

ANIMAL AND PLANT HEALTH
INSPECTION SERVICE
ENFORCEMENT OF THE ANIMAL
WELFARE ACT
WASHINGTON, D.C.
AUDIT REPORT NO. 33600-1-Ch

JANUARY 1995

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EXECUTIVE SUMMARY

ENFORCEMENT OF THE ANIMAL WELFARE ACT AUDIT REPORT NO. 33600-1-Ch

PURPOSE

We evaluated APHIS' enforcement of the Animal Welfare Act to determine whether its procedures and controls, as well as its overall enforcement authority, were sufficient to ensure that animal dealers and research facilities subject to its oversight were in compliance with the Act; whether APHIS made full use of its existing powers to enforce the Act; and whether APHIS took sufficient corrective actions on the recommendations from OIG's prior audit. Our prior audit found that APHIS was not inspecting all animal facilities on an annual basis.

Under the Animal Welfare Act, APHIS is responsible for ensuring the humane care and treatment of warmblooded animals used by research facilities, sold by dealers, or transported in commerce. Part of this responsibility requires APHIS to ensure that the facilities and dealers obtain the animals legally. To meet this responsibility, APHIS issues licenses and registration certificates to qualified animal care facilities, inspects the facilities to determine compliance with animal welfare standards and regulations, and undertakes various enforcement activities when facilities are out of compliance with the Act. During fiscal year 1993, APHIS performed 17,593 inspections at 9,411 sites in addition to other inspections relating to the licensing and registration of animal care facilities.

RESULTS IN BRIEF

APHIS does not have the authority, under current legislation, to effectively enforce the requirements of the Animal Welfare Act. For instance, the agency cannot terminate or refuse to renew licenses or registrations in cases where serious or repeat violations occur (such as the use of animals in unnecessary experiments, or failure to treat diseases and wounds). In addition, APHIS cannot assess monetary penalties for violations unless the violator agrees to pay them, and penalties are often so low that violators regard them merely as part of the cost of doing business.

We also found that not all dogs and cats were covered by the pet protection provisions of the Animal Welfare Act, which give pet owners 5 days to claim their pets from pounds or shelters before the

animals can be sold to research facilities. While licensed dealers must wait the 5 days before acquiring the animals for resale to research facilities, the research facilities themselves may buy the animals directly from the shelters as early as they wish. We found that two universities in different States had purchased numerous animals from pounds and shelters without observing the waiting period.

We also determined that APHIS could make more effective use of its existing enforcement powers. Because APHIS does not inspect research facilities before issuing the initial registrations, noncompliance with the standards of the Act by a newly registered facility may go undetected until APHIS' first inspection up to a year later. Monetary penalties were not always aggressively collected and were in some cases arbitrarily reduced. APHIS also generally accommodated facility operators who routinely refused APHIS inspectors access to their facilities, instead of issuing suspensions or taking other available enforcement actions. As a result, facilities had little incentive to comply with the requirements of the Act. We identified several instances in which facilities continued to commit violations even after the violations had been identified by APHIS.

APHIS inspections at research facilities did not sufficiently cover the activities of the Institutional Animal Care and Use Committees. These committees are established by the facilities at APHIS' direction to ensure that the animals are cared for and that unnecessary research is avoided. Without the proper inspections, there is insufficient assurance that the committees minimized pain and discomfort to research animals and prevented unnecessary experimentation. In addition, APHIS inspections did not identify instances where animals were shipped interstate without the required health certificates, or with incomplete certificates.

We found that APHIS had taken corrective actions on most of the recommendations from our prior audit. However, it still did not reinspect all locations where serious violations had previously occurred. It also did not use its tracking system effectively to prioritize upcoming inspections or track the completion of followup visits. For those inspections it performed, inspectors did not always properly classify those violations which endangered the health or safety of the animals, and which required followup visits. Consequently, some necessary followup visits were overlooked while less critical inspections continued to be made.

KEY RECOMMENDATIONS

We recommended that APHIS: Initiate legislation which would allow the agency to revoke, or withhold renewals of licenses and registrations; initiate legislation to extend the pet protection provisions of the Act to research facilities; and implement

procedures requiring that inspections be performed at all facilities prior to registration, and that registrations be withheld from any dealer which is not in compliance. We also recommended that APHIS strengthen its enforcement of the Act by holding dealers responsible for their full monetary penalties and by suspending the licenses of dealers who refuse to give APHIS access to their premises. Finally, we recommended that APHIS increase the effectiveness of its inspections by focusing on the activities of oversight committees at research facilities, by creating health certificates specific to each animal, and by tracking violations on the basis of their severity, as recommended in our prior audit.

AGENCY POSITION

The agency's response to the draft report, dated November 30, 1994, generally agreed with the findings and recommendations as presented, but in several instances the APHIS response did not provide sufficient corrective action to fully address the recommendations. Applicable portions of the APHIS response are incorporated, along with our position, within the Findings and Recommendations section of the report. The full text of the APHIS response is included as exhibit F of the audit report.

INTRODUCTION

BACKGROUND

The Animal and Plant Health Inspection Service (APHIS), an agency of the U.S. Department of Agriculture (USDA), is responsible for the administration of the Animal Welfare Act (Act). Under the Act,

APHIS, through its Regulatory Enforcement and Animal Care Division (REAC), is responsible for ensuring the humane care and treatment of warmblooded animals used for research or exhibition, and those raised or sold by dealers.

APHIS' statutory authority for this responsibility is based on the Animal Welfare Act of 1966 (Public Law 89-544) and its subsequent amendments. These amendments included: Prohibitions on the use of animals in fighting ventures; regulation of commercial transportation of animals; additional standards for the use of animals in research; and holding periods of at least 5 days for animals obtained by public and/or private pounds and shelters.

REAC, which was established in 1988, is responsible for the enforcement of the Act; a sub-unit of the division, Animal Care, is solely devoted to animal care activities. The Animal Care unit is administered through sector offices located in Annapolis, Maryland; Sacramento, California; Fort Worth, Texas; and Tampa, Florida. Recent restructuring of REAC resulted in the closing of the Minneapolis, Minnesota Sector Office, with its responsibilities being divided between the Annapolis and Fort Worth Sector Offices. Each sector office is staffed by animal care specialists, veterinary medical officers, and inspectors. These personnel are responsible for training inspectors, as well as the inspection of facilities which handle animals intended for research, exhibition, and sales as pets.

During fiscal year (FY) 1993, APHIS performed 17,593 inspections at 9,411 sites (for 7,695 facilities, some of which had multiple sites), and performed additional inspections relating to the licensing of facilities and animal carriers. Of these facilities, 1,400 were active in research and used 2,369,440 warmblooded animals in research, testing, or experimentation. (See figure 1.) In 1993, Congress appropriated about \$9.2 million for APHIS' Animal Welfare Act enforcement activities.

ANIMALS USED IN RESEARCH, EXPERIMENTS,
TESTING, AND TEACHING
FISCAL YEAR 1993

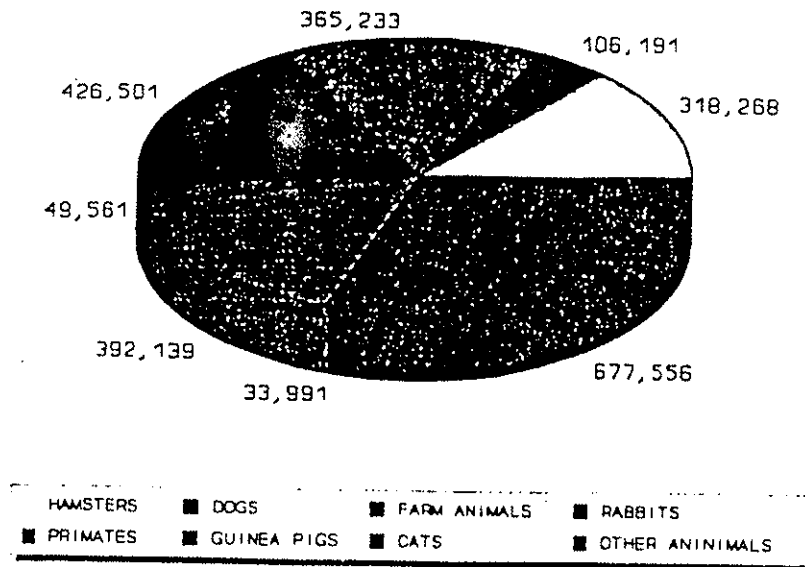


Figure 1

In March 1992, we issued an audit report (Audit No. 33002-1-Ch) on APHIS' compliance with the requirements of the Animal Welfare Act. This report concluded that APHIS could not ensure the humane care and treatment of animals at all dealer facilities as required by the Act. We reported that APHIS did not inspect dealer facilities with a reliable frequency, and it did not enforce timely correction of violations found during inspections.

OBJECTIVES

Our objective of this audit was to determine if APHIS' procedures and controls were sufficient to ensure that the facilities subject to its oversight were operating within the requirements of the Animal Welfare Act. The specific objectives were to determine:

- whether APHIS' statutory enforcement authority was sufficient to ensure that the facilities subject to its oversight were in compliance with the Animal Welfare Act;
- whether APHIS took sufficient enforcement actions to correct serious or ongoing violations of the Act; and
- whether APHIS took sufficient corrective actions based on the recommendations from the Office of Inspector General's (OIG) prior audit, including the establishment of systems to prioritize and track the performance of inspection visits.

SCOPE

The audit was performed at the APHIS National Office located in Hyattsville, Maryland, and at three of five sector offices (Minneapolis, Minnesota; Annapolis, Maryland; and Tampa, Florida).

At the national office and sector offices, we reviewed the inspections filed for 96 animal care facilities. We made site visits to 42 facilities, of which 26 were research facilities and 16 were licensed dealers. (See exhibit A for a list of the facilities we visited.) In addition, we reviewed stipulation files for 36 violations and control files for 97 complaints. As of September 30, 1993, APHIS reported a total of 7,695 facilities which came within its inspection authority under the Animal Welfare Act, of which 1,433 were research facilities, 4,154 were dealers, and 2,108 were exhibitors and transporters.

We focused primarily on APHIS activities for FY's 1993 and 1994, but reviewed records from earlier periods as needed. To evaluate inspection and enforcement trends, we reviewed reports on these activities prepared during FY's 1992 through 1994.

To evaluate APHIS' controls and procedures in place to ensure compliance with the Animal Welfare Act, we reviewed information maintained on APHIS' computerized tracking systems for inspections and investigations, reviewed licensee and registrant files, and conducted interviews with REAC staff members. At the selected facilities, we performed routine inspections, including a walk-through of the facilities and a review of the records. As part of each inspection, we were accompanied by an inspector or veterinary medical officer from APHIS' Animal Care Unit. We conducted the audit in accordance with Government Auditing Standards.

METHODOLOGY

To accomplish the audit objectives, we judgmentally selected the sector offices to visit based on the amount of research and dealer activity. At each office we judgmentally selected States and facilities to visit based upon the number of licensees and registrants within a State and the location of the facilities. We evaluated the adequacy of monitoring and oversight operations by the national and sector offices, and reviewed past inspection reports to determine the level of compliance by the inspected facilities and the adequacy of followup actions taken by APHIS at problem facilities. We reviewed APHIS' management tracking system to ensure that all facilities were inspected timely. We also reviewed records and files for facilities under investigation by APHIS, and interviewed REAC staff members. Finally, we inspected research facilities and animal dealers to assess compliance with the Animal Welfare Act.

