PLAINTIFFS' EXHIBIT K

To Plaintiffs' Opposition to Defendants' Motion
For Summary Judgment
Civ. No. 03-2006 (EGS/JMF)

U.S. Department of Agriculture

Office of Inspector General
Western Region

Audit Report

APHIS Animal Care Program
Inspection and Enforcement Activities

Report No. 33002-3-SF
September 2005

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

September 30, 2005

REPLY TO
ATTN OF: 33002-3-SF

TO: W. Ron DeHaven
Administrator
Animal and Plant Health Inspection Service

ATTN: William J. Hudnall
Deputy Administrator
Marketing and Regulatory Programs

FROM: Robert W. Young /s/
Assistant Inspector General
for Audit

SUBJECT: APHIS Animal Care Program – Inspection and Enforcement Activities

This report presents the results of our audit of the subject program. Your September 28, 2005, response to the draft report, excluding attachments, is included as exhibit E of the report. Excerpts from your response and the Office of Inspector General's positions have been incorporated into the relevant sections of the report.

We agree with your management decision for Recommendations 2, 3, 6, 7, 9, 12, 14 through 18, and 20. The actions needed to reach management decision on Recommendations 1, 4, 5, 8, 10, 11, 13, and 19 are identified in the Findings and Recommendations section of the report. Please follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer.

In accordance with Department Regulation 1720-1, please furnish a reply within 60 days describing the corrective action taken or planned and the timeframes for implementation of those recommendations for which management decision has not yet been reached. Please note that the regulation requires a management decision to be reached on all recommendations within a maximum of 6 months from report issuance.

We appreciate the cooperation and assistance provided by your staff during our audit.

Executive Summary

Results In Brief

Animal care and use in the United States is a controversial topic with varying points of view from the public, animal rights groups, breeders, research laboratories, and others. In 1966, the Secretary of Agriculture was given the statutory authority to enforce the Animal Welfare Act (AWA), which set minimum standards of care and treatment for certain warm-blooded animals[1] bred for commercial sale, used in research, transported commercially, or exhibited to the public.

This report presents the results of our audit of the Animal and Plant Health Inspection Service's (APHIS) Animal Care (AC) unit, which has the responsibility of inspecting all facilities covered under the AWA and following up on complaints of abuse and noncompliance. We also reviewed AC's coordination with the Investigative and Enforcement Services (IES) staff, which provides support to AC in cases where serious violations have been found. In addition, we evaluated the effectiveness of the Institutional Animal Care and Use Committees (IACUCs)—the self-monitoring committees at the research facilities responsible for ensuring compliance with the AWA.

We found that most AC employees are highly committed to enforcing the AWA through their inspections and are making significant efforts to educate research facilities and others on the humane handling of regulated animals. However, we identified several ways in which AC should improve its inspection and enforcement practices to ensure that animals receive humane care and treatment and that public safety is not compromised.

- *Due to a lack of clear National guidance, AC's Eastern Region is not aggressively pursuing enforcement actions against violators of the AWA.*[2] We found that regional management significantly reduced its referrals of suspected violators to IES from an average of 209 cases in fiscal years (FYs) 2002-2003 to 82 cases in FY 2004. During this same period, regional management declined to take action against 126 of 475 violators that had been referred to IES.[3] In contrast, the Western Region declined action against 18 of 439 violators.

[1] Regulated animals are any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warmblooded animal. It excludes birds, rats of the genus *Rattus*, mice of the genus *Mus*, bred for use in research; horses not used for research; and other farm animals such as livestock and poultry under certain circumstances.
[2] The data in this section, which we compiled from IES records, may include some Horse Protection Act cases, for which AC is also responsible.
[3] IES estimates that these cases cost APHIS at least $291,000 to investigate.

We found cases where the Eastern Region declined to take enforcement action against violators who compromised public safety or animal health. For example, one AC inspector requested an investigation of a licensee whose primate had severely bitten a 4-year-old boy on the head and face. The wounds required over 100 stitches. Although this licensee had a history of past violations, IES has no record of a referral from AC. In another case, the Eastern Region did not take enforcement action when an unlicensed exhibitor's monkey bit two pre-school children on separate occasions. The exhibitor failed to provide a sufficient public barrier and failed to handle the animal to ensure minimal risk to the public.

