



U.S. Department of Agriculture



**Office of Inspector General
Northeast Region**

Audit Report

Implementation of the Federal Research Misconduct Policy in the U.S. Department of Agriculture

**Report No. 50099-11-Hy
March 2005**



UNITED STATES DEPARTMENT OF AGRICULTURE
OFFICE OF INSPECTOR GENERAL
Washington, D.C. 20250



March 31, 2005

REPLY TO

ATTN OF: 50099-11-Hy

SUBJECT: Implementation of the Federal Research Misconduct Policy
in the U.S. Department of Agriculture

TO: Joseph J. Jen
Under Secretary
Research, Education and Economics

This report presents the results of the subject audit. Your March 25, 2005, response to the draft report is included as exhibit A with excerpts and the Office of Inspector General's position incorporated in the relevant Findings and Recommendations sections of the report.

Based on your response, we have accepted management decision on Recommendations 1 and 4. Follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer. Final action on the management decisions should be completed within 1 year of the date of this report to preclude being listed in the Secretary's Management Report. The information needed to reach management decision on Recommendations 2, 3, and 5 is described in the Office of Inspector General's Position sections of the report.

Please furnish the information needed to reach management decisions on the three remaining recommendations within 60 days. Please note that Departmental Regulation 1720-1 requires a management decision for all recommendations within a maximum of 6 months from the date of report issuance, and final action to be taken within 1 year of each management decision.

We appreciate the courtesies and cooperation extended to us by members of your staff during the review.

/s/

ROBERT W. YOUNG
Assistant Inspector General
for Audit

Executive Summary

Implementation of the Federal Research Misconduct Policy in the United States Department of Agriculture (Audit Report No. 50099-11-Hy)

Results in Brief

In fiscal year (FY) 2004, the U.S. Department of Agriculture (USDA) was authorized to spend nearly \$2.1 billion to conduct or support research and development. The Department provides funding for studies as diverse as human nutrition to new crop technologies. Because research plays a vital role in the Department's mission, ensuring its integrity must be a top priority. The objectives of our review were to determine whether (1) the Department had finalized and implemented a Department-wide research misconduct policy that was in compliance with the policy established by the Office of Science and Technology (OSTP) or had monitored its agencies to ensure that individual agency policies complied with the Federal Policy on Research Misconduct (OSTP Policy), and (2) the Department had ensured that agencies provided guidance to and oversight of extramural research activities. However, despite a Federal mandate to implement a research misconduct policy in 2001, the Department did not develop a research misconduct policy and did not coordinate an oversight process for consistently and effectively applying it. As prescribed by OSTP, a research misconduct policy should include:

- A definition of research misconduct and the elements of a research misconduct finding.
- Instructions for handling research misconduct allegations and adjudication, including standards for objectivity and timeliness.
- Safeguards for informants and subjects of allegations.
- Possible administrative actions for research misconduct findings.

Although USDA was required to implement the OSTP Research Misconduct Policy by December 6, 2001, the Department did not assign this responsibility to a specific agency or group.

In the absence of a Department-wide policy, the Department did not ensure individual agency policies satisfy OSTP requirements or provide guidance to individual agencies to develop OSTP-compliant research misconduct policies. Except for the Forest Service (FS), all USDA agencies operate under a patchwork of policies that do not fully comply with the OSTP Research Misconduct Policy. Seven agencies, whose FY 2004 appropriations for research totaled an estimated \$733 million, have no official research misconduct policies; among them is the Cooperative State Research, Education, and Extension Service (CSREES), which disburses the most extramural research dollars. Another agency, Agricultural Research Service, was appropriated over \$1 billion in FY 2004 and has a research misconduct policy that is not in compliance with OSTP requirements. Of the agencies

that receive major research funding, only the FS, which received \$299 million for research in FY 2004, has an OSTP-compliant research misconduct policy in place.

