inspections to determine compliance, AMS will verify that those FDA inspections have taken place and the facilities are in good standing.

## **OIG Position**

We accept AMS' management decision for this recommendation.

### **Finding 3: AMS Did Not Sufficiently Document its Approval and Denial of PVP Process Points**

AMS lacked documentation to support the decisions it made to approve approximately 189 PVP process points and an unknown number of denied PVP process point applications.<sup>54</sup> In addition, AMS' official website documenting its list of approved PVP process points was not accurate, since we found that 3 of the 80 certificates with the approved PVP process points did not match the list shown on the website.<sup>55</sup> These issues occurred because AMS relied on division staff to make the decision to approve or deny a company's PVP application without implementing sufficient oversight or documentation requirements. AMS also relied on its audit staff to monitor the website listing without requiring them to do so, or to establish the procedures and oversight necessary to ensure an accurate listing of PVP process points. As a result, we were unable to substantiate whether AMS treated all requests fairly and equitably in order to facilitate the competitive marketing of agricultural products. In addition, AMS provided inaccurate information on its public website that FSIS uses as one of its sources for making decisions on approving the labeling of PVP shielded products to consumers.

The Office of Management and Budget (OMB) requires agency management to develop and maintain a well-defined documentation process. That process should contain an audit trail, verifiable results, and specific document retention periods so that someone not connected with the procedures can understand the assessment process.<sup>56</sup> In addition, OMB issued guidelines that directed Government agencies to develop information resources management procedures for reviewing and substantiating the quality of information before it is disseminated.<sup>57</sup> While AMS retained some documentation on approved PVP process points, it was neither organized in a manner that allowed us to understand the agency's assessment process nor verified for accuracy before publishing that information on the internet.

#### **Approval and Denial of PVP Process Points**

AMS program officials provided us with a list, in May 2014, which identified approximately 189 different approved PVP process points.<sup>58</sup> At that time, program officials also explained their process in reviewing and approving a company's PVP process point (e.g., "all vegetarian diet," etc.), and provided a copy of its guidance, dated July 2012. According to that guidance, a company must submit an application to request AMS' services to verify a certain process the company plans to use in marketing its agricultural product.<sup>59</sup> An AMS PVP manager reviews a company's application and decides whether or not the application should be moved forward to

---

<sup>54</sup> Our totals are approximate because, in order to avoid double counting AMS' list of companies' process points, we eliminated the duplicate process points that contained similar wording.

<sup>55</sup> PVP certificates may list multiple claims/process points.

<sup>56</sup> OMB Circular No. A-123(I)(A), Management's Responsibility for Internal Control, revised December 21, 2004.

<sup>57</sup> OMB Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, Federal Register / Vol. 67, No. 36 /, Page 8453, dated February 22, 2002.

<sup>58</sup> Similar claims were not included as part of this count.

<sup>59</sup> GVD 1000 Procedure, Section 7, dated July 20, 2012.

the review committee;<sup>60</sup> be assigned for a desk audit; or be approved, denied, or returned to the client for additional information. When we requested documentation to support the AMS officials' decision process or reasoning for approving the approximately 189 PVP process points, AMS officials stated that they do not always document the decision making process for approving a PVP process point. AMS officials said they do not require committee review for process points that have already been approved for another company. These officials stated that meeting minutes are kept for each review committee meeting held, but the decision process or information on how the application would fit the parameters of the PVP program is not documented.<sup>61</sup> We found that, while AMS' PVP policy did mention the review committee, it did not require that the committee review all applications.

We reviewed the minutes from all nine committee meetings held from January 2012 through August 2014, and found that those minutes did not document the reasons for approving or denying a company's proposed PVP process point. AMS did not require all 189 process points to be reviewed and approved by the committee and we were unable to determine which process points were discussed during those meetings. In addition, we found that the meeting minutes did not document how a particular process point would be approved, since it did not explain how it would meet PVP program requirements (such as the process point must be auditable, verifiable, etc.).<sup>62</sup> We also attempted to review the last 3 years of denied applications; however, AMS officials stated that they did not have a file system that accurately listed all PVP applications it denied. AMS officials explained that, even though program officials can process a company's application, the final decision to approve or deny an application is made by AMS' Grading and Verification Division's Deputy Director.<sup>63</sup> However, the deputy director did not maintain documentation of his decisions.

