



April 2017

# FOOT-AND-MOUTH DISEASE

## USDA's Evaluations of Foreign Animal Health Systems Could Benefit from Better Guidance and Greater Transparency

Accessible Version

## Why GAO Did This Study

Foot-and-mouth disease (FMD) is a virus that causes painful lesions, making it difficult for livestock to stand or eat and greatly reducing meat and milk production. No FMD cases have been recorded in the United States since 1929. Federal regulations restrict fresh beef imports from countries where the disease is present because the disease may survive in untreated, uncooked beef (beef), and can be costly to control and eliminate. According to USDA, an outbreak of FMD could cause grave damage to the U.S. beef industry, which had a retail value of \$95 billion in 2014.

GAO reviewed (1) USDA's process for evaluating the animal health systems of countries seeking to export beef products to the United States, and (2) how this process could be improved. GAO analyzed documentation supporting seven countries' requests for FMD animal health system evaluations. GAO also reviewed federal regulations, guidance, and a key trade agreement; and interviewed knowledgeable USDA and industry officials.

## What GAO Recommends

GAO is making three recommendations including that USDA clarify its guidance on how staff should document analysis of a foreign country's animal health system and the results of in-country visits to verify information. USDA agreed with GAO's recommendations and described actions it is taking or plans to take to implement them.

View [GAO-17-373](#). For more information, contact Steve D. Morris at (202) 512-3841 or [morris@gao.gov](mailto:morris@gao.gov).

## FOOT-AND-MOUTH DISEASE

### USDA's Evaluations of Foreign Animal Health Systems Could Benefit from Better Guidance and Greater Transparency

## What GAO Found

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service's (APHIS) process for evaluating the animal health systems of countries seeking to export beef to the United States consists of five steps:

- A country requests that APHIS evaluate its animal health system.
- APHIS gathers information about the country's system, including documents identifying (1) veterinary control and oversight programs, (2) vaccination programs, (3) animal identification and movement controls, (4) laboratory diagnostic capabilities, and (5) animal-disease emergency-response measures.
- APHIS conducts in-country visits to verify and supplement this information.
- APHIS does a risk analysis to determine whether the country's beef products pose a risk to U.S. livestock and begins to draft a risk analysis report.
- APHIS determines an estimated risk level, which is included in the risk analysis report with a description of any mitigation measures the country must implement to ensure the safety of its beef exports. A report is completed and made public only for countries whose beef presents low risk. Countries whose beef poses a greater risk will not be eligible to export beef to the United States.

APHIS could strengthen its evaluation of foreign animal health systems by improving transparency to stakeholders, including the public. APHIS guidance instructs staff to adhere to timeframes for carrying out evaluations to ensure a lengthy process is completed efficiently. But the guidance does not instruct staff how to ensure evaluations are fully transparent. For example, APHIS guidance does not

- direct staff to document their analysis of country information and include all problems and concerns identified and how they were resolved;
- direct staff how to effectively document results of in-country visits, although the guidance requires these visits be documented; and
- indicate how to incorporate guidance on transparency from USDA's Chief Information Officer and the Office of Management and Budget into final risk analysis reports.

Without sufficient guidance instructing staff to document such items, it is unclear (1) how APHIS verifies country information and assesses its reliability; (2) how problems identified are ultimately addressed to APHIS's satisfaction; and (3) what methodologies, sources, assumptions, and uncertainties may influence its risk analysis. Further, according to the World Organisation for Animal Health, because risk analysis is inherently subjective, the process must be documented transparently. During GAO's review, APHIS acknowledged the weaknesses in its guidance and formed a team to begin work to address them. By completing this effort, APHIS may be better able to ensure that it has assessed risks fairly and consistently across countries and over time, and that the process is transparent to the public and other stakeholders.

---

# Contents

---

Letter	1
Background	4
APHIS Performs Documentation Reviews, Site Visits, and Risk Analyses to Evaluate Foreign Countries Seeking to Export Beef to the United States	11
Improved Documentation Could Enhance Transparency of APHIS's Evaluations of Foreign Countries' Animal Health Systems	16
Conclusions	28
Recommendations for Executive Action	29
Agency Comments and Our Evaluation	29
Appendix I: Objectives, Scope, and Methodology	35
Appendix II: Comments from the U.S. Department of Agriculture	39
Appendix III: GAO Contact and Staff Acknowledgments	42
GAO Contact	42
Staff Acknowledgments	42
Appendix IV: Accessible Data	43
Data Tables	43
Agency Comment letter	46
Related GAO Products	50
Table	
Table 1: Animal and Plant Health Inspection Service's (APHIS) In-country Site Visits and Whether a Trip Report Was Completed for Selected Countries' Beef Import Evaluations	22
Data for Figure 1: Status of Foot-and-Mouth Disease (FMD) Animal Health System Evaluations Conducted by Animal and Plant Health Inspection Service (APHIS), March 2017	43

---

Data for Figure 2: Animal and Plant Health Inspection Service's (APHIS) General Process for Evaluating a Foreign Country's Animal Health System	45
Figure 3: Three Key Components Included in Animal and Plant Health Inspection Service's (APHIS) Risk Analyses	45

---

Figures

Figure 1: Status of Foot-and-Mouth Disease (FMD) Animal Health System Evaluations Conducted by Animal and Plant Health Inspection Service (APHIS), March 2017	9
Figure 2: Animal and Plant Health Inspection Service's (APHIS) General Process for Evaluating a Foreign Country's Animal Health System	11
Figure 3: Three Key Components Included in Animal and Plant Health Inspection Service's (APHIS) Risk Analyses	14

---

**Abbreviations**

APHIS	Animal and Plant Health Inspection Service
CFR	Code of Federal Regulations
FMD	Foot-and-Mouth Disease
FSIS	Food Safety and Inspection Service
GAO	Government Accountability Office
OIE	World Organisation for Animal Health (Office International des Epizooties)
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures
USDA	U.S. Department of Agriculture
WTO	World Trade Organization

This is a work of the U.S. government and is not subject to copyright protection in the United States. The published product may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.



April 28, 2017

Congressional Requesters

Foot-and-mouth disease (FMD) is a highly contagious viral disease affecting cloven-hooved animals such as cattle, pigs, sheep, and goats. The virus can survive in the environment for many months, and can be transmitted among animals by air or through contact with feed, soil, tools, clothing, shipping containers, and untreated meat products, including beef.<sup>1</sup> Although the disease generally does not infect humans and is not considered a public health or food safety threat, livestock suffer painful blisters inside the mouth and on hooves, making it difficult for them to stand or eat and causing severely diminished meat and milk production. The disease spreads so rapidly that control can be difficult, sometimes requiring the widespread slaughter of both infected and potentially infected livestock. According to the U.S. Department of Agriculture (USDA), in 2014, the retail value of the U.S. beef industry was \$95 billion. An outbreak of FMD could cause billions of dollars in losses as well as loss of export markets attributable to mandatory slaughter, among other factors.<sup>2</sup>

USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for protecting U.S. livestock from the introduction of foreign animal diseases, including FMD.<sup>3</sup> The United States has not had a documented case of FMD since 1929 and does not vaccinate its livestock against the disease. Federal regulations prohibit the import of certain livestock—for example, cattle and swine—and their products (including meat) from countries or regions that have not been officially recognized by APHIS as free of FMD. Products that have undergone treatment—such as cooking—that will inactivate the FMD virus are not, under certain

---

<sup>1</sup> Untreated meat products are those that have not been cooked, cured, or deboned and aged, a process that lowers pH to below 6.0 to inactivate the FMD virus. The findings in this report apply to fresh (chilled or frozen), untreated meat products. For purposes of this report, any mention of beef refers to fresh—not cooked or cured—beef.

<sup>2</sup> Philip L. Paarlberg, John G. Lee, Ann Seitzinger; "Potential Revenue Impact of an Outbreak of Foot-and-Mouth Disease in the United States," *Journal of the American Veterinary Medical Association* (Apr. 1, 2002).

<sup>3</sup> Foreign animal diseases are those that are not known to be present in the United States. APHIS also has responsibilities for protecting U.S. agriculture and natural resources against plant pests.

conditions, subject to these prohibitions. Therefore, a country seeking to export beef to the United States must generally demonstrate to APHIS that it is free from FMD and that it does not vaccinate against FMD. Countries that vaccinate are not considered free from FMD because, according to APHIS, vaccination has not proven a foolproof method for protecting all susceptible animals.<sup>4</sup>

However, APHIS has determined that beef from vaccinating countries that have not had recent outbreaks may still be safe for import under certain conditions. APHIS has allowed beef imports from one such vaccinating country—Uruguay—since 2003, and in July 2015, the agency determined that beef from certain regions within Brazil and Argentina could also be safely imported into the United States. While both Brazil and Argentina currently vaccinate against FMD, according to APHIS, there is no evidence that they have experienced FMD outbreaks since 2006.

You asked us to review APHIS’s approach to protecting U.S. livestock from FMD, which may be transmitted through beef imports. This report examines (1) the steps APHIS takes to evaluate the animal health systems of foreign countries seeking to export beef to the United States and (2) how APHIS’s process could be improved, if at all.<sup>5</sup>

To address these objectives, we reviewed relevant federal statutes, federal regulations, federal and World Organisation for Animal Health (OIE)<sup>6</sup> guidance documents, and a key international trade agreement regarding imports of beef. To gain a better understanding of APHIS’s process for protecting U.S. livestock from FMD, we focused our review on APHIS’s evaluations of the animal health systems of seven countries or

---

<sup>4</sup> Vaccines cannot immunize livestock against all strains of the disease. In addition, livestock may not respond to vaccination with full immunity and, if infected, may go undetected in a herd.

<sup>5</sup> For the purposes of this report, an animal health system is a country’s entire animal health program, including veterinary infrastructure, veterinary authority, disease control measures, laboratory capacity and capability, import controls, and livestock industry practices. APHIS officially refers to its evaluations of animal health systems as “animal health status” evaluations.

<sup>6</sup> The World Organisation for Animal Health was formerly known as the Office International des Epizooties (OIE), and kept its historical acronym of OIE after changing names. OIE is an intergovernmental organization created in response to the need to fight animal diseases on a global level, and is tasked with improving animal health worldwide. One of its stated objectives is to promote safety in international trade of animals and animal products.

specific regions within those countries: Northern Argentina, 14 states in Brazil (comprising a single export region), Colombia, Japan, Paraguay, Singapore, and Uruguay. With the exception of Uruguay, we chose these countries or regions for review because they had the following characteristics:

- the countries requested an animal health system evaluation for FMD for the purpose of exporting beef to the United States, and
- either APHIS has completed an evaluation and lifted the import prohibition on the country's beef within the past 5 years, or APHIS is currently conducting an evaluation to determine whether the import prohibition on the country's beef can be safely lifted.

Uruguay does not fit these parameters, as APHIS lifted the import prohibition on the country's beef in 2003; however, it is a country for which APHIS conducted a *quantitative* risk analysis, an evaluative approach that was not applied to the other six countries in our review, which all received *qualitative* risk analyses.

The information we obtained from APHIS's evaluations of the seven countries we reviewed is not generalizable, but provided us with a greater understanding of the key steps that comprise a foreign animal health system evaluation. We did not evaluate the scientific or technical validity of APHIS's risk analyses, nor did we question APHIS's decisions to lift the import prohibition on Argentina, Brazil, Japan, and Uruguay's beef. (Final risk analysis reports have not yet been prepared for Colombia, Paraguay, and Singapore.) Instead, we focused our review on APHIS's process for conducting and documenting its evaluations of the animal health systems in the seven countries in our review. Additionally, we reviewed APHIS's evaluations of animal health systems to determine how well the agency incorporated standards for documentation and transparency. We also reviewed Food Safety and Inspection Service (FSIS) guidance for conducting food safety equivalence evaluations to further understand the steps required before a country may begin exporting beef to the United States.<sup>7</sup> To develop an understanding of APHIS's process for conducting and documenting FMD risk analyses, we reviewed the final FMD risk

---

<sup>7</sup> USDA's Food Safety and Inspection Service evaluates foreign food safety systems to establish that a country's system meets the equivalent standards for food safety as are present in the United States (known as an equivalence determination), and that meat, poultry, catfish, and egg products destined for export to the United States are safe for human consumption.