Likewise, the Department does not have a Department-wide research misconduct policy that addresses extramural research misconduct referrals, allegations, investigations, and adjudications. Nine USDA agencies do not have policies that address allegations and investigations for extramural research misconduct. As a result, USDA agencies rely on extramural institution policies, which may not be in the Department's and public's best interests.

Apart from being out of compliance with Federal law, the Department has already found itself in problematic situations that reflect the need for a Department-wide research misconduct policy. In a highly publicized case, a graduate student at Michigan State University (MSU) pled guilty to staging a burglary to conceal that he had fabricated data for a CSREES-funded study of swine pneumonia. The student was ordered to pay \$69,000 in restitution, only a fraction of the \$750,000 in USDA funds MSU received to conduct the research. Although CSREES froze additional funding for the study, it is not clear how the agency will reclaim the funds already expended by the university. Also of concern, CSREES did not have a staff dedicated to independently review MSU's research misconduct policies or a liaison within the Department to whom it could refer such a review. CSREES has no assurance that the weakness in internal controls that allowed the fraudulent research to remain undetected for a period of at least 2 years may not affect other USDA-funded research.

As the MSU case demonstrates, the development of an OSTP-compliant research misconduct policy (that addresses both intramural and extramural research activities) would serve the Department's and public's best interests. Until it complies with the OSTP, the Department will not be able to assess the extent of fabrication, falsification, and plagiarism in USDA-funded research, or consistently and fairly handle research misconduct allegations once detected. Ultimately, if the Department continues to take an inconsistent approach toward research misconduct, USDA's standing in the Federal research community may be at stake.

Recommendations In Brief

We recommend that the Department develop and implement a Department-wide, OSTP-compliant research misconduct policy. We also recommend that the Department-wide research misconduct policy include specific instructions applicable to USDA-funded research and proposals submitted for research funding. The Departmental policy should address agency responsibilities to oversee extramural institutions' research misconduct policies and procedures, with an emphasis on determining the institutions' ability to adequately

resolve research misconduct allegations. The Departmental policy should specify:

- A requirement that extramural research institutions report all allegations of research misconduct to the USDA.
- Roles and responsibilities for oversight and involvement in the investigation, adjudication, and recapture of funds when it is in the Department's and public's best interests.
- A contact point within the Department to coordinate and conduct evaluations of the research misconduct policies of extramural research organizations.

Departmental Response

The Department generally agreed with the recommendations in our report (see exhibit A). The Under Secretary for Research, Education and Economics (REE) provided a consolidated response for the Department. Specifically, the Department agreed that a centralized body for research misconduct will be established within the Department. The Office of the Undersecretary REE will be accountable for coordinating research misconduct policies and procedures. Within three months of acceptance of management decisions, REE will publish a Federal Register notice which accepts the OSTP definition of research misconduct as the USDA definition. The notice will include a statement that USDA will follow the OSTP Federal Policy by defining the responsibility of USDA agencies in designing and implementing guidelines for fair and timely procedures and for taking agency administrative actions as they relate to research misconduct. REE will develop general guidance for the investigation of research misconduct allegations and assign a person to coordinate research misconduct across the USDA for both intramural and extramural research. All USDA research organizations will announce, within nine months of issuance of the Federal Register notice, their policies for adequately resolving research misconduct allegations to include providing contact information for reporting research misconduct in terms and conditions applied to awards, and intramural agencies will announce, through standard means to its employees, how research misconduct should be reported.

OIG Position

We agree with the actions taken and planned by the Department in response to the report's recommendations. We have accepted management decision on Recommendations Nos. 1 and 4. For Recommendations Nos. 2, 3, and 5, we have explained in the Findings and Recommendations section of the report the actions the Department needs to take for acceptance of management decision. The Department's written response is included as exhibit A of the report.