FINDINGS AND RECOMMENDATIONS

I. APHIS LACKS THE REGULATORY AUTHORITY TO ADEQUATELY ENFORCE THE ANIMAL WELFARE ACT

We found that in many instances, APHIS does not have sufficient authority over animal research and other facilities to properly enforce the requirements of the Animal Welfare Act. For instance, APHIS cannot revoke registrations or suspend operators to deal with serious or repeat violations without a lengthy administrative hearing process. During this hearing process, the operator can continue to commit the violations for which the facility was originally cited.

APHIS' procedures classify violations of the Act as either direct or indirect. Direct violations are those that affect the health and well-being of the animals. These could include crowded cages, neglect, unsanitary conditions, poor postoperative veterinary care, and untreated diseases and wounds. Indirect violations are those that do not affect the health of the animals and could include poor recordkeeping, damaged cages, poor housekeeping, etc.¹ APHIS must enforce compliance with the Act in these areas. It must also ensure that animals are obtained legally, and that pet owners are given sufficient time to reclaim their pets from animal shelters. In this regard, APHIS needs to work to expand the pet protection provisions of the Act to include research facilities. These facilities are currently able to obtain dogs and cats directly from animals shelters and pounds without concern for the 5-day waiting period imposed on animal dealers.

Existing Federal regulations give APHIS only limited authority to deal with facilities whose actions threaten the health and safety of

¹ APHIS - Regulatory Enforcement and Animal Care Policy Memorandum No. 205, "Inspection Procedures Relative to Documentation of Noncompliance Items Under the Animal Welfare Act," August 31, 1992.

the animals under their care. APHIS can issue warning letters,² suspend a facility's operations for a period not to exceed 21 days,³ or enter into a "stipulation agreement" under which the operator of the facility agrees to pay a specified amount, up to \$2,500 per violation. If the facility operator refuses to correct cited violations, or pay an agreed-to stipulation, APHIS' only alternative is to refer the case to the Office of the General Counsel (OGC) for a hearing before an administrative law judge. Currently, APHIS cannot refuse to renew licenses or registrations for any cause except failure to apply for renewal or for nonpayment of the required license fee.

**APHIS CANNOT REFUSE TO
RENEW LICENSES AND
REGISTRATIONS FOR SERIOUS
VIOLATORS**

FINDING NO. 1

Under existing legislation, APHIS does not have the authority to withhold renewals of licenses and registrations for animal dealers, handlers, or research facilities for any reasons other than failure to request such renewals or to pay the license fee. Although APHIS can secure the termination of an operator's license or registration through the administrative hearing process, this process can take over 3 years. As a result, APHIS must automatically renew the license or registration of all animal facility operators who apply for renewal, even in cases where APHIS is aware of serious and repeat violations of the Animal Welfare Act. Our audit disclosed 28 instances in the Northeast and Southeast Sectors in which APHIS had renewed licenses or registrations to facilities which were in direct violation of the Act, thereby potentially jeopardizing the health and well-being of the animals under their care.

APHIS regulations require registered facilities, which include researchers, handlers, and transporters of animals covered by the Act, to register with APHIS every 3 years.⁴ The regulations also require that animal dealers, exhibitors, or operators of auction sales be licensed by APHIS on an annual basis.⁵ All licensed or registered facilities must acknowledge that they have received a copy of the applicable regulations and standards, and agree in

² APHIS - Regulatory Enforcement and Animal Care Policy Memorandum 910, "Guidelines for Issuance of Civil Penalty Stipulation Agreements for Apparent Violations of the Animal Welfare Act," August 18, 1992.

³ 9 CFR 4.10(a), dated January 1, 1992.

⁴ 9 CFR 2.25(a), and 2.30(a), dated January 1, 1992.

⁵ 9 CFR 2.1, dated January 1, 1992.

writing to comply with the regulations.⁶ Failure to comply with the required reporting requirements or to pay the required fees results in termination of the license. However, the Act and regulations do not give APHIS the direct authority to terminate licenses and registrations, or to refuse their renewal for any other cause, including violations of the regulations and endangerment of animals.

As part of our audit, we visited three facilities in the Northeast Sector whose licenses or registrations were renewed even though APHIS was aware of direct, ongoing violations. The following provides details of the visits.

- The registration for one animal research facility (registration no. [redacted]), was renewed by APHIS on August 24, 1993, despite the fact that the last inspection by APHIS personnel on June 18, 1993, had disclosed both direct and indirect violations. This facility was issued a warning letter on May 19, 1992, citing the poor condition of the dog kennel and problems with floor surfaces. The APHIS inspection in June 1993 showed that these problems continued to exist, and also identified inadequately maintained records of the animals and their veterinary care, and inadequate research protocols (proposals) that did not provide for preoperative and postoperative care for animals undergoing surgical procedures. APHIS required immediate corrective action on the dog kennel, a direct violation, and all of the violations were to be corrected by July 19, 1993; however, no followup visit was performed before the registration was renewed.

We visited this facility, accompanied by an APHIS inspector, on September 28, 1993, more than a month after the renewal. Our visit disclosed 30 instances of noncompliance with the regulations, of which 4 had been identified as repeated violations during the prior inspection. These repeated violations included peeling paint, no identification of where the test animals had been obtained, no medical records, and no written guidelines for preoperative and postoperative procedures.

- A State university, which operates several research sites under registration no. 34-R-017, received its 3-year registration renewal on March 7, 1993. A prior inspection on August 11, 1992, disclosed three direct and three indirect violations. These violations included approval of protocols which did not justify the number of animals used or explain completely how they would be used. The three direct violations, which could have jeopardized the health and well-being of the animals, required a followup inspection. The followup inspection, which took place on October 14, 1992,

⁶ 9 CFR 2.2, 2.26, and 2.30(b), dated January 1, 1992.

disclosed that one direct and all three indirect violations had not been corrected and resulted in a \$600 penalty against the facility. The university's registration was renewed with no determination having been made as to whether the violations had been corrected. However, APHIS would still have had no option but to process the renewal, regardless of the results of a followup inspection. Subsequent visits on August 17, 1993, and March 17, 1994, disclosed that direct violations had still not been corrected.

- During the period of January 3, 1991, through May 25, 1994, APHIS renewed the license for a Class B dealer in Indiana, (license no. []) on four occasions. This was done even though the operator of the facility had been referred to OGC in 1991 for an administrative hearing because he was suspected of operating an animal handling site that had not been reported to APHIS, and maintaining inaccurate records of dogs purchased from individuals and pounds. In addition, the operator repeatedly denied APHIS inspectors access to the facility during this period, even though the regulations require that APHIS personnel have reasonable access in order to perform inspections.⁷ APHIS personnel attempted to perform inspections on 14 different occasions during this period, and were refused admittance on 11 of these. In two instances where APHIS was allowed to make its inspections, after scheduling appointments in advance, it found no animals on the premises.

At the time of our audit, the case had been with OGC for nearly 3 years, but no action had been taken to schedule an administrative hearing to revoke or suspend the dealer's license. A complaint was issued to the dealer in June 1994, after OIG issued a Management Alert. APHIS officials estimated that it would take up to 1 year after the complaint was issued before an administrative hearing would be held.

The above examples (also see exhibit E) demonstrate the need for APHIS to be able to refuse renewals to serious violators of the Animal Welfare Act, or to revoke them when necessary, without having to initiate an administrative hearing process, which may take over 3 years to complete.

⁷ 9 CFR 2.3(a), dated January 1, 1992.

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RECOMMENDATION NO. 1

Initiate legislation to amend the Animal Welfare Act to provide APHIS with the authority to immediately revoke, or to withhold renewals of licenses and registrations for facilities which are seriously out of compliance with the Animal Welfare Act or which refuse to cooperate with APHIS.

Animal and Plant Health Inspection Service Response

In its response to the draft report, dated November 30, 1994, APHIS agreed that such legislation would enhance its enforcement efforts, and stated that USDA is cooperating with Congressional offices to expand enforcement authorities by providing drafting services and consultation. The response stated that APHIS will continue to serve in an advisory capacity, and anticipated that such legislation would be proposed during 1995.

OIG Position

APHIS' response does not clearly address the recommendation, in that it does not state the means by which the agency will initiate the needed legislation. To enhance its enforcement authority, we believe that APHIS needs to take the lead in working with the Office of Management and Budget and the Department in initiating and drafting legislation for Congress' consideration. To reach a management decision on this recommendation, APHIS needs to provide us with specific details on its intended actions, including timeframes, to initiate such legislation.

THE PET PROTECTION PROVISIONS OF THE ANIMAL WELFARE ACT NEED TO BE EXPANDED TO COVER ALL DOGS AND CATS

FINDING NO. 2

research facilities. As a result, the waiting period established to prevent family pets from being used in research was not always observed. We also noted several cases in which licensed dealers did not observe the mandatory waiting period, or obtained animals from random sources which could not be verified.

We found that two universities in two States were able to bypass the pet protection provisions of the Animal Welfare Act by obtaining dogs and cats directly from animal shelters and pounds. This was possible because the provisions of the Act apply only to Class B licensed animal dealers, not to registered research facilities. Also, we found instances in which licensed dealers failed to provide the required certifications when selling animals to

The Animal Welfare Act and the regulations⁹ established a 5-day waiting period during which licensed dealers cannot purchase dogs and cats from "random sources" such as dog pounds, animal shelters, etc. The purpose of the pet protection provisions is to ensure that family pets cannot be purchased by dealers and resold to research facilities before the owners of the animals have an opportunity to reclaim them. Under these provisions, a Class B licensed dealer cannot purchase dogs and cats from any source other than (a) another dealer licensed by APHIS, (b) a State, county, or city-owned and operated animal pound or shelter, or (c) a private pound or shelter licensed by the State, city, or county. A dealer may not purchase animals from individuals who have not bred and raised the animals on their own premises. Each dog or cat purchased from a random source must be accompanied by a signed certification that the animal has been held for a minimum of 5 days before the sale.

- These provisions, however, are not binding on registered research facilities. As a result, we found that two universities we visited were able to legally obtain dogs and cats from random sources without observing the 5-day waiting period. Examples of our findings are noted below.

- One State university (registration no. 34-R-017) obtained dogs and cats for its research programs from four county pounds. We reviewed pound records for 53 dogs obtained by the university over a 3-week period, and found that 29 of the dogs had been held for 4 days or less by the pounds.

The university's laboratory animal resource department purchased the pound animals and resold them to the university's various colleges involved in research activities. A university official stated that they obtained approximately 95 percent of the dogs used for research from local pounds. The university reported that during 1992 and 1993 they used a total of 1,470 dogs for research. This type of activity should require the university's Laboratory Animal Resource Department to be licensed as a Class B dealer.

- Another State university (registration no. 55-R-005) obtained dogs from two county pounds. We reviewed the records for 24 dogs purchased from these sources and were unable to obtain any documentation to show how long they had been held by the pounds. An official at one of the pounds stated that their State law requires a holding period of 3 days regardless of the identity of the purchaser, but records for the 24 dogs we checked were not available.

It is possible that other universities and research facilities are obtaining animals in this way, and we believe that in order to be

⁹ 9 CFR 2.133, dated July 22, 1992.

effective, the pet protection provisions of the Act need to be expanded to cover research facilities as well as dealers.

In addition, we noted that in some cases even licensed dealers were not observing the 5-day holding period when purchasing animals from random sources, or did not maintain records to certify that this had been done. It should be noted that animal pounds and shelters are not bound by the requirements of the Act; it is incumbent upon the licensed dealers and brokers to ensure that the 5-day waiting period has been complied with. However, the following instances illustrate cases where this was not done.