---

analysis reports for Northern Argentina, the 14-state region of Brazil, Japan, and Uruguay. To further expand our understanding of how APHIS conducts and documents FMD risk analyses, we also reviewed the only other three countries with risk analysis reports completed within the past 5 years for FMD: Croatia, Malta, and Peru. Appendix I provides additional information on our scope and methodology. In addition, we list related GAO products at the end of this report.

We conducted this performance audit from December 2015 to April 2017, 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.

---

## Background

USDA is responsible for protecting U.S. livestock from foreign animal diseases. The steps USDA takes to do so must comply with international trade agreements to which the United States is a signatory. This section presents information on how regulatory restrictions may be lifted by USDA to allow countries to export beef to the United States. Because regulation must occur in a manner consistent with United States' international trade agreements, the information is prefaced by a discussion of relevant trade agreement obligations.

---

### International Trade Agreement Obligations

As a member of the World Trade Organization (WTO), and a signatory to the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), the United States has agreed to follow guiding principles aimed at promoting safe and fair international trade.

**Fair trade practices:** The WTO SPS Agreement allows countries to establish sanitary measures to protect animal health and ensure food is safe for human consumption, but these sanitary measures must not arbitrarily or unjustly discriminate among signatories to the agreement. Sanitary measures refer to laws, regulations, requirements, and procedures designed to protect a country's livestock from animal diseases. Sanitary measures might include, for example, testing and inspecting for pathogens. To facilitate fair and consistent trade practices,

the SPS Agreement encourages countries to adopt international standards, guidelines, and recommendations where they exist. The OIE has established standards, guidelines, and recommendations for animal health matters, while the Codex Alimentarius Commission has done so for food safety matters. However, under the WTO's SPS Agreement, countries are authorized to impose stricter sanitary measures than those offered by the OIE and Codex Alimentarius Commission as long as the countries have a scientific justification and are not inconsistent with any other provisions of the agreement.

**Regionalization:**<sup>8</sup> For the purposes of international trade, signatories to the SPS Agreement have agreed to evaluate the animal health systems of regions that can be all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities.<sup>9</sup>

**Equivalence:** Signatories to the SPS Agreement have agreed to treat other countries' sanitary measures as equivalent—even if those measures differ from their own—provided that the exporting country can demonstrate that its measures achieve the importing country's level of sanitary protection.

---

## USDA Regulation of Imported Beef

USDA delegates responsibilities for ensuring the safety of beef imports to two internal agencies: APHIS and the Food Safety and Inspection Service (FSIS). APHIS has lead responsibility for preventing foreign animal diseases from entering the United States and evaluates foreign countries' animal health systems to establish that a country's livestock does not carry animal diseases and that its system can effectively prevent, detect, and control a disease outbreak should one occur. FSIS evaluates foreign food safety systems to establish that the country's system meets the equivalent standards for food safety as are present in the United States (known as an equivalence determination), and that meat destined for export to the United States is safe for human consumption. Importantly,

---

<sup>8</sup> Regionalization is the concept that animal health and disease risk resulting from imported products can vary by regions defined by climatological, geographical, and biological factors rather than by national political boundaries.

<sup>9</sup> For the purposes of this report, we generally refer to all export regions as "countries," even if the export region does not encompass the entire country. For example, the export regions of Northern Argentina and a 14-state region of Brazil are included in our review, but we refer to those regions as the "countries" of Argentina and Brazil, respectively.

---

both APHIS's and FSIS's evaluations must be satisfactorily completed before a country is eligible to export beef to the United States.<sup>10</sup>

### Animal Health System Evaluations

Because foreign beef entering the United States must be free from animal diseases such as FMD, APHIS prohibits imports of beef from countries where FMD may be present.<sup>11</sup> As a precaution, APHIS considers FMD to be present in all countries unless it has independently completed an animal health system evaluation to confirm that FMD does not exist in the country. In line with obligations under the SPS Agreement, APHIS will, upon request, consider evaluating the animal health system of a specific region within a country rather than evaluating the entire country.<sup>12</sup> For example, APHIS has conducted animal health system evaluations for various regions within Argentina, Brazil, and Namibia.

As permitted by the SPS Agreement, foreign animal health systems may differ among signatories, but they must, in all cases, provide an appropriate level of protection to ensure that the country's beef destined for export does not harbor the FMD virus. APHIS conducts its evaluations in accordance with *Application for Recognition of the Animal Health Status of a Region*, the federal regulation that establishes the factors APHIS must assess to determine whether the country satisfies this requirement.<sup>13</sup> If, at the conclusion of an evaluation, APHIS determines that the overall risk is low and that a country's request to export beef to the United States can be safely granted, APHIS will indicate in the *Federal Register* its intent to lift the import prohibition.<sup>14</sup> APHIS allows for

---

<sup>10</sup> A country's ability to export beef—once it has been determined eligible to do so—may also be affected by import quotas and tariffs.

<sup>11</sup> Discussion in this report is specific to FMD. APHIS also prohibits meat imports from countries where certain other animal diseases are present.

<sup>12</sup> APHIS defines a region as a geographic land area with identifiable geological, political, or surveyed boundaries. According to APHIS, the concept of regionalization is rooted in the concept that restrictions on the movement of animals and animal products for the purpose of disease control are biologically and ecologically most logical when applied to areas that are geographically homogenous with respect to disease distribution and livestock infrastructures.

<sup>13</sup> 9 C.F.R. § 92.2.

<sup>14</sup> APHIS will indicate its intent in the *Federal Register* either through a public notice or a proposed rule, depending on the specific provisions of the evaluation.

a public comment period and is to consider all public comments before issuing its final determination. The import prohibition on beef may be lifted in one of two ways:

- APHIS may classify a country as FMD-free and add the country to the agency's official list of countries declared free of FMD. Inclusion on the FMD-free list removes the import prohibition on certain livestock and their products—including meat—from that country.<sup>15</sup> In some cases, however, APHIS may impose certain conditions on exports from a country classified as FMD-free if APHIS believes the country may be at elevated risk for an FMD outbreak in the future. For example, if a country shares a common land border with or supplements its domestic meat supply with meat from countries that APHIS has not declared FMD-free, APHIS requires the country to certify that, among other things, its exported beef was derived from animals that have never spent time in a country where FMD exists.<sup>16</sup>
- Some countries may not qualify for FMD-free status because they vaccinate against the disease. According to APHIS, in these cases, a country may still have the import prohibition on its beef lifted by seeking a “commodity-based” evaluation. An FMD-free animal health system evaluation would eliminate the import prohibition on live cattle and all commodities derived from cattle, including beef, from a specific country or region.<sup>17</sup> In contrast, a commodity-based evaluation involves lifting the import prohibition on specific commodities, such as beef only. To lift the import prohibition on beef following a commodity-based evaluation, APHIS must amend federal regulations to add the country, the meat or meat product for which the country has been evaluated, and any required mitigations. Generally, countries having the import prohibition lifted through a commodity-based evaluation must implement safety measures—or mitigations—to reduce the risk that these meat products may be contaminated with

---

<sup>15</sup> Imports of meat from animals that are susceptible to FMD—including cattle, sheep and swine—are restricted under federal regulation. Achieving FMD-free status lifts the import prohibition on these products. However, swine are also susceptible to other regulated diseases—such as classical swine fever—and pork imports are also restricted based on these diseases.

<sup>16</sup> Currently, there are 60 countries included on the FMD-free list, 36 of which are subject to these additional export requirements.

<sup>17</sup> In addition, APHIS regulations allow the agency to place certain restrictions on imports from FMD-free regions because of the region's proximity to or trading practices with FMD-affected regions. 9 C.F.R. § 94.11.

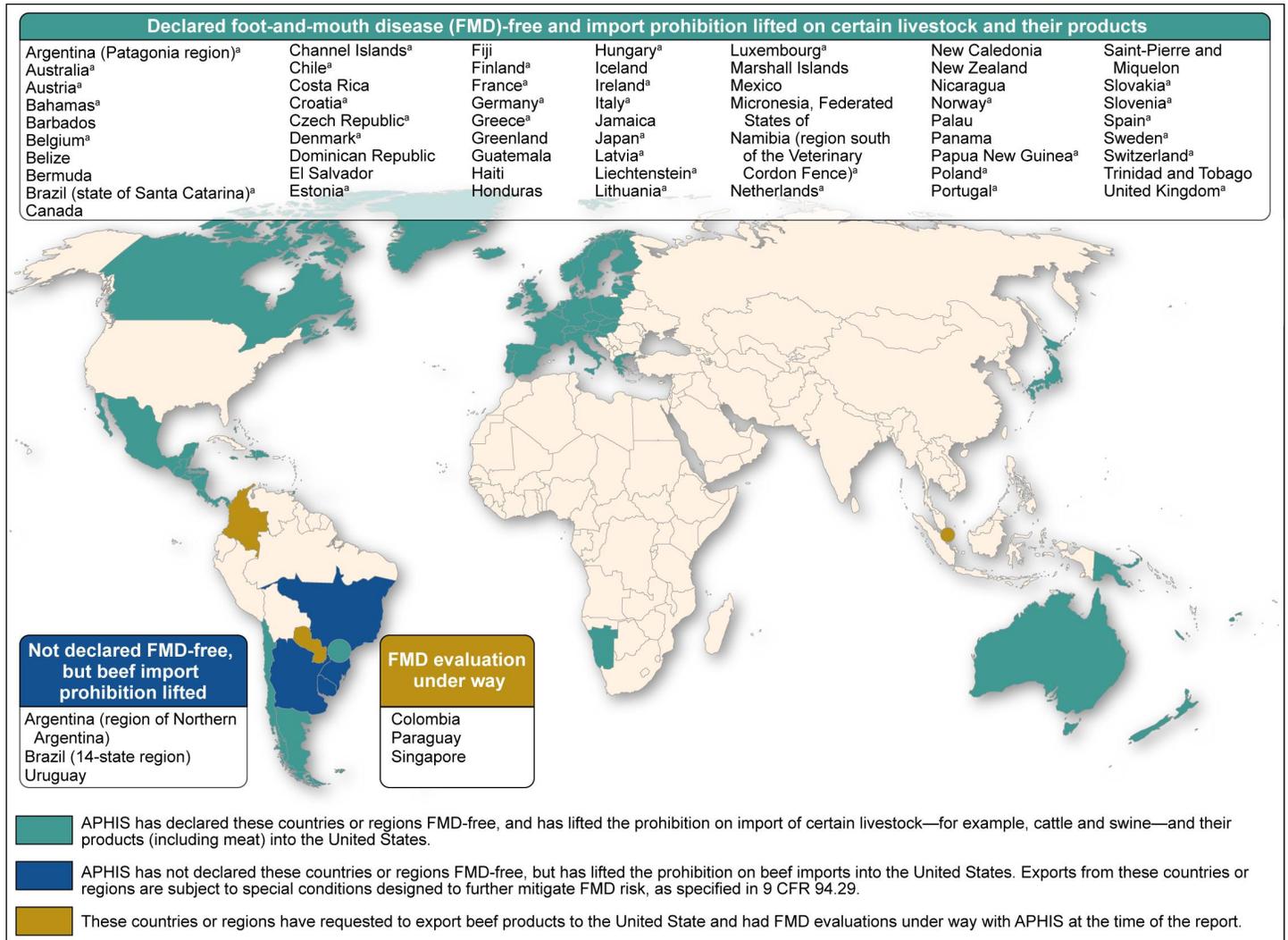
FMD. For example, mitigations that effectively inactivate the FMD virus include deboning and maturation.<sup>18</sup> To date, three countries—Uruguay, and certain regions of Argentina and Brazil—that have not experienced outbreaks of FMD in many years but continue to vaccinate have had the import prohibition on beef lifted through this method. Two additional such countries—Colombia and Paraguay—had evaluations under way at the time of our review.