### **Publishing PVP Process Point Information**

AMS issues a certificate that lists every approved process point and, as of September 30, 2014, the agency had issued 80 PVP certificates to 51 different companies.<sup>64</sup> AMS also published these verified process points on its website under the title of "Official Listing of Approved USDA Process Verified Programs." In September 2014, we compared the process points listed on those 80 PVP certificates to AMS' official listing on its website and determined that 3 of those 80 did not match what was listed on the website. For two of those three certificates, which related to an export verification process point, we found that the website did not list those process points. However, we found that AMS had approved those companies' process points in November 2013, but had not updated the website with the latest information. For the third certificate, a company was given one certificate for two locations that verified four process

---

<sup>60</sup> Reviews are held as needed (not required) to facilitate the timely review of new applications, assessment results, requests for extension of scope of an approved program, submission of standards, and requests for extension of GVD accreditation activities.

<sup>61</sup> This committee includes AMS personnel from its grading and verification division, depending on availability of staff. The committee conducts a review of a client's application to determine if the claim meets PVP requirements.

<sup>62</sup> GVD 1001A Policy, Section 4.1, dated July 12, 2013.

<sup>63</sup> AMS officials informed us at the exit conference that the Grading and Verification Division's Deputy Director is now the Livestock, Poultry, and Seed Program, Quality Assessment Division Director.

<sup>64</sup> The number of companies participating in the program fluctuated from 54 to 51 between May 2014 and September 2014.

points. However, only one of those locations was listed on the website as being verified for all the process points; the other location was only shown as verified for two of the four process points. This certificate was issued in June of 2014, but, again, AMS did not update its website with that information.

We found that the information on AMS' website was available to the public and used by another Federal agency. For example, FSIS is the only Federal agency with the authority to approve a food label on a consumer product. In discussions with FSIS officials, we found that they use AMS' website to verify whether a company has a PVP-approved process point before they will approve the use of a label with that same PVP claim stated on it. While FSIS officials stated that they generally use AMS' website, they would also contact AMS if they had questions about an approved process point.

We found that AMS' process to maintain its official listing of approved PVP certificates was undocumented. AMS officials explained that, after a PVP audit report (as the result of either a desk or onsite audit) is completed and a certificate is issued to the company, AMS would then update the official listing on its website. Those officials also stated that the PVP Program Manager reviews the accuracy of the official listing; however, officials stated that this is not a documented requirement. AMS officials also stated that companies would call AMS if they found incorrect information on the website.

AMS' decisions on the approval or denial of PVP process points can have a major effect on a company's marketing of agricultural products. As noted in Finding 1, FSIS and AMS were cited in a private company's petition alleging unfair marketing practices, and AMS' PVP program was mentioned in a private organization's lawsuit citing deceptive claims on consumer packaging. If AMS was called to defend its decisions about approval or denial of a PVP claim, it would not always have the documentation to substantiate its fair and equitable treatment of all approved and denied PVP process points. In addition, AMS' lack of procedures for ensuring accurate information on its website could affect FSIS' decision on whether to approve a company's label containing a PVP claim. Overall, AMS needs to establish documented procedures and oversight to ensure it can support its decisions and be able to provide accurate information to other agencies and the public on both approved and denied PVP process points.

## **Recommendation 8**

Develop and implement the procedures and oversight necessary to ensure a well-defined documentation process for approving and denying PVP applications. Those procedures should require, at a minimum, that AMS document all PVP requests, the actions taken on those requests, the reasons for those actions, and all decisions made.

## **Agency Response**

In its November 13, 2015 response, AMS officials agreed with this recommendation and referred to their response to Recommendation 2. AMS also stated that it updated the QAD 1115 Procedure - Program Review Committee on October 26, 2015, to incorporate a formalized decision making process. AMS also developed a QAD 1115D - Form Process Point Inquiry Log, dated November 10, 2015, to track Program Review Committee decisions and developed

the QAD 1115E - Decision Matrix, dated September 9, 2015, to illustrate the process of approving or denying new process verified points.

### **OIG Position**

We accept AMS' management decision for this recommendation.

### **Recommendation 9**

Develop and implement the procedures and oversight necessary to ensure the AMS listing of approved PVP process points are reviewed and amended as needed to ensure the list is accurate, complete, and supported.

