AVIATION SANITATION

FDA Could Better Communicate with Airlines to Encourage Voluntary Construction Inspections of Aircraft Galleys and Lavatories

Accessible Version
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What GAO Found

Most commercial aircraft undergo voluntary inspections to ensure that galleys and lavatories are constructed and assembled to meet the Food and Drug Administration’s (FDA) sanitation standards, according to industry representatives. Twenty-seven percent of the inspections FDA conducted between fiscal years 2015 and 2019 found objectionable conditions. But in nearly all of these instances, the conditions identified, such as the need for additional sealant in areas where there was a gap or seam, were corrected by the airline or aircraft manufacturer during the inspection. However, some regional airline representatives told GAO that their aircraft do not receive these construction inspections, either because larger airlines with which they have contracts told them the inspections were unnecessary or because they did not believe the inspections were relevant to them.

FDA provides these inspections free of charge, upon request of aircraft manufacturers or airlines, and aircraft passing inspection receive a certificate of sanitary construction. Representatives of one aircraft manufacturer said they view the certificate as beneficial because their customers see it as a guarantee that the aircraft was constructed in a way that decreases the likelihood of microbial contamination, pests, and insects. While the construction inspections are important, they are not required, and FDA does not proactively encourage airlines to request them. By developing a process for communicating directly to all U.S.-based commercial airlines, including regional airlines, to encourage them to receive construction inspections, FDA could better ensure that aircraft meet FDA sanitation standards to protect passenger health.

What GAO Recommends

GAO recommends that FDA develop a process for communicating directly with all U.S.-based commercial airlines to encourage them to request construction inspections. FDA generally agreed with our recommendation.

FDA faces several challenges in providing construction inspections and is taking steps to address these challenges. For example, the demand for inspections by manufacturers and airlines is unpredictable, and FDA inspectors are responsible for inspections at multiple locations. To help mitigate these challenges, officials we interviewed from four FDA field offices said they usually request advance notice from industry to allow the agency time to allocate the necessary resources for construction inspections.

View GAO-20-612. For more information, contact Steve Morris (202) 512-3841 MorrisS@gao.gov
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September 8, 2020

The Honorable John Hoeven
Chairman
The Honorable Jeff Merkley
Ranking Member
Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies
Committee on Appropriations
United States Senate

The Honorable Sanford Bishop, Jr.
Chairman
The Honorable Jeff Fortenberry
Ranking Member
Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies
Committee on Appropriations
House of Representatives

More than 813 million passengers flew on U.S. airlines in fiscal year 2019, according to the Federal Aviation Administration (FAA).¹ Air travel is one of the safest modes of transportation, according to the U.S. Department of Transportation,² but if aircraft galleys and lavatories do not

¹Federal Aviation Administration, “FAA Projections Show Strong U.S. Air Travel Demand,” (Washington, D.C.: Mar. 26, 2020). According to FAA, while passenger air travel numbers have declined following the onset of the Coronavirus Disease 2019 (COVID-19) pandemic, historically, millions of passengers have used air travel each year.

²According to the Bureau of Transportation Statistics, between 2002 and 2016, air travel had a lower fatality rate compared to other forms of transportation, such as by passenger car. U.S. Department of Transportation, Bureau of Transportation Statistics, Transportation Statistics Annual Report 2017 (Washington, D.C.: 2017).
meet sanitation standards, passengers and crew could be at risk. For example, if galley and lavatory surfaces are not tightly sealed, insects may gain access, and dust, liquid, or other substances may not be properly cleaned away.

The U.S. Food and Drug Administration (FDA), under the Department of Health and Human Services, administers the Interstate Travel Program (ITP) to help prevent the introduction, transmission, or spread of communicable diseases from one state or U.S. territory to another via aircraft and other modes of transportation. Through this program, FDA seeks to ensure that passenger aircraft on domestic routes are assembled and operated in a manner that promotes sanitary conditions. For purposes of sanitary assembly, FDA does so by inspecting aircraft galleys and lavatories at the request of aircraft manufacturers and airlines. Generally, these inspections, which we refer to as construction inspections, occur before the aircraft is put into service to begin transporting passengers. FDA can also arrange with manufacturer and airline representatives to conduct inspections themselves through partnership agreements to determine conformity with requirements.

3Sanitation of galleys and lavatories is a key component of the overall sanitation of an aircraft. Accordingly, FDA has specific regulations that relate to these areas. While this report focuses on galleys and lavatories on aircraft, GAO also has work related to overall aircraft sanitation and safety. GAO has made recommendations that the Department of Transportation develop a comprehensive national aviation-preparedness plan and that FAA identify long-term research and development priorities. See GAO, Air Travel and Communicable Diseases: Status of Research Efforts and Action Still Needed to Develop Federal Preparedness Plan, GAO-20-655T (Washington, D.C.: June 23, 2020) and GAO, Aviation Safety: More Research Needed on the Effects of Air Quality on Airliner Cabin Occupants, GAO-04-54 (Washington, D.C.: Jan. 16, 2004).

4Information available as of March 2020 from the Centers for Disease Control and Prevention indicate that the COVID-19-causing coronavirus may be able to survive for several days on steel, which is used in aircraft. For further information on the coronavirus and COVID-19, see GAO, Science & Tech Spotlight: Coronaviruses, GAO-20-472SP (March 2020).

5While the Federal Aviation Administration under the U.S. Department of Transportation is responsible for aircraft safety, FDA is responsible for aircraft sanitation through the ITP. To meet its objectives for the ITP, FDA inspects passenger-carrying conveyances during aircraft assembly and operation as well as the support facilities for those conveyances. These conveyances include aircraft, charter coaches, railroad passenger cars, and vessels that operate in interstate traffic. Support facilities include caterers and commissaries (which supply food and beverages), watering points, and waste-handling facilities. According to FDA, there is limited risk for illness related to food on aircraft, in part, because the food is mostly prepackaged.