Figure 1 shows the countries for which APHIS has lifted the prohibition on certain meat imports to the United States under each of these two methods.

---

<sup>18</sup> Deboning meat and maturation—an aging process that reduces pH levels in meat to below 6.0 and increases acidity—are both intended to decrease the risk that beef might be contaminated with the FMD virus. The pH is a figure expressing the acidity or alkalinity of an object, with lower values being more acidic, higher values being more alkaline, and 7 being neutral.

**Figure 1: Status of Foot-and-Mouth Disease (FMD) Animal Health System Evaluations Conducted by Animal and Plant Health Inspection Service (APHIS), March 2017**



Source: GAO analysis of APHIS information. | GAO-17-373

<sup>a</sup> Exports from these countries or regions are subject to special conditions designed to further mitigate FMD risk, as specified in 9 CFR 94.11.

Once the import prohibition has been lifted, the country maintains that status unless it experiences an FMD outbreak or another problem that could potentially change the risk posed by the country's beef exports. If an outbreak is identified, APHIS officials said they would reinstate the import prohibition. However, the Consolidated Appropriations Act of 2016

required the Secretary of Agriculture to establish a prioritization process for APHIS to conduct follow-up reviews of countries or regions that have received animal health status recognitions by APHIS.<sup>19</sup> In January 2017, APHIS announced its plan to prioritize these follow-up reviews based on the level of risk the imports might pose to the United States.<sup>20</sup>

### Food Safety System Evaluations

Imported beef must meet the Federal Meat Inspection Act's safety standards applied to beef produced in the United States. As such, FSIS restricts imports of beef until the agency has evaluated the country's food safety system and determined that the system meets applicable safety standards. According to FSIS guidance,<sup>21</sup> food safety system evaluations are necessary for FSIS and the American consumer to develop and maintain trust in imported beef.

FSIS reviews and analyzes information related to a country's food safety system to determine whether the country's system provides the same level of protection against food hazards as is achieved domestically. As permitted by the SPS Agreement, foreign food safety systems need not be identical to the U.S. system, but they must employ sanitary measures that provide this equivalent level of protection. FSIS then conducts an on-site equivalence evaluation to verify that the country has satisfactorily implemented all laws, regulations, and requirements. Should FSIS determine that the country's system meets all applicable standards and that the country's request to export beef to the United States can be

---

<sup>19</sup> Pub. L. No. 114-113, § 752, 129 Stat. 2283 (2016).

<sup>20</sup> APHIS will prioritize follow-up reviews using a three-tier system: With respect to FMD, Tier 1 includes countries that are not recognized as FMD-free but for which APHIS has lifted the import prohibition on certain animals or products; Tier 2 includes countries that are recognized as FMD-free but where special restrictions are applied due to the country's proximity or trade relationships with countries that APHIS has not recognized as FMD-free; Tier 3 includes countries recognized as FMD-free. Additionally, APHIS will prioritize its review within each of these three tiers using five risk-based criteria: disease, region, commodity, time and other risk-based factors.

<sup>21</sup> U.S. Department of Agriculture, Food Safety and Inspection Service, "Process for Evaluating the Equivalence of Foreign Meat, Poultry, and Egg Products Food Regulatory Systems;" Washington, D.C., July 2011.

safely granted, it will add the country to the agency's list of countries eligible to export beef to the United States.<sup>22</sup>

## APHIS Performs Documentation Reviews, Site Visits, and Risk Analyses to Evaluate Foreign Countries Seeking to Export Beef to the United States

APHIS's process for evaluating foreign countries seeking to export beef to the United States includes gathering and evaluating information about a country's animal health system, usually performing one or more in-country site visits to substantiate the information and address any concerns, and conducting a risk analysis to estimate the potential risk to U.S. livestock posed by the importation of the country's beef.<sup>23</sup> Figure 2 illustrates this process.

**Figure 2: Animal and Plant Health Inspection Service's (APHIS) General Process for Evaluating a Foreign Country's Animal Health System**



Source: GAO analysis of APHIS information. | GAO-17-373

<sup>a</sup> Information gathering may take place throughout the entire process.

**Initial request for evaluation:** Foreign countries seeking to export beef to the United States must request that APHIS evaluate the country's animal health system. Generally, a country makes a standard request for an animal health system evaluation, for which APHIS requires the country

<sup>22</sup> Like APHIS, before placing a country on the list of countries eligible to export beef to the United States, FSIS publishes a proposed rule in the *Federal Register*, notifying the public of the intent to allow the country to export beef to the United States. FSIS must allow the public to comment on the proposed rule, and is to consider all public comments before issuing a final rule regarding the country's eligibility to export.

<sup>23</sup> This process is the one APHIS uses for evaluating foreign animal health systems, regardless of disease or commodity. For illustrative purposes, risk analysis and risk estimation are shown in figure 2 as separate steps. According to APHIS, however, risk estimation is included in risk analysis.

to submit information designed to establish the adequacy of its system and to demonstrate the country has the necessary infrastructure to detect and respond to an FMD outbreak should one occur.<sup>24</sup> For standard animal health system evaluations, APHIS requires that countries submit information on the following eight evaluation factors:<sup>25</sup>

1. *Scope of the evaluation being requested:* The requesting country provides a detailed description of the export region for which it is requesting an animal health system evaluation for FMD and, if applicable, the products it wishes to export.
2. *Veterinary control and oversight:* The requesting country provides information to demonstrate adequacy of its veterinary infrastructure and ability of its veterinary authority to oversee animal health activities, monitor for FMD, and implement FMD control measures.
3. *Disease history and vaccination practices:* The requesting country provides information on the history of FMD in the evaluated region and its vaccination program.
4. *Livestock demographics and traceability:* The requesting country provides information on livestock demographics and its ability to track those animals' movements in the event of an FMD outbreak.
5. *Epidemiological separation from potential sources of infection:* The requesting country provides information on its ability to prevent FMD from entering the export region.
6. *Surveillance:* The requesting country provides information showing its surveillance system can detect FMD quickly in the event of an outbreak.

---

<sup>24</sup> If a country has either never experienced FMD or has not had a case of FMD within the last 25 years, it can request a designation of "historically free" from FMD. There is no distinction between the "FMD-free" and "historically FMD-free" designations, but a country requesting historically free status would submit slightly different information to APHIS than it would for a standard animal health system evaluation. For example, a country requesting historically free status is not required to submit information on surveillance practices because APHIS takes into account that countries that have been free from FMD for more than 25 years would not be expected to have significant levels of active surveillance.

<sup>25</sup> APHIS consolidated these evaluation factors into their current form in 2012. Prior to 2012, there were 11 evaluation factors for standard animal health system evaluations. APHIS stated that the changes would make clearer the types of information APHIS needs from a requesting region in order to conduct an evaluation.

7. *Diagnostic laboratory capabilities:* The requesting country provides information to demonstrate it is capable of effectively diagnosing FMD.
8. *Emergency preparedness and response:* The requesting country provides information on its FMD preparedness and response capabilities.

**Information gathering:** After the country has made its initial request for evaluation and submitted supporting documentation related to the eight evaluation factors, APHIS will assemble a review team, which typically consists of one or more APHIS staff with technical expertise in fields such as veterinary medicine, epidemiology, microbiology, and virology. Review teams may also include laboratory specialists and quantitative risk analysis experts, if appropriate. Review teams evaluate the country's information and, if necessary, request additional information. APHIS also gathers information from publicly available sources, scientific literature, and audit reports issued by other auditing agencies. The information-gathering process continues until APHIS is confident that it has sufficient information to identify potential weaknesses, if any, in the country's animal health system that might affect its ability to identify and control FMD.

**In-country site visit:** APHIS conducts in-country site visits to verify and supplement information already gathered. Site visit teams consist of one or more APHIS staff who were part of the review team, but may also include technical specialists, such as laboratory experts, if necessary. Additionally, APHIS may invite chief veterinary officials from one or more U.S. states to be part of the site visit team.<sup>26</sup> APHIS site visit teams request to visit certain locations in the country based on potential animal health system risks or weaknesses that were identified while evaluating the country's information. Site visit verification activities typically include reviews of record-keeping protocols and coordination among federal, regional, and local animal health officials. APHIS officials told us that site visits are a critical component of the evaluation process because these visits allow them to assess whether the country's animal health system functions in practice as it was described in the country's documentation. APHIS aims to address all of its concerns with a single site visit, but multiple visits may be necessary during an animal health system evaluation. Depending on the country's responsiveness, document

---

<sup>26</sup> APHIS staff said that including these individuals helps increase the agency's transparency and bolsters confidence with the public.

reviews and subsequent site visits may take several years, APHIS officials said.

**Risk analysis:** Once APHIS is satisfied that it has gathered and verified all necessary information regarding a country’s animal health system, and has investigated all potential weaknesses, it will conduct a risk analysis to determine whether the country’s request to export beef to the United States can be safely granted. According to APHIS officials, the agency generally follows OIE guidelines for conducting import risk analyses, which include, among other things, three components: an entry assessment, an exposure assessment, and a consequence assessment. Figure 3 provides descriptions of each of these components.

**Figure 3: Three Key Components Included in Animal and Plant Health Inspection Service’s (APHIS) Risk Analyses**

Entry assessment	Exposure assessment	Consequence assessment
Estimates the likelihood of a foot-and-mouth disease (FMD)-contaminated commodity entering the United States.	Estimates the likelihood of susceptible animals in the United States being exposed to an FMD-contaminated commodity, and the means by which that exposure may occur.	Estimates the biological, environmental, and economic consequences associated with the establishment and the spread of FMD in the United States.

Source: GAO analysis of APHIS and World Organisation for Animal Health (OIE) information. | GAO-17-373

Note: These risk analysis components are included in all animal health system evaluations, regardless of animal disease or commodity being evaluated. Other components include things such as hazard identification and risk management.

APHIS’s analysis of the eight evaluation factors comprises the entry assessment portion of the risk analysis. In line with OIE guidelines, entry assessments may be quantitative or qualitative, or a combination of both.<sup>27</sup> In all cases, APHIS conducts a thorough qualitative evaluation

<sup>27</sup> According to the OIE, quantitative assessments are not necessarily more objective or precise than a qualitative approach. The qualitative approach is suitable for the majority of import risk analyses and is currently the most common type of assessment undertaken to support routine import decision making. However, in some circumstances it may be useful to adopt a quantitative approach as an adjunct to a qualitative assessment to, for example, gain further insights into a particular problem or compare risk mitigation strategies. Additionally, OIE states that for many diseases—particularly those such as FMD that have well-developed, internationally agreed-upon animal health standards—there is broad agreement concerning the likely risks. In such cases, it is more likely that a qualitative assessment is all that is required.

based on the eight evaluation factors, but may also employ a quantitative approach if the agency believes it is appropriate.

For example, agency officials said that they employed a quantitative approach in a risk analysis for bovine spongiform encephalopathy (mad cow disease) to determine whether live cattle and other susceptible products could be safely imported from Canada. That assessment, completed in 2007, used quantitative methods to estimate the prevalence of disease in adult cattle in Canada, and this was used in a quantitative model that considered the potential exposure via live cattle imports. The other components of this assessment, including the consideration of release and exposure via blood and blood products, could not readily be mathematically modeled, and therefore qualitative methods were used.