As a result, the two regions are inconsistent in their treatment of violators; the percentage of repeat violators (those with 3 or more consecutive years with violations) is twice as high in the Eastern Region than in the Western Region. Eastern Region inspectors believe the lack of enforcement action undermines their credibility and authority to enforce the AWA.

- *Discounted stipulated fines assessed against violators of the AWA are usually minimal.* Under current APHIS policy, AC offers a 75-percent discount on stipulated fines[4] as an incentive for violators to settle out of court to avoid attorney and court costs. In addition to giving the discount, we found that APHIS offered other concessions to violators, lowering the actual amount paid to a fraction of the original assessment. An IES official told us that as a result, violators consider the monetary stipulation as a normal cost of conducting business rather than a deterrent for violating the law.[5]

- *Some VMOs did not verify the number of animals used in medical research or adequately review the facilities' protocols and other records.*[6] We found that 13 of 16 research facilities we visited misreported the number of animals used in research. In reviewing the protocols, some Veterinary Medical Officers (VMOs) did not ensure that the facilities provided them with a complete universe of protocols from which to select their sample. These VMOs told us that the selection process was based on "good faith" and that they relied on the facilities to provide them with accurate records. In addition, a VMO did not review readily available disposition records that disclosed unexpected animal deaths at a research facility.

- *Some IACUCs are not effectively monitoring animal care activities or reviewing protocols.* During FYs 2002 through 2004, the number of research facilities cited for violations of the AWA has steadily increased

[4] These fines are not mandatory but agreed to by the violator.
[5] This was also discussed in OIG Audit No. 33600-1-Ch issued in January 1995.
[6] Protocols are the researchers' proposals for the use of animals in research.

from 463 to 600 facilities. Most VMOs believe there are still problems with the search for alternative research, veterinary care, review of painful procedures, and the researchers' use of animals.

- *AC's Licensing and Registration Information System (LARIS) does not effectively track violations and prioritize inspection activities.* The LARIS database records AC inspections and archives violation histories for all breeders, exhibitors, research facilities, and others. We determined that the system generates unreliable and inaccurate information, limiting its usefulness to AC inspectors and supervisors.

- *FMD and IES did not follow the law and internal control procedures in their processing and collection of penalties.* APHIS' Financial Management Division (FMD) did not transfer 81 of 121 delinquent AC receivables totaling $398,354 to the U.S. Department of Treasury for collection as required by the Debt Collection Improvement Act of 1996 (see exhibit A). In addition, IES did not comply with APHIS' internal cash controls to secure the collection of fines.

Recommendations In Brief

To ensure consistent treatment of violators, we recommend that AC incorporate specific guidance in AC's operating manual that addresses referrals and enforcement actions. We also recommend that AC review all cases where the regions decline to take enforcement actions against violators.

To increase the effectiveness of stipulated fines, we recommend that APHIS eliminate the automatic 75-percent discount for repeat violators or direct violations,[7] calculate fines based on the number of animals affected per violation, and seek legislative change to increase fines up to $10,000 for research facilities.

AC needs to emphasize the need for more detailed reviews of protocols, including those where animals are not present at the facility during the inspection. AC also needs to require research facilities to identify annually the number of protocols in their annual reports, and require the VMOs to verify the number of animals used in research.

To reduce the number of violations, AC needs to modify regulations to require IACUCs to conduct more frequent reviews of facilities identified as repeat violators (3 or more consecutive years with violations). We also recommend that AC require IACUCs to implement policies to fully train committee members on protocol review, facility inspections, and the AWA.

[7] Direct violations have a high potential to adversely affect the health and well-being of the animal.

For LARIS, AC needs to implement temporary measures to address system deficiencies until the new system is operational. Finally, IES and FMD need to follow APHIS policies for internal controls over cash collection, and FMD must timely process receivables for collection.

Agency Response

In its September 28, 2005, written response to the draft report, the APHIS National Office concurred with the report findings and recommendations, except for Recommendation 13. APHIS' response is included in exhibit E of this report.

OIG Position

We accept APHIS' management decision for Recommendations 2, 3, 6, 7, 9, 12, 14 through 18, and 20. The actions needed to reach management decision on Recommendations 1, 4, 5, 8, 10, 11, 13, and 19 are identified in the Findings and Recommendations section of the report. Please follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer.

