



May 2018

ANIMAL USE IN FEDERAL RESEARCH

Agencies Share Information, but Reporting and Data Quality Could Be Strengthened

Accessible Version

Why GAO Did This Study

Research facilities, including those managed by federal agencies, use a wide range of animals in research and related activities each year. The Animal Welfare Act and the Health Research Extension Act have varying requirements for federal agencies and others to protect the welfare of and report on the use of different research animals to APHIS and NIH.

GAO was asked to review several issues related to animals used in federal research. This report examines (1) the extent to which APHIS and NIH have provided federal facilities with guidance for reporting their animal use programs, (2) the extent to which APHIS and NIH have shared agencies' animal use information with the public, and (3) stakeholder views on federal agencies' sharing additional information. GAO identified federal agencies that used vertebrate animals in research in fiscal years 2014 through 2016, reviewed their reports to APHIS and NIH, and examined publicly available data. GAO also surveyed a nongeneralizable sample of stakeholders from federal agencies and animal advocacy, research and science, and academic organizations.

What GAO Recommends

GAO recommends that APHIS clarify its reporting instructions and fully describe the potential limitations of the animal use data it makes available to the public. USDA stated that APHIS will take steps to implement GAO's recommendations, with the exception of clarifying reporting instructions for activities outside the United States. GAO continues to believe that APHIS needs to ensure complete reporting of such activities by federal facilities.

View [GAO-18-459](#). For more information, contact Steve Morris at Morriss@gao.gov or John Neumann at neumannj@gao.gov, or call (202) 512-3841.

ANIMAL USE IN FEDERAL RESEARCH

Agencies Share Information, but Reporting and Data Quality Could Be Strengthened

What GAO Found

The Department of Health and Human Services' (HHS) National Institutes of Health (NIH) and the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) have provided guidance to federal research facilities on what they must report about their animal use programs under the Health Research Extension Act and the Animal Welfare Act, respectively. Federal research facilities we reviewed met NIH's reporting instructions. However, APHIS's instructions have not ensured consistent and complete reporting in three areas: research with birds, activities outside the United States, and field studies outside a typical laboratory. By clarifying its instructions, APHIS could improve the quality of animal use data it receives from agencies.

APHIS and NIH voluntarily share some information about agencies' animal research with the public. In particular, APHIS posts to its website data on agencies' annual use of animals covered by the Animal Welfare Act, and NIH publicly posts a list of research facilities with approved animal use programs. However, APHIS does not describe potential limitations related to the accuracy and completeness of the data it shares as called for by USDA guidance. For example, APHIS does not explain that the data do not include birds used for activities that are covered by the Animal Welfare Act and may include field studies that are not covered by the act. APHIS could increase the data's usefulness to the public by making such disclosures.

Federal agencies may have additional information about their animal use programs, including data on vertebrate species used but not reported to APHIS; the purpose of research activities; and internal inspection reports. However, stakeholders GAO surveyed had different views on agencies' sharing such data with the public. Some stakeholders, particularly animal advocacy organizations, cited the need for more transparency and oversight while others, including federal agencies and research and science organizations, raised concerns about the additional administrative burden on agencies.

Animal Species Covered by the Animal Welfare Act and the Health Research Extension Act

	Animal Welfare Act	Health Research Extension Act*
Species covered	Dogs, cats, nonhuman primates, guinea pigs, hamsters, rabbits, horses used for research purposes, and other warm-blooded animals, with certain exceptions	Any live, vertebrate animal
Species not covered	Invertebrates Birds, rats of the genus <i>Rattus</i> , and mice of the genus <i>Mus</i> , bred for use in research Livestock or poultry used in certain agricultural research Cold-blooded vertebrates, such as fish and reptiles	Invertebrates

Source: GAO analysis of the Animal Welfare Act and the Office of Laboratory Animal Welfare's Public Health Service Policy on Humane Care and Use of Laboratory Animals. | GAO-18-459.

*The act covers research funded by the public health service agencies of the U.S. government.

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Abbreviations

APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
AWA	Animal Welfare Act
FOIA	Freedom of Information Act
HHS	Department of Health and Human Services
NIH	National Institutes of Health
NASA	National Aeronautics and Space Administration
USDA	U.S. Department of Agriculture

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May 31, 2018

Congressional Requesters

U.S. research facilities, including those managed by federal agencies, use a wide range of animal species in research, testing, teaching, and experimentation.¹ These activities can occur in laboratories or field settings and have many purposes, such as developing knowledge about human disease diagnosis and treatment, testing medicines and other products for toxicity, training professionals in veterinary methods, and conserving animal populations. Federal agencies conducted research using animals at about 120 domestic and international research facilities in fiscal years 2014 through 2016. For example, the Departments of Defense, Health and Human Services (HHS), and Veterans Affairs have used rats, mice, nonhuman primates, and other species in research on disease prevention and treatment. The U.S. Department of Agriculture (USDA) has used cattle, poultry, and other agricultural species in research on animal production and health and on the effects of animal agriculture on the environment, among other things. The Departments of Commerce and the Interior and other agencies have also conducted conservation research on a wide range of species, often in the field.

Research with animals has led to advances in scientific understanding, but it has also raised concerns about animal welfare. In particular, concerns about the welfare of animals used in research encompass a range of factors, such as efforts to minimize pain, the suitability of living conditions, the negative effects on wild populations when animals are removed or handled, and the care provided for animals when they are no longer needed for research. In response to these and other concerns, the U.S. government has implemented statutes, regulations, and policies that govern how animals are to be cared for and used for certain purposes, including research conducted by federal and nonfederal facilities.

In particular, the USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for implementing the Animal Welfare Act. APHIS is to:

¹Our report focuses on federal research facilities and does not generally distinguish between research, testing, teaching, and experimentation activities; we use the term "research" to encompass all of these activities.

- implement standards for the humane handling, care, treatment, and transportation of the species covered by the act,
- routinely inspect nonfederal research facilities for compliance with those standards, and
- collect information from federal and nonfederal research facilities about their uses of animals covered by the act.²

The HHS's National Institutes of Health (NIH) is responsible for establishing guidelines implementing certain provisions of the Health Research Extension Act of 1985. Specifically, NIH is responsible for reviewing federal and nonfederal research facilities' animal care and use programs to determine whether they meet relevant standards and are thereby eligible to receive funding from HHS's Public Health Service agencies, including NIH.³ To complete this review, NIH collects information from research facilities about their use of animals. NIH's review includes federal agencies that wish to receive Public Health Service funding.

These and other statutes also address, to varying degrees, actions that federal and nonfederal research facilities must take to collect and report information about their animal research activities to APHIS, NIH, or the public. For example, the regulations implementing the Animal Welfare Act require that all research facilities annually report information about their use of certain animals to APHIS. Likewise, the Health Research Extension Act requires that facilities that receive Public Health Service funding report information about their animal use program to NIH. The public may request information about agencies' research activities using procedures established under the Freedom of Information Act (FOIA), which requires federal agencies to provide the public with access to government information, with some exceptions, on the basis of the principles of openness and accountability in government.⁴

²The Animal Welfare Act regulations define a federal research facility to mean each department, agency, or instrumentality of the United States which uses live animals for research or experimentation; for the purpose of this report, we use the term agency.

³In addition to NIH, the Public Health Service agencies are the Agency for Healthcare Research and Quality; Agency for Toxic Substances and Disease Registry; Centers for Disease Control and Prevention; Food and Drug Administration; Health Resources and Services Administration; Indian Health Service; and Substance Abuse and Mental Health Services Administration.

⁴5 U.S.C. § 552.

You asked us to review several issues related to federal agencies' use of animals in research and related activities—specifically, research with their own staff using their own facilities and equipment. This report examines:

- the extent to which APHIS and NIH provided federal agencies with guidance for reporting on their animal use programs,
- the extent to which APHIS and NIH share information on animal use with the public, and
- stakeholders' views on federal agencies' sharing of additional information.

We focused our review on federal agencies that conduct research with vertebrate animals. Our review did not examine the research performed by nonfederal entities using federal funding. We sought to identify agencies that conduct activities with vertebrate species because the Animal Welfare Act and the Health Research Extension Act govern activities with vertebrate species but not activities with invertebrate species.

Using these criteria, we focused our review on 10 agencies that we identified as conducting such activities (with their own staff using their own facilities and equipment) during fiscal years 2014, 2015, or 2016. The agencies are Commerce, Defense, HHS, Department of Homeland Security (DHS), Interior, USDA, VA, the Environmental Protection Agency (EPA), the National Aeronautics and Space Administration (NASA), and the Smithsonian Institution.⁵ We chose to analyze these agencies' activities and compliance with the reporting requirements over the 3-year period in order to better identify issues that might not be evident in examining a single year, and fiscal year 2016 was the most recent year for which data reported to APHIS were available. To identify these 10 agencies, we contacted a total of 14 independent agencies that we believed were likely to conduct research using vertebrate animal species based on information from USDA, HHS, and other relevant sources. We asked the 14 agencies to identify the species of vertebrate animals that they used in research within the 3-year time frame. Four agencies

⁵Within the departments listed above, we also identified sub-agencies that conducted research activities, such as the departments of the Army and Navy within the Department of Defense and the National Park Service and Fish and Wildlife Service within the Department of the Interior. The Smithsonian Institution is considered a trust instrumentality of the United States. See 20 U.S.C. §§ 41 et seq. In this report, we use the term "agencies" to include the Smithsonian Institution.

responded that they did not conduct research with vertebrate animals in fiscal years 2014 through 2016. Therefore, they did not meet our criteria for inclusion in our review. See appendix I for detailed information on the activities of the 10 agencies included in our review.

To examine the extent to which APHIS and NIH provided federal agencies with guidance for reporting on their animal use programs, we took the following steps:

- **APHIS.** We reviewed the Animal Welfare Act and its implementing regulations and interviewed agency officials to identify relevant reporting requirements and determine whether they were consistent with APHIS's reporting instructions. To assess the instructions, we examined how agencies followed them in practice. In particular, we obtained from APHIS the data that federal agencies or their facilities submitted for fiscal years 2014 through 2016 to determine whether agencies submitted reports as expected.⁶
- **NIH.** We reviewed the Health Research Extension Act and accompanying NIH policy to identify the information that federal research facilities must provide to NIH to be eligible for Public Health Service funding. We also reviewed NIH's guidance to research facilities on how to obtain eligibility for funding. To assess the guidance, we examined its implementation through NIH and other federal agencies' actions. In particular, we determined whether NIH had current approvals for all federal research facilities receiving such funding through interviews with NIH officials and by reviewing NIH documents. We then reviewed a sample of 16 assurances from federal facilities chosen by randomly selecting a facility from each agency or sub-agency that had approved animal care and use programs.⁷ We compared the information in the selected assurance documents with NIH's guidance to determine whether the documents contained key information.

We also took steps to assess the reliability of information that APHIS provided us about federal agencies and facilities that report to it under the Animal Welfare Act and information that NIH provided on federal research

⁶The Animal Welfare Act regulations define a reporting facility to be that segment of the research facility, or that department, agency, or instrumentality of the United States, that uses or intends to use live animals in research, tests, experiments, or for teaching.

⁷Eight federal agencies have animal care programs approved by NIH. Some agencies have multiple sub-agencies with approved programs.

facilities receiving Public Health Service funding. In particular, we cross-checked animal use information from APHIS with animal use information we obtained directly from the 10 agencies in our review of their facilities' research activities. In addition, we checked summary data on animal use that we obtained from APHIS against the annual reports that federal agencies sent to APHIS under the Animal Welfare Act to determine whether the data were consistent. We also reviewed NIH's website for information about research facilities with approved assurances, and we reviewed NIH documentation and queried NIH officials about their process for ensuring that facilities receiving Public Health Service funding for animal research have an assurance. Based on these steps, we determined that the APHIS and NIH information on federal facilities that conduct animal research was sufficiently reliable for examining APHIS and NIH guidance to agencies on reporting about their animal use programs.

To examine the extent to which APHIS and NIH share information on animal use with the public, we interviewed agency officials and reviewed agency websites. In particular, we interviewed APHIS officials to identify the agency's current policies and procedures for collecting and posting to its website the annual reports the agency receives from research facilities. We reviewed the APHIS website to document the timespan covered by the data that are posted and the methods by which the data can be searched by the public. We also reviewed APHIS's posting of annual report data against USDA's data quality requirements, which state that USDA's agencies and its offices will strive to ensure that the information they disseminate for the public is substantively accurate, reliable, and unbiased and presented in an accurate, clear, complete, and unbiased manner.⁸ We interviewed NIH officials to identify the agency's policies and procedures for making public information about research facilities that seek approval for a Public Health Service animal welfare assurance, such as the identity of facilities with approved assurances or descriptions of their animal care programs.⁹

For insight into stakeholders' views on federal agencies' sharing additional information, we surveyed federal departments and agencies

⁸U.S. Department of Agriculture, Office of the Chief Information Officer, *Information Quality Activities: General Requirements*, accessed March 30, 2018, <https://www.ocio.usda.gov/policy-directives-records-forms/information-quality-activities>.