As part of the overall process, the risk analysis—along with a summary of important information supporting the risk analysis—is presented in a final risk analysis report, which is made available to the public prior to removal of the prohibition on beef imports from the country.<sup>28</sup>

**Risk estimation:** Results from the entry, exposure, and consequence assessments are integrated to produce an overall measure of the FMD risk associated with importing a country's products. Certain products, including beef, can be treated during the production process to mitigate the risk of carrying the FMD virus. Examples of mitigation treatments for beef include deboning, aging, and lymph node removal. If APHIS believes that any of these mitigation treatments are necessary, it must determine that the country can effectively apply the treatments to beef destined for export to the United States. Additionally, APHIS may impose other mitigation measures such as requiring that the beef come from animals that are born, raised, and slaughtered in regions that APHIS has recognized as free of FMD. If, after considering mitigation treatments and other potential mitigation measures that might reduce the risk of FMD, APHIS finds the overall risk to be sufficiently low, it removes the prohibition on beef imports from that country.

---

<sup>28</sup> In APHIS's *Federal Register* entry indicating its intent to lift the import prohibition on a country's beef, the agency provides information on how the public can access the risk analysis report and other supporting documents on <https://www.regulations.gov/>.

---

## Improved Documentation Could Enhance Transparency of APHIS's Evaluations of Foreign Countries' Animal Health Systems

APHIS could strengthen its foreign animal health system evaluations and provide greater transparency in how it determines whether the import prohibition on a country's beef may be safely lifted by better documenting its actions during three phases of the evaluation process: (1) the agency's analysis of information gathered from foreign countries and other sources, (2) in-country site visits, and (3) risk analyses. Existing guidance is not adequate to ensure that such documentation will occur.

---

### Existing Guidance Does Not Ensure APHIS's Analysis of Information Gathered about Foreign Animal Health Systems is Adequately Documented

APHIS guidance for how to conduct animal health system evaluations helps streamline the lengthy process that can sometimes take years, but it does not provide detailed instructions for how staff should document their analysis of information gathered. In addition, APHIS has not developed a systematic means of storing, organizing, and managing the information it gathers about foreign countries' animal health systems.

In 2011, APHIS established internal agency guidance that identified the actions comprising an animal health system evaluation, with the goal of streamlining the agency's evaluation process to make it more efficient. The 2011 guidance follows the key phases of an animal health system evaluation, detailing actions staff should take in gathering information, managing documentation, planning and conducting in-country site visits, following up on site-visit information requests, performing risk analyses, and facilitating regulatory action to remove the prohibition on beef imports to the United States.

While the 2011 guidance identifies the steps staff should undertake to ensure the information gathered about a foreign country's animal health system is complete, it does not provide instructions on how staff should document their analysis of the information. For example, review team members are expected to evaluate a country's information and provide input to the review team leader, but the 2011 guidance does not indicate the type of input that should be provided, nor does this guidance direct

staff to document any analysis that they may have done during their evaluation. As a result, we found limited documentation that such input had been provided as directed or of analyses that may have been done for the seven animal health system evaluations we reviewed. For example, we identified written meeting notes from 2003 indicating that APHIS staff had met and had expressed concerns about the quality of data provided by Brazilian authorities. The notes indicated that follow-up was needed before the risk analysis could proceed. We found no additional documents regarding such concerns for the other animal health system evaluations.

Similarly, the 2011 guidance also directs the review team's leader to request additional information from foreign officials if the country's information is incomplete or unclear. For five of the seven countries in our review, we identified evidence that APHIS requested additional information from foreign officials to support their evaluations. We did not, however, find documentation in any of these cases indicating whether or how APHIS analyzed the foreign officials' responses and determined whether their responses were adequate.

APHIS staff said that they do not generally document—in work papers or other materials apart from the risk analysis report—how they analyzed the information gathered to identify potential weaknesses in a foreign country's animal health system. These officials also said that the analysis of a foreign country's information is fully documented in the final risk analysis report and that preparing separate analytical documents would be unnecessarily duplicative. But risk analysis reports are not intended to detail all of the concerns or problems that APHIS identified during the course of an animal health system evaluation, nor do these reports discuss how those concerns were resolved to APHIS's satisfaction. According to APHIS officials, evaluations of a country's animal health system are conducted specifically to determine whether import prohibitions may be lifted. If significant weaknesses are identified during the review, the evaluation is terminated. In those instances, a final risk analysis report is neither completed nor made public, as there would be no regulatory action taken. Therefore, all of the risk analyses supporting a regulatory action reflect only those situations where all significant animal health concerns had been adequately resolved through the evaluation. However, without a separate step linking the analysis of a country's information to the final risk analysis report, it is difficult to track how APHIS staff analyzed the information, assessed its validity and reliability, determined that the information was sufficient to identify any potential weaknesses in the country's animal health system, and resolved any

concerns. For example, APHIS and the Canadian Food Inspection Agency conducted a joint in-country site visit to Argentina in 2005.<sup>29</sup> During that visit, the teams discovered that Argentina's legislation regarding swill feeding was insufficient and that swill feeding regulations were not properly enforced.<sup>30</sup> These issues are documented in the Canadian Food Inspection Agency's risk assessment report. The Canadian agency determined the risk to Canada from Argentina beef was acceptable, but recommended in the risk assessment report that Argentina take action to correct the deficiencies. In contrast, APHIS did not document any issues it may have found with Argentina's swill feeding legislation or that the country's failure to properly enforce swill feeding regulations had been resolved. Without a separate step linking documentation of deficiencies encountered to the risk analysis reports, there is no way to track such issues to their resolution.

Under federal standards for internal control concerning practices to achieve agency objectives, federal entities are to adequately record important transactions, such as activities that support regulatory decision making.<sup>31</sup> Appropriate and prompt documentation of such activities helps the entity achieve its objectives and helps maintain the relevance and value of such activities for decision-making purposes. Promptly recording the analysis of information it receives from foreign countries may better equip APHIS to evaluate animal health systems consistently across countries and over time, and ensure continuity during times of staff turnover. Additionally, sufficient documentation of analysis, discussions, and conclusions drawn during evaluations would support APHIS's commitment to transparency and help the agency to defend its decisions to stakeholders and other entities, such as the WTO.

One approach to ensuring that agency staff understand an organization's expectations about when and how to record important information and

---

<sup>29</sup> According to APHIS officials, the Canadian Food Inspection Agency and APHIS coordinate joint in-country site visits when possible if they have concurrent animal health system evaluations under way.

<sup>30</sup> According to APHIS, swill feeding is the most likely pathway for susceptible livestock to be exposed to FMD. Swill is food scraps or waste and may inadvertently contain FMD-contaminated meat. Among species known to be susceptible to FMD, only swine are likely to be fed discarded meat. However, because FMD is highly contagious, it could easily be transferred to other livestock, including cattle.

<sup>31</sup> GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: September 2014).

regulatory activities is to direct them to follow requirements outlined in agency guidance. Federal standards for internal control state that agency management should clearly document—in management directives, administrative policies, or operating manuals—the processes it uses to ensure it is achieving its objectives. The Office of Management and Budget has also emphasized the importance of developing internal agency guidance, stating that guidance serves critical functions in regulatory programs, channeling the discretion of agency employees, enhancing fairness, and ensuring equal treatment of similarly situated parties. By developing specific guidance directing staff to document their analysis of information supporting animal health system evaluations, APHIS could better ensure that it has fairly and consistently evaluated the risks associated with beef imports across countries and over time and that the process is transparent to the public and other stakeholders.

Further, APHIS does not have a systematic means of storing, organizing, and managing the information gathered during an animal health system evaluation. We found that documentation submitted by foreign officials, information collected during site visits, and written communications with foreign officials were stored on a centralized database. But the information was not systematically organized according to the eight evaluation factors. Such information was commonly stored without any consistency in file naming conventions, with some documents filed by the date received, by subject matter, or by source, among other methods, making it difficult to easily identify which documents supported different aspects of the evaluation. Consequently, interested stakeholders may find it difficult to replicate APHIS's evaluation. For example, an official from the National Cattlemen's Beef Association said that the association's staff attempted to replicate the Brazil evaluation, but the lack of organization in APHIS documents made it difficult for them to understand how the information APHIS gathered had been used to support the final risk analysis report. In addition, the absence of a document storage, organization, and management system may also have delayed APHIS's response to the association's Freedom of Information Act request for documents supporting APHIS's evaluations of Argentina and Brazil. According to an association official, it took almost one year to receive the relevant documents regarding the Brazil (14 states) evaluation, and as of October 2016, the association had yet to receive documents relevant to the Northern Argentina evaluation. In both cases, the National Cattlemen's Beef Association did not receive the documents before the public comment period had expired for the proposed rules to lift the import prohibition on beef from those regions. The official told us that as a result,

the association was not able to submit fully informed comments on the proposed rules.

According to federal standards for internal control, federal entities are to develop an information system that supports the agency's objectives, including processes, data, and technology that allow management to obtain, store, and process information. Implementing a standardized system for managing relevant information could help APHIS track the evaluation process over time and support a more efficient and transparent means of satisfying stakeholder requests for information. This may be especially important in situations where it takes many years to reach a regulatory decision, as was the case with the Argentina and Brazil evaluations, which each took about 13 years to complete.

We discussed our preliminary findings with APHIS officials in October 2016 and December 2016, raising concerns about the lack of (1) written guidance for performing animal health system evaluations, (2) analytical documentation supporting these evaluations, and (3) a systematic means of managing supporting documentation. APHIS officials acknowledged that improvements may be necessary in these three areas. Citing our preliminary findings, APHIS assembled a team in October 2016 to begin developing additional guidance, which the agency expects to implement in early 2017. According to APHIS officials, this guidance will better explain how documentation and other evidence should be used when evaluating foreign animal health systems. The team is also tasked with developing a new information management system. In December 2016, agency officials said they had developed a prototype for this new information management system using a software platform called "SharePoint." The official directing the effort said that APHIS expects to begin testing the system soon, and to bring the system into full operation in early 2017. According to this official, the new system will be used to store, organize, and manage information collected for some of the significant earlier foreign animal health system evaluations, as well as for future foreign country evaluation requests. This new system will provide APHIS the systematic means needed for managing the supporting documentation for its animal health system evaluations, including for each of the eight evaluation factors, as discussed.

---

## APHIS Lacks Adequate Guidance for Documenting Site Visits and Agency Staff Did Not Complete Reports for Most Site Visits

APHIS's 2011 guidance for evaluating animal health systems directs agency staff to complete a trip report for each site visit. Participants in the site visit are directed to provide their notes to the review team leader within 15 days of returning from the trip. According to the 2011 guidance, the trip report should be drafted by the review team leader and must include information on the places visited, the reason for visiting each place, the information gathered, and a summary of the major findings of the site visit team. APHIS officials noted that trip reports prior to issuance of the 2011 guidance generally were completed, though it was at the discretion of the evaluation team. Similarly, an APHIS official told us that the instructions issued in the 2011 guidance were not considered mandatory in order to allow some flexibility to accommodate circumstances in which staff felt a full report was not needed. For example, this official said that some in-country site visits do not warrant a trip report, such as those focused only on updating certain aspects of the risk analysis, those for which APHIS was confirming that nothing had changed since its last in-country site visit, or those for which APHIS needed to verify whether changes it had recommended had been implemented by the foreign country. However, more senior APHIS officials affirmed that trip reports have been a requirement since the agency issued the 2011 guidance and should be completed for all in-country site visits.

For the seven countries we reviewed, we found that APHIS did not always document in-country site visits, even after trip reports were required in 2011. For example, APHIS site visit teams conducted four in-country site visits to Argentina and four to Brazil from 2002 through 2015, but did not complete trip reports for any of these eight total in-country site visits. Additionally, trip reports were prepared for only five of nine in-country site visits that took place after the 2011 guidance was issued. APHIS officials acknowledged that documenting site visits is an important task and that some trip reports had not been prepared, but should have been. The officials said that they had taken steps to further emphasize to staff that agency guidance requires such documentation. Table 1 below summarizes the site visits conducted for each of the countries in our review and whether a trip report was completed for each of these visits.