### **Agency Response**

In its November 13, 2015 response, AMS agreed with the recommendation and stated that its QAD 1000 Procedure – Quality Systems Verification Programs General Policies and Procedures addresses this requirement. AMS also stated that in this case, however, it contends that the finding was an isolated administrative error and can be addressed through further training. AMS further stated that it addressed this issue via training with all auditors involved in the PVP in early October, 2015.

### **OIG Position**

We accept AMS' management decision for this recommendation.

### **Recommendation 10**

Develop and implement continuous monitoring procedures to ensure all process points posted on its website are supported, and remove and add process points as needed to ensure a complete and accurate listing.

### **Agency Response**

In its November 13, 2015 response, AMS agreed with the recommendation and stated that it conducted a root cause analysis and determined that this was an isolated incident. AMS further stated that revisions to existing procedures and additional training should prevent this incident from reoccurring. In a subsequent correspondence, dated November 20, 2015, AMS officials stated that QAD 1000 was updated to reflect the monitoring procedures. In addition, AMS officials stated they addressed this issue via training, held October 5-9, 2015, with all auditors involved with PVP.

### **OIG Position**

We accept AMS' management decision for this recommendation.

## Scope and Methodology

---

Our audit reviewed AMS' controls over USDA's PVP to ensure the approval and proper use of the USDA name and PVP shield during FYs 2012 through 2014. We performed our audit work at the AMS and FSIS national offices in Washington, D.C. We included FSIS as part of the scope because that agency has the regulatory authority to approve a label that is placed on meat and poultry products sold to consumers. FSIS bases its decisions on consumer labels with the PVP statement of "USDA Process Verified" on AMS approval of a company for the PVP. Therefore, we limited our review to FSIS' operations at its Labeling and Program Delivery Division, located in Washington, D.C.<sup>65</sup> For our review of AMS' PVP, we also performed work at eight different private companies in seven States—Colorado, Georgia, Illinois, Nebraska, North Carolina, Pennsylvania, and South Dakota. We performed our audit fieldwork from May 2014 through May 2015.

On May 6, 2014, AMS officials provided us with their "Official Listing of Approved Process Verified Programs," divided into four categories: Livestock, Poultry, Seed, and Grain. Combined, there were 54 companies, with approximately 189 different PVP process points verified by AMS.<sup>66</sup> Livestock companies represented the largest number of process points with 35 companies using 167 process points; poultry had 4 companies using 10 process points; seed had 14 companies using 4 process points; and grain had 1 company using 8 process points. We selected a non-statistical sample of seven private companies that participated in the PVP program from AMS' official listing. We selected those companies to ensure our sample included at least one company from each of the four categories of PVP. In addition to the four categories, we also based our selection on the following factors: (1) high number of separate PVP process points; (2) companies that used the PVP label on final products to consumers; (3) process points that could be considered subjective in nature; and (4) if AMS had an audit scheduled during our planned site visits.

During our site visit to a feedlot reviewed by one umbrella company, we identified issues relating to the controls that prevent cattle being treated with hormones or fed antibiotics. Since this could affect international trade, we decided to add one more umbrella company and additional feedlots to our review. We selected a non-statistical sample of 18 more feedlots to determine whether those issues were identified at additional feedlots. We selected those feedlots based on whether they used the "Non Hormone Treated Cattle" and Never Ever 3 PVP claims.

In total, we sampled 8 of the 54 (15 percent) companies that represented 78 of the approximately 189 (41 percent) process points.<sup>67</sup> Of the 8 companies we selected, 4 were livestock using 60 process points, 2 were poultry using 8 process points, 1 was a seed company using 2 process points, and 1 was a grain company using 8 process points.

---

<sup>65</sup> We performed a limited review of FSIS' operations because FSIS-approved labels related to less than 5 percent of all PVP process points verified by AMS in FY 2014.

<sup>66</sup> Our totals are approximate because, in order to avoid double counting AMS' list of companies' process points, we eliminated the duplicate process points that contained similar wording.

<sup>67</sup> While we selected 78 process points to review, we were unable to review the supporting documentation maintained onsite for one of the process points for one pork company due to the ongoing Porcine Epidemic Diarrhea outbreak.

We did not rely upon an information technology (IT) system for identifying the universe or our non-statistical sample of companies and process points. Therefore, we did not perform any additional testing to evaluate the agency's IT system used and make no representation as to the adequacy of the agency's IT systems or reports.