- We traced one dog, purchased for research by a university in Maryland, to a Class B dealer (license no. []) this dealer, in turn, purchased the dog from another licensed dealer (license no. []) in Indiana, which refused to provide us access to its records. (See Finding No. 1.) APHIS, in an earlier attempt to trace the source of dogs which this dealer purchased, questioned the source of 28 of 29 dogs that were checked. In several cases, the "sellers" did not acknowledge any sales to this dealer, or could not be located.
- Another dog, purchased by the same Maryland university on March 1, 1994, came from a Class B licensed dealer in Pennsylvania (license no. []) which, in turn, obtained the dog from an animal care facility in Canada. We were not, therefore, able to verify that the required holding period was observed; however, APHIS was to follow up on this case.

We contacted two individuals who had sold dogs to the Pennsylvania dealer, and found that they had not actually bred and raised four of the five dogs we checked. Both individuals stated that they did not understand the purpose of the certification that they signed, other than that they needed to sign it to sell the dogs.

- At another Class B dealer (license no. []), we found four instances where dogs were purchased from pounds before the end of the 5-day holding period. In one case, the dog was purchased the day after it arrived at the pound, while in the other three cases the dogs were held for only 4 days.

RECOMMENDATION NO. 2a

Initiate legislation to amend the pet protection provisions of the Animal Welfare Act to include registered research facilities as well as licensed dealers.

Animal and Plant Health Inspection Service Response

APHIS' November 30, 1994, response to the draft report did not address the agency's position on this recommendation, other than to say that current legislation does not require research facilities to comply with the cited provisions.

OIG Position

We recognize that APHIS will need additional authority to require research facilities to comply with these provisions. Therefore, we believe that APHIS needs to work with the Department, Office of Management and Budget, and the Congress to initiate and draft the necessary legislation. To reach a management decision, APHIS needs to provide us with specific details, including timeframes, of its plans to initiate and draft the recommended legislation.

RECOMMENDATION NO. 2b

Review the activities of research facility no. 34-R-017 to determine whether the facility should be prohibited from reselling purchased animals, and take corrective action as necessary.

Animal and Plant Health Inspection Service Response

In its response to the draft report, dated November 30, 1994, APHIS stated that the cited facility is State-supported, and is exempt from obtaining a dealer's license because it does not meet the definition of a "person" under the Act. A registered research facility is able to transfer/sell animals within internal departments without being required to obtain a license, since the facility is registered as one entity. If a research facility (other than State-supported) also operates as a "dealer," which includes the transferring or selling of any animals to external entities or individuals, a USDA dealers license would be required. APHIS believes that since the cited research facility sells the animals only to its own sub-units, it is not required to be licensed as a dealer.

OIG Position

We accept APHIS' management decision.

RECOMMENDATION NO. 2c

Take appropriate actions, such as suspensions or stipulations, against the cited dealers for selling random-source dogs whose sources cannot be verified.

Animal and Plant Health Inspection Service Response

In its response to the draft report, dated November 30, 1994, APHIS stated that REAC has cited multiple USDA licensed dealers for fraudulent recordkeeping concerning the inability to verify sources. REAC has also initiated procedures to: Randomly select records during routine unannounced inspections; use national APHIS traceback form 7400 in an attempt to verify sources of animals; and establish a national database of geographical marketing channels of random source animals which assists in measuring compliance with regulations, including the holding period. The response stated that the first action was implemented as of March 1994, and the others are targeted for implementation in October 1995.

OIG Position

We concur with APHIS' planned measures to assist in identifying violators. However, the response does not address the recommendation in that it does not specify what actions will be taken against the dealers cited in the finding. To reach a management decision on this recommendation, APHIS needs to provide us with a time-phased plan describing the enforcement actions to be taken against these dealers.

II. APHIS NEEDS TO TAKE STRONGER ENFORCEMENT ACTIONS TO CORRECT SERIOUS OR REPEAT VIOLATIONS OF THE ANIMAL WELFARE ACT

APHIS has several enforcement options available to it in cases where serious violations of the Animal Welfare Act are discovered. These actions include suspension of a facility's license for a period of up to 21 days, and the application of monetary "stipulations" or fines. While these enforcement powers are not always adequate to allow APHIS to effectively deal with many violators (See Findings Nos. 1 and 2), more aggressive use of the agency's existing enforcement powers could discourage violations in other cases.

APHIS regulations and policies state that APHIS may, rather than issuing a complaint seeking a civil penalty against a violator under the Act, enter into an agreement (stipulation) under which the violator agrees to pay a specified amount per violation.⁹ By entering into a stipulation agreement rather than seeking a civil penalty, APHIS can avoid the lengthy delays associated with the administrative hearing process. Violators have 20 days to agree and pay the stipulation; nonpayment of the stipulation within the 20-day timeframe entitles APHIS to pursue civil penalties through the administrative hearing process.

We found that in the case of animal research and other facilities which must register with APHIS, inspections were not performed to assess compliance with the Animal Welfare Act before the facilities' initial registrations. Because of this, facilities which violated the Act were not required to correct such violations before being registered. Collection of monetary stipulations was not aggressively pursued, and in some cases APHIS officials arbitrarily decreased the amount of stipulations that had been established by the sector offices. Facilities which openly refused to allow inspections by APHIS personnel were generally accommodated by APHIS, instead of being suspended from operations until the inspections were allowed. As a result, we found several instances in which facilities continued to violate the Act and regulations even after the violations were identified by APHIS. APHIS also needs to place additional emphasis on the inspection of Institutional Animal Care and Use Committee activities and on the use of health certificates for interstate shipments of dogs and cats. Inspections at dealer and research facilities did not always identify violations regarding committee activities and the use of health certificates.

⁹ 9.CFR 4.11(a), dated January 1, 1992.

**APHIS NEEDS TO ESTABLISH
PROCEDURES THAT REQUIRE
PREREGISTRATION
INSPECTIONS**

FINDING NO. 3

APHIS' procedures do not require preregistration inspections of new facilities to ensure that these facilities are in compliance with the standards of the Animal Welfare Act and its associated regulations. APHIS regulations allow the issuance of registrations, which each facility must have in order to operate legally, based entirely on the information contained in their written application. As a result,

an APHIS-registered facility could operate for periods of up to a year without being visited by APHIS inspectors. Our sample of research facilities, which included two recently opened facilities which had not yet received their first APHIS inspections, disclosed that both were out of compliance with the requirements of the Animal Welfare Act.

Regulations state that all research facilities performing experiments on animals, as well as all animal handlers or carriers, must be registered by APHIS before commencing operations.¹⁰ Also, the regulations require registered facilities to agree to comply with the regulations and standards by signing the registration form¹¹. However, there is no specific requirement that APHIS visit a facility prior to registration.

Our visits to the two recently opened research facilities disclosed the deficiencies noted below.

- We visited one research facility in Maryland (registration no. [] on March 7, 1994, about 6 weeks after APHIS registered the site. At the time of this visit, the facility had 66 guinea pigs and 25 rabbits on hand. We found 11 indirect violations, including bedding and food that was improperly stored, and cages that were crowded and not sufficiently cleaned to dispel the odor of animal urine. In addition, the facility had not always prepared protocols for activities involving animals, and its committee had not met to review and approve those that had been prepared.

The president of this facility agreed with the findings. He stated that he was not familiar with all of the Animal Welfare Act requirements and that a pre-inspection and meeting with the inspector would have been helpful in starting an operation that met all animal care standards.

¹⁰ 9 CFR 2.25(a) and 2.30(a), dated January 1, 1992.

¹¹ 9 CFR 2.26, dated January 1, 1992.

- The registration for another research facility (registration no. 58-R-117) was approved on February 18, 1994. We visited the facility on April 25, 1994, about 9 weeks after APHIS registered the facility to operate. The inspection of the facility disclosed that no training program had been developed to ensure that personnel who handled animals were qualified, and that training given was documented. In addition, the temporary outdoor holding pen would have exposed animals to rain and other adverse weather conditions.

The facility's director of quality assurance stated to us that a training plan would be developed at the next committee meeting to ensure that personnel were properly qualified for animal care activities. She also stated that they would take adequate measures to ensure the animals in the holding pen were protected from adverse conditions.

Although not specifically required by the regulations, pre-registration inspections are the only reliable means at APHIS' disposal to ensure that the facilities which it registers are operating in compliance with the provisions of the Act. Because a newly registered facility may not be inspected for up to a year, the Department could be subject to adverse publicity if serious violations by such a facility became public knowledge.

RECOMMENDATION NO. 3

Require that inspections be performed at all animal research and handling facilities prior to registration, and that registrations be withheld from any facility which is not in compliance.

Animal and Plant Health Inspection Service Response

APHIS' response, dated November 30, 1994, stated that existing statutes require the agency to issue a registration to a facility even though noncomplaint items exist at the time of "pre-registration" inspections. This inspection requirement will be implemented during fiscal year 1996.

OIG Position

While we agree with APHIS' proposal to implement new inspection requirements, the response does not provide sufficient details on these requirements for us to reach a management decision. Also, while we agree that APHIS does not currently have the authority to terminate an existing registration, our analysis of the Act and associated regulations revealed no requirement that APHIS issue new registrations to facilities which it knows to be out of compliance.

If APHIS determines that it does not have the authority to deny registrations to violators, the agency needs to seek additional authority and should draft the necessary legislation for submission to Congress. To reach a management decision on this recommendation, APHIS needs to provide us with specific information on the new inspection guidelines to be implemented during fiscal year 1996. This information should include the intended policies for dealing with facilities which are found to be out of compliance with the Act at the time of the pre-registration inspections. If new legislation is needed, the response should also include proposed actions and timeframes for the drafting and submission of the proposed legislation.

APHIS NEEDS TO ASSESS LARGER MONETARY STIPULATIONS

FINDING NO. 4

operators consider the stipulations as a normal cost of doing business rather than an incentive to comply with the Act. We visited six facilities where APHIS had previously levied stipulations, and found that five of these had continued to commit violations of the Act. One of these facilities had committed direct violations of the Act, which jeopardized the well-being of the animals.

The Act permits APHIS to assess monetary stipulations against facilities which violate the Act as an alternative to other actions such as suspensions or administrative hearings. The maximum amount of a stipulation is \$2,500 per violation. However, an APHIS policy memorandum dated April 1, 1994, suggested that stipulations against licensed or registered facilities be in the range of \$100 to \$250 per violation. The memorandum also recommended stipulations of between \$250 and \$500 for operating without a license or registration. Our analysis showed that in FY 1994, the total stipulations per cited facility had totaled \$300 or less.

Of the 42 facilities that we visited, APHIS had previously assessed stipulations against 6 for violations of the Act. However, we found that in five of the six cases, the stipulations had not resulted in the correction of the cited problems. Examples of this are detailed below.

- We found that one facility in Pennsylvania (license no. [redacted]) was issued a warning notice on July 26, 1991, for violations of the regulations. The facility continued to

have repeated violations such as inadequate veterinary care (direct violation), improper identification of all live dogs and cats, inadequate records, and failure to provide adequate shelter from the elements. A Civil Penalty Stipulation Agreement, dated October 30, 1992, penalized the facility in the amount of \$1,500. However, this facility has continued to commit violations. A recent attempt by APHIS to determine the source of 10 dogs disclosed that 5 of the sales were apparently fictitious. This case was recently submitted to OGC for an administrative hearing.

- Another facility (license no. []) received a warning letter on November 25, 1991, for failure to properly identify all live dogs and failure to keep surfaces impervious to moisture. The facility continued to repeat the violations, which APHIS classified as indirect violations, and on September 30, 1992, a Civil Penalty Stipulation Agreement was sent in the amount of \$200.

The dealer received another stipulation on October 25, 1993, for repeated failure to maintain outdoor housing facilities in good repair, and for failure to adequately clean and sanitize dog enclosures. Another \$200 stipulation was assessed as a result of these indirect violations. We were refused access by the dealer in our attempted visit, and therefore could not verify whether corrections had been made.