**Table 1: Animal and Plant Health Inspection Service's (APHIS) In-country Site Visits and Whether a Trip Report Was Completed for Selected Countries' Beef Import Evaluations**

Country/Region	Year of site visit	Was an official trip report prepared?
Northern Argentina	2005	No
	2006	No
	2009	No
	2013	No
Brazil (14 States)	2002	No
	2003	No
	2006	No
	2013	No
Colombia	2007	No
	2008	No
	2011	Yes
	2012	Yes
	2015	Yes
Japan	2011	Yes
Paraguay	2008	No
	2014	No
	2015	No
Singapore	2014	Yes
Uruguay	2000	No
	2001	No
	2002	Yes

Source: GAO analysis of APHIS documents | GAO-17-373

In-country site visits allow APHIS staff to verify and supplement information previously gathered. APHIS guidance does not, however, direct staff to document the specific steps they took to verify that information or determine its reliability. The guidance also does not state that staff should document how they analyzed the effectiveness of a country's efforts on each of the eight evaluation factors. As a result, where in-country site visits were documented, there was variation in the degree to which APHIS staff recorded their specific verification activities or on-site analysis. For example, a 2011 trip report for Japan explicitly described how the team observed Japanese officials taking steps to ensure that meat entering the country had been appropriately treated to eliminate pathogens, as required by Japanese agricultural regulations. One component of a 2011 trip report for Colombia, however, was less

explicit about the team's activities. The trip report stated that the evaluation team had found diagnostic lab procedures and tests for FMD to be adequate, but did not state what the team had done to determine their adequacy.<sup>32</sup>

APHIS officials said they have not developed specific guidance for documenting in-country site visits because each country's evaluation is unique and, as such, the process cannot be standardized. The uniqueness of each animal health system evaluation, however, should not preclude APHIS from developing a more systematic approach to documenting site visit activities. FSIS has developed a standardized approach to documenting its analysis of foreign food safety systems, including its in-country site visits. Somewhat like the eight factors APHIS uses to evaluate foreign animal health systems, FSIS uses six components to evaluate a country's food safety system.<sup>33</sup> In contrast to APHIS, FSIS directs its staff to clearly document their analysis of each country's food safety system in an electronic "component analysis verification form." The form lays out the criteria—usually regulations—against which FSIS staff should assess foreign food safety systems. But, importantly, it also provides a method for recording both foreign officials' information submissions to FSIS, and FSIS's findings and activities—including those from site visits—in one place and in a consistent format. Information that FSIS staff must record in this form includes follow-ups with foreign officials, methodologies used to verify information, results of verification efforts, and the staff's final analysis and conclusions. The information recorded in the component analysis verification form is later included, as appropriate, in a food safety equivalence report.<sup>34</sup> Without a written trip report, it is difficult to know: (1) how APHIS staff verified information they had previously collected or received regarding a country's animal health system; (2) what concerns, if any, staff may have

---

<sup>32</sup> Colombia's FMD evaluation has not yet been completed. APHIS officials told us that they intend to include more detailed information on the country's laboratory diagnostic procedures in the final risk analysis report, which will be made available to the public.

<sup>33</sup> The six components included in FSIS's evaluation of a foreign food safety system are organization and administration; inspection system operation, product standards, labeling, and humane handling; sanitation; hazard analysis and critical control points; chemical residues testing; and microbiological testing. To start this evaluation, known as an equivalence determination, FSIS asks the relevant foreign government entity to complete a self-reporting tool that includes questions related to each of these components.

<sup>34</sup> FSIS calls this report an audit report. The report may include, if appropriate, FSIS's tentative determination of equivalence.

---

identified during the trip; (3) whether those concerns were communicated to country officials; and (4) how country officials responded to these concerns.

As discussed, federal standards for internal control state that documentation of important agency activities is essential for supporting the decision-making process. APHIS guidance states that the review team leader should prepare a trip report within 28 days of returning from the in-country site visit. Because the results from in-country site visits are one component used to determine whether the import prohibition on beef should be lifted, such visits should be thoroughly documented. An animal health system evaluation can take place over the course of many years, and sufficient documentation can enable APHIS to more easily review its site visit observations and findings after the passage of time to ensure that all potential risks or gaps in information were addressed before the agency lifts the import prohibition on beef. Again, one means of ensuring that staff understand these documentation requirements is to issue guidance clarifying expectations. Federal standards for internal control and Office of Management and Budget guidance underscore that internal agency guidance is an important tool for helping an organization enhance fairness and ensure equal treatment. Guidance that directs staff to document their in-country site visit verification activities would help APHIS ensure its process is fair, consistent, and transparent to the public and other stakeholders.

---

### APHIS Lacks Sufficient Guidance to Ensure Risk Analyses Are Transparently Documented

According to APHIS 2011 guidance, staff should format risk analysis reports in accordance with OIE guidelines, but the guidance provides no further details on how such reports should be crafted to ensure an acceptable level of transparency in accordance with federal quality information guidelines. APHIS officials told us that in documenting risk analyses, staff use prior risk analysis reports as templates and generally structure the reports in line with OIE guidance. Officials said that they believe staff observations, methodology, and conclusions are adequately incorporated into the risk analyses. According to OIE, the process of analyzing risk is inherently subjective, whether the process uses quantitative or qualitative analytical techniques. This subjectivity exists, according to OIE, in large part because some critical data required to assess risk may not be readily available or are of uncertain reliability. Therefore, it is important that a risk analysis be as transparent as

possible. The more transparent the analysis, the more defensible the risk analysis report will be, according to OIE.

Like OIE, the Office of Management and Budget and USDA's Chief Information Officer direct staff drafting documents supporting regulatory actions—including risk analyses—to transparently document the analytical methods employed, sources of information used, reliability of the data or information included in the analysis, and any relevant uncertainties and assumptions, among other things.<sup>35</sup> The guidelines from USDA's Chief Information Officer suggest that transparency is essential to ensuring objectivity in regulatory actions, and that transparency helps to clarify key uncertainties as well as assumptions upon which an analysis is based.

However, the extent to which APHIS effectively addressed these transparency guidelines varied in the risk analysis reports we reviewed. Some reports provided greater detail on: (1) the methodologies staff used to verify information gathered about a country's animal health system, (2) the assumptions they made in conducting their risk analyses, and (3) the extent to which the data or information gathered were considered reliable. For example, with regard to data reliability, the 2014 risk analysis for Croatia stated that APHIS relied upon older data from 2006 to assess the country's international passenger traffic patterns. Because it is suspected that people entering a country from areas where FMD is present may carry the virus on their clothing or other items, it is important that border areas are adequately staffed to identify potential sources that could carry and transmit FMD. The 2014 Croatia risk analysis report acknowledges that the 2006 data were still relevant, providing an indication of the total proportion of passengers typically entering the country via four key pathways: land, air, sea, and rail.<sup>36</sup> In contrast, in Brazil's 2015 risk analysis report, APHIS described an evaluation of livestock populations using animal census data collected sometime between 2000 and 2003

---

<sup>35</sup> Office of Management and Budget, *Updated Principles for Risk Analysis*, OMB Memorandum M-07-24 (Washington D.C.: 2007). USDA's Office of the Chief Information Officer guidelines are based on a provision of the Treasury and General Government Appropriations Act for FY 2001 (Pub. L. No. 106-554, §515, 114 Stat. 2763A-153 (2000)), also known as the Information Quality Act).

<sup>36</sup> According to APHIS officials, before lifting the ban on Croatia's meat imports, APHIS obtained more recent data and found that the data did not affect the results of the risk analysis because the relative proportion of passengers using each of the pathways had not changed significantly.

without explaining why the data were still considered relevant. Substantial changes in the size of livestock populations could impact the sufficiency of a country's animal disease surveillance efforts and resources.

APHIS also has used a dated study to support consequence assessments in four out of seven risk analysis reports we reviewed. Specifically, in the reports for Uruguay, Peru, Argentina, and Brazil, APHIS cited a 1979 study that estimated the economic impacts of an FMD outbreak in the United States. APHIS adjusted the study's estimates to account for changes in prices for some years after 1979—the year the study was published—and the year the risk analysis reports were prepared.<sup>37</sup> But APHIS did not explain in these four risk analysis reports how other components of the 1979 study that supported the cost estimates—such as the number of livestock that would need to be slaughtered or vaccinated in the event of an FMD outbreak, or the amount of time needed to sufficiently control an outbreak—were still reliable after more than 30 years.<sup>38</sup>

With regard to sources of information, we found that APHIS's risk analysis reports for both Argentina and Brazil were supported, in part, with documents that may only have been available in Spanish and Portuguese.<sup>39</sup> Although federal regulation and APHIS's 2011 guidance both state that evaluation staff should accept documents only in English from foreign officials, an APHIS official said that they require document translations only if the documents are critical to the analysis or if no one on staff is fluent in the foreign country's language.<sup>40</sup> According to APHIS

---

<sup>37</sup> The Uruguay (2002) and Peru (2011) risk analyses were adjusted to 2001 dollars using the Consumer Price Index, while the Argentina (2015) and Brazil (2015) risk analyses were adjusted to 2011 dollars using the Implicit Price Deflator. The Consumer Price Index and the Implicit Price Deflator are economic indices used to adjust for inflation, but they are calculated differently. The Consumer Price Index uses the weighted average price of a basket of consumer goods and services, while the Implicit Price Deflator uses a base year's gross domestic product to make the calculation.

<sup>38</sup> Nasser A. Aulaqi, E. Hunt McCauley, William M. Miller, John C. New, Jr., and W.B. Sundquist, *A Study of the Potential Economic Impact of Foot-and-Mouth Disease in the United States*, University of Minnesota, in cooperation with USDA Animal and Plant Health Inspection Service, (May 1979).

<sup>39</sup> Because APHIS lacks a consistent organizing scheme for the documentation it has received from foreign officials, it was impossible for us to determine if documents submitted in Spanish or Portuguese had also been submitted to APHIS in English. The foreign language document files did not usually indicate if another version of the file existed in English or the name of a corresponding English language file, if any.

<sup>40</sup> 9 CFR § 92.2(b).

officials, because APHIS had a review team leader on staff who was fluent in both Spanish and Portuguese, they did not translate all of the documents and used some foreign language versions to support the risk analysis report. However, an official from the National Cattlemen's Beef Association told us that the association found it difficult to fully understand APHIS's analysis because it did not have someone on staff that could review the supporting documentation in Spanish or Portuguese. Similar concerns regarding a lack of transparency in risk analysis reports were raised in comments submitted to APHIS during the public comment period for proposed rule changes for Argentina and Brazil beef. In both cases, commenters stated that because some of the documentation supporting APHIS's risk analysis was in the country's native language, APHIS's research methodology and the manner in which the agency arrived at its conclusions were not transparent.

With regard to disclosure of assumptions and uncertainties, APHIS sometimes did not disclose assumptions or uncertainties about the data and information used in its risk analysis reports. APHIS's evaluation of Uruguay entailed a quantitative analysis, unlike the other evaluations we reviewed, which were qualitative analyses. According to an APHIS official, assumptions and uncertainties are typically disclosed in analyses that use mathematical models. Since the risk analysis reports we reviewed primarily employed a qualitative analytical approach, such disclosures were not necessary, this official said. Guidelines concerning transparency issued by the Office of Management and Budget, USDA's Chief Information Officer, and OIE, however, do not indicate that disclosures about uncertainties in the data or assumptions made about the data used should be limited to only quantitative analyses. One of OIE's guiding principles for risk analysis—whether it be qualitative or quantitative in nature—is that it should document assumptions and uncertainties, and the effect of these on the final risk estimate.