To accomplish our audit objectives we:

- Reviewed applicable laws, Federal regulations, OMB guidance, and agencies' policies and procedures pertaining to the internal controls and processes governing PVP labels and process points.
- Interviewed AMS officials from its national office on their controls to review and approve a company's use of PVP process points.
- Interviewed FSIS officials at its Labeling and Program Delivery Division to determine their review and approval procedures for labels placed on meat and poultry products sold to consumers.
- Interviewed AMS Livestock, Poultry, Seed, and Grain supervisors and program officials on their process to oversee the PVP program.
- Interviewed AMS audit staff and evaluated their procedures for conducting audits, issuing reports, and following up on corrective actions.
- Evaluated the effectiveness of AMS' suspension and removal process when a company does not meet PVP requirements.
- Interviewed participants (from various AMS program divisions) that were part of Program Review Committee meetings to evaluate their process to ensure that all process verified points added value to the product or service under a PVP claim.
- Evaluated the adequacy of AMS' coordination with other agencies (i.e., FSIS and FDA) in regards to the PVP claims using the USDA name and PVP shield and whether they represented truth in labeling.
- Evaluated the effectiveness of the field staff's implementation of AMS' policies, procedures, and instructions related to a company's claims utilizing the USDA name and PVP shield.
- Evaluated AMS' documentation process relating to PVP process point approvals and denials.<sup>68</sup>

We conducted this audit 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 based on our audit objectives.

---

<sup>68</sup> While AMS retained some documentation on approved PVP process points, it was not organized in a manner that allowed us to gain an understanding of the agency's assessment process. However, we did not consider this a scope limitation because we were able to report that their approval process was not adequately supported and documented.

## Abbreviations

---

AMS	Agricultural Marketing Service
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
FY	fiscal year
GVD	Grading and Verification Division
ISO	International Organization for Standardization
IT	information technology
OMB	Office of Management and Budget
PVP	Process Verified Program
QMS	Quality Management System
USDA	The Department of Agriculture

## Exhibit A: Fieldwork Sites

---

Exhibit A below lists the sites visited by company, State, number of locations visited, and number of process points reviewed.

Company	State Visited	Number of Locations Visited	Number of Process Points Reviewed <sup>69</sup>
1	Illinois	2	8
2	Illinois	1	2
3	Pennsylvania	1	7
4	Colorado and Nebraska	14	27
5	Georgia	8	12
6	Nebraska and South Dakota	9	9
7	Illinois	1	8
8	North Carolina	7	4
TOTALS		43	77

---

<sup>69</sup> While we selected 78 process points to review, we were unable to review the supporting documentation maintained onsite for one of the process points for one company due to the ongoing Porcine Epidemic Diarrhea outbreak.



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



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

**DATE:** November 13, 2015

**TO:** Steve Rickrode  
Deputy Assistant Inspector General for Audit  
Office of the Inspector General

**FROM:** Anne Alonzo /s/  
Administrator

**SUBJECT:** Office of the Inspector General (OIG) Official Draft Report – Evaluation of  
USDA’s Process Verified Programs

The Agricultural Marketing Service (AMS) appreciates the thoughtfulness and effort employed in assessing the USDA Process Verified Program (PVP). We have reviewed the Official Draft report and have general comments, background information, and responses to each of the recommendations.

#### **AMS’s General Comments**

AMS is pleased to note that the report did not identify any significant deficiencies of the program itself. Rather, it identified recommendations related to processes and procedures, which are easily rectified. In fact, AMS has addressed 9 of the 10 recommendations, and is working diligently to address the remaining recommendation.

As is needed with any longstanding program, AMS recently revisited PVP processes and operating procedures and made improvements to strengthen the program. In response to the audit – and to ensure consistency, increase efficiency, and protect the integrity of the PVP – AMS moved the program to a single management structure that works across commodity programs. By merging procedures that were previously housed in separate AMS program areas into a uniform management structure that deals with all commodities, AMS has been able to address many of the audit findings. As described in this response, the recent changes in the USDA PVP build on the program’s strong tradition of helping agricultural suppliers differentiate their products in an increasingly competitive marketplace, and they provide the public with even greater transparency and confidence in the “USDA Process Verified” shield.

This response also addresses various minor inaccurate statements in the narrative and the findings.