⁹Specifically, we interviewed NIH officials regarding the Office of Laboratory Animal Welfare's Public Health Service Policy on Humane Care and Use of Laboratory Animals.

that conduct research as well as nonfederal organizations and individuals we identified as having knowledge and interest in animal research. We surveyed the 10 federal agencies that we identified as conducting research with vertebrate animals in fiscal years 2014, 2015, or 2016. All 10 agencies provided at least one response, with some providing responses from multiple sub-agencies or components. The total number of federal responses was 20.

We also sent surveys to a nongeneralizable sample of 28 nonfederal stakeholders identified using a “snowball selection” methodology.¹⁰ We sought to gather perspectives from a variety of stakeholders, and our sample included organizations that advocate on behalf of animals; research and science organizations; individuals from academia; and other stakeholders we identified as having knowledge of animal research issues and a national focus or representation.¹¹ Nineteen of these 28 groups completed the survey.¹² See app. II for a complete list of respondents.

The survey asked about specific types of information about animal use and whether stakeholders believed federal agencies should proactively and routinely share such information with the public on a website or by other means. In particular, we asked respondents for their views on whether agencies should routinely make available to the public information that we determined agencies may possess for internal decision-making purposes and, under certain circumstances, may provide to other parties, including NIH or a private organization for accreditation of a facility’s animal care program. Such information could include data on all vertebrate animals used, information on the purpose of specific research activities, and general descriptions of the agency’s animal care program. The survey also asked whether stakeholders reviewed and used annual reports that APHIS posts on its website and what changes

¹⁰A “snowball selection” process may use multiple methods to identify a sample population and generally includes asking members of the population to recommend other members. We selected stakeholder organizations using Internet searches for national organizations that had public positions on animal welfare and animal research issues; a review of participants at animal research meetings, and the recommendations of officials from federal agencies and other organizations.

¹¹We did not exclude any stakeholders we identified as meeting our inclusion criteria.

¹²Most stakeholders who declined to participate said they either lacked adequate knowledge to respond to our questions or did not want to take a position on the survey topics.

stakeholders would like to see, if any, in how APHIS collects and posts annual report data on its website. See app. III for a summary of the stakeholders' suggested changes. We included these questions to understand the extent to which stakeholders use available data and whether they had suggestions for changes in how APHIS currently makes data routinely available. We did not ask stakeholders a similar question about NIH because that agency does not proactively provide data to the public about federal agencies' use of animals in research.

We conducted this performance audit from April 2017 to May 2018 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

The Department of Agriculture Administers the Animal Welfare Act

USDA's APHIS is responsible for implementing the Animal Welfare Act. The act and its implementing regulations govern, among other things, how federal and nonfederal research facilities must treat particular species of warm-blooded animals to ensure their humane treatment when used in research, teaching, testing, or experimentation.¹³ The Animal Welfare Act's definition of "animal" excludes birds, rats of the genus *Rattus*, and mice of the genus *Mus* when those animals are bred for use in research. The act also excludes horses not used for research purposes and other farm animals used or intended for use as food or fiber or in certain types of research.¹⁴ The Animal Welfare Act also excludes cold-blooded animals—such as fish, reptiles, or amphibians—and

¹³The Animal Welfare Act also governs the activities of other parties such as animal exhibitors and dealers. However, those parties and their activities are not within the scope of this review.

¹⁴Under the Animal Welfare Act, the definition of animal excludes certain farm animals, such as livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber.

invertebrates.¹⁵ See table 1 for a summary of the animals covered and not covered by the Animal Welfare Act. (Animals covered by the Health Research Extension Act are also included in table 1 and described in the next section.)

Table 1: Animal Species Covered by the Animal Welfare Act and the Health Research Extension Act

	Animal Welfare Act	Health Research Extension Act
Covered species	Any live animal from the list below used for research, teaching, testing, or experimentation: <ul style="list-style-type: none"> • Dogs • Cats • Nonhuman primates • Guinea pigs • Hamsters • Rabbits • Horses used for research purposes • Other warm-blooded animals, with exceptions described below 	Any live, vertebrate animal used or intended for use in research, training, experimentation, or biological testing or for related purposes.
Non-covered species	<ul style="list-style-type: none"> • Invertebrates, such as insects and cephalopods • Birds, rats of the genus <i>Rattus</i>, and mice of the genus <i>Mus</i>, bred for use in research • Livestock or poultry used as food or fiber or used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber • Cold-blooded vertebrates, such as fish and reptiles 	Invertebrates, such as insects and cephalopods

Sources: GAO analysis of the Animal Welfare Act and the Office of Laboratory Animal Welfare's Public Health Service Policy on Humane Care and Use of Laboratory Animals. | GAO-18-459.

The Animal Welfare Act and its regulations contain specific standards for research facilities. These include:

- **Registration.** Nonfederal research facilities that conduct activities regulated by the Animal Welfare Act must register with APHIS. The act does not require that federal research facilities register with APHIS. APHIS does, however, assign federal research facilities certificate numbers that it uses to track whether they have submitted their required annual report (see below). As of March 2018, APHIS had assigned such numbers to 157 federal research facilities. Some

¹⁵Vertebrate species are distinguished by the possession of a backbone or spinal column, and include mammals, birds, reptiles, amphibians, and fishes. Invertebrates do not possess a backbone or spinal column, and include insects, mollusks, crustaceans, corals, and other animals.

of these federal research facilities, such as VA, have elected to report information to APHIS on an individual basis, while others, such as the HHS's Centers for Disease Control and Prevention, submit a single report covering research facilities in several states.

- **Annual report.** Reporting facilities that used or intended to use live animals in research, tests, experiments, or for teaching must submit a retrospective annual report about those animals to APHIS on or before December 1 of each calendar year.
- **Standards for humane handling, care, treatment, and transportation of animals.** The Animal Welfare Act directs research facilities to meet certain standards of care for the animal species that are covered by the act. The standards of care are tailored to particular species of animals or groups of species.
- **Institutional Animal Care and Use Committees.** Research facilities must appoint a committee to, at least semi-annually, review the facility's program for humane care and use of animals, to inspect all facilities, and to prepare reports of its evaluation.¹⁶ The committee is responsible for reviewing research proposals to determine whether the proposed activities are in accordance with the act or there is an acceptable justification for a departure from the act.
- **Federal inspections.** APHIS officials have the authority to inspect nonfederal research facilities, records, and animals to enforce the provisions of the act. The Animal Welfare Act does not expressly

¹⁶Under the Animal Welfare Act and its implementing regulations, an Institutional Animal Care and Use Committee shall be composed of a chairman and at least two additional members. At least one shall be a doctor of veterinary medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at the research facility. At least one shall not be affiliated in any way with the facility other than as a member of the committee. The Animal Welfare Act states that in the case of federal research facilities, this committee shall report deficiencies or deviations found during inspections to the head of the federal agency conducting the research rather than to APHIS. The agency head conducting the research shall be responsible for all corrective action to be taken at the facility and the granting of all exceptions to inspection protocol.

provide APHIS the authority to inspect federal research facilities, and APHIS will not do so unless invited.¹⁷

The Animal Welfare Act exempts farm animals, other than horses, from its coverage when they are used or intended for use as food or fiber or in agricultural research that is intended to improve animal nutrition, breeding, management, or production efficiency, or to improve the quality of food or fiber. According to officials with USDA's Agricultural Research Service (ARS), most of the agency's research activities fall under this exemption. Nevertheless, in February 2016, APHIS and ARS signed a memorandum of understanding concerning laboratory animal welfare. The intent of the memorandum of understanding is to maintain and enhance agency effectiveness and avoid duplication by allowing APHIS to use applicable sections of the Animal Welfare Act's requirements, regulations, and standards to inspect ARS animal research facilities. Among the provisions of the memorandum, ARS agreed to register its animal research facilities with APHIS and submit an annual report to APHIS. As of March 2018, 35 ARS animal research facilities were voluntarily registered with APHIS, and ARS facilities submitted their first annual reports for activities conducted in fiscal year 2016.

NIH Administers the Health Research Extension Act

NIH, within the Department of Health and Human Services, administers the Health Research Extension Act. The act calls for the Director of NIH to establish guidelines that govern how certain research institutions that conduct activities using animals are to consider animal welfare. In particular, the guidelines govern how those research institutions—including federal facilities—that receive funding from Public Health Service agencies are to ensure the humane treatment of all vertebrate animals used in biomedical or behavioral science research. NIH conducts site visits at selected institutions to assess compliance with the act. Whereas the Animal Welfare Act applies to certain warm-blooded animals, the definition of animals used for the purposes of the Health

¹⁷Federal agencies may inspect their own animal use programs. For example, according to the officials from VA, the agency's Office of Research Oversight evaluates the health and well-being of animals in department facilities, reviews oversight functions, such as the work of Institutional Animal Care and Use Committees, and investigates allegations of non-compliance with animal welfare requirements. In technical comments on a draft of this report, an official from the Department of Homeland Security said the agency has a robust and active oversight program.

Research Extension Act covers all vertebrates, including mice, rats, and fish species that are commonly used in laboratory research (see table 1).

Under the act, research institutions are required to provide certain information to NIH in order to be eligible for Public Health Service funding. In particular, they must provide for NIH approval a document that describes their animal care and use program and that assures that the facility meets applicable standards. NIH calls for research institutions to provide, among other information, a commitment to comply with all applicable provisions of the Animal Welfare Act and other federal statutes and regulations relating to animals, a description of the facility, and an “average daily inventory” of species housed at the facility. In addition, research institutions approved for Public Health Service funding must annually report changes in their animal use program to NIH. As of September 2017, NIH had approved 111 federal facilities across 8 agencies for funding under the act.¹⁸

APHIS and NIH Have Instructed Federal Agencies to Provide Data on Animal Use, but APHIS’s Instructions Have Not Ensured Consistent and Complete Reporting

As directed by the regulations implementing the Animal Welfare Act, the 10 agencies we reviewed submitted to APHIS the required annual reports on their use of animals covered by the act from fiscal years 2014 through 2016. However, APHIS’s reporting instructions have not ensured consistent and complete reporting because they have been unclear about which animal species, activities, and activity locations are required to be reported for the purposes of the Animal Welfare Act. Federal facilities that conduct activities with animals using Public Health Service funding that we reviewed met NIH requirements to provide assurance documentation about their animal use programs and to provide required annual reports for fiscal years 2014 through 2016.

¹⁸This number of approved facilities does not include Department of Energy National Laboratories. We did not include the Department of Energy in our scope because it did not conduct research in fiscal years 2014 through 2016 with its own staff using its own facilities and equipment.

Federal Agencies Generally Report to APHIS on Animal Use, but APHIS Has Not Provided Sufficient Instructions to Ensure Consistent and Complete Reporting

The Animal Welfare Act regulations require federal agencies that use or intend to use live animals in research to report on their use of these animals. As directed by APHIS, these agencies, or their individual research facilities, must submit an annual report to APHIS on or before December 1 of each calendar year. APHIS instructs research facilities to submit an annual report that:

- includes information about animals covered by the Animal Welfare Act's regulations and the number of such animals used as well as those held for use but not used, and
- provides assurances that the facility has met applicable standards, such as standards for the appropriate use of anesthetic, analgesic, and tranquilizing drugs.¹⁹

In addition, facilities must report whether the animals fall into one of three categories related to pain or distress and the efforts the facilities took to relieve pain or distress.²⁰ Facilities must also attach a summary of any activity that did not meet the standards of the act but that were approved by the facility's Institutional Animal Care and Use Committee.

All 10 of the federal agencies we reviewed submitted annual reports to APHIS showing that their facilities had used animals in research in fiscal years 2014 through 2016. APHIS has procedures in place to track which agencies' facilities have reported and to notify any that have not done so. For example, APHIS has developed schedules for sending reminders to

¹⁹The Animal Welfare Act regulations also call for research facilities to, among other things, (1) assure that each principal investigator has considered alternatives to painful procedures and (2) include in their annual reports explanations of any exceptions to the act's standards that have been approved by an Institutional Animal Care and Use Committee.

²⁰The Animal Welfare Act regulations call for research facilities to report information on the number of animals, listed by common name, used in one of three use categories: (1) activities involving no pain or distress, or use of pain-relieving drugs; (2) activities involving pain or distress in which appropriate anesthetic, analgesic, or tranquilizing drugs were used; and (3) activities involving pain or distress and for which anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures. The act requires facilities to attach to the annual report an explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used.

facilities that have not yet reported. APHIS expects federal research facilities that it has assigned certificate numbers but that did not use any animals in a particular fiscal year to submit a report with that information.

APHIS data show that the 10 federal agencies in our review reported that their facilities used more than 210,000 animals covered by the Animal Welfare Act in fiscal years 2014 through 2016.²¹ However, in our comparison of federal agencies' annual reports to APHIS with their responses to our request for information about their activities, we found instances in which agencies did not report activities covered by the act or did not report similar activities consistently across facilities. These conditions resulted, in part, from APHIS not providing sufficient instructions on the research activities that federal agencies are to include in their annual reports. Additionally, we found that facilities reported species not covered by the act. As a result, the data that research facilities submit to APHIS in their annual reports may not accurately reflect the facilities' uses of animals covered by the act. We identified three areas in which federal agencies' annual reports were inconsistent or incomplete: birds, animal use outside the United States, and field studies.