6These inspections could also occur after a retrofit to a galley or lavatory.
During construction inspections, FDA or its industry partners check that the aircraft galley and lavatory were assembled in a way that promotes easy cleaning and that the potable water system has been correctly installed. If construction inspections are not available on a timely basis, airlines may delay putting aircraft into service rather than transport passengers without assurance that the aircraft comply with FDA’s sanitation standards. This delay could lead to revenue loss.\textsuperscript{7}

While FDA requires that aircraft comply with FDA’s sanitation standards, FDA does not require that aircraft be inspected for compliance with construction standards. However, the voluntary inspections are the primary mechanism by which FDA oversees compliance with its sanitation standards for the construction of aircraft galleys and lavatories.\textsuperscript{8}

Aircraft that pass a construction inspection receive a certificate of sanitary construction that shall be prominently displayed.

FDA may also inspect aircraft that are already in service. Such inspections, which we refer to as in-service inspections, are relatively brief and occur between scheduled flights. The purpose of FDA’s in-service inspections is to identify sanitation issues on aircraft that are transporting passengers. According to FDA officials, investigators are checking the cleaning and maintenance conditions of the aircraft galleys and lavatories, including observing the waterspouts and coffee pots for rust or other debris and ensuring that the lavatory appears clean. Only FDA conducts these inspections.

A House Report accompanying the 2019 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill included a provision for GAO to review FDA’s process to ensure proper sanitation in aircraft galleys and lavatories. This report (1) examines the extent to which aircraft are inspected to ensure compliance with FDA’s sanitation standards, and (2) discusses challenges FDA faces in providing aircraft inspections to ensure compliance with the standards, and how FDA is addressing those challenges.

For both objectives, we

\textsuperscript{7}Since the certificates are voluntary, airlines may choose to put an aircraft into service without an inspection or a certificate.

\textsuperscript{8}FDA’s sanitation standards are outlined in regulation at 21 C.F.R. Part 1240 on Control of Communicable Diseases and 21 C.F.R. Part 1250 on Interstate Conveyance Sanitation.
• reviewed applicable criteria, including FDA regulations at 21 C.F.R. Part 1240 on Control of Communicable Diseases and 21 C.F.R. Part 1250 on Interstate Conveyance Sanitation and relevant FDA guidance documents;

• analyzed FDA policy and guidance documents regarding how to conduct construction inspections;

• interviewed FDA headquarters officials to determine what policies and guidance they use in their efforts to oversee the sanitation of aircraft galleys and lavatories and identify challenges FDA faces in meeting the need for aircraft inspections;

• conducted site visits in the Seattle area and Atlanta—the two FDA field offices that issued the most certificates of sanitary construction between calendar years 2017 and 2019⁹—to meet with FDA investigators and officials, an aircraft manufacturer, and representatives from one airline to observe how aircraft lavatories and galleys are inspected;¹⁰

• interviewed FDA officials in two additional field offices—Dallas and Florida—that issued large numbers of certificates of sanitary construction to obtain information about how they conducted aircraft galley and lavatory inspections;¹¹

• interviewed officials from seven different industry organizations representing aircraft manufacturers, commercial airlines, and

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⁹Seattle issued 1,909 certificates, or 68 percent of the total, and Atlanta issued 248 certificates, or 9 percent of the total. FDA refers to some of their offices as District Offices and others as Division Offices. To simplify, we use the term “field offices.”

¹⁰We interviewed FDA officials from the Atlanta and Seattle FDA field offices. In addition, during our Seattle site visit, we interviewed Boeing officials and took a tour of The Boeing Everett Factory, in Everett, Washington, near Seattle—an airplane production building owned by Boeing, where the Boeing 747, 767, 777, and 787 are produced. During this tour, we observed a Boeing official with authority from FDA to conduct a construction inspection of a recently constructed Boeing aircraft. We also interviewed Delta Air Line representatives during our Atlanta site visit to obtain their views on FDA’s inspection process and any challenges they have experienced with FDA. The views obtained from FDA investigators, aircraft manufacturers, and airline representatives, during these site visits are not generalizable but provide a range of perspectives regarding FDA aircraft inspections.

¹¹Dallas issued 136 certificates, and Florida issued 131 certificates, or about 5 percent each.
airline industry associations, as well as representatives of two manufacturers of aircraft for U.S.-based airlines, four network airlines, five low-cost airlines, and five regional airlines, to gather their views on the clarity of FDA’s policies, as well as their

12These organizations include Airlines for America, the Association of Flight Attendants, the Association of Professional Flight Attendants, the International Air Transport Association, the International Flight Services Association, and the Regional Airlines Association. We also interviewed representatives from one private contracting firm—FDA Aerospace Solutions. According to the website, FDA Aerospace Solutions is a highly specialized group of aerospace engineers, licensed technicians, inspectors, and program administrators focused solely on FDA regulatory compliance and aircraft certification under the Code of Federal Regulations Title 21, Part 1250.

13The aircraft manufacturers we interviewed or received written responses from are Airbus and Boeing.

14By reviewing our past work on the airline industry and a Department of Transportation Office of Inspector General report, we identified the following five network airlines: Alaska Airlines, American Airlines, Delta Air Lines, Hawaiian Airlines, and United Airlines. We interviewed or received written responses from all except Alaska Airlines, which declined to be interviewed. See GAO, Airline Competition: The Average Number of Competitors in Markets Serving the Majority of Passengers Has Changed Little in Recent Years, but Stakeholders Voice Concerns About Competition, GAO-14-515, (Washington, D.C.: June 2014) and Department of Transportation, Office of Inspector General, FAA Oversight Is Not Keeping Pace With the Changes Occurring in the Regional Airline Industry, Report No. AV2018012 (Washington, D.C.: Dec. 19, 2017).

15We identified five low-cost airlines by reviewing our past work on the airline industry. See GAO-14-515. The five low-cost airlines we interviewed or received written responses from are Allegiant Air, Frontier Airlines, JetBlue Airways, Spirit Airlines, and Southwest Airlines.