## **PVP Background and Purpose**

The Agricultural Marketing Act of 1946 (hereafter referred to as “the Act”) directed the Department of Agriculture (USDA) to facilitate the marketing of U.S. agricultural products in a way that allowed consumers to obtain the quality products that they wanted. From the Act’s inception, AMS provided services – such as meat grading – by directly certifying products in the facilities where they were manufactured. AMS employees could directly examine meat attributes such as cutting specification or color to determine if the meat met a standard that would allow it to be stamped and marketed as “USDA Certified” or “USDA Accepted as Specified.”

Over time, industry stakeholders asked AMS to verify attributes related to how livestock were raised before they arrived at the processing facilities where AMS employees were stationed. Many raising attributes, such as livestock feeding regimen, were impossible to certify by simply examining the animal or the resulting meat cuts at the processing facility. To accommodate these requests, AMS started auditing livestock production facilities as part of its third-party verification services, enabling resulting meat cuts to be marketed with an AMS third-party verification.

In 2001, AMS developed the Quality Systems Verification Program (QSVP), which offers a suite of voluntary, audit-based verification services. QSVPs are designed to provide companies with confidence that farms or ranches are adhering to process points – such as livestock feeding regimens – even when AMS agents are not at the facility, and before the livestock are processed and enter commerce as meat products with associated marketing claims. The PVP is one example of a QSVP.

The PVP provides agricultural businesses with third-party, objective verification of a particular standard or process point. In turn, companies with approved USDA PVPs are allowed to make marketing claims on packages of products – including claims related to food raising and processing statements – and market themselves as “USDA Process Verified” with use of the “USDA Process Verified” shield and term. The PVP thus assures buyers that claims associated with the “USDA Process Verified” shield are subject to rigorous, on-site, third-party audits conducted by independent Federal employees.

Process verification based on an audit of a company’s quality management system is distinct from the testing and certification of a product to a specific standard. Only the latter can guarantee to the consumer that the product meets the requirements, such as no added antibiotics. Process verification, however, can provide confidence that the company’s management supports such claims. The PVP is unique in that it requires USDA to conduct the audit, allows the company to market USDA’s verification, and ensures a high level of transparency about the process point being verified.

Under the PVP, companies describe the specific process points they wish to have verified by AMS through routine audits. In contrast, other QSVP services offered by AMS, such as the Quality System Assessment (QSA) programs, can have program requirements outlined by AMS or another party and do not require the same level of documented quality management by

participating firms. For example, most of AMS' QSA audit activities fall under the category of Export Verification activities, which are based on government-to-government agreements with international trading partners regarding specific foreign market requirements (e.g., meat must be harvested from cattle less than 30 months of age). With PVPs, companies outline their own specific requirements, demonstrate their commitment to documented quality management, and AMS ensures their adherence to those requirements via routine on-site audits.

### **AMS Processes Related to PVPs**

The OIG report asserts that AMS used a "segmented process" in relation to which process points (referred to as "claims" in the report) are approved as part of a PVP program. OIG also stated that AMS maintained insufficient documentation regarding the approval or disapproval of such points. AMS disagrees with this characterization. While AMS concurs that the procedures governing the PVP needed clarification – and the agency already made such changes – the PVP has always had clearly defined procedures. These procedures outline the specific requirements that a company must address in its quality management system when applying for a USDA PVP, how AMS handles those applications once submitted (e.g., audit process, providing publicly available information about approved process points on the website), and how a company can use the PVP shield in its marketing.

OIG's summary findings also assert that AMS lacked documentation on decisions regarding the approval of 189 PVP process points and denied applications for service. AMS believes this is a misleading statement. Historically, different program areas had their own procedures for considering new process points, but AMS documentation (e.g., procedure regarding the use and conduct of the review committee and committee meeting records) demonstrates that AMS had a process to determine whether or not to approve new process points **and** that AMS had a well-defined process for approving process points (e.g., audit reports). Documents provided to OIG clearly described the conditions that warranted a formal committee review (e.g., a process point that was dissimilar to a process point currently being verified under another program, and program denials, suspensions, and withdrawals). AMS feels it would be a poor use of resources to convene a review committee each time a company submits an application for a process point that AMS already verifies for a different company. In other words, convening such a committee each time a company submitted a previously-approved process point related to age or source verification would dramatically increase costs to customers without adding value. AMS agrees that the process regarding *denied* applications could be improved, as outlined in response to Recommendation 8, and has already implemented a process to document such items.