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Abbreviations Used in This Report

AMS	Agricultural Marketing Service
APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
CSREES	Cooperative State Research, Education, and Extension Service
DHHS	Department of Health and Human Services
ERS	Economic Research Service
FAS	Foreign Agricultural Service
FR	Federal Register
FS	Forest Service
FY	Fiscal Year
GIPSA	Grain Inspection, Packers, and Stockyards Administration
MSU	Michigan State University
NASS	National Agricultural Statistics Service
NWRC	National Wildlife Research Center
OCFO	Office of the Chief Financial Officer
OGC	Office of the General Counsel
OIG	Office of Inspector General
OSTP	Office of Science and Technology Policy
OSTP Policy	Federal Policy on Research Misconduct
PAD	Planning and Accountability Division
PHS	Public Health Service
REE	Research, Education and Economics
UConn	University of Connecticut
USDA	U.S. Department of Agriculture

Background and Objectives

Background

Established in 1976, the Office of Science and Technology Policy (OSTP) provides scientific and technological analysis and counsel to the President with respect to major Federal policies, plans, and programs.¹ OSTP works with the private sector, State and local governments, the science and higher education communities, and other nations to develop and implement sound science and technology policies.

Because advances in the sciences depend on the reliability of the research record, OSTP designed the Federal Policy on Research Misconduct (OSTP Policy), issued in December 2000, to govern all federally funded research and proposals submitted for research funding. The OSTP Policy defines research misconduct and establishes basic guidelines for conducting fair and timely investigations of alleged or suspected infractions. Published in the Federal Register (FR) on December 6, 2000, the Government-wide policy allowed agencies 1 year to implement its requirements, either by regulation or another administrative mechanism.²

The OSTP Policy defines research misconduct as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. A response to a research misconduct allegation consists of inquiry, investigation, and adjudication phases. According to the OSTP Policy, a finding of research misconduct requires: (1) a significant departure from accepted practices of the relevant research community, (2) misconduct that is committed intentionally, knowingly, or recklessly, and (3) proof of the allegation through a preponderance of evidence.

Agency policies and procedures for both intramural and extramural research programs must conform to the OSTP Policy. When Federal agencies and research institutions share responsibility for the research process, the agencies retain ultimate oversight responsibilities. In most cases, agencies rely on the researcher's home institution to make the initial response to a research misconduct allegation. At any time, however, the Federal agency may proceed with its own inquiry or investigation and may elect not to defer to the research institution.

U.S. Department of Agriculture (USDA) agencies within each mission area³ engage in or support some form of research as defined by the OSTP Policy. The policy covers all fields of science, engineering, and mathematics, including research in economics, education, linguistics, medicine,

¹ The National Science and Technology Policy, Organization, and Priorities Act of 1976 (Public Law 94-282) established OSTP within the Executive Office of the President.

² 65 FR, pages 76260 – 76264.

³ USDA mission areas headed by an Under Secretary with significant research funding include: Natural Resources and Environment; Farm and Foreign Agricultural Services; Research, Education and Economics; and Marketing and Regulatory Programs.

psychology, social sciences, and statistics; it also applies to studies involving human or animal subjects. Our review included nine USDA agencies that perform research. The following table lists agencies along with their research budget appropriations, in millions of dollars:

Agency	Appropriated Research \$ (Millions)	
	2003	2004
Agricultural Research Service (ARS) ⁴	\$1,043	\$1,090
Cooperative State Research, Education, and Extension Service (CSREES) ⁵	603	613
Agricultural Marketing Service (AMS)	6	6
Forest Service (FS) ⁶	286	299
Animal and Plant Health Inspection Service (APHIS)	28	29
Economic Research Service (ERS)	69	71
Foreign Agricultural Service (FAS)	2	2
Grain Inspection, Packers, and Stockyards Administration (GIPSA)	5	7
National Agricultural Statistics Service (NASS)	5	5
Totals	\$2,047	\$2,122

In addition to complying with the OSTP Policy, agencies continue to be responsible for reporting all known or suspected violations of law or regulations, misconduct, and other irregular activities in USDA programs or by USDA employees to the Office of Inspector General (OIG).