One method of ensuring that agency staff draft risk analysis reports that incorporate the vital elements of transparency advocated by the Office of Management and Budget, USDA's Chief Information Officer, and OIE is to develop appropriate agency guidance and direct staff to follow it. As discussed earlier, federal standards for internal control and the Office of Management and Budget underscore the importance of drafting effective internal agency guidance to help an organization achieve its goals and objectives and enhance fairness, ensuring the equal treatment over time of similarly situated parties.

---

## Conclusions

The United States has kept its livestock free of FMD since 1929, successfully avoiding the financial losses that typically accompany an outbreak, such as those associated with trade bans on exports and the slaughter of FMD-infected or potentially-infected animals to stop spread of the disease. APHIS has conducted animal health system evaluations that entail a substantial effort to gather and analyze a country's regulatory documentation and other relevant information and data. The effort also involves in-country site visits to verify information, assess how regulatory controls function in practice, and address questions and concerns that may arise as a result of the analysis.

But APHIS does not generally document how information gathered was analyzed to identify potential weaknesses in a foreign country's animal health system. In addition, trip reports for in-country site visits were not always prepared—despite agency guidance directing staff to do so—and, when prepared, did not consistently explain how information had been verified. Better guidance would help ensure that agency staff understand expectations about when and how to record important information supporting regulatory activities, and could help ensure that APHIS is conducting animal health system evaluations consistently across countries and over time. In addition to lacking documentation of key activities, APHIS does not have an effective method for storing, organizing, and managing information obtained during the course of an evaluation. APHIS's lack of an adequate information management system makes it difficult to identify which documents received from foreign officials are intended to support various aspects of the evaluation.

Finally, APHIS's risk analysis reports are not consistently transparent because they do not always clearly document the methodology used to evaluate key factors of a country's animal health system, the reliability of data used in the risk analysis report, and other important characteristics that would help the public understand how a regulatory decision was made.

As APHIS moves forward to implement a new information management system and begins to draft additional agency guidance, it will need to ensure that both serve to mutually enhance transparency of foreign animal health system evaluations. In particular, APHIS must ensure:

- 
- that this agency guidance reflects the importance of documenting, separately from the final risk analysis report, how analysis of each evaluation factor was carried out;
  - that this guidance—including requirements to document foreign site visits—is not optional; and
  - that the risk analysis reports include key characteristics of transparency called for in both federal and OIE guidance.

---

## Recommendations for Executive Action

To improve USDA's evaluations of foreign countries' animal health systems, we recommend that the Secretary of Agriculture direct the Administrator of APHIS to take the following three actions:

1. complete its efforts to develop agency guidance, clarifying that
  - staff must document, separately from the final risk analysis report, how key information gathered about a foreign country's animal health system was analyzed and how the information supports each of eight evaluation factors, and
  - in-country site visits must be appropriately and consistently documented in trip reports and should detail verification activities;
2. complete its efforts to develop an information management system to better store, organize, and manage documentation gathered about a foreign country's animal health system; and
3. develop guidance promoting greater transparency in risk analysis reports in accordance with the quality information guidelines issued by USDA's Chief Information Officer and guidance from the Office of Management and Budget.

---

## Agency Comments and Our Evaluation

We provided a draft of this report to USDA for review and comment. In its written comments, reproduced in appendix II, USDA agreed with the report's recommendations. USDA also provided technical comments, which we incorporated as appropriate.

In response to our recommendation that APHIS develop agency guidance that clarifies that staff must document how key information gathered about a foreign country's animal health system was analyzed and ensure

that in-country site visits are documented as required, USDA stated that APHIS has developed agency guidance addressing the major components needed to evaluate information received from foreign authorities. All staff members have been instructed to use this guidance for current and future animal health system evaluations. APHIS also has plans to assess use of this guidance in the next 6-12 months to ensure that it is working as intended and to identify any needed revisions. To assist staff in ensuring their analyses are transparent, consistent, and complete, USDA said APHIS has developed a special analytical tool that will document information provided to APHIS by foreign authorities and provide a method for recording any staff concerns. Existing guidance also has been clarified to ensure that staff members understand site visit reports are mandatory, and not optional. Taking these steps will meet the intent of our recommendation.

With regard to our recommendation that APHIS develop an information management system to better store, organize, and manage its evaluation documentation, USDA stated that APHIS has completed a new centralized Project Tracking System to better manage the documentation. All APHIS staff have access to the system, so all documents can be stored in one location. The system includes a Project Tracking Form for each evaluation that provides an overview of who is working on the project, status of major milestones, and final deliverables when complete. USDA said that the new tracking system also establishes a framework for each project and allows documents—such as correspondence, references, risk analysis, and rulemaking—to be stored in one place. Implementing these actions will address our recommendation.

To address our recommendation that USDA develop guidance promoting greater transparency in accordance with quality information guidelines issued by USDA's Chief Information Officer and the Office of Management and Budget, USDA stated that APHIS will develop such guidance and that it will include such things as standards for disclosing the reliability of data used in risk assessments, in particular assumptions and uncertainties. The guidance also will outline key source documents that can be made publicly available along with the final risk assessment for an evaluation. In addition, USDA said that APHIS has instructed its staff that it is mandatory that all documents submitted by another country for an evaluation must be in English. Completion of these steps will address the intent of our recommendation.

---

We are sending copies of this report to the appropriate congressional committees, the Secretary of Agriculture, the Administrator of the Animal and Plant Health Inspection Service, and other interested parties. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-3841 or [morriss@gao.gov](mailto:morriss@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix III.

A handwritten signature in black ink that reads "Steve D. Morris". The signature is written in a cursive, slightly slanted style.

Steve D. Morris  
Director, Natural Resources and Environment

---

*List of Requesters*

The Honorable Michael Conaway  
Chairman  
Committee on Agriculture  
House of Representatives

The Honorable Pete Sessions  
Chairman  
Committee on Rules  
House of Representatives

The Honorable John Cornyn  
United States Senate

The Honorable Joe Barton  
House of Representatives

The Honorable Michael Burgess  
House of Representatives

The Honorable John R. Carter  
House of Representatives

The Honorable Jim Costa  
House of Representatives

The Honorable Eric "Rick" Crawford  
House of Representatives

The Honorable Henry Cuellar  
House of Representatives

The Honorable John Culberson  
House of Representatives

The Honorable Blake Farenthold  
House of Representatives

The Honorable Bill Flores  
House of Representatives

The Honorable Louis Gohmert  
House of Representatives

The Honorable Kay Granger  
House of Representatives

The Honorable Jeb Hensarling  
House of Representatives

The Honorable Sam Johnson  
House of Representatives

The Honorable Kenny Marchant  
House of Representatives

The Honorable Michael McCaul  
House of Representatives

The Honorable Pete Olson  
House of Representatives

The Honorable Ted Poe  
House of Representatives

The Honorable Kurt Schrader  
House of Representatives

The Honorable Lamar Smith  
House of Representatives

The Honorable Mac Thornberry  
House of Representatives

The Honorable Filemon Vela  
House of Representatives

The Honorable Randy K. Weber  
House of Representatives

The Honorable Roger Williams  
House of Representatives

---

Letter

---

The Honorable Ted S. Yoho  
House of Representatives

## Appendix I: Objectives, Scope, and Methodology

This report addresses the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service's (APHIS) approach to protecting U.S. livestock from foot-and-mouth disease (FMD), which may be transmitted through beef imports. Specifically, this report examines (1) the steps APHIS takes to evaluate the animal health systems of foreign countries seeking to export beef to the United States and (2) how APHIS's process could be improved, if at all.

To address these objectives, we reviewed relevant federal statutes and applicable federal regulations concerning animal health and trade of animal products.<sup>1</sup> Additionally, we reviewed federal and World Organisation for Animal Health (OIE)<sup>2</sup> guidance documents, and a key international trade agreement regarding imports of beef. Specifically, we reviewed the federal Animal Health Protection Act, as well as APHIS guidance documents on evaluating animal health systems and the information that is needed for APHIS to conduct such evaluations.<sup>3</sup> OIE documents we reviewed were the organization's requirements for FMD-free status and information on conducting and reporting import risk analyses.<sup>4</sup> International trade agreement documents we reviewed

---

<sup>1</sup> 9 C.F.R. part 92, *Importation of Animals and Animal Products: Procedures for Requesting Recognition of Regions*; 9 C.F.R. part 94, *Rinderpest, Foot-and-Mouth Disease, Newcastle Disease, Highly Pathogenic Avian Influenza, African Swine Fever, Classical Swine Fever, Swine Vesicular Disease, and Bovine Spongiform Encephalopathy: Prohibited and Restricted Importations*.

<sup>2</sup> The World Organisation for Animal Health was formerly known as the Office International des Epizooties (OIE), and kept its historical acronym of OIE after changing names. OIE is an intergovernmental organization created in response to the need to fight animal diseases on a global level, and is tasked with improving animal health worldwide. One of its stated objectives is to promote safety in international trade of animals and animal products.

<sup>3</sup> APHIS, Veterinary Services, Regional Evaluation Services, *Clarification of Information Requested for Recognition of a Region*, undated; *Process for Foreign Animal Health Status Evaluations, Regionalization, Risk Analysis, and Rulemaking*, undated; *Guidelines for Conducting Regionalization Evaluations* (September 2011).

<sup>4</sup> World Organisation for Animal Health (OIE), *Handbook on Import Risk Analysis for Animals and Animal Products*, Vol. 1 and 2 (Paris, France: 2010); *Terrestrial Animal Health Code – Import Risk Analysis*, Chapter 2 (Paris, France: 2015); and *Terrestrial Animal Health Code – Infection with FMD Virus*, Chapter 8 (Paris, France: 2015).

included the World Trade Organization's Sanitary and Phytosanitary Measures Agreement signed by member nations and the related guidelines on implementing sanitary practices for exported agricultural products.<sup>5</sup> We also identified and analyzed best practices supporting transparency in regulatory decision-making suggested by the Office of Management and Budget, the Government Accountability Office (GAO's *Standards for Internal Control in the Federal Government*), and USDA's Chief Information Officer.<sup>6</sup> Additionally, we reviewed the Federal Records Act, which addresses records management by federal agencies.<sup>7</sup> To develop an understanding of the challenges USDA faces in ensuring the health of U.S. livestock, we reviewed USDA Office of the Inspector General's recent relevant reports on border inspections and import controls of beef and live animals.<sup>8</sup>

To gain a better understanding of APHIS's process for protecting U.S. livestock from FMD, we focused our review on APHIS's evaluations of the animal health systems of seven countries or specific regions within those countries. We chose six of the seven countries for review because they had the following characteristics: (1) the countries requested an animal health system evaluation for FMD for the purpose of exporting beef to the United States and (2) APHIS has either completed evaluations and lifted the import prohibition on the country's beef within the past 5 years, or APHIS is currently conducting an evaluation to determine whether the import prohibition on the country's beef can be safely lifted. The six countries or specific regions within countries we reviewed were: Northern

---

<sup>5</sup> World Trade Organization, *Sanitary and Phytosanitary Measures Agreement*, Geneva, Switzerland: Jan. 1995; Committee on Sanitary and Phytosanitary Measures, *Guidelines to Further the Practical Implementation of Article 6 of the Agreement On the Application of Sanitary and Phytosanitary Measures, G/SPS/48* (Geneva, Switzerland: May 16, 2008).

<sup>6</sup> USDA, Office of the Chief Information Officer, *Information Quality Activities*. Accessed May 26, 2016, <https://www.ocio.usda.gov/policy-directives-records-forms/information-quality-activities>. Office of Management and Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Notice; Republication*, FR 8452 (Feb. 22, 2002); and GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: September 2014).

<sup>7</sup> 44 USC §3101, et. seq.

<sup>8</sup> U.S. Department of Agriculture, Office of the Inspector General, *Animal and Plant Health Inspection Service: Transition and Coordination of Border Inspection Activities Between USDA and DHS, Report No. 33601-0005-Ch* (Washington, D.C.: March 2005); *USDA's Controls Over the Importation and Movement of Live Animals, Report No. 50601-0012-Ch* (Washington, D.C.: March 2008).