AMS also has a well-defined procedure when it comes to applying for and maintaining an approved PVP. Each company is required to submit for review an application for service, a cover letter that clearly defines the scope of the program, and a complete copy of the company's documented program. The company's program is evaluated by a program review committee, and, if approved, is assigned to an auditor for a desk audit. If all quality management system and process requirements are met, the auditor schedules an initial on-site audit, followed by a six-month surveillance audit and then a one-year anniversary audit, with continual at least annual audits thereafter. Companies maintain their approved PVPs by continuing to demonstrate adherence to the requirements.

The OIG report describes several different activities conducted as part of a PVP audit, but AMS believes that the report does not adequately convey the robustness of the PVP requirements or of an audit itself. PVP audit requirements are based on the internationally-recognized International Organization for Standardization (ISO) 9001 quality management systems standard, which includes extensive documentation, an internal audit, and management review requirements. AMS performs PVP audits using the internationally-recognized standard, ISO 19011, which details audit management and performance activities, auditor competence, and auditor evaluation requirements. The OIG report implies that AMS identifies corrective actions companies must make, which is not accurate. Instead, AMS issues an audit report to the company describing any non-conformances and the need for corrective action.

The report also implies that all companies and process points may not be treated the same, which is patently false. For example, the OIG report says that AMS takes a “judgmental sample” of umbrella companies’ clients to ensure the umbrella companies are following AMS guidance. AMS uses the same procedures when auditing every company operating under a PVP, including those commonly referred to as “umbrella companies.” Approval of umbrella companies’ activities is subject to the same judgment as management systems auditing – the basis for all AMS audit practices – in which trained auditors have a level of discretion with regard to sample sizes. As outlined in ISO 19011:2011, “Judgement-based sampling relies on the knowledge, skills, and experience of the audit team. The appropriate use of sampling is closely related to the confidence that can be placed in the audit conclusions.” AMS provides auditors with guidelines to ensure that they sample each location where there is an activity related to a process point.

The OIG report also refers to “multi-million dollar poultry operations” as being representative of the PVP clients of today. While some of AMS’ customers are sizable companies, we believe that this description implies that PVPs are used only by corporate or large organizations, which is not the case.

After a company passes an onsite audit and addresses any non-conformances that exist, AMS issues a PVP certificate that describes the company’s approved process points and permits the company to market it as a USDA PVP claim. As noted in the report, AMS maintains a public listing of all approved PVP companies, along with their corresponding process points. At any given time, there are roughly 190 process points listed on the website. In the report, OIG refers to three instances where the process point listed on the website did not match directly with the verbiage on the certificate. AMS believes that providing additional context would have added clarity to the report and corrected the implication that companies were making false claims. In fact, in the three examples cited by OIG, the firms were not listed as approved even though they were. Furthermore, no regulatory agency used the AMS website as a reference when determining if a labeling claim was truthful and not misleading. In other words, regulatory agencies depend on the information presented to them by the firm, such as a valid certificate stating that the firm has successfully passed their PVP audit by AMS, and does not use the AMS website to make that determination.

Similarly, AMS does not dispute that the “tenderness guaranteed” process point in the case cited should not have been approved. We do, however, believe providing context (e.g., listing the

number of process points reviewed) within the report would paint a much more accurate picture of the strength of the PVP program. Stating that the “reliability of the USDA name and PVP shield” is at risk is, we believe, an unnecessary generalization given that the program in question was not simply a “tenderness guaranteed” program nor was the company even marketing product as “tenderness guaranteed”.

## **Management of the PVP**

The report focuses on the different management areas in AMS that previously administered PVPs. In the past, audits for the livestock and poultry industries were managed by two separate program areas within AMS. In 2012, AMS merged its Livestock and Seed Program with its Poultry Programs, but the consolidation of Divisions within the newly-formed Livestock, Poultry, and Seed Program is still ongoing. The merger of the organizations managing the audit function, including the PVP, was not effectuated until the fall of 2014. Today’s Quality Assessment Division, which includes grading and auditing functions, comprises what was once five separate divisions in two distinct programs. In addition, the report references organizational units, such as the Poultry Division, that did not even exist at the time of the audit.

## **Recommendation 1**

Develop and implement a single agency policy that not only documents that policy but also identifies the standards for the types (e.g. age, source, cage-free, etc.) of claims AMS will allow to carry the PVP shield.