APHIS personnel stated that the stipulations, because of the small dollar amounts involved, are considered a normal cost of doing business by many facility operators. The effectiveness of the stipulations is further reduced by the fact that APHIS does not aggressively pursue collection. (See Finding No. 5.)

The monetary stipulation could be used as a more effective enforcement tool if APHIS levied greater dollar amounts. The average stipulation assessed in FY 1994 averaged under \$300 per case, although APHIS has the authority to assess \$2,500 per violation. Larger monetary stipulations could discourage repeat violations and would provide an incentive for licensees and registrants to comply with the requirements of the Act.

RECOMMENDATION NO. 4

Establish a schedule which cites the monetary penalties to be assessed for each type of direct and indirect violation, with amounts that progressively increase with repeat violations up to the \$2,500 limit.

Animal and Plant Health Inspection Service Response

APHIS' response to the draft report, dated November 30, 1994, stated that a work group is developing a schedule of penalties to be assessed for each type of direct and indirect violation. This will be completed no later than October 1, 1995.

OIG Position

We agree with APHIS' management decision.

APHIS NEEDS TO STRENGTHEN CONTROLS OVER STIPULATION AGREEMENTS

FINDING NO. 5

APHIS did not always take appropriate administrative action when violators of the Animal Welfare Act did not pay the penalties established by stipulation agreements. In some cases, this occurred because APHIS did not have sufficient evidence to refer the cases for administrative hearings. Also, APHIS accepted late payments and/or reduced the payment amounts required by the agreements instead of suspending the violators or referring them for administrative hearings. Unless APHIS is prepared to take aggressive collection action against facilities who do not pay stipulations on a timely basis, the effectiveness of stipulation agreements as an enforcement tool could be reduced.

During FY's 1992 and 1993, APHIS entered into 389 stipulation agreements with violators of the Animal Welfare Act. Violators paid \$128,000 for 281 of the 389 stipulations. (See Figure 2.) Our review showed that in five cases, APHIS entered into stipulation agreements without being in a position to refer the cases to OGC for administrative hearings in the event of nonpayment of the stipulation amount. In no instance did APHIS take other administrative actions, such as suspension of the violators' licenses.

PAID AND UNPAID STIPULATIONS
FISCAL YEARS 1992-93

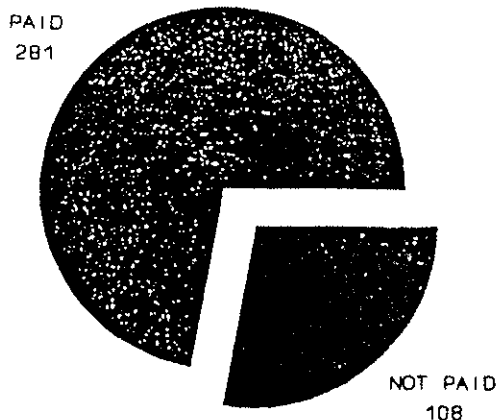


Figure 2

Also, we found that for 73 of 281 paid stipulations, APHIS accepted payments 31 to 276 days after the date of the agreement. These cases were not referred for an administrative hearing when payments were not made within 20 days as required. In two cases, the sector office reduced stipulation amounts from \$550 to \$250 without proper approval when the facilities declined to pay. The acceptance of late payments and payment reductions for some violators while other violators are held to the stipulation agreements could give the appearance of favoritism for certain violators.

On April 1, 1994, APHIS issued stipulation guidelines that required stipulations to be issued only after an investigation had been completed.¹² The guidelines, if followed, would prevent stipulations from being entered into for cases that do not warrant referral for administrative hearings. The guidelines also require the violator to pay the stipulation amount within 20 days, but do not indicate the action to be taken if payment is not received.

To ensure that stipulations are effective as enforcement tools, APHIS should not enter into stipulation agreements unless the case can be referred for an administrative hearing. However, APHIS should be prepared to take aggressive followup action on all unpaid stipulations, including suspension of licenses or registrations, or referral for administrative hearings. The acceptance of late payments without additional penalties, and reductions in payments, should be discontinued except in special circumstances and only with written approval by APHIS Headquarters.

¹² APHIS - Regulatory Enforcement and Animal Care Policy Memorandum 910, "Stipulation Guideline," April 1, 1994.

RECOMMENDATION NO. 5

Amend the regulations to require that facility operators who do not pay stipulations on a timely basis be immediately referred for administrative hearings. Also, amend the regulations to prohibit sector offices from reducing previously set stipulation amounts without proper authorization from the national office.

Animal and Plant Health Inspection Service Response

In its response to the draft report, dated November 30, 1994, APHIS stated that unpaid stipulation cases are immediately referred for formal administrative action, which includes filing of a complaint and the opportunity for a hearing. Sector offices no longer issue civil penalty stipulations; these are now issued by the Regulatory Enforcement Staff at APHIS Headquarters.

OIG Position

We agree with APHIS' action in transferring the stipulation authority from the sector offices to REAC. However, at the time of our audit, unpaid stipulations were still not generally being referred for administrative hearings as stated in the response. To reach a management decision, therefore, APHIS needs to provide us with information on any actions it has already taken to ensure that unpaid stipulations are timely referred. If the actions have not already been taken, APHIS needs to provide us with its time-phased plan for their implementation.

APHIS NEEDS TO TAKE ENFORCEMENT ACTIONS AGAINST FACILITIES WHICH REFUSE ACCESS TO APHIS INSPECTORS

FINDING NO. 6

bring into question APHIS' ability to effectively function as an enforcement agency. For FY 1993, APHIS reported to Congress that a total of 3,186 inspection visits could not be completed.

At 3 of 16 licensed dealers, we were unable to perform visits because we were refused admittance to the dealers' places of business. All of the attempted visits were made during normal business hours. In two of the cases, the dealers had histories of refusing to submit to inspections by APHIS personnel. Despite this, these dealers continued to operate under APHIS licenses, and as a result could

APHIS regulations¹³ state that all licensed and registered facilities are required to be available for inspection during reasonable hours (defined as the period between 7:00 a.m. and 7:00 p.m.); or during hours agreed to between the owner of the facility and APHIS.

We found, however, that in three cases the owner/operators of the facilities refused admittance to both OIG and APHIS personnel. Details of these cases are noted below.

- We attempted to visit an Indiana animal dealer (license no. [] on May 25, 1994, but were refused admittance by the owner's wife on the grounds that she was getting ready for work and did not have time for an inspection. The owner himself did not appear, despite the fact that an appointment had been made previously to schedule the inspection. We found that the owner of the kennel had a long history of noncompliance with APHIS and of violating the Animal Welfare Act. Since January 1, 1991, APHIS had attempted to enter the premises on 14 different occasions. In all but one case, the dealer was notified in advance of the planned visit. In 11 of these cases, APHIS was either refused admittance outright, or could not get in because the owner was gone. In two cases where APHIS personnel were allowed to enter the facility, both times with appointments, no animals were found onsite.
- On March 2, 1994, we attempted to perform an inspection at a Class A dealer in Pennsylvania (license no. []). The owner refused to allow us access for the inspection, stating that he had to prepare for his daughter's wedding. We observed, however, that the facility was in operation at that time, and that puppies were being loaded onto a pet store truck.
- Another Pennsylvania animal dealer (license no. []), which we attempted to visit on March 2, 1994, also refused us access for the inspection. In this instance, the owner's wife was present but stated that we could not visit because her husband, the owner, was not present. This also occurred when APHIS attempted to make an inspection on February 7, 1994, as a result of which the owner was required to schedule operating hours (3:00 p.m. to 7:00 p.m.) during which he would be available for inspection.

Furthermore, APHIS also had reported in its Animal Welfare Enforcement Report to Congress a total of 3,186 attempted inspections during fiscal year 1993. An attempted inspection is one that APHIS personnel could not complete because representatives of the inspected entities were not onsite. Figure 3 provides a

¹³ 9 CFR 2.126 and 2.38(b), dated January 1, 1992.

breakdown of the 25,547 inspections performed by APHIS during FY 1993, of which attempted inspections make up 12.5 percent.

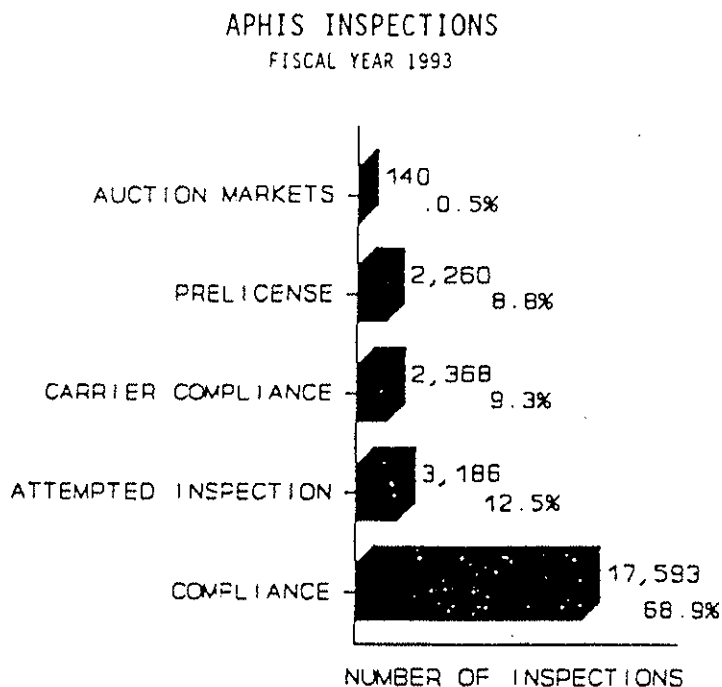


FIGURE 3

In order to effectively monitor compliance with the Animal Welfare Act, APHIS needs reasonable access to licensed and registered facilities to perform inspections. Such inspections should, to the extent practical, be unannounced so that owners and operators cannot remove animals from the premises or otherwise conceal violations before the inspector arrives. However, APHIS has not taken sufficient action to deal with facility owners who either openly refuse to allow inspections or are generally not available during their scheduled operating hours. In the case of dealer no. [redacted], noted above, APHIS inspectors generally called ahead to schedule appointments because of the owner's repeated refusal to cooperate in allowing inspections. We issued a Management Alert to APHIS regarding this case on June 3, 1994, resulting in the suspension of the dealer's license. APHIS needs to take similar actions in all cases where the agency is prevented from obtaining free access to licensed or registered facilities.

RECOMMENDATION NO. 6a

Suspend the license or registration of any facility that refuses access to APHIS personnel during scheduled working hours.

Animal and Plant Health Inspection Service Response

APHIS' response to the draft report, dated November 30, 1994, stated that the agency's authority to suspend licenses is limited to 21 days without the opportunity for a hearing. This suspension authority has been used only in cases where the animal's health is found to be in jeopardy.

OIG Position

We acknowledge the limitations of APHIS' suspension authority under current legislation. However, it remains the most effective enforcement tool available to the agency which does not require the time-consuming process of an administrative hearing. A facility operator's refusal to allow access to APHIS inspectors is a direct challenge to the agency's enforcement authority, and failure to take timely action in such cases could undermine APHIS' overall ability to enforce the Act. To reach a management decision on this recommendation, APHIS needs to provide us with a time-phased plan to implement the recommendation.

RECOMMENDATION NO. 6b

Immediately refer for administrative hearings any facility operators who repeatedly refuse access to APHIS personnel, so that their licenses or registrations can be revoked.

Animal and Plant Health Inspection Service Response

In its response to the draft report, dated November 30, 1994, APHIS stated that registrations cannot be revoked. An investigation, alleged violation, and referral for formal administrative action would be necessary prior to any request for an administrative hearing. A 21-day summary suspension and civil penalty stipulation are options which can be used in the cited instances.