Argentina, 14 states in Brazil (comprising a single export region), Colombia, Japan, Paraguay, and Singapore. APHIS's evaluations for Northern Argentina, the 14-state region in Brazil, and Japan were completed within the past 5 years; evaluations for Colombia, Paraguay, and Singapore are ongoing. We also reviewed efforts of one additional country, Uruguay, to have the import prohibition on its beef lifted. The import prohibition on beef from Uruguay was lifted in 2003, but it is a country for which APHIS conducted a *quantitative* risk analysis, an evaluative approach that was not applied to the other six countries in our review. For the other six countries we reviewed, APHIS is performing or has performed a *qualitative* risk analysis.<sup>9</sup> The information we obtained from APHIS's evaluations of the seven countries we reviewed is not generalizable, but provided us with a greater understanding of the key steps that comprise a foreign animal health system evaluation.

We did not evaluate the scientific or technical validity of APHIS's risk analyses, nor did we question APHIS's decisions to lift the import prohibition on Argentina, Brazil, Japan, and Uruguay's beef. Instead, we focused our review on APHIS's process for conducting and documenting its evaluations of the animal health systems in the seven countries in our review. Additionally, we reviewed APHIS's animal health system evaluations to determine how well the agency incorporated standards for documentation and transparency as established in guidance issued by USDA's Chief Information Officer, the Office of Management and Budget, and GAO. Our analysis of APHIS's evaluations of the animal health systems in these seven countries included a review of available, relevant documents gathered from those countries' officials in support of their requests to export beef to the United States, communications between APHIS and country officials regarding those documents, APHIS's written reports, and APHIS officials' notes documenting their in-country investigations of foreign animal health systems. We reviewed only documents in English, although many supporting documents were in the foreign country's official language. We also interviewed APHIS officials with Veterinary Services, National Import Export Services, and Regionalization Evaluation Services in Maryland, as well as evaluation staff in Maryland and North Carolina who evaluated the beef export requests of the seven countries in our review.

---

<sup>9</sup> A *quantitative* risk analysis is a method of assessing various aspects of risk—such as the likelihood of a beef product becoming infected with a disease prior to export—using a mathematical model and expressing that risk numerically. A *qualitative* risk analysis expresses various aspects of risk in non-numerical terms, such as high, medium, or low.

To develop an understanding of APHIS's process for conducting and documenting FMD risk analyses, we reviewed the final FMD risk analysis reports for Northern Argentina, the 14-state region of Brazil, Japan, and Uruguay. (Final risk analysis reports have not yet been prepared for Colombia, Paraguay, and Singapore). To further expand our understanding of how APHIS conducts and documents FMD risk analyses, we also reviewed the only other three countries that, according to APHIS, have had risk analysis reports completed within the past 5 years for FMD: Croatia, Malta, and Peru. These countries sought animal health system evaluations for non-beef or unspecified product exports to the United States. We also reviewed Food Safety and Inspection Service (FSIS) guidance for conducting food safety equivalence evaluations to further understand the steps required before a country may begin exporting beef to the United States. Finally, we interviewed officials with FSIS, which certifies that foreign food safety systems are equivalent to the U.S. system; an official with the Canadian Food Inspection Agency, which is the Canadian agency responsible for ensuring the safety of food products, including beef; and the Chief Veterinarian from the National Cattlemen's Beef Association, a trade group that consists of 28,000 members and 175,000 beef producers and feeders.

We conducted this performance audit from December 2015 to April 2017, 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.

## Appendix II: Comments from the U.S. Department of Agriculture



United States Department of Agriculture

Office of the Secretary  
Washington D.C. 20250

March 21, 2017

Mr. Steve D. Morris, Director  
Natural Resources and Environment  
Government Accountability Office  
441 G Street NW  
Washington, DC 20548

Dear Mr. Morris:

Thank you for providing the United States Department of Agriculture (USDA) the opportunity to comment on the Government Accountability Office's (GAO) Draft Report, "Foot-and-Mouth Disease: USDA's Evaluations of Foreign Animal Health Systems Need Better Guidance and Greater Transparency" (17-373). We have a strong, science-based system that has successfully prevented the entry of FMD into the United States, and we are always open to ways to further improve our processes. We have addressed the Recommendations made to the Secretary of Agriculture.

### GAO Recommendation

To improve USDA's evaluations of foreign countries' animal health systems, GAO recommends that the Secretary of Agriculture direct the Administrator of APHIS **to complete its efforts to develop agency guidance, clarifying that staff must document, separate from the final risk analysis report, how key information gathered about a foreign country's animal health system was analyzed and supports each of eight evaluation factors; and that, in-country site visits must be appropriately and consistently documented in trip reports and should detail verification activities.**

### USDA Response

USDA agrees with this Recommendation. APHIS has developed a document – "*Guidance for the Application of the 8 Factors for Animal Health Status Evaluations of Foreign Regions*" – that provides guidance for the evaluation of the diverse and complex information pertaining to the eight evaluation factors. This guidance addresses the major components needed to evaluate the information received from a region requesting an evaluation. All staff members have been instructed to use this guidance for all current and future evaluations. APHIS will evaluate the use of this guidance in the next 6-12 months to ensure that it is working as intended and to identify any needed revisions.

An Equal Opportunity Employer

Steve Morris  
Page 2

The guidance document identifies the objective and rationale for collecting and evaluating the information for each of the eight factors. This is followed by the major components that should be considered to thoroughly evaluate if the region can adequately control the entry risk to the US for the hazard of concern. Because each evaluation differs in the interdependent relationship between the region, the commodity and the hazard, the list of major components for evaluation for each factor is not exhaustive and may not apply to every case. The guidance document includes a tool - *The 8 Factor Evaluation Tool* – that will be used to ensure transparency, consistency, and completeness of the entry assessment and to provide documentation for the determination of the region’s animal health status. For each evaluation, the tool will be updated as the region provides additional information and the site visit is completed, documenting the steps taken by the region to provide acceptable information for all 8 factors. In the event a region is not successful in providing acceptable information, this will provide documentation of the evaluation team’s specific concerns. The final analysis and rationale of conclusions regarding all of the information received and the site visit observations will be detailed in the risk assessment document.

APHIS has instructed all staff members that they must follow existing guidance documents. This specifically includes requirements for site visit reports as outlined in a September 2011 document, “Guidelines for Conducting Regionalization Evaluations.” This document contains information on site visit planning, logistics, and management. It also includes instruction on generating a site visit report. To address the GAO concern that site visit reports were not consistently completed, in October 2016 APHIS instructed all staff members that following the September 2011 document is mandatory.

**GAO Recommendation**

To improve USDA’s evaluations of foreign countries’ animal health systems, GAO recommends that the Secretary of Agriculture direct the Administrator of APHIS to **complete its efforts to develop an information management system to better store, organize, and manage documentation gathered about a foreign animal health system.**

**USDA Response**

USDA agrees with this Recommendation. APHIS has developed an information management system – the Project Tracking System (PTS) – to better manage the documentation. This was completed at the end of January. All staff members have access to the system, so all documents can be stored in one location. There is a Project Tracking Form for each project that provides an overview of who is working on the project, status of major milestones, and final deliverables when complete. In addition to the project tracking form, there are folders for various types of documents such as correspondence, references, risk analysis, rulemaking, etc. This provides an

Steve Morris  
Page 3

established framework for each project and allows documents to be stored in one location. The system was created with input from all staff and was tested prior to implementation. APHIS is now in the implementation stage, and all staff have been directed to populate the information for active evaluations, followed by any evaluations on hold. All active evaluations should be populated by the end of April, 2017.

**GAO Recommendation**

To improve USDA's evaluations of foreign countries' animal health systems, GAO recommends that the Secretary of Agriculture direct the Administrator of APHIS to **develop guidance promoting greater transparency in risk analysis reports in accordance with the quality information guidelines issued by USDA's Chief Information Officer and the Office of Management and Budget.**

**USDA Response**

USDA agrees with this Recommendation. APHIS agrees that transparency is crucial in all documents that support regulatory decisions. APHIS will develop guidance that addresses various aspects of improving transparency. This guidance will outline key source documents (such as information received from the region under evaluation) that can be made publicly available along with the final risk assessment. It will identify expected standards for making disclosures about data and for identifying uncertainties and assumptions where appropriate. The guidance will also reinforce the USDA Information Quality Guidelines, and will address all reviewers to consider the Information Quality Guidelines as a specific part of their review.

APHIS has already addressed some components of this recommendation. Existing guidance – the September 2011 document previously referenced – addresses the fact that documents should be submitted in English. APHIS has instructed staff that it is mandatory to follow this guidance, and will ensure that documents submitted in a language other than English must be translated. APHIS has also strengthened measures to ensure proper citations in risk assessments. APHIS has ensured that all staff officers have access to and training in software – Endnote 8 – that assists with this process. This software improves the ability to track references and properly cite sources in the final document.

Sincerely,



Kevin Shea  
Acting Deputy Under Secretary  
Marketing and Regulatory Programs

---

## Appendix III: GAO Contact and Staff Acknowledgments

---

### GAO Contact

Steve D. Morris, (202) 512-3841 or [morriss@gao.gov](mailto:morriss@gao.gov)

---

### Staff Acknowledgments

In addition to the contact named above, James R. Jones, Jr. (Assistant Director), Kevin Bray, John Delicath, Barbara El Osta, Justin Fisher, Sara Sullivan, Kiki Theodoropoulos, Breanna Trexler, and Ginny Vanderlinde made key contributions to this report.

---

## Appendix IV: Accessible Data

---

### Data Tables

---

**Data for Figure 1: Status of Foot-and-Mouth Disease (FMD) Animal Health System Evaluations Conducted by Animal and Plant Health Inspection Service (APHIS), March 2017**

**Countries with Declared foot-and-mouth disease (FMD)-free and import prohibition lifted on certain livestock and their products**

- Argentina (Patagonia region)\*
- Australia\*
- Austria\*
- Bahamas\*
- Barbados
- Belgium\*
- Belize
- Bermuda
- Brazil (state of Santa Catarina)\*
- Canada
- Channel Islands\*
- Chile\*
- Costa Rica
- Croatia\*
- Czech Republic\*
- Denmark\*
- Dominican Republic
- El Salvador
- Estonia\*
- Fiji
- Finland\*

- France\*
- Germany\*
- Greece\*
- Greenland
- Guatemala
- Haiti
- Honduras
- Hungary\*
- Iceland
- Ireland\*
- Italy\*
- Jamaica
- Japan\*
- Latvia\*
- Liechtenstein\*
- Lithuania\*
- Luxembourg\*
- Marshall Islands
- Mexico
- Micronesia, Federated States of
- Namibia (region south of the Veterinary Cordon Fence)\*
- Netherlands\*
- New Caledonia
- New Zealand
- Nicaragua
- Norway\*
- Palau
- Panama
- Papua New Guinea\*
- Poland\*

- Portugal\*
- Saint-Pierre and Miquelon
- Slovakia\*
- Slovenia\*
- Spain\*
- Sweden\*
- Switzerland\*
- Trinidad and Tobago
- United Kingdom\*

**Countries Not declared FMD-free, but beef import prohibition lifted**

- Argentina (region of Northern Argentina)
- Brazil (14-state region)
- Uruguay

**Countries with FMD evaluation underway**

- Colombia
- Paraguay
- Singapore

---

**Data for Figure 2: Animal and Plant Health Inspection Service's (APHIS) General Process for Evaluating a Foreign Country's Animal Health System**

1. Initial request for evaluation
2. Information gathering
3. In-country site visit
4. Risk analysis
5. Risk estimation

---

**Figure 3: Three Key Components Included in Animal and Plant Health Inspection Service's (APHIS) Risk Analyses**

- "Entry assessment" Estimates the likelihood of a foot-and-mouth disease (FMD)-contaminated commodity entering the United States.