## **Agency Response**

AMS is committed to increasing transparency of the USDA PVP. The audit services are now managed through a single set of revised audit procedures and overseen by a single organizational unit. AMS updated the QAD 1001 Procedure to clarify the parameters of the USDA Process Verified Program and will update the Official Listing (Business Directory) by providing additional information on process points and linking those points to available standards and definitions.

On page 9, OIG references an application for a PVP that involved a number of process points: Poultry Care, Raised Cage Free, All Vegetarian Diet, No Animal By-Products, Tenderness Guaranteed and No Antibiotics Ever. These are all listed on the AMS website, and those which require further explanation are footnoted with the necessary references. The application and process manuals outline all process points and how the company intends to meet them, and AMS verified compliance through routine surveillance audits.

The report focuses a great deal on the cage-free claim, stating that AMS should not verify a practice that could “mislead the consumer” and erroneously implying that the Food Safety and Inspection Service (FSIS) would not have been petitioned over the use of the claims were it not for the AMS PVP. This is untrue. FSIS responded to the petition by stating that the cage-free claim is true and accurate, and FSIS has repeatedly approved “cage free” claims on labels that are not associated with the PVP. Approval for label claims on meat and poultry products rests solely with FSIS. AMS’ review of any marketing material referencing the PVP is only to ensure that process points are properly associated with the PVP shield itself.

Estimated Completion Date: AMS expects to provide additional information on process points via the Official Listing (Business Directory) by the end of 2015.

### **Recommendation 2**

Develop and implement a process that requires an independent review committee to approve or deny all new PVP claim applications.

### **Agency Response**

AMS concurs with this recommendation. At the time of the audit, a Program Committee Review procedure was in place for both the Poultry Program and the Livestock and Seed Program, but they were not yet combined, leading to each Program using different methodologies to arrive at a decision. Even though there were two documents, each Program's procedures required it to maintain records of decisions. Since Program Review Committee decisions depended on receiving the request in the form of a manual for new applicants or an expansion of scope request for existing applicants, discussions with potential and existing applicants about potential process points were not vetted using the Program Review Committee Procedure (because it was not required by the procedure).

To remedy this gap and provide greater transparency to the process point vetting process, AMS now operates the PVP under a single Program Committee Review Procedure, QAD 1115, which has been updated to incorporate a formalized decision-making process regardless of when or how an inquiry is received by the Program. AMS also tracks Program Review Committee decisions through the QAD 1115D - Form Process Point Inquiry Log and uses the QAD 1115E - Decision Matrix to illustrate the process for reviewing new process verified points.

Estimated Completion Date: AMS considers this recommendation completed.

### **Recommendation 3**

Review all existing PVP certificates to ensure documentation exists on how each one (e.g., raised cage free) meets AMS' revised policy, and immediately rescind the use of the PVP shield for claims that do not meet that policy or schedule audits to verify that the claims are still valid.

### **Agency Response**

AMS concurs with this recommendation. While the PVP previously allowed companies to process verify points that were only "beyond the requirements of regulations or a standard under which clients in the same industry generally operate," the QAD 1001 Procedure has been updated to remove this requirement. AMS has reviewed the Official Listing, PVP Certificates of Conformance, and related audit reports to ensure the approved process point(s) meet the current requirements as outlined in the QAD 1001 Procedure.

Estimated Completion Date: AMS considers this recommendation completed.

### **Recommendation 4**

Implement the controls and oversight necessary to ensure that AMS does not approve or renew PVP certificates until they have passed AMS audits for each year those claims are marketable.

**Agency Response**

AMS concurs with this recommendation. AMS has reviewed the processes used to ensure proper control and oversight of the PVP. AMS updated the QAD 1001 Procedure to ensure all process points are verified during a company's annual PVP audit. Any process point not verified during a company's annual audit will be identified in the official report and subsequently removed from the Official Listing and Certificate of Conformance. Companies are audited at least annually and may be audited more frequently. In October 2015, AMS provided additional training to all audit staff on audit procedures and management of process points when an applicant is not actively producing during an onsite audit.

Estimated Completion Date: AMS considers this recommendation completed.

**Recommendation 5**

Provide a clear definition or rename the Never Ever 3 program and indicate what, if any, protein levels are acceptable under those PVP certificates.