Objectives

The purpose of our audit was to determine whether: (1) the Department had finalized and implemented a Department-wide, OSTP-compliant policy addressing research misconduct or had monitored its agencies to ensure that their individual policies complied with the OSTP Policy, and (2) the Department had ensured that agencies provided guidance to and oversight of the extramural research institutions as directed by the OSTP Policy.

⁴ ARS, the Department's largest in-house research agency, leads the Department's agricultural research effort and conducts research related to nutrition, technology, the environment, and other topics that affect Americans on a daily basis.

⁵ The CSREES awards the largest amount of funding to extramural research programs at universities and other institutions.

⁶ According to its Internet website, the FS is the largest forestry research organization in the world, providing technical and financial assistance to State and private forestry agencies.

Findings and Recommendations

Section 1. Departmental Oversight

Finding 1

USDA Has Not Complied With the Federal OSTP Research Misconduct Policy

USDA did not comply with the OSTP Policy that required the Department to develop a research misconduct policy and provide a coordinated oversight process to consistently and effectively implement it. A Department-wide policy was to be in place by December 6, 2001. Instead, USDA agencies relied on individual practices, many of which fell short of OSTP requirements, to deal with research misconduct. When CSREES staff became aware of the OSTP Policy, they attempted to establish a unified effort between USDA research agencies and drafted a policy that they believed could be used Department-wide. Lacking Department-level support, these efforts ceased and no specific USDA agency or group was assigned responsibility to implement the proposed policies. At the time of our review and after interviewing representatives from several agencies, we did not identify any formal Department-wide coordinated effort to bring the Department into compliance.

The Department does not have procedures in place to guide researchers, who know of or are concerned about potential research misconduct allegations, in reporting allegations. The Department does not have Department-wide procedures in place for research misconduct to consistently and effectively handle allegations. In addition, the Department cannot ensure that researchers are fully aware of their responsibility to protect the integrity of USDA-funded research.

To comply with the OSTP requirements, a Department-wide policy must: define research misconduct in terms of fabrication, falsification, or plagiarism; establish the elements of a research misconduct finding; provide instructions for handling research misconduct allegations and adjudication, including standards for objectivity and timeliness; provide safeguards for informants and subjects of allegations; and address possible administrative actions for research misconduct findings.

No Department-wide OSTP-Compliant Policy

The Department did not implement a coordinated oversight process to bring the USDA into compliance with the OSTP Policy. The Department did not issue any guidelines about what constitutes research misconduct and what to do when misconduct is suspected or known. Additionally, the Department did not ensure that individual agency policies satisfy OSTP requirements.

In the absence of a Department-wide policy, we considered whether individual agencies have OSTP-compliant research misconduct policies. We examined nine USDA agencies that perform or fund research. The FS⁷ had an OSTP-compliant policy, implemented through an interim directive.⁸ ARS had a policy that did not include critical oversight components for extramural USDA-funded projects. None of the remaining seven agencies had research misconduct policies:

Agency	OSTP-Compliant Agency Policy
ARS	Inadequate
CSREES	None
AMS	None
FS	Yes
APHIS	None
ERS	None
FAS	None
GIPSA	None
NASS	None

Lack of Extramural Research Misconduct Oversight

OSTP Policy requires research misconduct policies and procedures to address oversight of extramural research. Agencies have ultimate oversight responsibilities for federally funded research. The Department does not have a Department-wide research misconduct policy or a policy that addresses extramural research misconduct. Additionally, eight agencies do not have individual policies to address allegations and investigations at extramural institutions. See Section 2 for further details.

Early Implementation Efforts Abandoned

Representatives from several USDA research agencies (AMS, ARS, APHIS, CSREES, ERS, FS, and NASS), as well as from the OIG and USDA's Office of the General Counsel (OGC), met to discuss a Department-wide research misconduct policy to comply with the OSTP Policy. Staff from CSREES informally assumed the group leadership role to develop a Department-wide policy. In December 2001, the group prepared a draft policy and submitted it to USDA agency representatives and the OGC for comment.