Use of Birds

In 2002, Congress amended the definition of animal in the Animal Welfare Act to exclude birds that are bred for use in research.²² However, APHIS instructs facilities to not report any birds in their annual reports, regardless of whether they were bred for research. Five agencies reported to us that their research facilities used birds in fiscal years 2014 through 2016—including some not bred for research and therefore potentially covered by the act—but that they followed APHIS's instructions to not report them.²³ According to APHIS officials, since Congress amended the definition of animal in the act, the agency has been aware of the need to define which birds are covered by the act and should, among other things, be reported to APHIS by research facilities.

The Animal Welfare Act and birds

- **Animal Welfare Act**

The term animal excludes birds **bred** for use in research.

- **APHIS's 2017 instructions for completing the annual report**

"[D]o NOT report the use of ... birds, reptiles, fish or other animals which are exempt from the regulation under the [Animal Welfare Act]."

Sources: Animal Welfare Act and APHIS documents. | GAO-18-459

²¹In fiscal years 2014 through 2016, some facilities also reported to APHIS that they did not have any animal use to report for that year. For example, about 40 federal research facilities and VA hospital facilities reported to APHIS that they had not used any animals covered by the Animal Welfare Act in fiscal year 2016.

²²Farm Security and Rural Investment Act of 2002, Pub. L. No. 107-171, tit. X, subtit. D, § 10301, 116 Stat. 134, 491.

²³These were the Departments of Defense and the Interior, HHS, USDA, and the Smithsonian Institution.

The officials said that until the agency has defined birds covered by the act, they do not believe that it is appropriate to require research facilities to report their use of birds.

However, as of February 2018, APHIS had not provided us with a schedule or plan for defining birds covered by the act or for developing reporting requirements for those birds. As a result, it is unclear when, or if, APHIS will require research facilities to report their use and treatment in research of birds that are covered by the Animal Welfare Act. Until APHIS develops such requirements, federal (and other) research facilities will have incomplete information about what information they should include in annual reports submitted to APHIS, and APHIS will not have assurance that annual reports from research facilities fully reflect research activities covered by the act.

Animal Use outside the United States

The Animal Welfare Act regulations define a reporting facility to include a department, agency, or instrumentality of the United States. Officials from USDA's Office of the General Counsel told us that there is no exclusion in the act or its regulations for federal research facilities that are located outside of the United States. However, APHIS does not instruct federal research facilities to report activities involving animal use outside the United States. Of the 10 agencies with federal research facilities that submitted annual reports to APHIS, we identified three through our initial contacts and follow-up interviews that conduct activities outside the United States involving animals that may be covered by the Animal Welfare Act: the Departments of Commerce and Defense and the Smithsonian Institution. We found that officials from the three agencies had a different understanding of their obligation to report those activities to APHIS. A senior official from the Department of Commerce's National Marine Fisheries Service said that he knew of no reason to not report on studies conducted outside the United States and that the agency had reported such activities in fiscal year 2017. On the other hand, officials from the Department of Defense and the Smithsonian Institution told us that APHIS officials have instructed them not to report activities conducted outside of the United States. As a result, the Department of Defense and the Smithsonian Institution did not report animal use in their non-domestic facilities in fiscal years 2014 through 2016. With instructions from APHIS that federal research agencies report all activities covered by the Animal Welfare Act, regardless of location, APHIS and the public would have greater assurance that annual reports fully reflect

The Animal Welfare Act and reporting facilities

- **Animal Welfare Act regulations**

"The reporting facility shall be that segment of the research facility, or that department, agency, or instrumentality of the United States, that uses or intends to use live animals in research, tests, experiments, or for teaching."

- **APHIS's 2017 Instructions for completing the annual report**

The instructions do not instruct federal research facilities to report activities involving animal use outside the United States.

Sources: Animal Welfare Act regulations and APHIS documents. | GAO-18-459

activities covered by the act and that agencies are reporting such activities consistently.

Animal Use in Field Studies

APHIS exempts some research involving wild animals from the requirements of the Animal Welfare Act regulations, including annual reporting. Specifically, in promulgating the current definition of “field studies” in regulation, APHIS stated, “if the research project meets the definition of field studies, the research project would not fall under the [Animal Welfare Act] regulation.” To qualify for this exemption, a study must take place in a free-living, wild animal’s natural habitat and not involve an invasive procedure, harm, or materially alter the behavior of an animal under study. APHIS’s instructions for annual reporting note this exemption. However, they do not sufficiently clarify the conditions under which a field study would qualify, nor do they point to any source providing clarifying language. For example, the instructions do not describe criteria research facilities could use to identify activities that are invasive, harmful, or materially alter behavior.

The Animal Welfare Act and field studies

- **Animal Welfare Act regulations**

“Field study means a study conducted on free-living wild animals in their natural habitat. However, this term excludes any study that involves an invasive procedure, harms, or materially alters the behavior of an animal under study.”

- APHIS’s 2017 instructions for completing the annual report

APHIS’s instructions do not sufficiently clarify the conditions under which a field study would be invasive, harmful, or materially alter behavior and, therefore, be covered under the act.

Source: Animal Welfare Act regulations. | GAO-18-459

We found that agencies have interpreted the field study exemption differently. For example,

- Officials from three agencies within the Department of the Interior told us that the agencies did field research with many species in fiscal years 2014 through 2016, but we found the agencies had different approaches to reporting that research to APHIS. Specifically, the U.S. Geological Survey and National Park Service reported using dozens of animal species to APHIS while the Fish and Wildlife Service did not report any. An official with the Fish and Wildlife Service explained to us that the agency did not report the animals to APHIS because they were only held temporarily. Officials from the Fish and Wildlife Service and U.S. Geological Service told us that APHIS’s guidance on field studies is confusing and causes discrepancies in reporting.
- NASA conducts research involving temporary capture, blood sampling, and tagging of animals to study any possible effects of NASA’s launch sites on the surrounding ecosystem, but the agency does not include these activities in its annual reports to APHIS. The National Marine Fisheries Service conducts field research also involving temporary capture, blood sampling, and tagging of marine mammals for various purposes. Some of the service’s research

facilities have reported these types of activities to APHIS, and according to a service official, the other facilities plan to do so.²⁴ An official from the service also told us that the agency has received inconsistent guidance from APHIS about what field research to report.

The National Marine Fisheries Service's facilities that have reported animal research to APHIS have represented a large portion of the overall number of animals that federal facilities reported in fiscal years 2014 through 2016. For example, in fiscal year 2016, the agency's facilities accounted for nearly 16,000 of about 82,000 animals reported to APHIS by the 10 federal agencies in our review. Therefore, whether these activities should or should not be reported will have a large effect on the total number of animals that federal facilities reported using for research.

APHIS officials told us that they are developing additional clarifying guidance on field studies and will publish the guidance for public comment in the third quarter of fiscal year 2018. However, APHIS has not yet released a draft of this guidance. A draft with criteria for identifying which field studies are covered by the Animal Welfare Act and therefore should be reported—for example, because the studies are considered to be invasive, harmful, or materially alter behavior—would enable APHIS to ensure that the research community's views are incorporated. With clearer instructions that include such criteria, APHIS and the public would have greater assurance that annual reports fully reflect activities covered by the act.

Federal Research Facilities We Reviewed Met Instructions to Report Information on Their Animal Care and Use Programs to NIH

NIH has provided guidance to federal and nonfederal research facilities about what they are required to report on their animal use, and federal facilities we reviewed met those requirements. In order to obtain funding from the Public Health Service agencies, research facilities must obtain approval from NIH of their animal welfare assurance statement and must provide annual reports to NIH. To obtain an approved assurance, a

²⁴In technical comments on a draft of this report, APHIS stated that the impact of blood sampling and tagging is both species and procedure specific. However, APHIS's instructions for annual reporting do not provide any information on how temporary capture, blood sampling, and tagging relate to the conditions under which a field study would be invasive, harmful, or materially alter behavior and, therefore, be covered under the act.

research facility must provide NIH with information about its animal care and use program. NIH provides facilities with a sample assurance document that describes the required information, including assurances of compliance with animal welfare standards signed by appropriate officials, a roster of Institutional Animal Care and Use Committee membership, an average daily census of animals, and other information. NIH's approval of an animal care program lasts up to 5 years, and according to NIH officials, the agency typically begins its review of a renewal after 4 years. To help facilities meet the annual report requirement, NIH provides an annual-reporting sample document that directs research facilities to update the animal care and use committee's roster and to note any change in accreditation from the private accreditation organization AAALAC International²⁵ and describe any significant changes in their animal care program, such as the species or number of animals maintained in housing. NIH officials told us the purpose of the assurances is to ensure that the proper facilities and procedures are in place to properly care for the animals, and that NIH does not use them as a public reporting tool.

Health Research Extension Act of 1985

[Guidelines shall require] animal care committees at each entity which conducts biomedical and behavioral research with funds provided under this Act (including the National Institutes of Health and the national research institutes) to assure compliance with the guidelines established [by the Director of NIH].

Source: Health Research Extension Act of 1985. | GAO-18-459

NIH has procedures to ensure that facilities that seek to receive funding from Public Health Service agencies have animal care programs with active assurances. NIH provided us with its data for tracking which facilities were receiving Public Health Service funding and which facilities had approved programs. As of November 2017, according to NIH data, all of the federal facilities receiving funding from Public Health Service agencies for activities involving animals had an active assurance. Using a sample of 16 assurances from federal facilities, we found that these assurances contained information called for by NIH, including signatures from institutional officials, rosters of Institutional Animal Care and Use Committees, and animal inventories. NIH data show that all assured facilities submitted annual reports in calendar years 2014, 2015, and 2016.²⁶

APHIS and NIH Publicly Share Some Federal Animal Use Information, but APHIS Does Not

²⁵AAALAC International was formerly the Association for Assessment and Accreditation of Laboratory Animal Care International.

²⁶NIH encourages research facilities to submit annual reports between January 1st and January 31st.

Describe the Quality of the Information It Shares

APHIS and NIH publicly report some information about federal agencies' use of research animals. Although the Animal Welfare Act does not require APHIS to share this information, APHIS posts the following on its website:

- **Annual reports from research facilities.** Research facilities' annual reports include data on the species and numbers of animals held and used for research, categorized by the steps taken to minimize pain and distress to the animal. The annual reports also include the facility's explanation of any exceptions to the Animal Welfare Act's standards and regulations during the reporting year. As of April 2018, APHIS's website included research facilities' annual reports from fiscal years 1999 through 2017.²⁷
- **National summaries of the annual reports.** APHIS prepares national summaries using the annual reports submitted by research facilities. APHIS's annual national-summary reports include data provided by research facilities on species and numbers of animals, categorized by state and by the steps taken to minimize pain and distress to the animal. As of March 2018, APHIS's website had national summary reports for fiscal years 2008 through 2016.²⁸ The national summaries do not categorize the data by types of facilities, such as federal or nonfederal research facilities.
- **Reports of APHIS inspections.** The APHIS inspection reports—typically of nonfederal facilities—could contain such information as descriptions of non-compliance, the number of animals involved in noncompliance, a correction deadline and a description of what

²⁷In technical comments on a draft of this report, APHIS officials noted that the explanations for exemptions to Animal Welfare Act standards reported by research facilities in fiscal years 2015 through 2017 remain under review with the agency's Freedom of Information Act Office.

²⁸According to APHIS's national summary report for fiscal year 2016, federal and nonfederal research facilities reported the use of more than 820,000 animals. Our analysis of APHIS data showed that federal facilities reported using about 82,000 of those animals. (In keeping with the memorandum of understanding between APHIS and ARS, ARS facilities reported to APHIS that they used more than 209,000 animals in agricultural research in fiscal year 2016. Those research activities involved farm animals, were not covered by the Animal Welfare Act, and were not included in the national summary report.)

should be done to correct the problem, and the date of the inspection. As of March 2018, APHIS's website contained reports of inspections at three federal facilities, including a zoo and an aquarium. This number does not include ARS research facilities, which APHIS inspects as part of its 2016 memorandum of understanding with ARS. As of March 2018, APHIS's website contained inspection reports for 19 ARS research facilities.

USDA's Chief Information Officer has provided guidance directing the department's agencies and offices to strive to ensure and maximize, among other things, the objectivity of information disseminated to the public. To ensure objectivity, the guidance directs that USDA agencies and offices ensure that the information they disseminate is presented in an accurate, clear, complete, and unbiased manner.

APHIS has not fully implemented this guidance for the animal use data it shares publicly. In particular, APHIS does not explain on its website potential limitations related to the accuracy and completeness of the annual reports that it provides to the public or in the national summaries of the annual reports that APHIS prepares. For example, APHIS does not explain that research facilities' annual reports may contain data on animals used for activities that are not covered by the Animal Welfare Act regulations, such as excluded field studies. Additionally, APHIS does not explain that the annual reports do not include birds not bred for research—and consequently covered by the Animal Welfare Act—because APHIS has instructed facilities to not report any birds. Furthermore, APHIS does not explain that it does not validate the accuracy and completeness of agencies' reporting. In particular, APHIS officials told us that they have the opportunity to validate reporting when they inspect nonfederal facilities, but do not have the authority to inspect federal research facilities unless invited to do so.