16The five regional airlines we interviewed are Compass, ExpressJet, Mesa Airlines, SkyWest Airlines, and Trans States Airlines. According to a report by the Regional Airline Association, as of 2018, there were 66 certified regional carriers. We identified regional airlines by reviewing documents from the Regional Airlines Association, which represents regional airlines. We scoped out regional airlines that we identified as being fully owned by another airline. For example, Endeavor Air is a regional airline that is owned by Delta. Envoy, Piedmont, and PSA Airlines are owned by American. Because we interviewed representatives from these network airlines (Delta and American), we decided not to include the regional airlines owned by these network airlines in our selection. The regional airlines we interviewed are independently owned and operated but may conduct contract work with network airlines. Five regional airlines we identified as fitting these criteria — Air Wisconsin, CommutAir, GoJet, Peninsula Airways, and Republic Airways — declined to be interviewed or did not respond to our request for an interview. According to multiple news articles in March 2020, Compass and Trans States Airlines announced they were ceasing operations as a result of the financial stresses caused by the COVID-19 outbreak.
experiences with and observations about the timeliness and consistency of FDA's inspections;¹⁷ and

- interviewed officials from FAA to learn about their role in aircraft safety.¹⁸

To examine the extent to which FDA inspects aircraft to ensure compliance with sanitation standards, we analyzed FDA data to determine the number of certificates of sanitary construction issued in calendar years 2017 through 2019 and how many of these certificates were issued under a partnership agreement. We found the data to be sufficiently reliable for the purposes of our reporting objectives.¹⁹ To determine the number and results of such inspections, we analyzed FDA's airline sanitation inspection data from fiscal years 2015 through 2019. We found these data to be sufficiently reliable for the purposes of our reporting objectives.²⁰

To discuss challenges FDA faces providing aircraft inspections to oversee compliance with the standards and how FDA is addressing those challenges, we interviewed FDA officials in the four field offices that issued the most certificates of sanitary construction in calendar years 2017 through 2019 to determine how those field offices schedule inspections for aircraft and to identify challenges those field offices have experienced in meeting the need for aircraft inspections, and actions they

¹⁷The views obtained from representatives of these groups are not generalizable but provide perspectives on challenges these groups may have faced interpreting FDA policy and whether FDA inspections have been timely and consistent.

¹⁸In addition to EPA and FAA, we also interviewed officials from the Occupational Safety and Health Administration within the U.S. Department of Labor to learn about their role in ensuring the safety of staff aboard aircraft. We determined their role—to ensure that employees work in a safe and healthful environment by setting and enforcing standards, and by providing training, outreach, education and assistance—was outside the scope of this engagement. We also interviewed officials from the Environmental Protection Agency to determine how their role to ensure safe water affects airline sanitation. We determined EPA's role was also outside the scope of this engagement.

¹⁹To determine the reliability of the data, we reviewed FDA documents and asked FDA officials to confirm the accuracy of our statements generated from our analysis of the data. We selected this time period because it was the most recent period for which FDA had data.

²⁰To determine the reliability of the data, we reviewed FDA documents and asked FDA officials to confirm the accuracy of our statements generated from our analysis of the data. We selected this time period because it was the most recent period for which FDA had data.
have taken in response to the challenges. Findings from these four offices cannot be generalized to all offices, but do illustrate the issues experienced by officials in these four locations, which issued about 86 percent of the certificates issued during the years included in our review.

In addition, to better understand aircraft water safety, we interviewed FDA officials to discuss their role in inspecting watering points—the specific place from which potable water is loaded on a conveyance, including aircraft. We also reviewed the Environmental Protection Agency’s (EPA) Aircraft Drinking Water Rule at 40 C.F.R. Part 141, Subpart X and interviewed officials from EPA to determine the agency’s role in implementing these regulations, which apply to the use of potable water on aircraft, including aircraft lavatories and galleys.

After the onset of the COVID-19 virus in the United States in the early spring of 2020, FAA officials indicated that the airline industry was expected to shrink, with nearly all U.S.-based airlines reducing the number of flights they offer and several laying off staff or going out of business altogether. The conditions described in this report prevailed through early spring 2020 and do not account for post-COVID-19 declines in the industry. In June 2020, the Bureau of Transportation Statistics reported that U.S. airlines carried 96 percent fewer scheduled service passengers in April 2020 than in April 2019.

We conducted this performance audit from April 2019 to September 2020 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.

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21 We interviewed officials from the Atlanta, Dallas, Florida, and Seattle FDA field offices because those offices issued the highest number of certificates of sanitary construction. We solicited their perspectives on the inspection process airlines go through to obtain such certificates and any challenges related to conducting inspections for the certificates. According to an FDA official, FDA field office staff may conduct certificate-of-sanitary-construction inspections, and our analysis of FDA data showed that all 18 FDA field offices did conduct at least one certificate-of-sanitary-construction inspection between calendar years 2017 and 2019.

22 As defined in EPA regulations, watering points are the water supply, methods, and facilities used for the delivery of finished water to the aircraft. These facilities may include water trucks, carts, cabinets, and hoses. 40 C.F.R. § 141.801.
Background

Airline Industry

The U.S. Department of Transportation estimated that at the end of 2018, the U.S. commercial fleet consisted of 7,356 passenger aircraft. However, according to FAA, because of the economic impacts from the COVID-19 pandemic, the U.S. commercial fleet is expected to decrease in size as airlines reduce their fleets in response to the decline in air travel.\textsuperscript{23}

The fleet is operated by three main types of airlines:

1. Network airlines were in operation before enactment of the Airline Deregulation Act of 1978. They are large, complex operations with thousands of employees and hundreds of aircraft. The five network airlines are Alaska Airlines, American Airlines, Delta Air Lines, Hawaiian Airlines, and United Airlines. These airlines provide service at various fare levels to a wide variety of domestic and international destinations.\textsuperscript{24}

2. Low-cost airlines generally entered the market after deregulation in 1978. They tend to operate less costly service. In addition to cost, one of the fundamental differences between network and low-cost airlines is their operational model. The five low-cost airlines are Allegiant Air, Frontier Airlines, JetBlue Airways, Southwest Airlines, and Spirit Airlines. While network airlines operate using hubs from “anywhere-to-everywhere,” low-cost airlines tend to operate point-to-point service between locations.

3. Regional airlines operate smaller aircraft—turboprops or regional jets with up to 100 seats—and generally serve smaller communities under

\textsuperscript{23}In addition to reductions in the fleet size due to the onset of COVID-19, the size of the U.S. commercial fleet may also fluctuate due to airlines’ retiring older aircraft or for other reasons. See GAO, \textit{Commercial Aviation: Airline Industry Contraction Due to Volatile Fuel Prices and Falling Demand Affects Airports, Passengers, and Federal Government Revenues}, GAO-09-393 (Washington, D.C.: Apr. 21, 2009).