OIG Position

We disagree that stipulations and suspensions are an appropriate response against facility operators who refuse access to APHIS

personnel on an ongoing basis. Our audit showed that stipulations are ineffective in such cases because of the difficulties in enforcing collection. While we agree that suspensions may be effective in dealing with less serious cases, this recommendation deals with chronic violators against whom such action would have already been taken. Under existing legislative authorities, APHIS' only remaining recourse after the 21-day suspension is to initiate an administrative hearing to revoke the operator's license. We do not believe, therefore, that APHIS' response is sufficient to address the recommendation. To reach a management decision, APHIS needs to provide us with a time-phased plan for implementing the recommendation.

**APHIS NEEDS TO PLACE MORE
EMPHASIS ON INSTITUTIONAL
ANIMAL CARE AND USE
COMMITTEES**

FINDING NO. 7

We found that the activities of Institutional Animal Care and Use Committees, which are responsible for evaluating the care, treatment, and use of animals at research facilities, did not always meet the standards of the Animal Welfare Act. We attributed this to the fact that committee members were not always fully aware of the Act's requirements, and also to the fact that APHIS inspections at research facilities

did not always cover the committees. As a result, committee activities did not always provide assurance that pain and discomfort of animals used in research activities would be minimized, or that unnecessary or repetitive experiments would not be performed.

Under the Act,¹⁴ each research facility is required to appoint a committee, to consist of a chairman and at least two additional members. The primary responsibility of a committee is to evaluate the care and treatment of animals kept by the facilities for research purposes, review proposed experiments to ensure that they have not already been performed elsewhere, and that any pain and suffering inherent in the experiments are minimized to the extent possible. These responsibilities are performed through semiannual inspections of the facilities, and through review and approval of research protocols, involving the use of animals.

At 26 research facilities, we evaluated the activities of the committees through reviews of committee meeting minutes, semiannual reviews, research protocols, and also through inspections of the facilities. We found that at 12 of the 26 facilities, the committees were not adequately fulfilling their responsibilities under the Act. Exhibit B summarizes protocol deficiencies, and exhibit C summarizes deficiencies with committee activities. The major deficiencies are shown below.

¹⁴ 9 CFR 2.31, dated January 1, 1992.

- Research protocols at four of the facilities did not contain written narrative descriptions of the methods and sources used to determine that alternatives to the procedures were not available.
- Research protocols at three facilities did not provide written assurance that the activities did not unnecessarily duplicate previous experiments.
- Research protocols at two facilities did not document a complete description of procedures designed to ensure that discomfort and pain to animals would be limited.
- Committees at two facilities began research activities prior to the protocol review or approval. At one facility, a protocol received "executive approval" from the committee chairman, who was also the principal researcher for the protocol.
- Committees at seven facilities did not properly complete the semiannual reports. For example, reports did not properly identify deficiencies, contain reasonable and specific plans and/or schedules with dates for correcting each deficiency.

Committee members at some of the research facilities, when questioned about these deficiencies, stated that they were not aware of the provisions of the Act which we cited. Further, our interviews with APHIS inspectors revealed that their inspections generally concentrated on the conditions at the facilities themselves, rather than on the activities of the committees or the adequacy of research protocols.

The deficiencies disclosed by our review show the need for tighter controls over the activities of the committees. We believe that APHIS needs to implement procedures to ensure that inspectors evaluate the activities of the committees when performing annual or followup inspections at research facilities. In addition, APHIS needs to issue a notice to all committees, clarifying the scope of their duties and responsibilities under the Act.

RECOMMENDATION NO. 7a

Implement procedures to require that all inspections at research facilities include an evaluation of the activities of the committee in ensuring the humane treatment of research animals.

Animal and Plant Health Inspection Service Response

In its response to the draft report, dated November 30, 1994, APHIS stated that it reviews internal practices used to determine Institutional Animal Care and Use Committee compliance during its inspections. APHIS is cooperating with other Government agencies and external organizations to address this issue. The agency plans to implement specific guidelines for REAC inspectors by July 1, 1995.

OIG Position

We agree with APHIS' management decision.

RECOMMENDATION NO. 7b

Issue a notice to all committees at research facilities to emphasize their responsibility to ensure that protocols are timely prepared and properly reviewed, and that the research facilities meet major requirements of the Animal Welfare Act.

Animal and Plant Health Inspection Service Response

In its response to the draft report, dated November 30, 1994, APHIS stated that the guidelines referenced in its response to Recommendation No. 7a would be used by the inspectors and by Institutional Animal Care and Use Committees for both regulatory and educational purposes. These guidelines will help to ensure compliance with the requirements of the Act.

OIG Position

During our audit, we noted that committee members at some facilities were not fully aware of their duties and responsibilities under the Animal Welfare Act and the regulations. Our recommendation that notices be sent to the registered research facilities was intended as a means of correcting this problem. The response, which proposes an alternative action, does not state how the research facilities and their Institutional Animal Care and Use Committees will be made aware of their responsibilities. To reach a management decision on this recommendation, APHIS needs to provide us with specific information, including timeframes, on how this will be accomplished.

**APHIS NEEDS TO PLACE
ADDITIONAL EMPHASIS ON THE
USE AND COMPLETION OF
HEALTH CERTIFICATES**

FINDING NO. 8

abnormalities that could endanger the animal, other animals, or public health. Our contacts with licensed dealers and animal care officials at research facilities disclosed that some were not aware that APHIS required health certificates for all interstate shipments.

APHIS regulations¹⁵ require that health certificates accompany dogs, cats, and nonhuman primates on all interstate shipments. These health certificates must be executed and issued by a licensed veterinarian. However, APHIS regulations do not specifically show how health certificates should identify animals covered by the certificates.

The following examples, and exhibit D, provide details of the shipments without certificates or incomplete certificates.

- One dealer, located in Michigan, shipped dogs to a research facility in Illinois without obtaining the required health certificates. The dealer stated that he was not aware that APHIS required health certificates for all shipments. Furthermore, he stated that the research facility did not question the shipments without the certificates.
- Two research facilities in North Carolina received shipments of dogs accompanied by health certificates that did not identify the dogs examined by the veterinarian. The certificates stated that all dogs were examined without identifying the dogs by tag numbers and/or description of the animal.

The problems with missing certificates and certificates with inadequate descriptions were not identified by APHIS inspections at the dealer and research facilities. APHIS needs to place additional emphasis on health certificates to ensure that they accompany all interstate shipments and clearly identify the animals examined by the veterinarian.

¹⁵ 9 CFR 2.78, dated January 1, 1992.

RECOMMENDATION NO. 8a

Require inspectors to conduct sufficient record reviews at dealers and research facilities to ensure health certificates are used when required and, when used, clearly identify the animals covered by the certificates.

Animal and Plant Health Inspection Service Response

The response to the draft report, dated November 30, 1994, stated that health certificates are required when transporting any dog, cat, or nonhuman primate in interstate commerce. These documents must be included in a dealer's recordkeeping system and are reviewed by APHIS during the course of inspections.

OIG Position

APHIS' response does not address the recommendation, since it implies that the agency's existing controls are sufficient and that no further action is needed. As stated in the finding, we concluded that the APHIS' controls are not sufficient to ensure that health certificates are used as required. To reach a management decision on this recommendation, APHIS needs to provide us with a time-phased plan to implement the recommendation.

RECOMMENDATION NO. 8b

Establish procedures that require health certificates to identify animals by tag number and description of the animal.

Animal and Plant Health Inspection Service Response

The response to the draft report, dated November 30, 1994, stated that APHIS Form 7001, Health Certificate, which is accepted for use in interstate shipments, contains space for recording tag numbers and other needed information to identify the animals; however, its use is not mandatory. APHIS Form 7006, Disposition of Dogs and Cats, also requires the preparer to enter information identifying the animals covered by the form. Upon issuance of final rules (Docket No. 92-158-1), use of this form will become mandatory. Animal identification information contained on this form can be used to record animal identification on the health certificate or other acceptable forms for interstate shipment.

OIG Position

We accept APHIS' management decision.

III. APHIS DID NOT FULLY ADDRESS PROBLEMS DISCLOSED IN A PRIOR AUDIT

OIG's previous audit of APHIS' administration of the Animal Welfare Act (Audit No. 33002-1-Ch) disclosed that APHIS did not have sufficient resources to make all required inspection visits. The audit recommended that APHIS develop a risk-based inspection system which would allow the agency to better prioritize its inspection visits. We found that most of the recommendations of the report were satisfactorily addressed, and that APHIS had brought in enough additional personnel to make inspection visits to all licensed and registered animal facilities on at least an annual basis.

However, we found that APHIS was still not able to make all of the required inspection visits. Although annual inspections were being performed at all facilities, APHIS was not always making the higher priority reinspections of facilities where direct violations had been identified. We attributed this in part to the fact that APHIS had not developed the recommended risk-based inspection system to prioritize the use of its inspection resources. In addition, the need for reinspection visits was not always known because inspectors incorrectly identified situations where the health or safety of animals were at risk as "indirect" violations. As a result, animals could be endangered because serious violations were not timely identified or corrected.

APHIS DID NOT PERFORM ALL REQUIRED REINSPCTIONS

FINDING NO. 9

visits were not made due to staffing limitations and budgetary cutbacks, despite the agency's stated policy that followup on direct violations would be a high priority in scheduling inspections. As a result, facilities are able to continue with practices which could jeopardize the health or safety of their animals without APHIS intervention.

APHIS issued policy memorandum No. 205 on August 31, 1992, which states that direct violations are a high priority concern in the enforcement of the Act. This memorandum defines a direct violation as one which endangers the health or well-being of animals. Also, Memorandum No. 205 requires that any direct violation noted by an

Although APHIS now inspects each licensed or registered animal facility at least annually, we found that required followup visits were not always made to facilities which had been cited for violations which endangered the health or safety of the animals under their care. APHIS officials stated that some followup

APHIS inspector be corrected within an appropriate timeframe, not to exceed 30 days. APHIS must perform a followup inspection within 45 days of the scheduled correction date.

Our review of inspection reports in four States (Delaware, Maryland, Michigan, and Pennsylvania) served by the Northeast Sector Office disclosed that of 16 research facilities that were cited for direct violations of the Act, 9 did not receive followup visits within the established timeframes. Of 22 Class A licensed dealers who were cited for direct violations, 9 did not receive visits within the timeframes. (See Figure 4.)

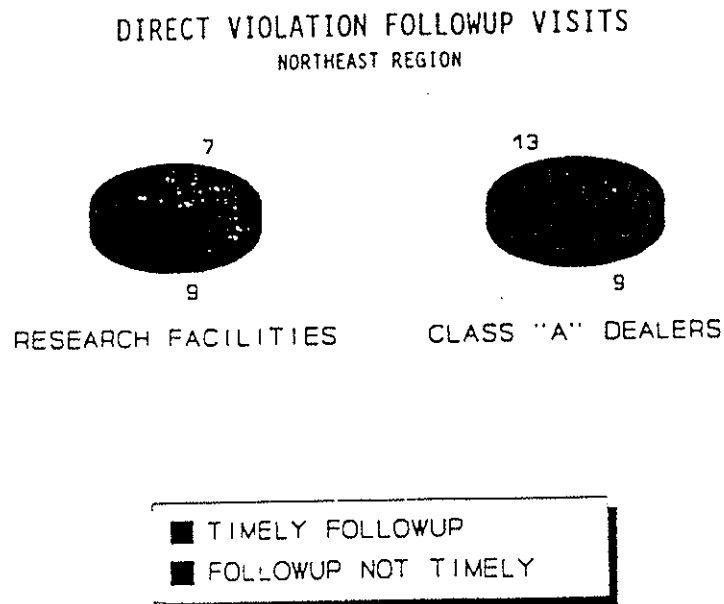


Figure 4

Thirty-two of the facilities were eventually reinspected, but 4 of the research facilities and 2 of the dealers had not been reinspected as of February 1994. For example:

- Two sites at a Michigan research facility (registration no. []) were cited for direct violations in August 1992. However, no followup visit was ever performed, and the sites were not visited again until the next routinely scheduled inspection in August of 1993. At that time, the inspectors found that the violations at one site had still not been corrected.
- A Pennsylvania research facility (registration no. []) was cited for a direct violation on June 21, 1993; however, as of the date of our review on February 15, 1994, more than 7 months later, no reinspection had taken place.