Some stakeholders responded to our survey that they use the data that APHIS reports on animal use to identify trends and practices within the research community. By fully implementing USDA guidance by explaining what the data represent and possible issues with their quality, APHIS could have more assurance that it is providing these data to users in a manner that is as accurate, clear, complete and unbiased as possible. Users could then be better equipped to properly analyze or assess the quality of the data, interpret the annual reports, and draw conclusions based on these data.

NIH posts a list of federal and nonfederal facilities with active assurances on its website. The Health Research Extension Act does not require NIH to make such information available through a public website, but NIH policy directs the agency to provide to Public Health Service agencies a list of facilities with such assurances. The list includes facilities that receive Public Health Service funding and facilities that have voluntarily requested NIH's review and approval of their programs. Our review did not identify federal facilities that were missing from or incorrectly included in NIH's posted list of assured facilities.

NIH does not regularly post other information—such as the facilities' average daily inventory of animals, the date they obtained an assurance, or the date they submitted their most recent annual report.—from research facilities' assurance documents. Therefore, we did not review in detail the information that agencies provide to NIH to determine its accuracy.

Stakeholder Groups Have Differing Views on Whether Agencies Should Share Additional Animal Use Information with the Public

Federal agencies may have additional information about their animal use programs. However, stakeholders who responded to our survey had different views about whether federal agencies should proactively and routinely make more information on animal use available to the public on their websites or other means than the data that APHIS and NIH currently provide.²⁹ Stakeholders other than animal advocacy organizations—including federal agencies, research organizations, academia, and others—generally expressed the view that federal agencies should not routinely make additional information available to the public, citing reasons including the existence of other methods to obtain this information and administrative burden. In contrast, stakeholders from animal advocacy organizations cited the need for more transparency and oversight as reasons that federal agencies should make additional

²⁹The 39 stakeholders who responded to our survey included 20 federal entities spread across 10 agencies. The remaining 19 stakeholders were from nonfederal organizations, consisting of eight animal advocacy organizations that advocate on behalf of animals, six research and science organizations, three individuals from academia, and two other stakeholders with knowledge of animal research issues. See app. II for a complete list of respondents.

information routinely available to the public, among other reasons. (See app. III for more information about stakeholders' responses to our questions).

More specifically, we asked stakeholders to provide their views on whether federal agencies should proactively and routinely report certain types of information to the public. We selected 10 types of information for stakeholders to consider, including some types of information that federal agencies may have for internal purposes and, in some instances, may provide to other agencies or organizations but that neither they nor others are required to proactively share with the public.³⁰ The types of information we asked stakeholders to consider included data on vertebrate animals that are not covered by the Animal Welfare Act, internal or external inspection reports, and general descriptions of agencies' animal use programs. See table 2 for the complete list of types of information we asked stakeholders to consider.

Table 2: Types of Information Included in a Stakeholder Survey Question about Agencies' Public Sharing of Animal Use Information

Type of information
1. A list of all species of vertebrate animals the agency used in research, teaching, testing, and experimentation, including those not covered by the Animal Welfare Act
2. The numbers of animals used within each vertebrate species, including those not covered by the Animal Welfare Act
3. Information about the degree to which the vertebrate animals experienced pain or distress, including those not covered by the Animal Welfare Act
4. The number of vertebrate animals categorized by the general purpose of the activity
5. The benefit derived, or expected to be derived, from the use of vertebrate animals
6. Resource expenditures, such as funding or staffing, by the federal agency to conduct activities that use vertebrate animals
7. Information, such as dates and findings, regarding APHIS inspections or site visits by any other internal or external body that evaluate the federal agency's animal care and use program
8. The agency's reports of potential violations, if any, provided to APHIS or HHS
9. The minutes of meetings related to animal use, such as those by the agency's Institutional Animal Care and Use Committee(s).
10. Any other annual reports the agency submits to any entities other than APHIS, such as HHS or the Association for Assessment and Accreditation of Laboratory Animal Care

³⁰For example, VA provided GAO with animal census data showing that more than 99 percent of the animals its research facilities used in fiscal years 2014 through 2016 were mice, rats, fish and frogs; these species are not covered by the Animal Welfare Act. In each of the 3 years, the agency used more than 340,000 animals not covered by the act. Because these animals are not covered by the Animal Welfare Act, the department is not required to report the use to APHIS.

Source: GAO. | GAO-18-459

Note: GAO asked federal agency representatives and nonfederal stakeholders whether federal agencies should proactively and routinely make the types of information shown in the table available to the public on a website or by other means.

For stakeholder groups that generally expressed the view that federal agencies should not make additional information available to the public on a proactive and routine basis, one of the most frequently cited reasons included that the public could obtain this information through other publicly available means. For example, several stakeholders said that agencies' reports of noncompliance to APHIS or NIH and data on resource expenditures are already available via the FOIA. One federal stakeholder said that it provides the public with information about the nature and extent of field research when it is required by the Marine Mammal Protection Act of 1972³¹ or the Endangered Species Act of 1973³² to obtain permits; the permitting processes include public notice and comment. In addition, some stakeholders said that certain types of information, such as the identity of the species used and the purpose and expected benefit of specific research projects are already published in peer-reviewed journals that are accessible to the public.

Several stakeholders also responded that providing additional information would impose an administrative burden on agencies. For example, several stakeholders said any potential public benefit from the additional information shared with the public would not justify the effort to collect and share the information, and one stakeholder said that providing certain types of information would reduce the time they have to do actual research. In addition, one stakeholder said that a requirement to make additional information available to the public would be in direct conflict with a 2016 law that directed NIH, the Food and Drug Administration, and USDA to look for ways to reduce administrative burdens associated with animal welfare regulations.³³

³¹Pub. L. No. 92-522, 86 Stat. 1027 (codified as amended at 16 U.S.C. §§ 1361-1423h).

³²Pub. L. No. 93-205, 87 Stat. 884 (codified as amended at 16 U.S.C. §§ 1531-1544).

³³The 21st Century Cures Act, Pub. L. No. 114-255, 2034(d), 130 Stat. 1033, 1060 (2016), directs the Director of NIH, in collaboration with the Secretary of Agriculture and the Commissioner of Food and Drugs, to complete a review by December 13, 2018, of applicable regulations and policies for the care and use of laboratory animals and make revisions, as appropriate, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals.

Other less frequently cited reasons that stakeholders gave for not believing that agencies should proactively and routinely share additional information with the public included:

- Certain information, such as expenditures on animal use, could be difficult to collect from disparate sources. For example, one federal agency said that much of its animal use funding is allocated in different areas of research and that it would need guidance to collect data on expenditures separately from each area.
- Disseminating information could jeopardize the security of facilities or personnel or disclose proprietary data. For example, one stakeholder said agency reports contain key details about federal research facilities that opposition groups could use to target personnel in those facilities.
- Disseminating information could confuse the public unless appropriate context is provided. One stakeholder said that the passive dissemination of data on animal research on a website, without appropriate context, would potentially increase public confusion and add misplaced scrutiny on animal use in federal research facilities.

For those stakeholder groups that generally expressed the view that federal agencies should make additional information available to the public on a proactive and routine basis, the most frequently cited reasons were the importance of transparency to allow the public to assess and understand animal use in federal research facilities and the need for oversight and accountability of federal agencies' use of animals. For example, some stakeholders responded that sharing additional information with the public would aid their efforts to monitor the reduction, refinement, and replacement of animals used in federal research.³⁴ One stakeholder also mentioned that sharing additional information could be easily done on a website and would give the public a more complete picture of the use of animals by federal research facilities. Several stakeholders also expressed the need for greater oversight and accountability of federal agencies' use of animals. For example, two

³⁴Reduction, refinement, and replacement are commonly referred to as "the 3Rs." A test method that reduces animal use decreases the number of animals required for testing while still achieving testing objectives. A test method that refines animal use lessens or eliminates pain or distress in animals, or enhances animal well-being. A test method that replaces animals substitutes traditional animal models with non-animal systems such as computer models or biochemical or cell-based systems, or replaces one animal species with a less highly developed one (for example, replacing a mouse with a worm).

stakeholders said that making additional information available about the degree to which animals experience pain or distress would help them assess whether federal programs' animal use is in compliance with specific provisions related to pain and distress in the Animal Welfare Act. Stakeholder groups less frequently cited other reasons for favoring routine reporting, such as:

- FOIA requests can take several months and sometimes years for agencies to fulfil.
- Certain information, such as the number of all vertebrate animals used by each agency—including those not reported under the Animal Welfare Act—should be easy to disseminate because federal agencies already collect or compile it for internal purposes.
- Additional reporting would align the federal government with other countries' practices. For example, according to one stakeholder, the European Union categorizes and publicly releases animal use numbers that are more detailed than those reported in the United States.³⁵

Conclusions

APHIS and NIH routinely collect information about federal agencies' research with vertebrate animals and provide the public with related information. Having access to this information can help the public observe trends in animal use in research and learn about facilities' compliance with standards of humane care.

Federal agencies met NIH's requirements for reporting on their animal use, but the data federal agencies provided to APHIS were not always consistent or complete. This situation resulted in part from APHIS's not providing sufficient instructions to federal research facilities for reporting on their use of animals covered by the Animal Welfare Act. In particular, APHIS instructs facilities to not report any birds in their annual reports, regardless of whether the birds are covered by the act. Although aware of this limitation, APHIS has not provided a schedule or plan for defining

³⁵European Union Directive 2010/63/EU regulates European Union countries' use of animals for scientific purposes. To increase transparency on animal research, some European countries, such as Denmark and the United Kingdom, post summaries of approved animal experiments on their national websites.

birds covered by the act or for developing reporting requirements for those birds. In addition, APHIS's instructions have not sufficiently clarified two areas of confusion and differing understanding among federal agencies: first, activities that involve animal use outside the United States and, second, the specific conditions under which field studies are or are not covered by the act. APHIS plans to develop clarifying guidance on field studies and will publish the guidance for public comment. By defining the birds that need to be reported, by instructing federal research facilities to report research activities outside the United States, and by working with the research community to develop clear criteria for identifying field studies, APHIS would have greater assurance that the data it receives from research facilities fully reflect the activities covered by the Animal Welfare Act.

APHIS has also not fully implemented the USDA's information dissemination policy that calls for the department's agencies to ensure information is presented in an accurate, clear, complete, and unbiased manner. In particular, APHIS does not explain issues related to the completeness and accuracy of the data it provides to the public, for example, issues such as inconsistencies in the types of field studies reported by federal agencies. By fully explaining these issues, the agency would improve users' ability to accurately interpret and analyze the data.

Recommendations for Executive Action

We are making the following four recommendations to APHIS:

The Administrator of APHIS should develop a timeline for (1) defining birds that are not bred for research and that are covered by the Animal Welfare Act, and (2) requiring that research facilities report to APHIS their use of birds covered by the act. (Recommendation 1)

The Administrator of APHIS should instruct federal agencies to report their use of animals covered by the Animal Welfare Act in federal facilities located outside of the United States. (Recommendation 2)

In developing the definition of field studies, the Administrator of APHIS should provide research facilities with clear criteria for identifying field studies that are covered by the Animal Welfare Act's regulations and that facilities should report to APHIS as well as field studies that facilities should not report. (Recommendation 3)

The Administrator of APHIS should ensure APHIS fully describes on its website how the agency compiles annual report data from research facilities, what the data represent, and any potential limitations to the data's completeness and accuracy. (Recommendation 4)

Agency Comments and Our Evaluation

We provided a draft of this report to Commerce, Defense, HHS, DHS, Interior, USDA, VA, EPA, NASA, and the Smithsonian Institution. USDA and VA provided written comments on the draft, which are presented in appendixes IV and V, respectively. In its written comments, USDA said that APHIS provided planned corrective actions and timeframes for implementing three of our four recommendations; APHIS disagreed with one recommendation. In its written comments, VA said that the report's conclusions were consistent with our findings.

Regarding our first recommendation that the Administrator of APHIS develop a timeline for (1) defining birds that are not bred for research and that are covered by the Animal Welfare Act, and (2) requiring that research facilities report to APHIS their use of birds covered by the act, USDA stated that APHIS will submit a recommendation and timeline by September 30, 2018, to USDA officials regarding the development of a definition for birds. USDA's comments did not specifically respond to our recommendation that APHIS also develop a timeline for requiring that research facilities report their use of birds covered by the act; we continue to believe that APHIS should develop such a timeline.

USDA's written comments stated that APHIS disagreed with our second recommendation that the Administrator of APHIS should instruct federal agencies to report their use of animals covered by the Animal Welfare Act in federal facilities located outside of the United States. USDA provided several reasons for the disagreement:

- USDA stated that the absence of an exclusion to the requirements of the Animal Welfare Act or its regulations for federal research located outside of the United States does not create a requirement to collect information about such facilities' use of animals. However, the Animal Welfare Act regulations define a reporting facility to include a department, agency, or instrumentality of the United States. In addition, officials from USDA's Office of the General Counsel told us that there is no exclusion in the act or its regulations for federal research facilities that are located outside the United States. We have

no reason to believe that such facilities should be excluded from the requirements of the Animal Welfare Act or its implementing regulations. We also note that in February 2018, APHIS officials told us that if federal agencies' activities involving animals outside of the United States are in fact covered by the Animal Welfare Act based on the specific facts and circumstances of their activities, they should report those activities to APHIS.