**Agency Response**

AMS acknowledges there were shortcomings in the Never Ever 3 Program. Accordingly, AMS has contacted Never Ever 3 Program participants and will either allow them to create their own program requirements or remove this process point from their PVP approval. This will allow program participants to continue to make the three objective claims that underpinned the Never Ever 3 Program, but AMS will no longer offer a standalone AMS Never Ever 3 Program underpinned by potentially misleading supply chain prerequisites.

Estimated Completion Date: AMS considers this recommendation completed.

**Recommendation 6**

Review and amend the verification requirements for the Never Ever 3 claim to ensure these claims are verifiable.

**Agency Response**

AMS concurs with this recommendation (See Agency Response to Recommendation 5). For those clients who wish to utilize a Never Ever 3 type claim, AMS will inform them of the need to consult with FSIS for prior label approval.

Estimated Completion Date: AMS considers this recommendation completed.

**Recommendation 7**

Coordinate with FDA to routinely obtain a current listing of feed providers that have failed FDA inspections. Provide this list to AMS auditors and umbrella companies to be used during their annual reviews to ensure PVP participants are not using feed providers that are violating FDA requirements.

**Agency Response**

AMS concurs with this recommendation (See Agency Response to Recommendation 5). Beyond the Never Ever 3 program, AMS will ensure that any PVP process point that relies upon FDA inspections to determine compliance, AMS will verify that those FDA inspections have taken place and the facilities are in good standing.

Estimated Completion Date: AMS considers this recommendation completed.

### **Recommendation 8**

Develop and implement the procedures and oversight necessary to ensure a well-defined documentation process for all approval and denial of PVP claims. Those procedures should require, at a minimum that AMS document all PVP requests, the actions taken on those requests, the reasons for those actions, and all decisions made.

### **Agency Response**

AMS concurs with this recommendation (See Agency Response to Recommendation 2).

AMS updated the QAD 1115 Procedure - Program Review Committee, to incorporate a formalized decision making process. AMS also developed a QAD 1115D - Form Process Point Inquiry Log to track Program Review Committee decisions and developed the QAD 1115E - Decision Matrix to illustrate the process of approving or denying new process verified points.

Estimated Completion Date: AMS considers this recommendation completed.

### **Recommendation 9**

Develop and implement the procedures and oversight necessary to ensure the AMS listing of approved PVP certificates and claims are reviewed and amended as needed to ensure the list is accurate, complete, and supported.

### **Agency Response**

AMS concurs with this recommendation. QAD 1000 Procedure – Quality Systems Verification Programs (QSVP) General Policies and Procedures addresses this requirement. In this case, however, AMS contends that the finding was an isolated administrative error and can be addressed through further training. AMS addressed this issue via training with all auditors involved in the PVP on October 5-7, 2015.

Estimated Completion Date: AMS considers this recommendation completed.

### **Recommendation 10**

Develop and implement continuous monitoring procedures to ensure all claims posted on its website are supported, and remove and add claims as needed to ensure a complete and accurate listing.

### **Agency Response**

AMS concurs with this recommendation. AMS conducted a root cause analysis and determined that this was an isolated incident. Revisions to existing procedures and additional training may not prevent this incident from reoccurring at some point in the future.

Estimated Completion Date: AMS considers this recommendation completed.

To learn more about OIG, visit our website at [www.usda.gov/oig/index.htm](http://www.usda.gov/oig/index.htm)

## How To Report Suspected Wrongdoing in USDA Programs

### Fraud, Waste, and Abuse

File complaint online: <http://www.usda.gov/oig/hotline.htm>  
Click on Submit a Complaint

Telephone: 800-424-9121  
Fax: 202-690-2474

**Bribes or Gratuities**  
202-720-7257 (24 hours a day)



The U.S. Department of Agriculture (USDA) prohibits discrimination in all of its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex (including gender identity and expression), marital status, familial status, parental status, religion, sexual orientation, political beliefs, genetic information, reprisal, or because all or part of an individual's income is derived from any public assistance program. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

To file a complaint of discrimination, write to USDA, Assistant Secretary for Civil Rights, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue, SW., Stop 9410, Washington, D.C. 20250-9410, or call toll-free at (866) 632-9992 (English) or (800) 877-8339 (TDD) or (866) 377-8642 (English Federal-relay) or (800) 845-6136 (Spanish Federal-relay). USDA is an equal opportunity provider and employer.