- A Pennsylvania animal dealer (license no [] was cited for a direct violation in March 1993. The followup inspection was made over 7 months later, at which time the inspection report indicated that the direct violations were corrected.

We also reviewed 17 inspection reports in the Southeast Sector Office which cited direct violations, and found that timely reinspections were not made for 6 of these.

As a result of APHIS not making timely followup visits, one research facility was allowed to continue to commit direct violations for an entire year, and thereby continued to endanger the health and well-being of the animals in its care. In another case, APHIS had no assurance that the direct violations cited in the last visit had been corrected after a period of more than 7 months. In each of these cases, APHIS cited a lack of staffing caused by budgetary cutbacks as the reason for not performing timely reinspections.

Based on the above, we continue to believe that APHIS needs to develop a risk-based system of performing inspections. Such a system would ensure that those inspections which are considered to be of the highest priority, such as reinspections of facilities where direct violations had been noted, would be performed first. Annual inspections of facilities where violations have not been found in the past, by contrast, could be assigned a lower priority. The implementation of such a system would allow APHIS to make the most efficient use of its inspection resources, and thereby increase its chances of identifying and correcting facilities which commit serious violations of the Act.

RECOMMENDATION NO. 9

Establish a risk-based inspection system to ensure that the highest priority inspections, such as reinspections of facilities where direct violations have been found, are performed before routine inspections or facilities with good records of compliance.

Animal and Plant Health Inspection Service Response

The response to the draft report, dated November 30, 1994, stated that a risk-based inspection system is in the developmental stages and will help prioritize the coordination of inspections within REAC sectors. Reinspections of facilities with documented direct noncomplaint items are currently given inspection priority. The risk assessment model has been established under Phase I of the process; Phase II, the field testing of the risk assessment model, is currently underway. APHIS plans to implement the system for all

research facilities in fiscal year 1996, and for all licensed dealers and exhibitors during fiscal year 1997.

OIG Position

We accept APHIS' management decision.

APHIS' COMPUTERIZED TRACKING SYSTEM DOES NOT ADEQUATELY SERVE ITS USERS

FINDING NO. 10

The Licensing Applicant Registration Information System (LARIS), a computerized tracking system which APHIS designed to track violations and prioritize inspection activities, did not effectively fulfill these functions. The system's output did not provide the information needed to track and schedule inspections. Also it did not always accurately show the extent of violations disclosed by inspections at animal care facilities. This occurred because system users were not given the opportunity to provide input into the design of the system. Also, sector office personnel responsible for its operation did not receive adequate training in the operation of the system.

LARIS, which was placed into service during March 1993, replaced the older License and Registration System. It was created as a result of a recommendation made in our previous audit, No. 33002-1-Ch, that APHIS develop a system which would allow prioritization of the inspection efforts. At that time, it was found that APHIS did not have sufficient personnel to visit all licensed and registered facilities once a year, and also to make the required followup inspections at facilities where direct violations had been identified. APHIS defined a direct violation as a violation which, due to its nature, jeopardizes the health and well-being of the animals at a facility. All other violations are classified indirect and are considered less serious.

Although we found that LARIS had been implemented in the Northeast and Southeast Sectors, it was not meeting its goals. The problems noted are detailed below.

- The reports produced by LARIS were not considered satisfactory by many of the system's users in the sector offices. One of the concerns expressed was the difficulty in obtaining special reports to meet needs of individual users. For example, sector office officials were not able to obtain a report for a specific time period identifying annual inspections which had been done or which still needed to be done. Sector office personnel were not able to replace the reported scheduled reinspection dates with the actual reinspection dates. A review of the reports would not determine if the planned reinspection were actually completed. In addition, one sector

office responded to a national office survey that only 11 of 35 reports were useful. These consisted mainly of various sorted listings of the licensed and registered facilities, and due dates for their next license or registration renewal.

Sector office personnel were not given the opportunity to provide input into the design of the system. As a result, sector offices developed their own systems to track annual and followup inspections that have been completed or still need to be done within a given year.

- When performing inspections of animal care facilities, each inspector fills out an Animal Care Inspection Report (APHIS Form 7008) citing each violation noted, and identifying it as direct or indirect. Sector office personnel enter this information into the LARIS database. The information in the database is then used as a means of determining which facilities have the greatest need to be inspected. In March 1993, the national office issued a policy letter instructing the sector offices to discontinue entering indirect violations into the database. The Southeast Sector Office, after following this policy for a short time, resumed entering indirect violations because sector officials recognized that the deletion of indirect violations misrepresented the degree of noncompliance at the inspected facilities.

In our comparison of 22 inspection reports to the LARIS database, we found that the information for 5 inspections was incorrect either because of input errors, or because inspectors had not correctly identified the violations as direct or indirect. Examples of this are shown below.

- The October 8, 1993, inspection report for licensed facility no. [] identified 3 direct and 19 indirect violations of the Animal Welfare Act. The LARIS database reported the 3 direct violations and only reflected 6 of the 19 indirect violations.
- The February 2, 1993, inspection report for facility no. [] cited one direct and two indirect violations. The LARIS database did not reflect any violations for this facility.
- The June 6, 1993, inspection report for facility no. [] showed two direct and six indirect violations. The LARIS database showed that only one indirect violation was cited by the inspection. We also noted that two of the indirect violations cited in the report had been misclassified, and should have been identified as direct violations. These violations, which related to animals crowded into insufficient space and animals placed in plastic containers with

insufficient ventilation, clearly affected their health and safety and should have been considered as direct violations.

Inspection reports did not clearly show the number of indirect and direct violations. The reports provided a narrative which described the violations but did not require the inspector to report a count of direct and indirect violations. Therefore, sector office personnel responsible for entering inspection results on the LARIS database needed to review the inspectors' written summaries to obtain a count of the violations. As a result, the LARIS system did not always accurately report the number of violations, which is needed to assign appropriate inspection priorities to animal care facilities.

Since APHIS does not have sufficient staff to make both annual inspections at all facilities and followup inspections at those where direct violations have been identified, the national and sector offices must be able to depend on LARIS as a tool to assist them in prioritizing their inspections. To be effective, the system should provide the national and sector offices with the means to track completed inspections and assign priorities to those inspections that still remain to be done, in order for the agency to make efficient use of its inspection personnel.

RECOMMENDATION NO. 10a

Obtain input from the users of the system at the national and sector offices, to determine which reports need to be added, deleted, or redesigned. At a minimum, reports showing completed inspections and due dates of upcoming inspections should be included in those regularly distributed to the sectors.

Animal and Plant Health Inspection Service Response

APHIS' response to the draft report, dated November 30, 1994, stated that an internal assessment and evaluation of REAC's automated systems is ongoing, and will be completed by April 1, 1995. While APHIS agreed that a report which would include both completed and upcoming inspections would be beneficial, the response stated that the sector offices have the responsibility for generating these reports; APHIS Headquarters does not generate individual reports containing inspection data for distribution to the sectors.

OIG Position

We agree with APHIS' proposal to conduct an internal assessment and evaluation of the computer systems used by REAC to monitor inspections. However, we disagree with APHIS' position that the sector offices should take the lead in generating the reports; none

of the sector offices we visited had such reports, and we believe that APHIS Headquarters needs to take the initiative in designing them and mandating their use. To reach a management decision on this recommendation, APHIS needs to provide us with a time-phased plan for the creation and implementation of the necessary report(s).

RECOMMENDATION NO. 10b

Determine the feasibility of programming LARIS to automatically assign priorities to scheduled inspections, based on available APHIS resources and severity of violations cited at various facilities.

Animal and Plant Health Inspection Service Response

APHIS' response, dated November 30, 1994, stated that the agency does not believe it feasible to program LARIS to automatically assign inspection priorities. The agency stated that the system could not be adequately programmed to include all necessary variables such as the immediate health and care of the animals at a facility, facility history, prior enforcement actions, or sensitive and visible program issues.

OIG Position

We accept APHIS' management decision.

RECOMMENDATION NO. 10c

Ensure that personnel responsible for using the system are provided sufficient training to ensure they can effectively use the system.

Animal and Plant Health Inspection Service Response

In its response dated November 30, 1994, APHIS agreed that additional training of personnel using LARIS may be necessary, and stated that the training would be provided on the basis of identified need.

OIG Position

We found no evidence that any formal training had been provided to users of LARIS; based on the problems we noted at the sector offices, we believe that at the minimum APHIS needs to provide basic training on the system's operation to all users. To reach a

management decision on this recommendation, APHIS needs to provide us with a time-phased plan to ensure that all key personnel receive at least the minimum training needed to properly perform their functions.

RECOMMENDATION NO. 10d

Require sector offices to enter indirect violations into the LARIS database, and establish procedures that will count all violations found under each part of the Act.

Animal and Plant Health Inspection Service Response

In its response dated November 30, 1994, APHIS stated that Form 7008, used by inspectors and sector personnel, details the nature of each indirect noncomplaint item. Followup for correction of these items takes place during the next routine facility inspection. Repeated noncompliance, either direct or indirect, is addressed through the appropriate enforcement action unless corrected. APHIS believes that these measures adequately address violations and noncompliance issues.

OIG Position

The purpose of our recommendation was to make the cited information available through LARIS. Although we agree that the information on violations is available from various sources, it is not readily accessible to inspectors or sector office personnel when setting priorities for inspection visits. We believe that for the risk-based inspection system to be effective, this information must be available to APHIS personnel as part of LARIS. To reach a management decision on this recommendation, APHIS needs to provide us with either a time-phased plan to implement the recommendation, or a proposal for alternative action which would address the cited conditions.

EXHIBIT A - AUDIT SITE LOCATIONS

NORTHEAST SECTOR

STATE	LICENSE OR REGISTRATION NUMBER
Delaware	
Maryland	
Michigan	
Pennsylvania	
Ohio	

EXHIBIT A - AUDIT SITE LOCATIONS

SOUTHEAST SECTOR

STATE	LICENSE OR REGISTRATION NUMBER
Florida	
North Carolina	

EXHIBIT A - AUDIT SITE LOCATIONS

NORTH CENTRAL SECTOR¹⁶

STATE	LICENSE OR REGISTRATION NUMBER
Illinois	
Indiana	

¹⁶ This sector's workload was combined with the South Central and Northeast Sector Offices. Facilities inspected during the audit are now serviced by the Northeast Sector.

EXHIBIT B - PROTOCOL DEFICIENCIES BY RESEARCH FACILITIES

REGISTRATION NUMBER	PROTOCOLS REVIEWED	PROTOCOL VIOLATIONS FOR ONE OR MORE PROTOCOLS						
		1	2	3	4	5	6	7
	3	3		3	3	3		
	3	3	3			3	3	
	5		4				2	
	5					1		1
	10				3			
	3		3		3			2
	1		1	1				
	1	1						
	5	5		5				

VIOLATION KEY:

1. Protocols did not contain a written narrative description of the methods and sources used to determine that alternatives to the procedures were not available.
2. Protocols did not contain an adequate justification for the number of animals used.
3. Protocols did not provide written assurance that the activities did not unnecessarily duplicate previous experiments.
4. Protocols lacked a complete description of the euthanasia method to be used.