- USDA's comments stated that the collection of information related to research activities outside of the United States does not enable or inform its daily administration of the Animal Welfare Act and its charge to ensure the humane treatment of animals. Rather, USDA stated that our recommendation would impose an additional regulatory burden on federal research facilities. As stated above, we have no reason to believe that such facilities should be excluded from the requirements of the Animal Welfare Act or its implementing regulations. Without such an exclusion, the regulatory burden already exists; our recommendation would simply have APHIS instruct federal agencies to meet that regulatory requirement.
- Finally, USDA commented that our recommendation would place APHIS in the position of collecting different information from "reporting facilities," as defined in the regulations, which in turn, would impact any summary presentation of information involving the use of animals. We understand that, if our recommendation were implemented, APHIS may receive "different" information from federal and nonfederal facilities; that is, federal research facilities might report activities outside of the United States while nonfederal facilities would not. However, as stated above, we have no reason to believe that such facilities should be excluded from the requirements of the Animal Welfare Act or its implementing regulations. Without such an exclusion, activities covered by the Animal Welfare Act in federal facilities located outside of the United States must already be reported. We also note that, as we state in our fourth recommendation, APHIS should inform the public about the nature of its data. That information could include describing any differences in reporting by federal and nonfederal research facilities.

For the reasons given above, we continue to believe that the Administrator of APHIS should instruct federal agencies to report their use of animals in activities covered by the Animal Welfare Act in federal facilities located outside of the United States.

In response to our third recommendation that the Administrator of APHIS take certain steps to clarify the definition of field studies that are covered

by the Animal Welfare Act, USDA stated that APHIS agreed to issue a guidance document by December 31, 2018. We appreciate APHIS's commitment to issuing new guidance on field studies, but note that USDA's written comments did not directly respond to the language in our draft recommendation that called for the agency to provide research facilities with clear examples of field studies that are covered by the Animal Welfare Act regulations. We also note that the Forest Service stated in technical comments that the extensive number and variation in wildlife species preclude providing specific examples of activities that meet a prescribed definition of a field study. The Forest Service suggested that we modify our recommendation to call for APHIS to provide criteria for how research facilities should determine which studies qualify as an exempted field study. We agreed with that suggestion and modified our recommendation to call on APHIS to provide research facilities with criteria to help research facilities determine which studies are covered by the Animal Welfare Act.

APHIS agreed with our fourth recommendation that the Administrator of APHIS direct the agency to fully describe animal use data on its website. USDA's comments stated that, beginning with the fiscal year 2017 summary activities, APHIS will describe how it compiles annual report data from research facilities, what the data represent, and any potential limitations to the data's completeness and accuracy. USDA stated that APHIS will update the website with this information by September 30, 2018.

In its written comments, VA stated that our overall descriptions of its animal research program were accurate. The agency also stated that it looks forward to a time when the use of animals in research is no longer needed, but until that time, the agency will use all necessary research strategies to reduce and prevent the suffering of veterans.

APHIS, HHS, and DHS also provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Agriculture, the Secretary of Commerce, the Secretary of Defense, the Secretary of Health and Human Services, the Secretary of Homeland Security, the Secretary of the Interior, the Secretary of Veterans Affairs, the Administrator of the Environmental Protection Agency, the Administrator of the National Aeronautics and Space Administration, the Secretary of the Smithsonian Institution, and

other interested parties. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff members have any questions about this report, please contact us at (202) 512-3841 or morriss@gao.gov or neumannj@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 VI.



Steve D. Morris
Director, Natural Resources and Environment



John Neumann
Director, Natural Resources and Environment

List of Requesters

The Honorable Jeanne Shaheen
Ranking Member
Subcommittee on Commerce, Justice, Science, and Related Agencies
Committee on Appropriations
United States Senate

The Honorable Ken Calvert
Chairman
Subcommittee on Interior, Environment, and Related Agencies
Committee on Appropriations
House of Representatives

The Honorable Betty McCollum
Ranking Member
Subcommittee on Interior, Environment, and Related Agencies
Committee on Appropriations
House of Representatives

The Honorable Cory A. Booker
United States Senate

The Honorable Elizabeth Warren
United States Senate

The Honorable Donald S. Beyer, Jr.
House of Representatives

The Honorable Ryan Costello
House of Representatives

The Honorable Raul M. Grijalva
House of Representatives

The Honorable Tom Marino
House of Representatives

The Honorable Erik Paulsen
House of Representatives

The Honorable Lucille Roybal-Allard
House of Representatives

The Honorable Edward R. Royce
House of Representatives

The Honorable Mike Simpson
House of Representatives

The Honorable Dina Titus
House of Representatives

The Honorable Niki Tsongas
House of Representatives

The Honorable Mimi Walters
House of Representatives

Appendix I: Animal Species Used in Research by Federal Agencies in Fiscal Years 2014 through 2016

Federal agencies conduct research with animals for a variety of purposes, including to benefit human or animal populations. We identified 10 agencies that conducted research using vertebrate animals in fiscal years 2014, 2015, or 2016 with their own staff using their own facilities and equipment.¹ Federal agencies also fund activities that use animals, meaning that the research is done by a nonfederal entity. However, we did not include those activities in our review.

In the process of identifying federal agencies that conducted research with animals, we also identified the wide range of vertebrate animal species that these agencies used from fiscal years 2014 through 2016. In response to our survey of agencies, we learned that some agencies conducted research with a dozen or more species of animal while others conducted activities with hundreds of species. For example, NASA reported to GAO that it used 16 species while the National Museum of Natural History—one of the four animal research facilities within the Smithsonian Institution that responded to our survey—reported it conducted research on about 1,400. Table 3 shows groups of vertebrate species the 10 agencies reported to GAO that they used in research in fiscal years 2014 through 2016.

Some of the species groups shown in table 3 are not covered by the Animal Welfare Act (i.e., amphibians, fish, and reptiles), while some animal species within a group may not be covered by the act. For example, farm animals are not covered by the Animal Welfare Act if researchers use them for agricultural purposes, such as improving animal nutrition, breeding management, or production efficiency, or for improving the quality of food or fiber, but are covered if researchers use them for human health purposes. Mice and rats are not covered by the Animal Welfare Act if they are of the genus *Mus* or *Rattus* and bred for use in research. Similarly, the act does not cover birds bred for use in research. Furthermore, agencies may have used animal species in a field study that

¹The Animal Welfare Act regulations define a federal research facility to include a department, agency, or instrumentality of the United States; for the purpose of this report, we use the term agency.

Appendix I: Animal Species Used in Research
by Federal Agencies in Fiscal Years 2014
through 2016

is not covered by Animal Welfare Act regulations. Agencies are not required by the Animal Welfare Act to report their use of animals that are not covered by the act to the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). Nevertheless, the agencies are required by other policies and statutes to ensure that they treat those animals humanely.²

Table 3: Federal Agencies That GAO Identified as Conducting Research with Vertebrate Animals, by Species Group, in Fiscal Years 2014 through 2016

Species group	Department of Agriculture	Department of Commerce	Department of Defense	Environmental Protection Agency	Department of Health and Human Services	Department of Homeland Security	Department of the Interior	National Aeronautics and Space Administration	Smithsonian Institution	Department of Veterans Affairs
Amphibians	YES		YES	YES	YES		YES		YES	YES
Birds	YES	YES	YES	YES	YES		YES	YES	YES	
Cats	YES		YES				YES		YES	YES
Dogs			YES		YES				YES	YES
Other Farm Animals	YES		YES		YES	YES				YES
Fish	YES	YES	YES	YES	YES		YES	YES	YES	
Guinea Pigs	YES		YES		YES	YES				YES
Hamsters	YES		YES		YES					YES
Horses/Mules/Burros	YES		YES				YES			
Marine Mammals		YES	YES				YES		YES	
Mice/Rats	YES		YES	YES	YES	YES	YES	YES	YES	YES
Non-Human Primates			YES		YES				YES	YES
Other Mammals	YES		YES	YES	YES		YES	YES	YES	YES
Pigs	YES		YES		YES	YES				YES
Rabbits	YES		YES	YES	YES	YES	YES			YES

²The U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training state that whenever U.S. government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the stated principles shall be considered. The first such principle is that the transportation, care, and use of animals should be in accordance with the Animal Welfare Act and other applicable federal statutes, guidelines, and policies. Other statutes could include the Marine Mammal Protection Act of 1972 and the Endangered Species Act of 1973, which address the treatment of certain species during field research.

**Appendix I: Animal Species Used in Research
by Federal Agencies in Fiscal Years 2014
through 2016**

Species group	Department of Agriculture	Department of Commerce	Department of Defense	Environmental Protection Agency	Department of Health and Human Services	Department of Homeland Security	Department of the Interior	National Aeronautics and Space Administration	Smithsonian Institution	Department of Veterans Affairs
Reptiles	YES	YES	YES				YES	YES	YES	
Sheep	YES		YES		YES		YES			YES

Source: GAO analysis of federal agencies' survey responses. | GAO-18-459

Note: GAO contacted 14 federal agencies to determine which, if any, conducted research, testing, or training with vertebrate animals in fiscal years 2014 through 2016 with their own staff using their own facilities and equipment. GAO also asked the agencies to identify the species of vertebrate animals they used in those activities. Ten agencies responded that they used vertebrate animals in that manner. GAO analyzed their survey responses to determine which agencies conducted activities using the groups of animal species shown in table 3. The agencies' activities with the species listed in the table were not necessarily governed by the Animal Welfare Act.

Appendix II: List of Federal and Nonfederal Participants in GAO's Survey

Federal departments, agencies, and components:

Department of Agriculture:

- Agricultural Research Service
- APHIS Veterinary Services
- APHIS Wildlife Services
- Forest Service

Department of Commerce:

- National Oceanic and Atmospheric Administration

Department of Defense

Department of Health and Human Services:

- National Institutes of Health
- Centers for Disease Control and Prevention
- Food and Drug Administration
- Health Resources and Services Administration

Department of Homeland Security Plum Island Animal Disease Center

Department of the Interior:

- Fish and Wildlife Service
- U.S. Geological Survey
- National Park Service

Department of Veterans Affairs

Environmental Protection Agency:

- National Exposure Research Laboratory
- National Health and Environmental Health Effects Research Laboratory
- National Center for Computational Toxicology

National Aeronautics and Space Administration

Smithsonian Institution

Animal advocacy organizations:

American Anti-Vivisection Society

Animal Legal Defense Fund

American Society for the Prevention of Cruelty to Animals

Animal Welfare Institute

Humane Society of the United States

People for the Ethical Treatment of Animals

Physicians Committee for Responsible Medicine

White Coat Waste Project

Research and science organizations:

Alzheimer's Association

American College of Laboratory Animal Medicine

American Veterinary Medical Association

Americans for Medical Progress

Federation of American Societies for Experimental Biology

National Association for Biomedical Research

Academic stakeholders (speaking as individuals and not
on behalf of their institutions):

Research professor from the New York University School of Medicine

Research professor from the Johns Hopkins Bloomberg School of Public
Health

Director from the Yale University Office of Animal Research Support

Other stakeholders:

American Association for Laboratory Animal Science

AAALAC International (formerly known as the Association for Assessment
and Accreditation of Laboratory Animal Care International)

Appendix III: Analysis of GAO's Survey about Whether Federal Agencies Should Publicly Provide Information on Their Use of Animals in Research, Testing, and Training