Findings and Recommendations

Section 1 Inspection and Enforcement Activities

While most Animal Care (AC) employees are committed to enforcing the Animal Welfare Act (AWA) and educating research facilities and businesses on the humane handling of animals, improved inspection and enforcement procedures would enhance public confidence that regulated animals receive humane care and treatment.

Of particular concern, AC management in the Eastern Region is not aggressively pursuing enforcement actions against violators of the AWA. The Eastern Region significantly reduced its referrals of suspected violators to the Investigative and Enforcement Services (IES) unit—from an average of 209 cases in fiscal years (FYs) 2002-2003 to 82 cases in FY 2004. When the region did refer cases to IES, management declined to take enforcement action against 126 of 475 violators (27 percent).

When violators are assessed stipulated fines, the fines are usually minimal and not always effective in preventing subsequent violations. Under current APHIS policy, AC gives an automatic 75-percent discount to almost all violators as a means of amicably reaching an agreement on the amount of the fines and avoiding court.

Finally, we noted that some VMOs when inspecting research facilities do not verify the number of animals used in medical research or adequately review the facilities' protocols and other records.

Finding 1 The Eastern Region Is Not Aggressively Pursuing Enforcement Actions Against Violators of the AWA

During FYs 2002-2004, AC's Eastern Region significantly reduced its referrals to the IES unit and declined to take enforcement action in 27 percent[8] of the cases where violations were cited. This occurred because the National Office did not provide clear direction concerning referrals and enforcement actions. Without established procedures that demonstrate how to apply general AC policy to specific cases, regional managers are left to implement AC guidelines as they deem appropriate. As a result, the regions are inconsistent in their treatment of violators; the percentage of repeat violators is higher in the Eastern Region than in the Western Region; and

[8] These numbers do not include cases where IES found no violations or had insufficient evidence to pursue enforcement action; however, the data may include some Horse Protection Act cases, which fall under AC's jurisdiction.

Eastern Region inspectors believe the lack of enforcement undermines their credibility and authority to enforce the AWA.

APHIS has not established national guidelines that specifically address when AC should refer cases to investigations. However, if a case is referred and IES determines that violations have occurred, the AWA[9] authorizes APHIS to impose civil penalties up to $2,750 per violation. APHIS may also suspend, for up to 21 days, the license of any facility[10] that violates provisions of the AWA. According to the AWA, the agency should give "due consideration to the appropriateness of the penalty with respect to the size of the business of the person involved, the gravity of the violation, the person's good faith, and the history of previous violations."[11]

Violations of the AWA are disclosed and confirmed through two separate processes: AC inspections and IES investigations. If AC inspectors identify serious violations during an inspection or if deficiencies remain uncorrected at a follow-up inspection, AC can refer the case to the IES staff. After IES conducts a comprehensive investigation, the case is returned to the appropriate AC region for enforcement action.

Minor infractions may be settled with an enforcement action such as an official notice of warning, while more serious cases may be resolved at the agency level through stipulated fines against the violator or through formal administrative action before an administrative law judge. Stipulated agreements allow alleged violators to pay a greatly discounted fine, have their license suspended, or both.

Decrease in the Number of Referrals to IES

Based on IES data, we determined that AC's Eastern Region significantly reduced the number of referrals to IES. Between FYs 2002-2003, the Eastern Region referred an average of 209 cases; in FY 2004, the region referred 82. In response, regional management told us that the best way to achieve compliance is through education, and enforcement actions such as fines and stipulations can at times promote hostility. The Assistant Regional Director for AC told us, "We do not want to punish violators for their past history...enforcement is a tool of last resort; it is better to get compliance first, if you can."

According to the IES Eastern Regional Director, AC advised him at the beginning of FY 2004 that he would not be receiving as many referrals as he had in the past. As a result, he told us that many suspected violators have not been investigated. A National Office official agreed that "the inspector and

[9] 7 U.S.C. 2149(a) dated March 25, 2004. The penalty was adjusted for inflation to $2,750 in June 2000.
[10] This excludes research facilities because they are not required to obtain licenses; they only register with AC.
[11] 7 U.S.C. 2149(b) dated March 25, 2004.