\textsuperscript{24}This report focuses on domestic air travel, but network airlines also serve international destinations.
capacity purchase agreements with network airlines. Some regional airlines are owned by a network airline, while others are independent. As of 2018, there were 66 regional airlines, including, for example, ExpressJet Airlines, Mesa Airlines, and SkyWest Airlines. According to a 2019 Regional Airlines Association report, more than 159 million passengers traveled on regional airlines in 2018, representing about 41 percent of scheduled passenger departures.

Regulations

FDA regulations outline a number of standards aircraft manufacturers and airlines must abide by to ensure sanitary conditions on aircraft; these standards include those for galleys and lavatories. For example:

- All kitchens, galleys, pantries, and other places where food is prepared, served, or stored shall be adequately lighted and ventilated.
- All places where food is prepared, served, or stored shall be constructed and maintained to be clean and free from flies, rodents, and other vermin.
- All plumbing shall be designed, installed, and maintained to prevent contamination of the water supply, food, and food utensils.
- Toilet and lavatory facilities of suitable design and construction shall be provided for use by food-handling employees. All toilet rooms shall be maintained in a clean condition.
- Aircraft shall be kept clean and free of flies and mosquitoes. An aircraft that becomes infected with vermin shall be placed out of service until it has been effectively treated.

25 Under a capacity purchase agreement, network airlines contract with regional airlines to provide air service beyond the network airline’s route network to increase their capacity and revenue. Agreement terms vary, but network airlines generally take on all commercial functions, such as brand marketing, flight scheduling, and ticket pricing, while the regional airlines are responsible for the aircraft and crews to operate the flights and provide ground and flight operations.


27 These FDA regulations include portions of 21 C.F.R. Part 1240 on Control of Communicable Diseases and 21 C.F.R. Part 1250 on Interstate Conveyance Sanitation. All commercial passenger aircraft engaged in interstate traffic are required to comply with FDA regulations pertaining to aircraft sanitation.
FDA's guidance also indicates that good fabrication techniques should preclude the use of sealants. When sealants are necessary, they shall be non-shrinking, easily cleanable, nonabsorbent, and wiped smooth. Resilient sealants shall be used in those areas where sealants may be subjected to loosening or cracking.

To confirm that aircraft have been assembled in a way that ensures conformance with these sanitation standards, FDA requires plans for the construction and major reconstruction of sanitary equipment or facilities to be submitted to FDA for review and conducts construction inspections to determine compliance with regulations and applicable construction guidelines. If the aircraft is in compliance, the FDA issues a certificate of sanitary construction. While conformance with the sanitation standards is required, aircraft are not required to obtain a certificate of sanitary construction.

FDA Aircraft Inspection Types

FDA may conduct two types of inspections on aircraft after they are assembled to ensure sanitary conditions on commercial aircraft operating on domestic routes:

1. Construction Inspections. FDA may conduct inspections to ensure that galleys and lavatories are installed in a way that ensures sanitary conditions. Such inspections are conducted after assembly but generally before the aircraft transports passengers. FDA provides these inspections on request of the aircraft manufacturer or airline, free of charge. Inspections include checking that sealant is smooth and placed in areas to prevent water or other substances from accumulating and ensuring that food contact surfaces, seams, and counter tops are smooth and easily cleanable. Additionally, FDA officials also told us the construction inspection includes ensuring the potable water system was installed correctly, the materials used are suitable for potable water, and that the system was disinfected and flushed resulting in a test showing no bacterial contamination.

Footnote:
28FDA conducts these two types of inspections only for aircraft subject to FDA’s Interstate Travel Program. Generally, this includes aircraft that fly domestic routes between two or more states. For example, airlines that only fly domestic routes within one U.S. state or territory, and do not transit another state, territory or foreign country, would not be subject to these sanitation standards because they are considered not to engage in “interstate” traffic.
These inspections can take a few hours or a few days depending on, among other things, the size of the aircraft and how many galleys and lavatories are on the aircraft, according to one FDA investigator we interviewed. Aircraft that pass a construction inspection receive a certificate of sanitary construction indicating the aircraft conforms to FDA’s sanitation standards. Aircraft that have been retrofitted with new galleys and lavatories may also be inspected by FDA and receive new certificates of sanitary construction prior to being placed back into service.29 According to FDA officials, the retrofit and changing of galley and lavatory units as well as changes to potable water and lavatory waste systems invalidates the originally issued certificate of sanitary construction. Because obtaining a certificate is not required, aircraft are not required to receive this type of inspection.

2. In-Service Inspections. FDA may, at its discretion, inspect aircraft that are already in service.30 Typically, these in-service inspections occur after an aircraft arrives at the airport gate and the passengers have exited but before the aircraft departs on its next flight. These inspections typically occur in less than an hour to accommodate the airline’s flight schedule. FDA’s guidance indicates that inspections of in-service aircraft should be performed consistent with available resources and indicates that inspections shall be performed “randomly… when time and opportunity allow.” According to the guidance, investigators should observe, among other things, the cleaning and maintenance conditions of the aircraft galleys and lavatories. Generally, as part of this inspection, the FDA investigator checks the aircraft’s galley and lavatories for general cleanliness, including observing the waterspouts and coffee pots for rust or other debris and ensuring that the lavatory appears clean.

FDA has made specific arrangements with some airlines and aircraft manufacturers to provide them with the authority to conduct construction inspections under partnership agreements. For example, according to FDA officials, FDA granted American Airlines a partnership agreement that has been renewed every 2 years that allows American Airlines personnel to conduct inspections for specific locations such as Dallas. In addition, Boeing has partnership agreements with the FDA field offices in Atlanta and Seattle; these agreements establish the conditions under which Boeing conducts construction inspections. Under FDA’s agreement with Boeing, the partnership agreement commences after FDA has

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29These retrofits may occur in the United States or overseas, according to airline industry representatives we interviewed.

30See, e.g., 21 C.F.R. § 1250.21.
conducted an inspection and issued a certificate for the first aircraft of that design. See figure 2, which shows an airline representative responding to findings from an inspection.