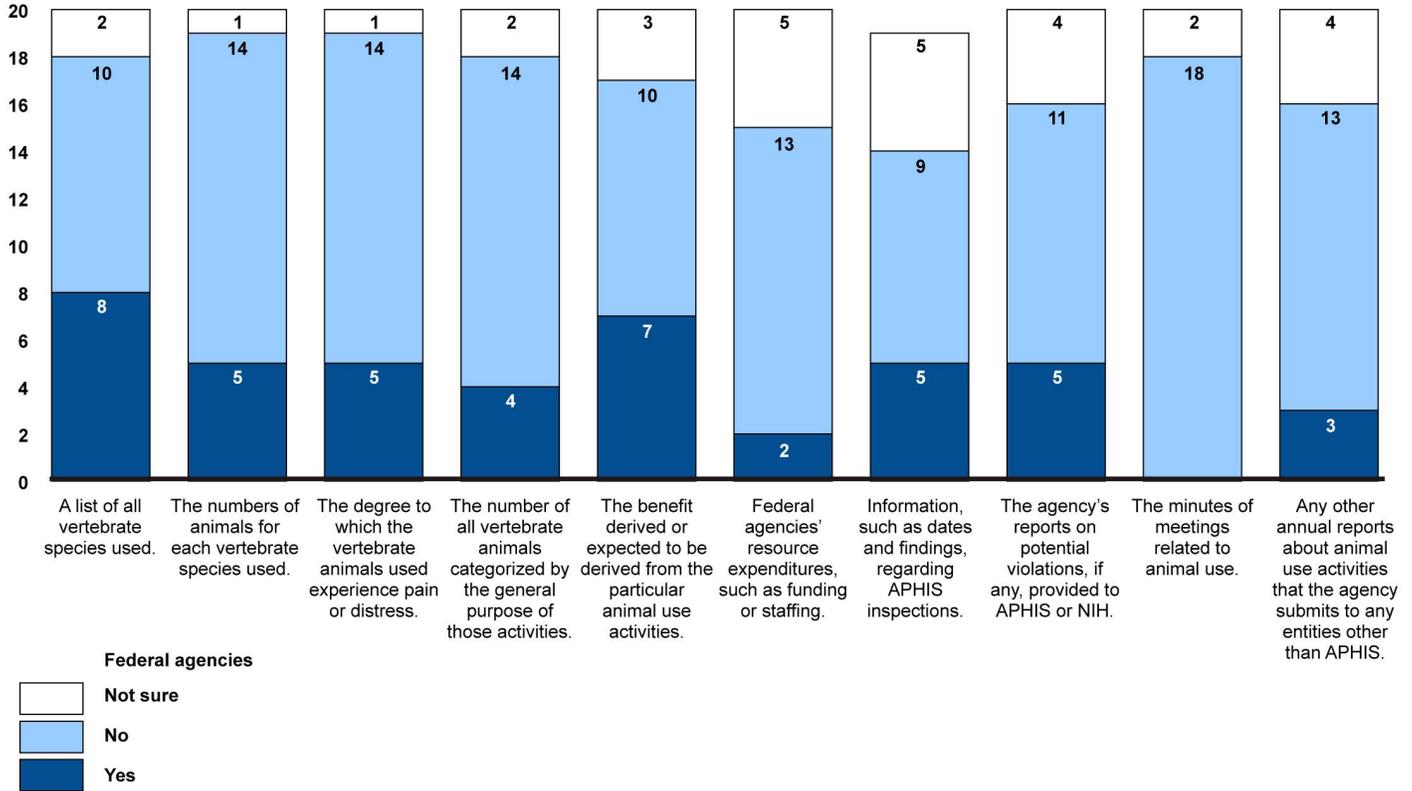
As described in this report, GAO conducted a survey of federal agencies and stakeholder groups regarding their opinions on whether federal agencies should proactively and routinely and publicly share information about their animals on a website or other means. The graphics in this appendix illustrate the responses to our survey by stakeholder group. The stakeholder groups included 20 federal departments, agencies, and sub-agencies that conduct animal research on vertebrate species; eight animal advocacy organizations that advocate on behalf of animals; six research and science organizations; and five other stakeholders including individuals in academia and other knowledgeable entities.¹ Stakeholders from federal agencies, research organizations, and academia and other entities except animal advocacy organizations generally expressed the view that federal agencies should not make additional information made routinely available to the public. (See figs. 1, 2, and 3, respectively.) In contrast, animal advocacy organizations generally expressed the view that federal agencies should make additional information routinely available to the public. (See fig. 4.) Figure 5 provides examples of stakeholders' statements explaining their views on whether federal agencies should or should not provide additional information to the public.

¹We received survey responses from 10 departments and agencies for a total of 20 responses. See app. II for a complete list of survey respondents.

Appendix III: Analysis of GAO's Survey about Whether Federal Agencies Should Publicly Provide Information on Their Use of Animals in Research, Testing, and Training

Figure 1: Summary of Federal Agency Respondents' Views on Whether Federal Agencies Should Make Certain Types of Information Available to the Public

Information about animals used in research, teaching, testing, and experimentation (20 respondents)

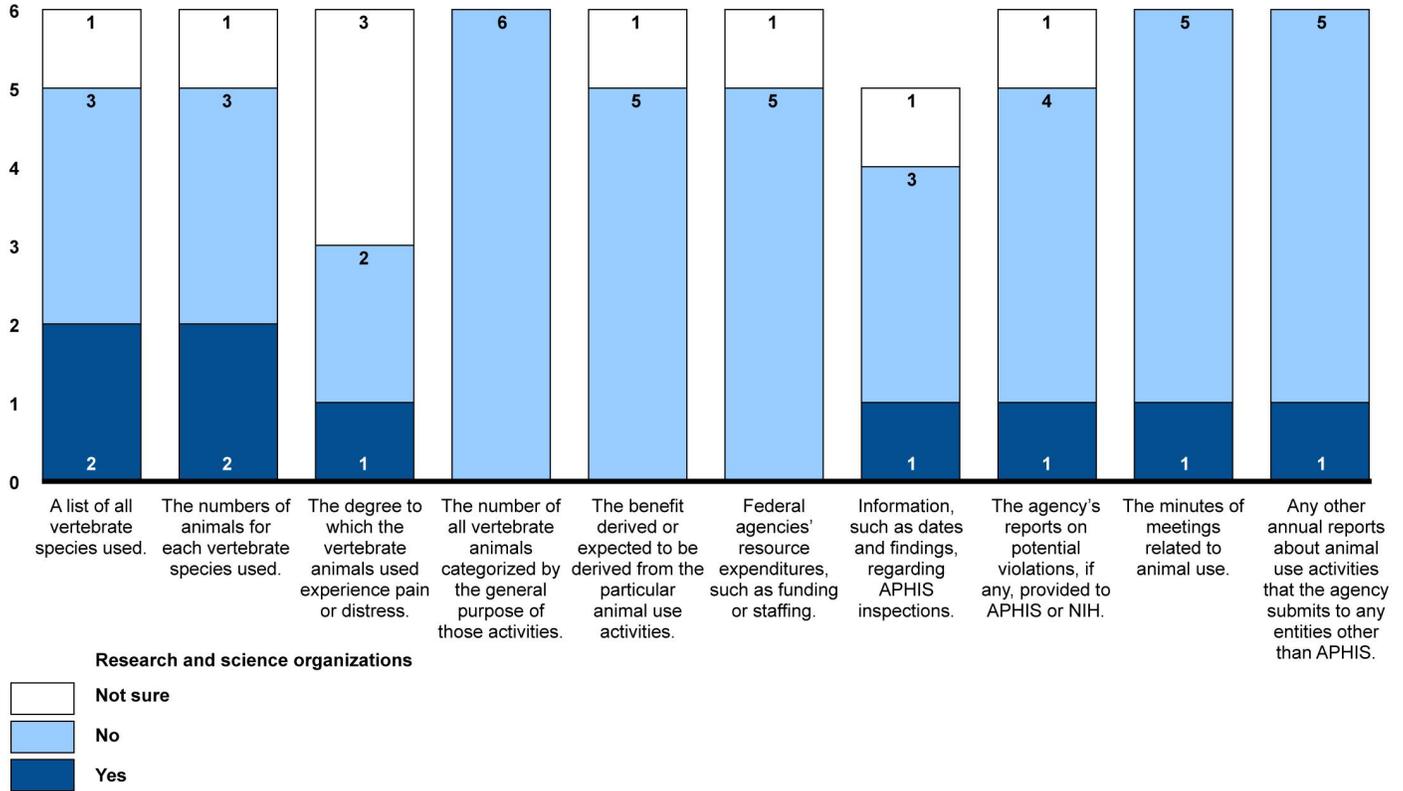


Source: GAO. | GAO-18-459

Appendix III: Analysis of GAO's Survey about Whether Federal Agencies Should Publicly Provide Information on Their Use of Animals in Research, Testing, and Training

Figure 2: Summary of Research and Science Organization Respondents' Views on Whether Federal Agencies Should Make Certain Types of Information Available to the Public

Information about animals used in research, teaching, testing, and experimentation (6 respondents)



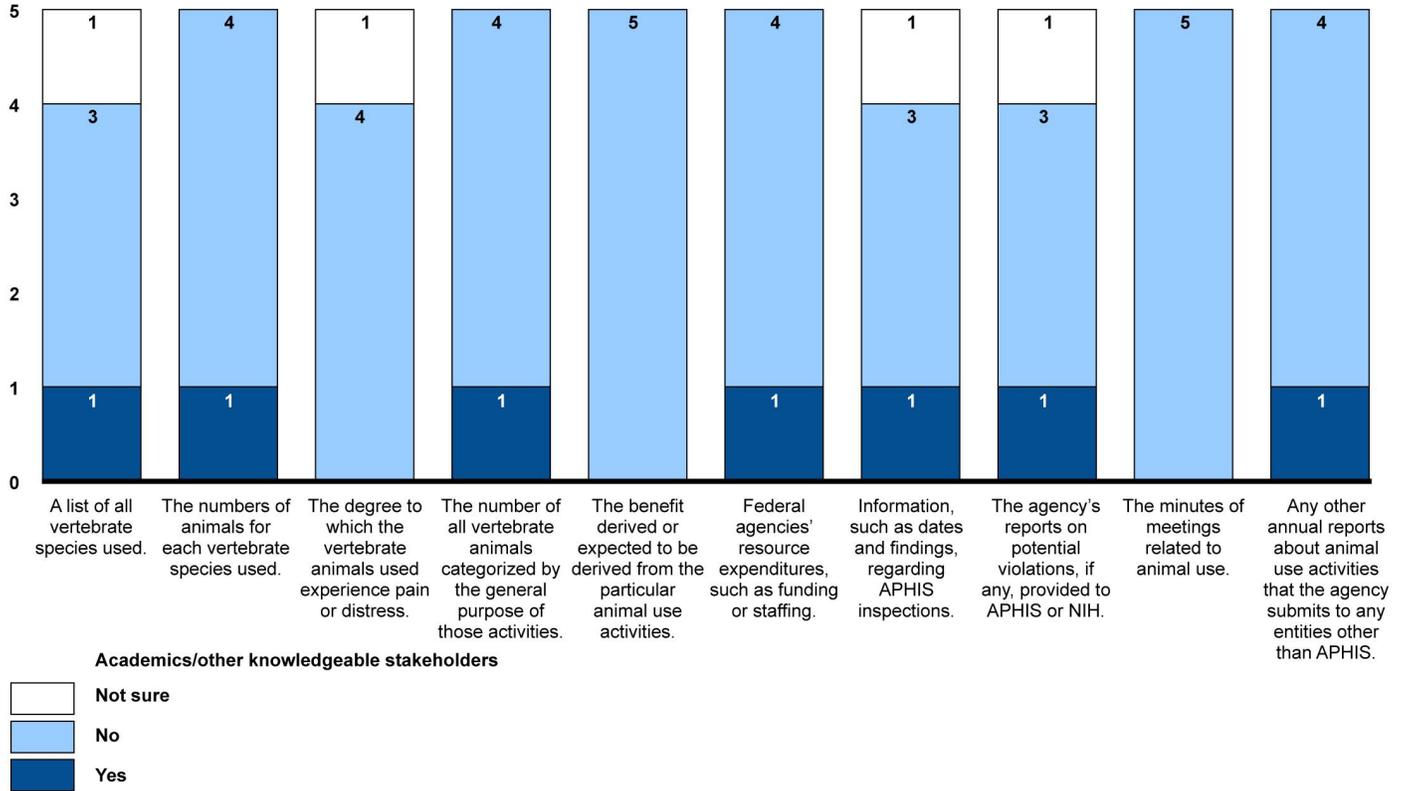
Source: GAO. | GAO-18-459

Notes: Results are not generalizable to all such entities. The responses are intended to represent the views of respondents only. The responses may not add to the total number of respondents because of a nonresponse to a particular question.

Appendix III: Analysis of GAO's Survey about Whether Federal Agencies Should Publicly Provide Information on Their Use of Animals in Research, Testing, and Training

Figure 3: Summary of Academic and Other Knowledgeable Stakeholder Respondents' Views on Whether Federal Agencies Should Make Certain Types of Information Available to the Public

Information about animals used in research, teaching, testing, and experimentation (5 respondents)



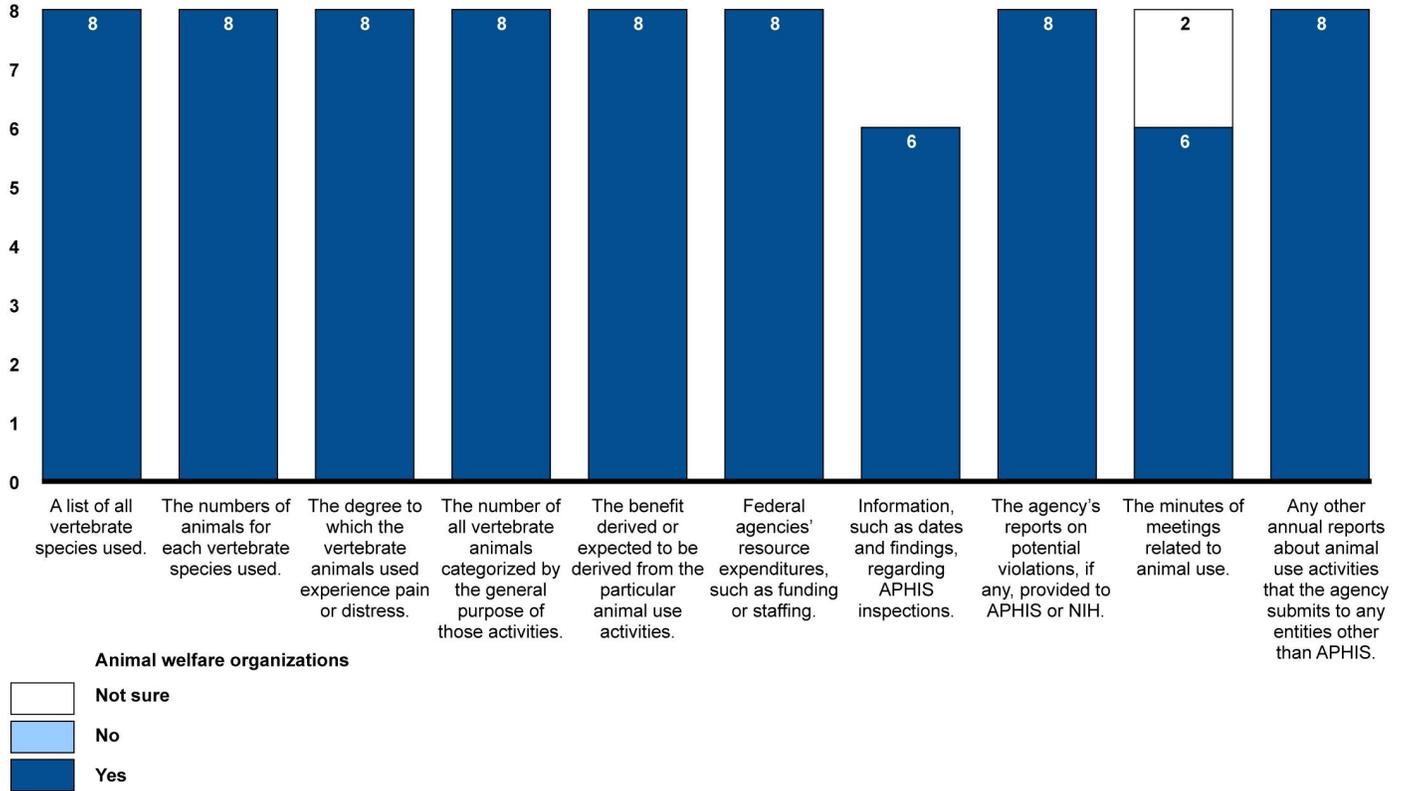
Source: GAO. | GAO-18-459

Note: Results are not generalizable to all such entities. The responses are intended to represent the views of respondents only.