EXHIBIT B - PROTOCOL DEFICIENCIES BY RESEARCH FACILITIES

5. Protocols did not provide proper preoperative procedures.
6. Protocols did not contain a complete description of the proposed use of the animals.
7. Protocols did not document a complete description of procedures designed to ensure that discomfort and pain to animals will be limited.

EXHIBIT C - DEFICIENCIES BY INSTITUTIONAL ANIMAL CARE AND USE COMMITTEES

REGISTRATION NUMBER	VIOLATIONS							
	1	2	3	4	5	6	7	8
			X					
		X						
	X	X		X	X			
		X						
		X						
		X	X	X			X	X
	X							
				X		X		
			X					
		X	X		X			
		X						

VIOLATION KEY:

1. Research activities began prior to protocol review or approval.
2. Semiannual reports did not properly identify deficiencies, or contain reasonable and specific plans and/or schedule with dates for correcting each deficiency.
3. There was no documentation that the semiannual reviews were reviewed and signed by a majority of the committee members.

¹⁷ Some or all of these noted violations were not in compliance during the previous inspections but were not reported by the APHIS inspector.

¹⁸ The inspector's report indicated that these violations were corrected, but they were not.

EXHIBIT C - DEFICIENCIES BY INSTITUTIONAL ANIMAL CARE AND USE COMMITTEES

4. The committee did not review ongoing protocols each year as required.
5. Committee members were not appointed by the Chief Executive Officer of the research facility.
6. The committee did not complete the semiannual report.
7. Facility inspections were completed 8 months apart instead of the required 6 months.
8. Facility inspection was completed by only one member of the committee.

EXHIBIT D - HEALTH CERTIFICATE DEFICIENCIES

RECEIVING FACILITY NUMBER	HEALTH CERTIFICATE ISSUED IN WHICH STATE	HEALTH CERTIFICATE DEFICIENCIES					
		1	2	3	4	5	6
	NONE ISSUED						X
	NONE ISSUED						X
	INDIANA	X	X	X	X		
	INDIANA	X	X	X	X		
	INDIANA	X	X	X	X		
	INDIANA	X	X	X	X		
	ALABAMA		X				
	ALABAMA		X				
	MICHIGAN	X	X	X	X	X	
	NONE ISSUED						X
	OHIO	X	X				
	OHIO	X	X				
	TENNESSEE	X	X	X	X		
	TENNESSEE	X	X	X	X		
	TENNESSEE	X	X	X	X		
	OHIO	X	X				
	TENNESSEE	X	X	X	X		
	TENNESSEE	X	X	X	X		

¹⁹Facilities shipped animals out of state without health certificates.

EXHIBIT D - HEALTH CERTIFICATE DEFICIENCIES

RECEIVING FACILITY NUMBER	HEALTH CERTIFICATE ISSUED IN WHICH STATE	HEALTH CERTIFICATE DEFICIENCIES					
		1	2	3	4	5	6
	TENNESSEE	X	X	X	X		
	PENNSYLVANIA		X				
	ILLINOIS				X		
	ILLINOIS				X		
	ILLINOIS				X		
	ILLINOIS				X		
	ILLINOIS				X		
	ILLINOIS				X		
	ILLINOIS				X		
	ILLINOIS				X		

DEFICIENCY KEY

- 1 Breeds of the animals were not identified.
- 2 Ages of the animals were not identified.
- 3 Sex of the animals was not identified.
- 4 Descriptions of the animals were incomplete.
- 5 Veterinarian certification statement was not completed.
- 6 No certificates were obtained and shipped with the animals.

EXHIBIT E - EXAMPLES OF CONDITIONS IDENTIFIED AT ANIMAL CARE FACILITIES



These photographs show floors that are deteriorating and have paint peeling up from them. In this condition, they cannot be easily cleaned and sanitized to prevent diseases.

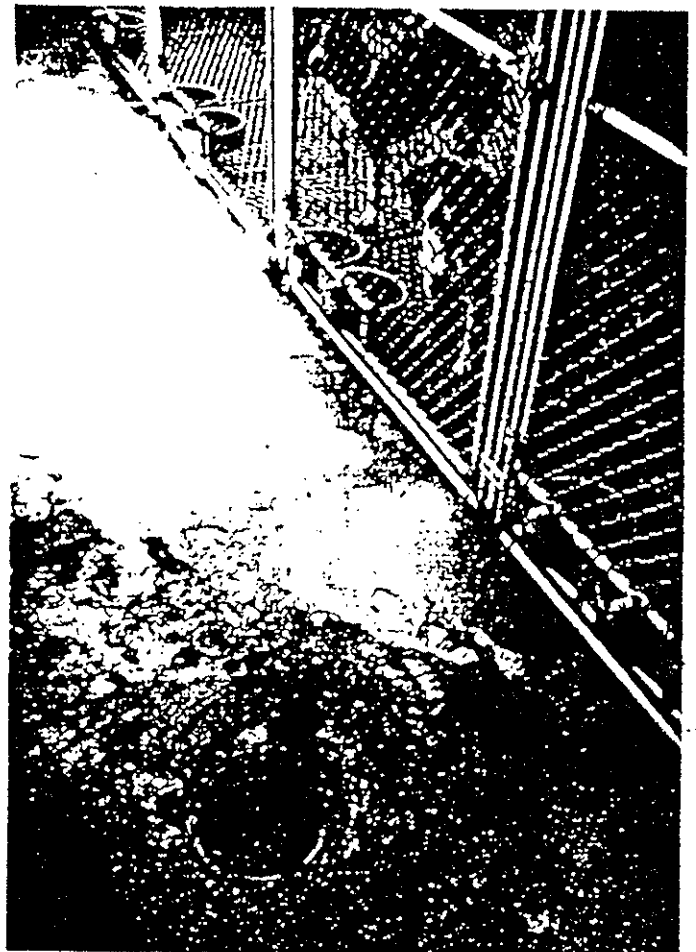


EXHIBIT E - EXAMPLES OF CONDITIONS IDENTIFIED AT ANIMAL CARE FACILITIES



This photograph (left) shows a large piece of paint (approximately 3" by 6") from the floor hanging over the edge of the water receptacle. The potential for contamination of water within the receptacle is apparent.



This photograph (right) shows large amounts of infectious waste materials stacked in the cage wash cleaning area.

EXHIBIT E - EXAMPLES OF CONDITIONS IDENTIFIED AT ANIMAL CARE FACILITIES



These photographs show improper disposal methods. As seen, a rabbit carcass is placed directly into the freezer. Also, this freezer was not properly cleaned, as blood and serum stains are apparent.

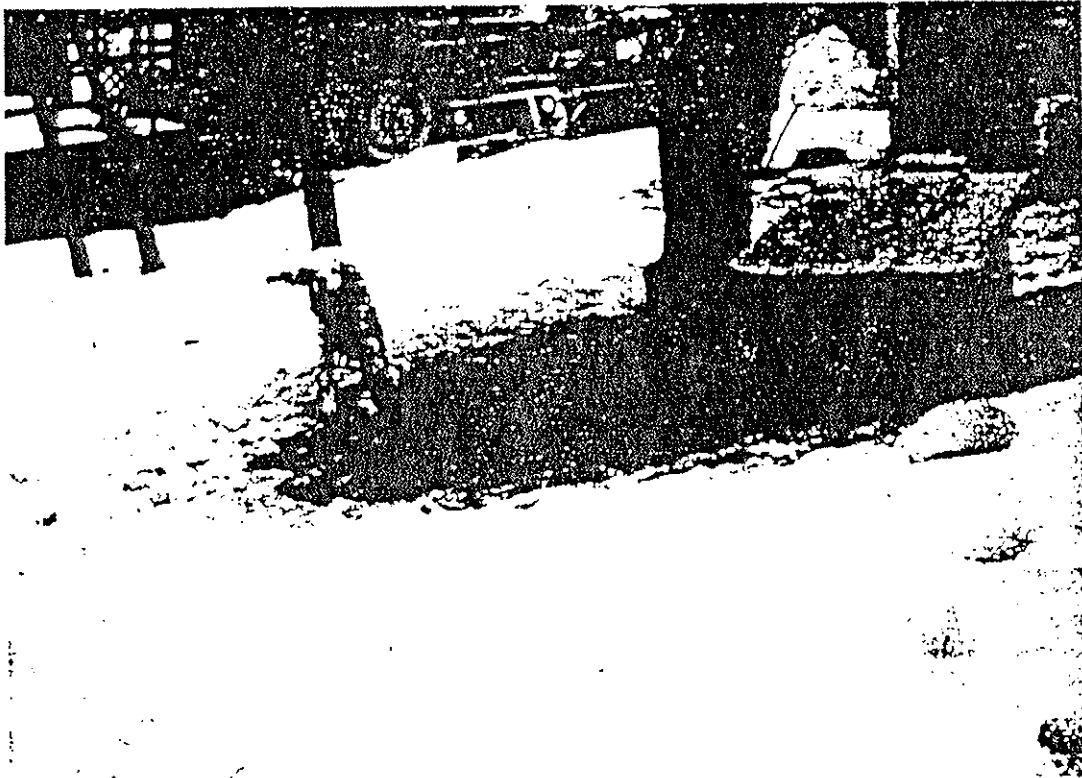


EXHIBIT E - EXAMPLES OF CONDITIONS IDENTIFIED AT ANIMAL CARE FACILITIES



This photograph shows dogs maintained in an area without a perimeter fence to protect them from predators. In addition, these animals have unsanitary water receptacles and food containers that do not protect the contents from contamination. Also, we noted excessive accumulations of fecal matter throughout the holding area.

*EXHIBIT E - EXAMPLES OF CONDITIONS IDENTIFIED AT
ANIMAL CARE FACILITIES*



This photograph shows another dog maintained in the same area without a perimeter fence. Also, this animal has the same type of unsanitary water receptacle and food container. Excessive fecal matter was observed throughout the holding area.

EXHIBIT F - ANIMAL AND PLANT HEALTH INSPECTION SERVICE'S RESPONSE TO THE DRAFT REPORT



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Subject: OIG Audit 33600-1-CH
Enforcement of the Animal Welfare Act

To: Stephen V. Fowkes
Director
Food, Consumer, Marketing
Inspection Services Division, OIG

Date: 12.3.93

We reviewed your recent report concerning our existing authorities to enforce the Animal Welfare Act (AWA) provisions and the corrective actions taken in response to your prior audit. The following information includes comments provided by management officials of the APHIS Regulatory Enforcement and Animal Care (REAC).

We request inclusion of the following additional information to clarify certain portions of the draft report:

Page 1, first paragraph, line 9

"Under the Animal Welfare Act, APHIS is responsible . . . and raised or sold by dealers, or transported in commerce."

Page 18, last paragraph, line 3

OIG quoted directly from the APHIS FY 1993 Animal Welfare Annual Report to Congress stating that an attempted inspection is one that APHIS personnel could not complete because ". . . (2) airport facilities were found to have no animals present." Since the Report's publication, APHIS, REAC, sectors have verified that carrier facilities found to have no animals present ~~are~~ counted as inspections rather than "attempted" inspections, and we request that the sentence read ". . . inspected entities were not onsite."

OIG Recommendation 1:

Initiate legislation to amend the AWA to provide APHIS with authority to immediately revoke, or withhold renewals of licenses and registrations for facilities which are seriously out of compliance with the Act or which refuse to cooperate with APHIS.