Figure 1: An Airline Representative Applying Additional Sealant in Response to an FDA Inspection

In addition to conducting construction and in-service inspections on aircraft, FDA further ensures airline sanitation by (1) requiring the submission to FDA of plans for the construction and major reconstruction of sanitary equipment or facilities for FDA review and (2) inspecting potable watering points at airports.\(^{31}\) For a brief overview of these

\(^{31}\)For the purposes of this report, we determined that FDA’s design reviews were outside the scope of our work because they occur prior to the assembly of an aircraft, and our report focuses on inspections that occur after aircraft assembly. We also scoped out watering point inspections because they do not occur on aircraft; rather, FDA investigators check the water trucks, carts, cabinets, and hoses that transport water to the aircraft.
inspections, which are not addressed in our objectives because they do not occur on aircraft, see appendix I.

Roles of Other Federal Agencies

Besides FDA, two other federal agencies have responsibility for regulating aircraft that fly domestic routes in the United States:

- FAA regulates aircraft safety. FAA officials told us that it conducts inspections during manufacturing to ensure that aircraft conform to design specifications, but it does not check for sanitation. They also said aircraft must adhere to safety standards with regard to lavatories and galleys and electrical systems to ensure these systems do not interfere with the safety of flight. FAA officials also told us that safety standards for lavatories and galleys also serve to protect crews and passengers, but such standards are aimed at issues such as hard landings and turbulence. FAA officials also said they may inspect not only the manufacturer of the aircraft but also the manufacturer of key components.  

- EPA regulates aircraft drinking water systems so that the water quality meets national standards. Generally, the monitoring process involves airlines taking samples of drinking water on aircraft and submitting the samples to a lab to test for the presence of “total coliform” and, where total coliform is detected, E.coli. The more disinfection and flushing that air carriers perform

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32For example, DOT’s Office of the Secretary requires airlines to ensure that certain aircraft have features to accommodate passengers with disabilities. Depending on the aircraft, those features may include movable aisle armrests, accessible lavatories, and stowage space for wheelchairs. See 14 C.F.R. Part 382, Subpart E. For more on accessibility to aircraft lavatories, see GAO, Aviation Consumer Protection: Few U.S. Aircraft Have Lavatories Designed to Accommodate Passengers with Reduced Mobility, GAO-20-258 (Washington, D.C.: Jan. 7, 2020).

33According to EPA’s website, “total coliforms” are a group of related bacteria that are (with few exceptions) nonharmful to humans. A variety of bacteria, parasites, and viruses, known as pathogens, can potentially cause health problems if humans ingest them. EPA considers total coliforms a useful indicator of other pathogens for drinking water. Total coliforms are used to determine the adequacy of water treatment and the integrity of the water distribution system.
per year, the fewer samples required per year. The results of these tests are submitted to EPA to ensure compliance with EPA's Aircraft Drinking Water Rule.

### Most Aircraft Receive Construction Inspections for Compliance with Sanitation Construction Standards, according to FDA and Industry, but Some Aircraft Do Not

FDA officials said that most aircraft receive a construction inspection for compliance with sanitation construction standards. Representatives from all the network and low-cost airlines we interviewed confirmed that they request such inspections. However, some regional airline representatives told us their aircraft do not receive construction inspections, and FDA does not directly communicate with all airlines to encourage them to receive such inspections.

### Most Aircraft Receive Construction Inspections, according to FDA and Industry

FDA officials we interviewed said most aircraft receive construction inspections to obtain certificates of sanitary construction, either from FDA or industry partners. According to FDA data, about 2,800 certificates were issued by FDA or its partners in calendar years 2017 through 2019. FDA issued 22 percent (629 of 2,813) of the certificates, while 78 percent (2,184 of 2,813) were issued as part of a partnership agreement, mainly

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34 C.F.R. § 141.803 provides a table entitled “Routine Disinfection and Flushing and Routine Sample Frequencies.” This table balances “Minimum routine disinfection & flushing per aircraft” with “Minimum frequency of routine samples per aircraft.” Airlines that disinfect and flush less frequently are required to submit samples more frequently.

35 EPA's Aircraft Drinking Water Rule establishes the required development and implementation of aircraft water system operations and maintenance plans. The plans include, among other things, routine disinfection and flushing of the water system, air carriers’ training requirements for key personnel, and periodic sampling of the onboard drinking water, as well as periodic self-inspections of each aircraft water system and immediate notification of passengers and crew when violations or specific situations occur.
under Boeing’s partnership agreement.\textsuperscript{36} In addition, representatives from most of the airlines we interviewed (11 of 14)\textsuperscript{37} told us they request this type of inspection.\textsuperscript{38} In particular, all of the representatives of network and low-cost airlines whom we interviewed and representatives of 2 of the 5 regional airlines we interviewed told us they request such inspections. While FDA collected data on the number of certificates that were issued from 2017 to 2019, it does not have information on how many aircraft might have been eligible for a certificate during that timeframe. We therefore could not calculate the percentage of aircraft that received inspections during that time.\textsuperscript{39}

Even though the certificates are not required, FDA officials and some airline representatives said that the certificates provide important benefits. FDA officials we interviewed said if an aircraft does not have the certificate, the airline may have challenges maintaining the aircraft in a sanitary manner, and representatives from some manufacturers and airlines that we interviewed agreed. Boeing representatives we interviewed said they view the certificate as beneficial because it guarantees to their customers that the aircraft was constructed in a way that allows the airline to operate it in a sanitary manner, with features that decrease the likelihood of microbial contamination, pests, and insects.

\textsuperscript{36}According to an FDA document, several FDA field offices are utilizing partnership agreements with aircraft manufacturers and airlines for issuance of certificates of sanitary construction because of an increase in aircraft construction and lack of FDA resources. For example, during calendar years 2017 to 2019, the FDA field office in Dallas issued 91 certificates of sanitary construction to American Airlines under a partnership agreement.