Appendix III: Analysis of GAO's Survey about Whether Federal Agencies Should Publicly Provide Information on Their Use of Animals in Research, Testing, and Training

Figure 4: Summary of Animal Advocacy Organization Views on Whether Federal Agencies Should Make Certain Types of Information Available to the Public

Information about animals used in research, teaching, testing, and experimentation (8 respondents)

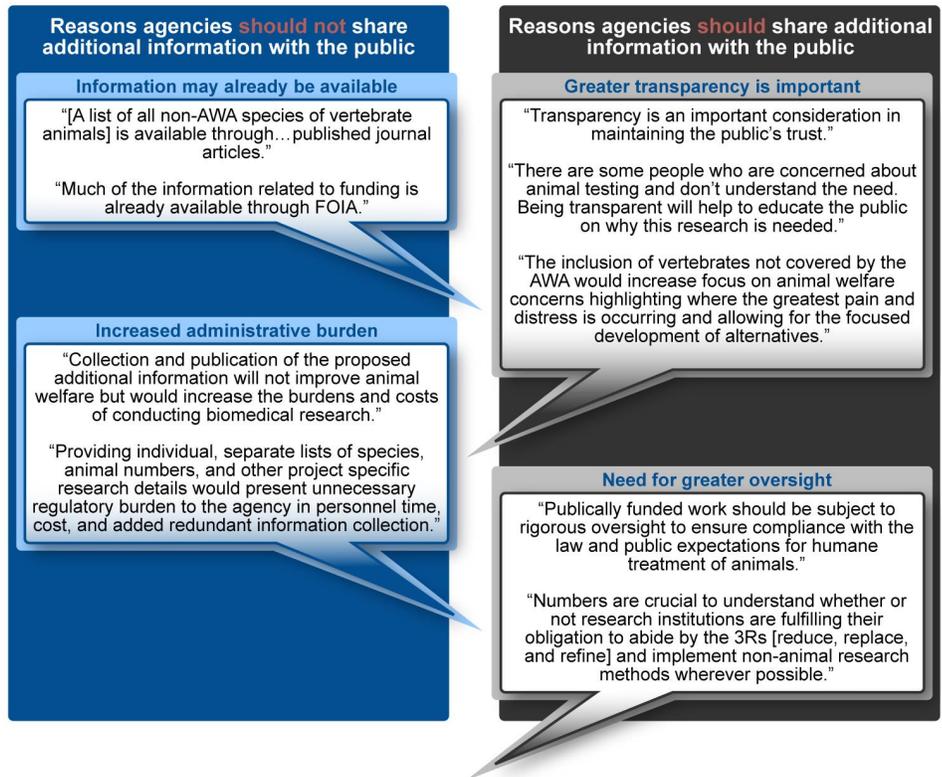


Source: GAO. | GAO-18-459

Notes: Results are not generalizable to all such entities. The responses are intended to represent the views of respondents only. The responses may not add to the total number of respondents because of a nonresponse to a particular question.

Appendix III: Analysis of GAO's Survey about Whether Federal Agencies Should Publicly Provide Information on Their Use of Animals in Research, Testing, and Training

Figure 5: Examples of Stakeholders' Reasons Why Federal Agencies Should or Should Not Share Additional Information with the Public



Source: GAO analysis of survey responses. | GAO-18-459

Notes: AWA stands for Animal Welfare Act.

GAO drew examples of statements from the most frequently cited reasons that stakeholders gave for their views that agencies should or should not share additional information with the public. The statements reflect the opinions of stakeholders who responded to the survey. GAO did not verify the statements for accuracy.

GAO also asked stakeholder groups in the survey about their opinion regarding whether the Animal and Plant Health Inspection Service (APHIS) should modify how it collects and posts annual report data under the Animal Welfare Act.² Seventeen of 39 stakeholders responded that they would like to see changes to the way APHIS collects and posts annual report data. Specifically, all stakeholders from animal advocacy organizations and individuals in academia would like to see changes to

²We did not ask stakeholders a similar question about the National Institutes of Health because that agency does not proactively provide data to the public about federal agencies' use of animals in research.

**Appendix III: Analysis of GAO's Survey about
Whether Federal Agencies Should Publicly
Provide Information on Their Use of Animals in
Research, Testing, and Training**

how APHIS collects and posts annual report data while some stakeholders from federal agencies and research and science organizations also noted that they would like to see changes. Table 4 provides examples of stakeholders' views and suggestions regarding such changes.

Table 4: Examples of Stakeholders' Suggestions for Changes They Would Like to See in the Way the Animal and Plant Health Inspection Service (APHIS) Collects and Posts Annual Report Data under the Animal Welfare Act

Modify or add information to the annual reports:

- Require research facilities to document the type of research for which animals are used and the level of pain and distress experienced by those animals. [This] will help to prioritize future development of alternatives.
- Collect information on the numbers of animals used in toxicity tests, including species not covered by the Animal Welfare Act. This would help stakeholders assess progress toward the goal of reducing such uses.
- Include the location of agencies' reporting facilities rather than just the location of the agencies' headquarters.
- Report more specific species rather than the large groups "nonhuman primates," "other farm animals," or "other animals."
- Require facilities to document animals that have been genetically-engineered for use in research.
- Break down dogs and cats between those bred for research and those from other sources (individuals, pounds, dealers).
- Identify which primates were wild-caught and which were bred for research—and whether or not they were imported.
- Indicate whether animals were used in a laboratory facility or in the field.

Other:

- *Revise submission process:* Reporting facilities should have access to a highly secure online submission process.
- *Revise search function:* The search function design makes it extremely difficult to select reports by category, such as specifically for government agencies, because it is entirely based upon key word searches.
- *Post annual reports in a timely manner.*
- *Make annual reports prior to 2013 available to the public:* Make annual reports prior to 2013 available on the APHIS website to identify trends on the numbers of animals or specific animals used at a facility over several years.

Source: GAO analysis of survey responses. | GAO-18-459.

Appendix IV: Comments from the Department of Agriculture



United States Department of Agriculture

Office of the Secretary
Washington D.C. 20250

MAY 22 2018

Steve Morris, Director
John Neumann, Director
Natural Resources and Environment
U.S. Government Accountability Office
441 G Street N.W.
Washington, D.C. 20548

Dear Mr. Morris and Mr. Neumann:

Thank you for providing the United States Department of Agriculture (USDA) the opportunity to comment on the Government Accountability Office's (GAO) Draft Report, "Animal Use in Federal Research: Agencies Share Information but Reporting and Data Quality Could Be Strengthened" (18-459). USDA has addressed the four Recommendations made to the Animal and Plant Health Inspection Service (APHIS) with their planned corrective actions and the timeframes for implementing these Recommendations.

Recommendation #1

The Administrator of APHIS should develop a timeline for 1) defining birds that are not bred for research and that are covered by the Animal Welfare Act, and 2) requiring that research facilities report to APHIS their use of birds covered by the act.

USDA Response

In response to this Recommendation, APHIS's Animal Care program agrees to submit a recommendation and timeline by September 30, 2018, to Department officials regarding the development of a definition for birds that are not bred for use in research and that are covered by the Animal Welfare Act (AWA), if used for regulated purposes.

Recommendation #2

The Administrator of APHIS should instruct federal agencies to report their use of Animals in activities covered by the Animal Welfare Act in federal facilities located outside of the United States.

APHIS Response

APHIS does not agree with this Recommendation. Although officials from USDA's Office of the General Counsel represented to GAO that there is no exclusion in the act or its regulations for federal research facilities that are located outside of the United States, the absence of an exclusion does not (expressly or impliedly) create any requirement to collect information about

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Steve Morris
Page 2

federal research facilities' use of animals outside of the United States. APHIS further maintains its position that the collection of information related to research activities outside of the United States does not enable or inform its daily administration of the Animal Welfare Act and charge to ensure the humane treatment of animals.

Beyond imposing an additional regulatory burden on federal research facilities, GAO's recommendation to collect such information from federal research facilities also places APHIS in the position of collecting different information from "reporting facilities," as defined in the regulations, which in turn, impacts any summary presentation of information involving the use of animals.

Recommendation #3

In developing the definition of field studies, the Administrator of APHIS should provide research facilities with clear examples of studies that are excluded from the definition of "field study" and are thus covered by the Animal Welfare Act regulations and that facilities should report to APHIS, as well as examples studies that meet the definition of "field study" that facilities should not report.

APHIS Response

In response to this Recommendation, APHIS agrees to issue a guidance document involving field studies by December 31, 2018.

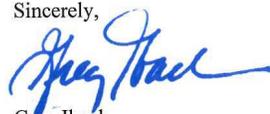
Recommendation #4

The Administrator of APHIS should ensure APHIS fully describes on its website how the agency compiles annual report data from research facilities, what the data represent, and any potential limitations to the data's completeness and accuracy.

APHIS Response

APHIS agrees to make changes in response to this Recommendation. Beginning with the Fiscal Year 2017 summary data reported to APHIS on the use of animals in regulated research activities, APHIS will describe how the agency compiles annual report data from research facilities, what the data represent, and any potential limitations to the data's completeness and accuracy. We will update the website with this information by September 30, 2018.

Sincerely,



Greg Ibach
Under Secretary
Marketing and Regulatory Programs

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Appendix V: Comments from the Department of Veterans Affairs



DEPARTMENT OF VETERANS AFFAIRS
WASHINGTON DC 20420

May 14, 2018

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

Dear Mr. Morris:

The Department of Veterans Affairs (VA) has reviewed the Government Accountability Office's (GAO) draft report, "**ANIMAL USE IN FEDERAL RESEARCH: Agencies Share Information but Reporting and Data Quality Could Be Strengthened**" (GAO-18-459).

The enclosure provides our general comment. VA appreciates the opportunity to comment on your draft report.

Sincerely,

A handwritten signature in black ink, appearing to read "Peter M. O'Rourke".

Peter M. O'Rourke
Chief of Staff

Enclosure

Enclosure

Department of Veterans Affairs (VA) Comments to
Government Accountability Office (GAO) Draft Report
***“ANIMAL USE IN FEDERAL RESEARCH: Agencies Share Information but
Reporting and Data Quality Could Be Strengthened”***
(GAO-18-459)

General Comment:

The overall descriptions of the Department of Veterans Affairs (VA) animal research program in the report are accurate, and we appreciate the Government Accountability Office (GAO) team’s careful attention to capturing this information in the report. The data in Table 3 on page 28 correctly show VA’s current use and non-use of each animal species in research.

Although the conclusions reached in the report have little impact on VA research and all involve actions by the Department of Agriculture, they are consistent with the findings in the report.

Ultimately, VA looks forward to a time when the use of animals in research are no longer needed, but until that time, all necessary research strategies will be used to reduce and prevent Veteran suffering. Alternatives to animal research such as tissue culture, “organs on a chip,” and computer simulations show promise that some use of animals in research might eventually be replaced by advancements in these techniques, but each of them have significant scientific and biological shortcomings. For instance, it is not possible to simulate something on a computer when the underlying biologic processes are not understood. Accordingly, today almost all new drugs are developed and tested in animals to evaluate their efficacy and safety. While it is true that many drugs that show promise in animal models do not end up being useful in humans, it is also true that the success rate of drugs developed using an approach such as a computer simulation would give a far lower rate of success, and greatly increase the risk of harm to people who take the new medication without at least some testing in another mammalian species. To abandon animal research at this time would freeze advancements in most areas of medicine and dramatically reduce the availability of new drugs and treatments, as well as greatly hamper new discoveries in biology that form the basis for new approaches to therapy.