- 
- “Exposure assessment” Estimates the likelihood of susceptible animals in the United States being exposed to an FMD-contaminated commodity, and the means by which that exposure may occur.
  - “Consequence assessment” Estimates the biological, environmental, and economic consequences associated with the establishment and the spread of FMD in the United States.

---

## Agency Comment letter

---

### Text of Appendix II: Comments from the U.S. Department of Agriculture

#### Page 1

March 21, 2017

Mr. Steve D. Morris, Director Natural Resources and Environment  
Government Accountability Office 441 G Street NW

Washington, DC 20548

Dear Mr. Morris:

Thank you for providing the United States Department of Agriculture (USDA) the opportunity to comment on the Government Accountability Office's (GAO) Draft Report, "Foot-and-Mouth

Disease: USDA's Evaluattons of Foreign Animal Health Systems Need Better Guidance and Greater Transparency" (17-373). We have a strong, scieyce-based system that has successfully prevented the entry of FMD into the United States, and we are always open to ways to further improve our processes. We have addressed the Recommendations made to the Secretary of Agriculture.

#### **GAO Recommendation**

To improve USDA's evaluations of foreign countries' animal health systems, GAO recommends that the Secretary of Agriculture direct the Administrator of APHIS to complete its efforts to develop agency guidance, clarifying that staff must document, separate from the final risk analysis report, how key information gathered about a foreign country's

animal health system was analyzed and supports each of eight evaluation factors; and that, in-country site visits must be appropriately and consistently documented in trip reports and should detail verification activities.

### **USDA Response**

USDA agrees with this Recommendation. APHIS has developed a document - "Guidance for the Application of the 8 Factors for Animal Health Status Evaluations of Foreign Regions" - that provides guidance for the evaluation of the diverse and complex information pertaining to the eight evaluation factors. This guidance addresses the major components needed to evaluate the information received from a region requesting an evaluation. All staff members have been instructed to use this guidance for all current and future evaluations. APHIS will evaluate the use of this guidance in the next 6-12 months to ensure that it is working as intended and to identify any needed revisions.

### Page 2

The guidance document identifies the objective and rationale for collecting and evaluating the information for each of the eight factors. This is followed by the major components that should be considered to thoroughly evaluate if the region can adequately control the entry risk to the US for the hazard of concern. Because each evaluation differs in the interdependent relationship between the region, the commodity and the hazard, the list of major components for evaluation for each factor is not exhaustive and may not apply to every case. The guidance document includes a tool - The 8 Factor Evaluation Tool - that will be used to ensure transparency, consistency, and completeness of the entry assessment and to provide documentation for the determination of the region's animal health status. For each evaluation, the tool will be updated as the region provides additional information and the site visit is completed, documenting the steps taken by the region to provide acceptable information for all 8 factors. In the event a region is not successful in providing acceptable information, this will provide documentation of the evaluation team's Specific concerns. The final analysis and rationale of conclusions regarding all of the information received and the site visit observations will be detailed in the risk assessment document.

APIDS has instructed all staff members that they must follow existing guidance documents. This specifically includes requirements for site visit reports as outlined in a September 2011 document, "Guidelines for

Conducting Regionalization Evaluations." This document contains information on site visit planning, logistics, and management. It also includes instruction on generating a site visit report. To address the GAO concern that site visit reports were not consistently completed, in October 2016 APHIS instructed all staff members that following the September 2011 document is mandatory.

### **GAO Recommendation**

To improve USDA's evaluations of foreign countries' animal health systems, GAO recommends that the Secretary of Agriculture direct the Administrator of APHIS to complete its efforts to develop an information management system to better store, organize, and manage documentation gathered about a foreign animal health system.

### **USDA Response**

USDA agrees with this Recommendation. APHIS has developed an information management system -the Project Tracking System (PTS) -to better manage the documentation. This was completed at the end of January. All staff members have access to the system, so all documents can be stored in one location. There is a Project Tracking Form for each project that provides an overview of who is working on the project, status of major milestones, and final deliverables when complete. In addition to the project tracking form, there are folders for various types of documents such as correspondence, references, risk analysis, rulemaking, etc. This provides an

### Page 3

established framework for each project and allows documents to be stored in one location. The system was created with input from all staff and was tested prior to implementation. APHIS is now in the implementation stage, and all staff have been directed to populate the information for active evaluations, followed by any evaluations on hold. All active evaluations should be populated by the end of April, 2017.

### **GAO Recommendation**

To improve USDA's evaluations of foreign countries' animal health systems, GAO recommends that the Secretary of Agriculture direct the Administrator of APHIS to develop guidance promoting greater transparency in risk analysis reports in accordance with the quality

information guidelines issued by USDA's Chief Information Officer and the Office of Management and Budget.

### **USDA Response**

USDA agrees with this Recommendation. APHIS agrees that transparency is crucial in all documents that support regulatory decisions. APHIS will develop guidance that addresses various aspects of improving transparency. This guidance will outline key source documents (such as information received from the region under evaluation) that can be made publicly available along with the final risk assessment. It will identify expected standards for making disclosures about data and for identifying uncertainties and assumptions where appropriate. The guidance will also reinforce the USDA Information \_ Quality Guidelines, and will address all reviewers to consider the Information Quality Guidelines as a specific part of their review.

APHIS has already addressed some components of this recommendation. Existing guidance - the September 2011 document previously referenced - addresses the fact that documents should be submitted in English. APHIS has instructed staff that it is mandatory to follow this guidance, and will ensure that documents submitted in a language other than English must be translated.

APHIS has also strengthened measures to ensure proper citations in risk assessments. APHIS has ensured that all staff officers have access to and training in software - Endnote 8 -that assists with this process. This software improves the ability to track references and properly cite sources in the final document.

Sincerely,

Kevin Shea

Acting Deputy Under Secretary Marketing and Regulatory Programs

---

## Related GAO Products

*Emerging Animal Diseases: Actions Needed to Better Position USDA to Address Future Risks.* [GAO-16-132](#). December 15, 2015.

*Biosurveillance: Additional Planning, Oversight, and Coordination Needed to Enhance National Capability.* [GAO-15-664T](#). July 8, 2015.

*Homeland Security: An Overall Strategy Is Needed to Strengthen Disease Surveillance in Livestock and Poultry.* [GAO-13-424](#). May 21, 2013.

*Biosurveillance: Nonfederal Capabilities Should Be Considered in Creating a National Biosurveillance Strategy.* [GAO-12-55](#). October 31, 2011.

*Influenza Vaccine: Federal Investments in Alternative Technologies and Challenges to Development and Licensure.* [GAO-11-435](#). June 27, 2011.

*Influenza Pandemic: Lessons from the H1N1 Pandemic Should Be Incorporated into Future Planning.* [GAO-11-632](#). June 27, 2011.

*Live Animal Imports: Agencies Need Better Collaboration to Reduce the Risk of Animal-Related Diseases.* [GAO-11-9](#). November 8, 2010.

*Influenza Pandemic: Monitoring and Assessing the Status of the National Pandemic Implementation Plan Needs Improvement.* [GAO-10-73](#). November 24, 2009.

*Influenza Pandemic: Gaps in Pandemic Planning and Preparedness Need to Be Addressed.* [GAO-09-909T](#). July 29, 2009.

*Influenza Pandemic: Continued Focus on the Nation's Planning and Preparedness Efforts Remains Essential.* [GAO-09-760T](#). June 3, 2009.

*Influenza Pandemic: Sustaining Focus on the Nation's Planning and Preparedness Efforts.* [GAO-09-334](#). February 26, 2009.

*Influenza Pandemic: HHS Needs to Continue Its Actions and Finalize Guidance for Pharmaceutical Interventions.* [GAO-08-671](#). September 30, 2008.

*Yellowstone Bison: Interagency Plan and Agencies' Management Need Improvement to Better Address Bison-Cattle Brucellosis Controversy.* [GAO-08-291](#). March 7, 2008.

*Plum Island Animal Disease Center: DHS Has Made Significant Progress Implementing Security Recommendations, but Several Recommendations Remain Open.* [GAO-08-306R](#). December 17, 2007.

*National Animal Identification System: USDA Needs to Resolve Several Key Implementation Issues to Achieve Rapid and Effective Disease Traceback.* [GAO-07-592](#). July 6, 2007.

*Influenza Pandemic: Efforts to Forestall Onset Are Under Way; Identifying Countries at Greatest Risk Entails Challenges.* [GAO-07-604](#). June 20, 2007.

*Avian Influenza: USDA Has Taken Important Steps to Prepare for Outbreaks, but Better Planning Could Improve Response.* [GAO-07-652](#). June 11, 2007.

*Plum Island Animal Disease Center: DHS and USDA Are Successfully Coordinating Current Work, but Long-Term Plans Are Being Assessed.* [GAO-06-132](#). December 19, 2005.

*Mad Cow Disease: An Evaluation of a Small Feed Testing Program FDA Implemented in 2003 with Recommendations for Making the Program a Better Oversight Tool.* [GAO-06-157R](#). October 11, 2005.

*Mad Cow Disease: FDA's Management of the Feed Ban Has Improved, but Oversight Weaknesses Continue to Limit Program Effectiveness.* [GAO-05-101](#). February 25, 2005.

*Combating Bioterrorism: Actions Needed to Improve Security at Plum Island Animal Disease Center.* [GAO-03-847](#). September 19, 2003.

*Foot and Mouth Disease: To Protect U.S. Livestock, USDA Must Remain Vigilant and Resolve Outstanding Issues.* [GAO-02-808](#). July 26, 2002.

*Mad Cow Disease: Improvements in the Animal Feed Ban and Other Regulatory Areas Would Strengthen U.S. Prevention Efforts.* [GAO-02-183](#). January 25, 2002.

---

---

## GAO's Mission

The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

---

## Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's website (<http://www.gao.gov>). Each weekday afternoon, GAO posts on its website newly released reports, testimony, and correspondence. To have GAO e-mail you a list of newly posted products, go to <http://www.gao.gov> and select "E-mail Updates."

---

## Order by Phone

The price of each GAO publication reflects GAO's actual cost of production and distribution and depends on the number of pages in the publication and whether the publication is printed in color or black and white. Pricing and ordering information is posted on GAO's website, <http://www.gao.gov/ordering.htm>.

Place orders by calling (202) 512-6000, toll free (866) 801-7077, or TDD (202) 512-2537.

Orders may be paid for using American Express, Discover Card, MasterCard, Visa, check, or money order. Call for additional information.

---

## Connect with GAO

Connect with GAO on [Facebook](#), [Flickr](#), [LinkedIn](#), [Twitter](#), and [YouTube](#).  
Subscribe to our [RSS Feeds](#) or [E-mail Updates](#). Listen to our [Podcasts](#).  
Visit GAO on the web at [www.gao.gov](http://www.gao.gov) and read [The Watchblog](#).

---

## To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

---

Website: <http://www.gao.gov/fraudnet/fraudnet.htm>  
E-mail: [fraudnet@gao.gov](mailto:fraudnet@gao.gov)  
Automated answering system: (800) 424-5454 or (202) 512-7470

---

## Congressional Relations

Katherine Siggerud, Managing Director, [siggerudk@gao.gov](mailto:siggerudk@gao.gov), (202) 512-4400,  
U.S. Government Accountability Office, 441 G Street NW, Room 7125,  
Washington, DC 20548

---

## Public Affairs

Chuck Young, Managing Director, [youngc1@gao.gov](mailto:youngc1@gao.gov), (202) 512-4800  
U.S. Government Accountability Office, 441 G Street NW, Room 7149  
Washington, DC 20548

---

## Strategic Planning and External Liaison

James-Christian Blockwood, Managing Director, [spel@gao.gov](mailto:spel@gao.gov), (202) 512-4707  
U.S. Government Accountability Office, 441 G Street NW, Room 7814,  
Washington, DC 20548