\textsuperscript{37}All four network airlines we interviewed (American, Delta, Hawaiian, and United), all five low-cost airlines we interviewed (Allegiant, Frontier, JetBlue, Southwest, and Spirit), and two out of the five regional airlines we interviewed (Compass and Trans States) said they request a construction inspection if the aircraft did not already have a certificate. Three out of five of the regional airlines we interviewed (Express Jet, Mesa, and SkyWest) said they do not seek construction inspections in any cases. One regional airline (Express Jet) said it would not request a construction inspection if the aircraft did not already have a certificate but would request a construction inspection after conducting a retrofit of an aircraft if the aircraft already came with a certificate.

\textsuperscript{38}As noted earlier, airlines may obtain certificates of sanitary construction by voluntarily receiving construction inspections from FDA or, in instances where the aircraft manufacturer or airline has a partnership agreement with FDA, by conducting their own construction inspections or relying on the manufacturer to conduct the inspections.

\textsuperscript{39}We could not determine the percentage of aircraft that received inspections, primarily because FDA does not track this information. While some information about the size of the commercial fleet is available in the private sector, specific information about how many aircraft do not have certificates is unavailable.
Boeing also said that many of its airline customers, including some international customers, have come to expect an aircraft with the certificate. One airline representative we interviewed said the airline has a strong incentive to obtain the certificate and avoid unsanitary conditions out of concern that passengers might share their concerns on social media.

According to FDA data, 27 percent (262 of 988) of the construction inspections it conducted between fiscal years 2015 and 2019 identified objectionable conditions, but in nearly all of these instances, the conditions identified, such as the need for additional sealant in areas where there was a gap or seam, were corrected by the airline or aircraft manufacturer during the inspection. FDA officials told us in cases where FDA finds objectionable conditions, FDA will issue a form detailing its findings to the airline or manufacturer and, in cases where the objectionable condition could not be remedied during the inspection, request corrective action. According to FDA, the consequence during a construction inspection for non-compliance is that a certificate would not be issued for that aircraft.

In addition to construction inspections, FDA conducts, at its discretion, a relatively small number of in-service inspections each year. FDA officials in each of the four field offices that we selected for our review said that they conducted, on average, one to three in-service inspections per office per year. In contrast, these four field offices issued 2,424 certificates of sanitary construction in calendar years 2017 through 2019, or an average of about 808 per year. FDA program and field officials told us they conduct few in-service inspections of aircraft, in part, because of resource constraints.

40The FDA dataset we analyzed to determine this percentage does not include the results of construction inspections conducted under a partnership agreement, through which the aircraft manufacturer or airline conducted the construction inspection on behalf of FDA. Accordingly, the denominator (988) used to calculate the percentage is less than the number of certificates issued from calendar years 2017 through 2019 (2,813).

41FDA does not collect data on the results of construction inspections conducted under partnership agreements because the inspections are not required. Boeing officials told us they correct any objectionable conditions identified by industry inspectors.
Some Aircraft Do Not Receive Construction Inspections, and FDA Does Not Directly Communicate with All Airlines to Encourage Them to Do So

Representatives of three of the five regional airlines we interviewed told us they do not request construction inspections. In addition, FDA data we analyzed showed that only a small percentage of certificates—3 percent (91 of 2,813)—were issued to regional airlines during the calendar years we reviewed (2017 through 2019), even though these airlines operate about 35 percent of the commercial fleet. Table 1 shows the number and percentage of construction certificates issued to various types of airlines and to airline manufacturers by FDA or under a partnership agreement in calendar years 2017 through 2019.

### Table 1: Certificates of Sanitary Construction Issued to Airlines and Aircraft Manufacturers, Calendar Years 2017-2019

<table>
<thead>
<tr>
<th>Type of entity that received certificate</th>
<th>Number of certificates issued</th>
<th>Percentage of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Network airlines</td>
<td>383</td>
<td>14</td>
</tr>
<tr>
<td>Low-cost airlines</td>
<td>262</td>
<td>9</td>
</tr>
<tr>
<td>Regional airlines</td>
<td>91</td>
<td>3</td>
</tr>
<tr>
<td>Other airlines(^a)</td>
<td>194</td>
<td>7</td>
</tr>
<tr>
<td>Aircraft manufacturers(^b)</td>
<td>1,883</td>
<td>67</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>2,813</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

Source: GAO analysis of FDA data. | GAO-20-612.

Note: Construction inspections may be conducted by FDA or by aircraft manufacturers and airlines with which FDA has partnership agreements. Certificates are generally issued after construction inspections of aircraft to ensure they are assembled in accordance with FDA sanitation standards.

\(^a\)“Other Airlines” may include international airlines.

\(^b\)Most of the certificates were issued by Boeing prior to delivery of aircraft to customers.

FDA does not directly communicate with all airlines to encourage them to receive construction inspections. Representatives from three of the five regional airlines we interviewed told us that they did not seek construction inspections, either because an airline partner told them the inspections were unnecessary or they thought the inspections were not relevant to them because they serve only prepackaged food. According to FDA officials, however, even airlines that serve only prepackaged food are at

\(^{42\text{One of these three regional airlines (Express Jet) said it may request a construction inspection after conducting a retrofit of the aircraft, but only if the aircraft had a certificate prior to conducting the retrofitting.}}\)
risk for sanitation issues. Aircraft that do not receive a construction inspection are unlikely to receive any inspection for compliance with FDA’s sanitary standards, given that in-service inspections are relatively infrequent.

FDA officials we interviewed acknowledged they were aware that some regional airlines were not requesting construction inspections. Because construction inspections are the primary mechanism by which FDA oversees compliance with sanitation standards for the construction of aircraft galleys and lavatories, its assurance that aircraft are in compliance is reduced when inspections do not occur. FDA does not generally communicate directly with airlines to inform them of the availability and importance of such inspections. However, according to federal standards for internal control, agency management should externally communicate the necessary quality information to achieve the entity’s objectives. By developing a process for communicating directly to all U.S.-based commercial airlines, including regional airlines, to encourage them to receive construction inspections, FDA could better ensure that aircraft meet FDA sanitation standards to protect passenger health.

FDA Faces and Is Addressing Several Challenges in Providing Aircraft Inspections

We interviewed FDA officials from four field offices that issued about 86 percent of the certificates of sanitary construction and found that FDA faces and is addressing several challenges in providing inspections of aircraft to ensure compliance with sanitation standards. More specifically, according to field office representatives, FDA faces four key challenges in providing inspections, three of which relate to construction inspections and one to in-service inspections.