We will use your findings to continue to make improvements and fulfill our mission of honoring America’s Veterans by conducting the research necessary to provide exceptional health care that improves Veterans’ health and well-being.

Appendix VI: GAO Contacts and Staff Acknowledgments

GAO Contacts

Steve D. Morris, (202) 512-3841 or Morriss@gao.gov

John Neumann, (202) 512-3841 or Neumannj@gao.gov

Staff acknowledgments

In addition to the individuals named above, Mary Denigan-Macauley (Acting Director), Joseph Cook (Assistant Director), Ross Campbell (Analyst-in-Charge), Kevin Bray, Tara Congdon, Hayden Huang, Marc Meyer, Amber Sinclair, and Rajneesh Verma made key contributions to this report.

Appendix VII: Accessible Data

Data Tables

Data Table for

Data Table for Figure 1: Summary of Federal Agency Respondents' Views on Whether Federal Agencies Should Make Certain Types of Information Available to the Public

Information about animals used in research, teaching, testing, and experimentation	Yes	No	Not sure
A list of all vertebrate species used	8	10	2
The numbers of animals for each vertebrate species used	5	14	1
The degree to which the vertebrate animals used experience pain or distress.	5	14	1
The number of all vertebrate animals categorized by the general purpose of those activities.	4	14	2
The benefit derived or expected to be derived from the particular animal use activities	7	10	3
Federal agencies' resource expenditures, such as funding or staffing.	2	13	5
Information, such as dates and findings, regarding APHIS inspections.	5	9	5
The agency's reports on potential violations, if any, provided to APHIS or NIH	5	11	4
The minutes of meetings related to animal use.	0	18	2
Any other annual reports about animal use activities that the agency submits to any entities other than APHIS.	3	13	4

Data Table for Figure 2: Summary of Research and Science Organization Respondents' Views on Whether Federal Agencies Should Make Certain Types of Information Available to the Public

Information about animals used in research, teaching, testing, and experimentation	Research and science organizations (6 total)		
	Yes	No	Did not answer
A list of all vertebrate species used	2	3	1
The numbers of animals for each vertebrate species used	2	3	1
The degree to which the vertebrate animals used experience pain or distress.	1	2	3

Appendix VII: Accessible Data

Information about animals used in research, teaching, testing, and experimentation	Yes	No	Did not answer
The number of all vertebrate animals categorized by the general purpose of those activities.	0	6	0
The benefit derived or expected to be derived from the particular animal use activities	0	5	1
Federal agencies' resource expenditures, such as funding or staffing, for activities that use vertebrate animals	0	5	1
Information, such as dates and findings, regarding APHIS inspections or site visits by any other internal or external body that evaluate the federal agency's animal care and use program	1	3	1a
The agency's reports on potential violations, if any, provided to APHIS or NIH	1	4	1
The minutes of meetings related to animal use, such as those held by the agency's Institutional Animal Care and Use Committee (s).	1	5	0
Any other annual reports about animal use activities that the agency submits to any entities other than APHIS, such as the NIH or the Association for Assessment and Accreditation of Laboratory Animal Care	1	5	0

Data Table for Figure 3: Summary of Academic and Other Knowledgeable Stakeholder Respondents' Views on Whether Federal Agencies Should Make Certain Types of Information Available to the Public

Academic and Others (5 total)

	Yes	No	Did not answer
A list of all vertebrate species used	1	3	1
The numbers of animals for each vertebrate species used	1	4	0
The degree to which the vertebrate animals used experience pain or distress.	0	4	1
The number of all vertebrate animals categorized by the general purpose of those activities.	1	4	0
The benefit derived or expected to be derived from the particular animal use activities	0	4	0
Federal agencies' resource expenditures, such as funding or staffing, for activities that use vertebrate animals	1	5	0
Information, such as dates and findings, regarding APHIS inspections or site visits by any other internal or external body that evaluate the federal agency's animal care and use program	1	3	1

Appendix VII: Accessible Data

	Yes	No	Did not answer
The agency's reports on potential violations, if any, provided to APHIS or NIH	1	3	1
The minutes of meetings related to animal use, such as those held by the agency's Institutional Animal Care and Use Committee (s).	0	5	0
Any other annual reports about animal use activities that the agency submits to any entities other than APHIS, such as the NIH or the Association for Assessment and Accreditation of Laboratory Animal Care	1	4	0

Data Table for Figure 4: Summary of Animal Advocacy Organization Views on Whether Federal Agencies Should Make Certain Types of Information Available to the Public

Animal welfare organizations (8 total)

Information about animals used in research, teaching, testing, and experimentation	Yes	No	Did not answer
A list of all vertebrate species used	8	0	0
The numbers of animals for each vertebrate species used	8	0	0
The degree to which the vertebrate animals used experience pain or distress.	8	0	0
The number of all vertebrate animals categorized by the general purpose of those activities.	8	0	0
The benefit derived or expected to be derived from the particular animal use activities	8	0	0
Federal agencies' resource expenditures, such as funding or staffing, for activities that use vertebrate animals	8	0	0
Information, such as dates and findings, regarding APHIS inspections or site visits by any other internal or external body that evaluate the federal agency's animal care and use program	6	0	0a

Information about animals used in research, teaching, testing, and experimentation	Yes	No	Did not answer
The agency's reports on potential violations, if any, provided to APHIS or NIH	8	0	0
The minutes of meetings related to animal use, such as those held by the agency's Institutional Animal Care and Use Committee (s).	6	0	2
Any other annual reports about animal use activities that the agency submits to any entities other than APHIS, such as the NIH or the Association for Assessment and Accreditation of Laboratory Animal Care	8	0	0

Data Table for Figure 5: Examples of Stakeholders' Reasons Why Federal Agencies Should or Should Not Share Additional Information with the Public

Reasons agencies should not share additional information with the public	Reasons agencies should share additional information with the public
<p><u>Information may already be available</u></p> <ul style="list-style-type: none"> • “[A list of all non-AWA species of vertebrate animals] is available through...published journal articles.” • “Much of the information related to funding is already available through FOIA.” 	<p><u>Greater transparency is important</u></p> <ul style="list-style-type: none"> • “Transparency is an important consideration in maintaining the public’s trust.” • “There are some people who are concerned about animal testing and don’t understand the need. Being transparent will help to educate the public on why this research is needed.” • “The inclusion of vertebrates not covered by the AWA would increase focus on animal welfare concerns highlighting where the greatest pain and distress is occurring and allowing for the focused development of alternatives.”
<p><u>Increased administrative burden</u></p> <ul style="list-style-type: none"> • “Collection and publication of the proposed additional information will not improve animal welfare but would increase the burdens and costs of conducting biomedical research.” • “Providing individual, separate lists of species, animal numbers, and other project specific research details would present unnecessary regulatory burden to the agency in personnel time, cost, and added redundant information collection.” 	<p><u>Need for greater oversight</u></p> <ul style="list-style-type: none"> • “Publically funded work should be subject to rigorous oversight to ensure compliance with the law and public expectations for humane treatment of animals.” • “Numbers are crucial to understand whether or not research institutions are fulfilling their obligation to abide by the 3Rs [reduce, replace, and refine] and implement non-animal research methods wherever possible.”

Agency Comment Letters

Text of Appendix IV: Comments from the Department of Agriculture

Page 1

Steve Morris, Director

John Neumann, Director

Natural Resources and Environment

Office of the Secretary Washington D.C. 20250

U.S. Government Accountability Office 441 G Street N.W.

Washington, D.C. 20548

Dear Mr. Morris and Mr. Neumann:

Thank you for providing the United States Department of Agriculture (USDA) the opportunity to comment on the Government Accountability Office's (GAO) Draft Report, "Animal Use in Federal Research: Agencies Share Information but Reporting and Data Quality Could Be Strengthened" (18-459). USDA has addressed the four Recommendations made to the Animal and Plant Health Inspection Service (APHIS) with their planned corrective actions and the timeframes for implementing these Recommendations.

Recommendation #1

The Administrator of APHIS should develop a timeline for 1) defining birds that are not bred for research and that are covered by the Animal Welfare Act, and 2) requiring that research facilities report to APHIS their use of birds covered by the act.

USDA Response

In response to this Recommendation, APHIS's Animal Care program agrees to submit a recommendation and timeline by September 30, 2018, to Department officials regarding the development of a definition for birds

that are not bred for use in research and that are covered by the Animal Welfare Act (AWA), if used for regulated purposes.

Recommendation #2

The Administrator of APHIS should instruct federal agencies to report their use of Animals in activities covered by the Animal Welfare Act in federal facilities located outside of the United States.

APHIS Response

APHIS does not agree with this Recommendation. Although officials from USDA's Office of the General Counsel represented to GAO that there is no exclusion in the act or its regulations for federal research facilities that are located outside of the United States, the absence of an exclusion does not (expressly or impliedly) create any requirement to collect information about

Page 2

federal research facilities' use of animals outside of the United States. APHIS further maintains its position that the collection of information related to research activities outside of the United States does not enable or inform its daily administration of the Animal Welfare Act and charge to ensure the humane treatment of animals.

Beyond imposing an additional regulatory burden on federal research facilities, GAO's recommendation to collect such information from federal research facilities also places APHIS in the position of collecting different information from "reporting facilities," as defined in the regulations, which in turn, impacts any summary presentation of information involving the use of animals.

Recommendation #3

In developing the definition of field studies, the Administrator of APHIS should provide research facilities with clear examples of studies that are excluded from the definition of "field study" and are thus covered by the Animal Welfare Act regulations and that facilities should report to APHIS, as well as examples studies that meet the definition of "field study" that facilities should not report.

APHIS Response

In response to this Recommendation, APHIS agrees to issue a guidance document involving field studies by December 31, 2018.

Recommendation #4

The Administrator of APHIS should ensure APHIS fully describes on its website how the agency compiles annual report data from research facilities, what the data represent, and any potential limitations to the data's completeness and accuracy.

APHIS Response

APHIS agrees to make changes in response to this Recommendation. Beginning with the Fiscal Year 2017 summary data reported to APHIS on the use of animals in regulated research activities, APHIS will describe how the agency compiles annual report data from research facilities, what the data represent, and any potential limitations to the data's completeness and accuracy. We will update the website with this information by September 30, 2018.

Sincerely,

Greg Ibach

Under Secretary

Marketing and Regulatory Programs

Text of Appendix V: Comments from the Department of Veterans Affairs

Page 1

John Neumann Director

Natural Resources and Environment

U.S. Government Accountability Office 441 G Street, NW

Washington, DC 20548

Dear Mr. Nuemann:

The Department of Veterans Affairs (VA) has reviewed the Government Accountability Office's (GAO) draft report, "ANIMAL USE IN FEDERAL RESEARCH: Agencies Share Information but Reporting and Data Quality Could Be Strengthened" (GAO-18-459).

The enclosure provides our general comment. VA appreciates the opportunity to comment on your draft report.

Sincerely,

Peter O'Rourke

Chief of Staff

Enclosure

Page 2

Steve D. Morris Director

Natural Resources and Environment

U.S. Government Accountability Office 441 G Street, NW

Washington, DC 20548

Dear Mr. Morris:

The Department of Veterans Affairs (VA) has reviewed the Government Accountability Office's (GAO) draft report, "ANIMAL USE IN FEDERAL RESEARCH: Agencies Share Information but Reporting and Data Quality Could Be Strengthened" (GAO-18-459).

The enclosure provides our general comment. VA appreciates the opportunity to comment on your draft report.

Sincerely,

Peter M. O'Rourke

Chief of Staff

Enclosure

Page 3

General Comment:

The overall descriptions of the Department of Veterans Affairs (VA) animal research program in the report are accurate, and we appreciate the Government Accountability Office (GAO) team's careful attention to capturing this information in the report. The data in Table 3 on page 28 correctly show VA's current use and non-use of each animal species in research.

Although the conclusions reached in the report have little impact on VA research and all involve actions by the Department of Agriculture, they are consistent with the findings in the report.

Ultimately, VA looks forward to a time when the use of animals in research are no longer needed, but until that time, all necessary research strategies will be used to reduce and prevent Veteran suffering. Alternatives to animal research such as tissue culture, "organs on a chip," and computer simulations show promise that some use of animals in research might eventually be replaced by advancements in these techniques, but each of them have significant scientific and biological shortcomings. For instance, it is not possible to simulate something on a computer when the underlying biologic processes are not understood. Accordingly, today almost all new drugs are developed and tested in animals to evaluate their efficacy and safety. While it is true that many drugs that show promise in animal models do not end up being useful in humans, it is also true that the success rate of drugs developed using an approach such as a computer simulation would give a far lower rate of success, and greatly increase the risk of harm to people who take the new medication without at least some testing in another mammalian species. To abandon animal research at this time would freeze advancements in most areas of medicine and dramatically reduce the availability of new drugs and treatments, as well as greatly hamper new discoveries in biology that form the basis for new approaches to therapy.

We will use your findings to continue to make improvements and fulfill our mission of honoring America's Veterans by conducting the research

necessary to provide exceptional health care that improves Veterans' health and well-being.

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