APHIS Response:

Currently, APHIS is enforcing the AWA under the authorities mandated by Congress. To expand enforcement authorities, Congress would be required to seek and support additional legislation. Such legislation would enhance our enforcement efforts. USDA has been cooperating with Congressional offices to expand enforcement authorities by providing drafting services and consultation. APHIS will continue to serve in an advisory capacity. It is anticipated that such legislation will be proposed during 1995.



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EXHIBIT F - ANIMAL AND PLANT HEALTH INSPECTION SERVICE'S RESPONSE TO THE DRAFT REPORT

Stephen V. Fovkes

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OIG Recommendation 2a:

Initiate legislation to amend the Act's pet protection provisions to include registered research facilities and licensed dealers.

APHIS Response:

Current AWA legislative authorities require all USDA licensed dealers to meet a holding period of 5 business days. Under the 1990 AWA amendment, a pound/shelter is not required to meet the 5-day holding period, if the registered research facility acquiring the animals is not also a USDA licensed dealer. We request your consideration of our management decision regarding this recommendation.

OIG Recommendation 2b:

Require research facility No. 34-R-017 to become licensed as a Class B dealer or immediately cease reselling purchased animals.

APHIS Response:

The identified research facility is State-supported and is exempt from obtaining a USDA dealer's license, as defined under "person" in the Act. A registered research facility is able to transfer/sell animals within internal departments without being required to obtain a USDA dealer's license, since the facility is registered as one entity. If a research facility (other than State-supported) also operates as a "dealer," which includes transferring/selling of any animal(s) to external entities or individuals, a USDA dealer's license would be required. APHIS requests concurrence with our management decision.

OIG Recommendation 2c:

Take appropriate actions, such as suspensions or stipulations, against cited dealers for selling random source dogs whose sources cannot be verified.

APHIS Response:

APHIS, REAC, has cited multiple USDA licensed dealers for violations due to fraudulent recordkeeping concerning the inability to verify sources. REAC has also initiated procedures to:

- 1) Randomly select records during routine unannounced inspections. This was accomplished in March 1994 via the Assistant Deputy Administrator's formal correspondence written to Animal Care Sector Supervisors;
- 2) use national APHIS traceback Form 7400 in an attempt to verify sources of animals; and

EXHIBIT F - ANIMAL AND PLANT HEALTH INSPECTION SERVICE'S RESPONSE TO THE DRAFT REPORT

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3) establish a national data base of geographical marketing channels of random source animals which assists in measuring compliance with regulations, including the holding period. The target date for implementation is October 1995.

We believe these issues have been appropriately addressed by REAC and request OIG acceptance of our corrective actions.

OIG Recommendation 3:

Require inspections to be performed at all animal research and handling facilities prior to registration, and require that registration be withheld from any facility not in compliance.

APHIS Response:

Existing statutes require APHIS to issue a registration to a facility even though noncompliant items exist at the time of "pre-registration" Agency inspections. This inspection requirement will be implemented during Fiscal Year (FY) 1996. Concurrence with our planned actions is requested.

OIG Recommendation 4:

Establish a schedule citing monetary penalties to be assessed for each type of direct and indirect violation, with amounts that progressively increase with repeat violations up to the \$2,500 limit.

APHIS Response:

A work group is developing a schedule of penalties to be assessed for each type of direct and indirect violation. This will be completed no later than October 1, 1995, and we believe this will fulfill management decision requirements.

OIG Recommendation 5:

Amend regulations to require facility operators who do not pay stipulations on a timely basis to be immediately referred for administrative hearings. Amend regulations to prohibit sector offices from reducing previously set stipulation amounts without proper authorization from the national office.

APHIS Response:

Unpaid stipulations are immediately referred for formal administrative action which includes filing of a complaint and the opportunity for a hearing. Sector offices no longer issue civil penalty stipulations; these are now issued by the Regulatory Enforcement Staff at our headquarters. We request OIG concurrence with our corrective actions and management decision.

EXHIBIT F - ANIMAL AND PLANT HEALTH INSPECTION SERVICE'S RESPONSE TO THE DRAFT REPORT

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OIG Recommendation 6a:

Suspend license or registration of any facility refusing access to APHIS personnel during scheduled work hours.

APHIS Response:

Our authority limits suspension of operation to licensed facilities (not registered facilities) for 21 days without the opportunity for hearing. This 21-day summary suspension has been used only in cases whereby the animal's health is found to be in jeopardy. Management decision resolution is requested.

OIG Recommendation 6b:

Immediately refer for administrative hearings facility operators who repeatedly refuse access to APHIS personnel so their licenses or registrations can be revoked.

APHIS Response:

As stated in the prior recommendation, such registrations cannot be revoked. An investigation, alleged violation, and referral for formal administrative action would be necessary prior to any request for an administrative hearing. A 21-day summary suspension and civil penalty stipulation are options which can be used in the cited instances. Therefore, we request OIG resolution consideration of this matter.

OIG Recommendation 7a:

Implement procedures requiring all inspections at research facilities to include evaluation of committee activities ensuring humane treatment of research animals.

APHIS Response:

We have reviewed internal practices used to determine Institutional Animal Care and Use Committee (IACUC) compliance during our inspections. APHIS is cooperating with other internal Government agencies and external organizations to address this issue. We plan to implement specific guidelines for REAC inspectors. Guidelines will be finalized for implementation by July 1, 1995. We believe our response satisfies management decision requirements.

OIG Recommendation 7b:

Issue a notice to all research facility committees and emphasize their responsibility to ensure protocols are timely prepared, properly reviewed, and that research facilities meet major requirements of the AWA.

EXHIBIT F - ANIMAL AND PLANT HEALTH INSPECTION SERVICE'S RESPONSE TO THE DRAFT REPORT

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APHIS Response:

The guidelines referenced in our response to Recommendation 7a will be utilized by our inspectors and IACUC Committees for both regulatory and educational purposes. These guidelines will help to ensure compliance with AWA requirements. Our comments to the prior OIG recommendation are applicable to No. 7b. Please advise if our response fulfills the resolution criteria.

OIG Recommendation 8a:

Require inspectors to conduct sufficient record reviews of dealers and research facilities to ensure health certificates are used when required; clearly identify animals covered by certificates.

APHIS Response:

Health certificates are required when transporting any dog, cat, or nonhuman primate interstate. These documents must be included in a dealer's recordkeeping system and are reviewed by APHIS during the course of inspections. We request approval of our management decision for this recommendation because we are examining these records.

OIG Recommendation 8b:

Establish procedures requiring health certificates to identify animals by tag number and a description of the animal.

APHIS Response:

APHIS Form 7001 (health certificate) and other forms are accepted for use during interstate shipments. Designated space for recording tag number and identification is included on the 7001. However, we do not believe the use of this particular form should be mandatory.

APHIS Form 7006 (Disposition of Dogs and Cats) requires listing of the animal's identification. Upon final rulemaking (Docket No. 92-158-1), use of the 7006 will be mandatory. Animal identification information contained on Form 7006 may be used to record individual animal identification on Forms 7001 or on other acceptable forms for interstate shipments.

OIG Recommendation 9:

Establish a risk-based inspection system ensuring the highest priority inspections, such as reinspections of facilities where direct violations have been found, are performed before routine inspections or inspections of facilities with good compliance records.

EXHIBIT F - ANIMAL AND PLANT HEALTH INSPECTION SERVICE'S RESPONSE TO THE DRAFT REPORT

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APHIS Response:

A risk-based system is in the developmental stages and will help prioritize the coordination of inspections within REAC Sectors. Reinspection of facilities with documented direct noncompliant items are currently given inspection priority. The risk assessment model has been established under Phase I of this process. Phase II is currently underway via testing this model in the field by selecting REAC veterinary inspectors and registered research facilities. We plan to implement this system for all research facilities in FY 1996. Risk assessment models will be developed for licensed dealers and exhibitors with a target date of completion during FY 1997.

OIG Recommendation 10a:

Obtain input from users of the system at the national and sector offices, to determine which reports need to be added, deleted, or redesigned. At a minimum, reports showing completed inspections and due dates of upcoming inspections should be included in reports regularly distributed to sectors.

APHIS Response:

REAC headquarters officials continue to address our automated system, LARIS, needs at the national and sector levels. Reports generated at sector offices reflect inspection data and direct noncompliant items. An internal assessment and evaluation of REAC's automated systems is ongoing and will be completed by April 1, 1995, and will identify findings and address immediate and future needs.

We agree with OIG that a report which includes completed inspections as well as upcoming inspections is beneficial to monitor compliance levels. However, sector offices have responsibility for generating these reports; REAC headquarters does not generate individual reports containing inspection data for distribution to the sectors. Each sector office has personnel who routinely input inspection data when it is received and provides reports to sector and field personnel.

OIG Recommendation 10b:

Determine feasibility of programming LARIS to automatically assign priorities to scheduled inspections, based on available APHIS resources and severity of violations cited at various facilities.

APHIS Response:

Our risk-based system used in conjunction with the inspector's judgment and program guidelines identify priorities for determining frequency of facility inspections. A system envisioned by OIG which automatically assigns inspection priorities could not include variables. Variables are used to determine reinspection priorities (e.g., immediate health and care of animals).

EXHIBIT F - ANIMAL AND PLANT HEALTH INSPECTION SERVICE'S RESPONSE TO THE DRAFT REPORT

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facility history, prior enforcement actions, sensitive and visible program issues). REAC does not plan to incorporate the suggested information into LARIS.

OIG Recommendation 10c:

Ensure personnel responsible for using the system are provided sufficient training to ensure effective use of the system.

APHIS Response:

We concur that additional training of personnel using LARIS may be necessary, and it will be provided on an as identified basis. Therefore, we request management decision concurrence.

OIG Recommendation 10d:

Require sector offices to enter indirect violations into LARIS database, and establish procedures to count all violations found under each part of the Act.

APHIS Response:

APHIS Form 7008, used by inspectors and sector personnel, details the nature of each indirect noncompliant item. Followup for correction of these items takes place during the next routine facility inspection. Repeated noncompliance, either indirect or direct, without implementation of corrective actions, is addressed by stipulation, investigation, or formal administrative action, as appropriate. We believe these available measures adequately address violations and noncompliance issues.

The statistics shown in Exhibits B and C, pages 34-37, reflect what was observed by the REAC inspector and the OIG auditor during the course of the audit and are not the result of formal administrative actions which found the cited facilities in violation of AWA regulations. The use of the term "violation/violations" in these two Exhibits incorrectly implies that all of the following have occurred:

- 1) Noncompliant items were documented by a REAC inspector during the course of an inspection;
- 2) a REAC investigation was completed and forwarded to headquarters, as an "alleged violation," for content review;
- 3) the alleged violation was forwarded for "formal administrative action;" and,
- 4) the facility, given due process and an opportunity for a hearing, was found to have committed AWA "violations."

Noncompliance is only a "violation" after having been found as such via the above formal process. The appropriate terminology, "deficiencies" is used in

EXHIBIT F - ANIMAL AND PLANT HEALTH INSPECTION SERVICE'S RESPONSE TO THE DRAFT REPORT

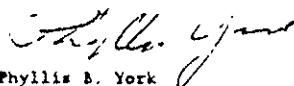
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the narrative for Finding No. 7, page 21, where Exhibits B and C were referenced.

Since use of the word(s) "violation/violations" in Exhibits B and C titles, columnar headings, and footnote references is incorrect, we request that OIG substitute correct terminology in both Exhibits in addition to publishing our response in the final version of the audit report. The word(s) "violation/violations" should be replaced with the term(s) "deficiency/deficiencies" in the Exhibits.

We will provide your office with updates of the progress of corrective actions for all identified recommendations as they occur. Thank you for the opportunity to examine and comment upon the findings and recommendations identified in your audit report.


Phyllis B. York
Acting Deputy Administrator
for Management and Budget