First, demand for FDA construction inspections is unpredictable, but airlines want FDA to conduct inspections within a short time frame. The demand for FDA’s construction inspections can be unpredictable, in part, because it depends on when airlines purchase and receive delivery of new aircraft. For example, representatives from one airline told us that the airline had purchased 20 aircraft in early 2015 and then requested a construction inspection for each aircraft, increasing the inspection workload in one FDA field office. FDA was unable to inspect four of the planes within the 2-week time frame the airline allotted; as a result, the
airline placed these four aircraft into service without inspection and without certificates.\textsuperscript{43} In addition, according to representatives from one airline we interviewed, delivery times for their new aircraft may not meet airline expectations because of manufacturing delays, so they may not be able to accurately predict when they will have new aircraft ready for inspection.

To help mitigate this challenge, officials that we interviewed from the four FDA field offices said they usually request advance notice from industry to allow the agency time to allocate the necessary resources for construction inspections. Representatives from most airlines we interviewed said they typically provide this advance notice and generally have their aircraft inspected within their desired time frames. The amount of advance notice FDA field offices request airlines to provide varies among offices, according to FDA officials. For example, officials from one FDA field office told us they are usually able to schedule construction inspections within 5 days of advance notice. Officials from other field offices said they can schedule construction inspections with 10 days to 2 weeks of advance notice. However, representatives of one airline told us they sometimes must wait longer than desired for construction inspections at the Atlanta field office and that delays may result in revenue losses that could amount to as much as $25,000 to $100,000 per aircraft per day. FDA officials at the Atlanta field office acknowledged a shortage of investigators at this location and said that wait times for inspections have posed challenges for FDA and industry. However, Atlanta field office officials told us that to address this challenge, they started to redesign their inspection schedule in fiscal year 2020 to include 2 weeks in Atlanta and 2 weeks in Greensboro, North Carolina, per month. The officials stated that this change should help the office better plan and allocate resources.

Second, staff are responsible for construction inspections at multiple locations. Officials in two of the four FDA field offices that we interviewed told us that FDA investigators at these locations conduct inspections at more than one geographic location.\textsuperscript{44} An FDA headquarters official we interviewed stated that about half of all FDA field offices are responsible

\textsuperscript{43}Representatives from this airline said after an aircraft is delivered they allot a 2 -week time period to prepare each aircraft for service and that they must have the aircraft inspected during that time frame in order to not cause delays putting the aircraft into service.

\textsuperscript{44}We conducted interviews in the four field offices because they accounted for about 86 percent of all certificates that FDA issued.
for inspections at multiple locations, while the other half primarily conduct inspections within the local area. Despite this situation, airline representatives we interviewed told us they were able to have their aircraft inspected within their expected time frames at most field offices. As noted above, an exception was the Atlanta field office, where FDA officials acknowledged a shortage of investigators. The officials explained that they inspect aircraft both there and in Greensboro, because FDA’s dedicated airline investigator in Greensboro left the agency. As a result, Atlanta-based investigators must travel to Greensboro to conduct construction inspections, which may delay some inspections while the investigator awaits approval of a travel authorization. Atlanta field office officials told us that the redesign of their inspection schedule, as discussed above, will allow them to more efficiently split time between the locations and better allocate resources. Officials from the Atlanta office said they have informed airlines of this schedule so they can plan accordingly.

Third, construction inspections compete for priority with other FDA responsibilities. For example, FDA field office officials told us that tasks related to implementation of the FDA Food Safety Modernization Act and congressional mandates have priority. FDA officials from one field office we interviewed said they must conduct construction inspections in addition to the work assigned specifically through its annual work plan. Such work may include inspections of facilities that manufacture dietary supplements or infant formula. In addition, FDA has a limited number of people trained to conduct aircraft inspections, and these individuals also inspect conveyances other than aircraft, such as trains. Moreover, because the ITP program falls under FDA’s food commodities program, the investigators who examine aircraft galleys and lavatories also conduct other types of inspections not related to the ITP program. FDA officials said that the agency once had specialists dedicated to the ITP but that several of these individuals had moved on to other positions or retired and that these positions have not always been filled. To address workload issues caused, in part, by staff shortages, an official in the Florida field

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45According to an FDA document, the Office of Regulatory Affairs’ (ORA) annual fieldwork plan is designed to provide field managers with foreign, import, and domestic resources and output projections deemed necessary to carry out FDA’s mission during a fiscal year. The work plan is a collaborative agreement between the respective FDA Center and ORA to try to accomplish pre-determined targets during the fiscal year. The work plan is flexible, and targets can be revised based on unforeseen circumstances such as emergency situations or changes in program priorities.
office said that FDA trained additional investigators across the state on how to conduct construction aircraft inspections.

Finally, FDA faces a challenge related to in-service inspections at all locations—namely that investigators have a short amount of time to conduct in-service inspections compared with construction inspections. These inspections occur after the incoming passengers disembark and before the outgoing passengers board the aircraft. FDA officials we interviewed told us that when an aircraft arrives at the gate of an airport, the aircraft will typically fly out again in about an hour. During that time, passengers have exited the aircraft, the cleaning crew has cleaned the aircraft cabin, and passengers on the outgoing flight have boarded the aircraft—which leaves little time for the in-service inspection. As a result, FDA investigators must conduct their inspections quickly, as opportunities allow, to avoid delaying outgoing flights. FDA officials we interviewed acknowledged this challenge but told us that they adapt their inspections to accommodate quick turnaround times.

Conclusions

To ensure that aircraft meet sanitation standards before being used to transport passengers, FDA provides inspections of aircraft galleys and lavatories when requested by the airlines and issues a voluntary certificate indicating that the galleys and lavatories are assembled in accordance with proper sanitation standards. Currently, FDA conducts these construction inspections on most aircraft that fly domestic routes in the United States. However, some aircraft, particularly those belonging to regional airlines, do not receive construction inspections because the airlines do not request them. Representatives of regional airlines told us they did not believe the inspections were relevant to them, based on information they received from their network airline partners. Such construction inspections are FDA’s primary mechanism for ensuring that aircraft comply with sanitation standards for the construction of aircraft galleys and lavatories, but FDA does not generally communicate directly with airlines to inform them of the availability and importance of such inspections. By developing a process for communicating directly to all U.S.-based commercial airlines, including regional airlines, to encourage them to receive construction inspections, FDA could better ensure that aircraft meet FDA sanitation standards to protect passenger health.
Recommendation for Executive Action

The Commissioner of FDA should establish a process for the agency to communicate directly with all U.S.-based commercial airlines, including regional airlines, to encourage them to request construction inspections to ensure compliance with the agency’s standards for the sanitary construction of aircraft galleys and lavatories. (Recommendation 1)

Agency Comments

We provided a draft of this report to FDA for review and comment. In its comments, reproduced in appendix II, FDA concurred with our recommendation. FDA also stated that it will review its existing outreach channels to allow airline stakeholders to actively and directly engage with it on construction inspections, including reviewing its website to determine if updates can be made to emphasize airline construction inspection information. FDA also provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, the Commissioner of the Food and Drug Administration, 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. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff members who made key contributions to this report are listed in appendix III.

Steve D. Morris
Director
Natural Resources and Environment
Appendix I: Overview of Design Review and Potable Watering Point Inspections

Design Review Inspections. The Food and Drug Administration (FDA) reviews construction plans to ensure that new equipment is manufactured using safe material, is free from defects in design and construction, is easy to maintain, and is designed for easy cleaning. Submission of construction plans for aircraft sanitary equipment is required by regulation. The regulation requires firms—including aircraft manufacturers and airlines—to submit plans to FDA for construction or major reconstruction of sanitary equipment on aircraft. FDA then reviews the plans to assess conformity with FDA requirements. For example, these requirements include that waste tanks be constructed of a material that is either corrosion-resistant or is coated and protected against corrosion; that all sinks’ internal angles and corners have a minimum continuous and smooth radius of at least 1/8 inch; and that counter tops be constructed of corrosion-resistant, durable, easily cleanable, non-absorbent, non-toxic, smooth material. According to FDA, design review inspections are conducted during construction of aircraft so that corrections may be initiated at a time that should assure compliance with these requirements since corrective actions are more easily taken before an aircraft enters passenger service.

Potable Watering Point Inspections. FDA must approve aircraft watering points and may inspect them for that purpose. Watering points refer to the specific place from which potable water is loaded on a conveyance, including aircraft. As part of this inspection, an FDA investigator is to observe a watering point to ensure it is sanitary. According to FDA, the investigator may also take a water sample from the watering point to test for the presence of pathogens such as E.coli. In conjunction with

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1For the purposes of this report, we determined that FDA’s design review inspections were outside the scope of our work because they occur prior to the assembly of an aircraft and our report focuses on inspections that occur after aircraft assembly.

2We also scoped out watering point inspections because they do not occur on aircraft; rather, FDA investigators check the water trucks, carts, cabinets, and hoses that transport water to the aircraft.
Appendix I: Overview of Design Review and Potable Watering Point Inspections

inspections of potable watering points and the servicing area undertaken as part of the Interstate Travel Program, FDA has agreed to coordinate regulatory activities with EPA with respect to the drinking and cooking water aboard aircraft.
Appendix II: Comments from the Food and Drug Administration
Appendix II: Comments from the Food and Drug Administration

August 19, 2020

Steve D. Morris
Director, Natural Resources & Environment
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Morris:

Attached are comments on the U.S. Government Accountability Office’s (GAO) report entitled, “Airline Food Safety and Sanitation” (Job code 103469/ GAO-20-612).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Sarah C. Arbes
Assistant Secretary for Legislation

Attachment
GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE’S DRAFT REPORT ENTITLED — AVIATION SANITATION: FDA COULD BETTER COMMUNICATE WITH AIRLINES TO ENCOURAGE VOLUNTARY INSPECTIONS OF AIRCRAFT GALLEYS AND LAVATORIES (GAO-20-612)

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

Recommendation

The Commissioner of FDA should establish a process for the agency to communicate directly with all U.S.-based commercial airlines, including regional airlines, to encourage them to request construction inspections to ensure compliance with the agency’s standards for aircraft galley and lavatory sanitation.

HHS Response

HHS concurs with GAO’s recommendation. FDA agrees that enhancing communication with U.S.-based commercial airlines, including major national and regional commuter airlines, to encourage them to request construction inspections can have a positive impact on efforts to gain compliance with the Agency’s standards for aircraft galley and lavatory sanitation and potable water system installation. FDA has a long history of working collaboratively with interstate travel conveyance stakeholders to provide public health oversight to the industry. As part of this collaboration, FDA and the airline industry connect through a variety of mechanisms to provide access to diverse industry partners. To effectively engage all relevant stakeholders, FDA will consider ways to enhance current mechanisms and coordinate with airlines on better communication.

FDA will review its existing outreach channels to allow airline stakeholders to actively and directly engage with the Agency on construction inspections. FDA will review its Interstate Travel Program website to determine if updates can be made to emphasize airline construction and reconstruction information. FDA maintains open dialog with airline organizations, including the Airlines for America (A4A), the Regional Airline Association (RAA), and the International Flight Services Association (IFSA). Members of A4A are comprised of major national airlines, whereas those of RAA are comprised of regional commuter airlines and those in IFSA include airlines and airline food suppliers. These industry associations are valuable partners in developing solutions to problems that concern the airlines and airline construction. FDA will continue to engage with these organizations in written correspondence and at relevant national industry meetings (such as the Environmental Protection Agency (EPA) biennial meeting on aircraft drinking water safety) and will include the topic of construction inspections. FDA will also continue to use these existing mechanisms to develop a better communication process with the airline industry on its efforts to improve industry practice and government oversight.
Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

Steve Morris (202) 512-3841 or MorrisS@gao.gov

Staff Acknowledgments

In addition to the contact named above, Anne K. Johnson (Assistant Director), Stuart Ryba (Analyst-in-Charge), William Gerard, Cindy Gilbert, Donna Morgan, Hadley Nobles, Cynthia Norris, and Courtney Thacker made key contributions to this report.

Appendix IV: Accessible Data

Agency Comment Letter

Accessible Text for Appendix II Comments from the Food and Drug Administration

Page 1

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Page 2

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