OGC responded on May 15, 2002, that the draft policy statement replicated the OSTP Policy's general guidelines. In lieu of issuing the draft, OGC recommended that the informal interagency group (cited above) develop a

⁷ Although FS has an OSTP-compliant policy in place, we were unable to judge its effectiveness because FS did not provide any research misconduct reports for our review. An FS official stated that the agency had received no reports of research misconduct.

⁸ FS Interim Directive No: 4080-2002-2, Research Administration Scientific Ethics, was approved February 8, 2002, and expired August 12, 2003. In response to questions raised during our audit, the FS reissued the Interim Directive for an additional 18 months effective July 21, 2004.

decision memorandum for the Secretary outlining USDA's options for implementing the OSTP Policy, including OGC's proposal that USDA agencies adopt their own policies.

OGC prepared a draft Secretary's memorandum and provided it to the informal interagency group. The draft memorandum directed agencies, including those with no written research misconduct guidance, to review their own regulations and policies to determine whether amendments or revisions were needed to comply with the OSTP Policy. In addition, the draft memorandum directed agencies to evaluate whether they could: (1) develop their own, specific written policies, (2) rely on the published OSTP Policy and guidance to achieve compliance, or (3) follow written policies of other USDA agencies.

Lacking formal Departmental direction and support, the interagency group took no action to develop the recommended decision memorandum, nor did it circulate the draft Secretary's Memorandum for approval. After the group received OGC's recommendations, its efforts to bring USDA into compliance with the OSTP Policy waned and a Department-wide policy remains to be completed.

We concluded that, while it is conceivable that individual agencies could establish separate policies to comply with the OSTP guidelines, this approach would result in unnecessary duplication of effort by many agencies. To ensure effective, consistent, and OSTP-compliant handling of research misconduct issues, the Department needs to develop and implement a Department-wide research misconduct policy.

Recommendation No. 1

Coordinate and develop a Department-wide, OSTP-compliant research misconduct policy. Include specific guidelines as provided in Section 2, Recommendations No. 4 and 5.

Departmental Response. USDA concurs with the recommendation. Research, Education and Economics (REE) will serve as the coordinating body for research misconduct within the Department and will assign responsibility within the Office of the Undersecretary to be accountable for coordinating research misconduct policies and procedures. Within 3 months of acceptance of these management decisions, REE will publish a FR notice, which accepts the OSTP definition of research misconduct as the USDA definition. CSREES will take the lead on preparing and publishing the FR notice.

OIG Position. We accept the management decision. For acceptance of final action, provide the Office of the Chief Financial Officer, Planning and Accountability Division (OCFO/PAD), a copy of the FR notice and highlight

the acceptance of the OSTP definition of research misconduct as the USDA definition.

Recommendation No. 2

Coordinate and develop an effective management oversight process for agency implementation of the Department-wide OSTP-compliant research misconduct policy.

Departmental Response. USDA concurs with the recommendation for a centralized body to coordinate OSTP-compliant research misconduct policies. REE will have general oversight and serve as the coordinating body for research misconduct for USDA. Language within the Federal Register announcement will include a statement that the USDA will follow the OSTP Federal Policy to define the responsibility of USDA agencies in designing and implementing guidelines for fair and timely procedures and for taking agency administrative actions as they relate to research misconduct. REE will be responsible to ensure that each agency has conformed to OSTP guidance and that among agencies there is, to the extent practical, consistent policies and procedures, particularly for extramural research.

Implementation of the Federal Policy will be the responsibility of each USDA agency, which, if not already in place, will develop, announce and execute procedures appropriate to its own organizational structure within nine months of the above-mentioned Federal Register announcement.

OIG Position. We concur with the intent of the proposed actions. To reach management decision, please provide OIG with clarification of whether the language in the Federal Register notice (Recommendation No. 1) will include the USDA policy defining the responsibility of USDA agencies in designing and implementing guidelines for fair and timely procedures and for taking agency administrative actions as they relate to research misconduct. Additionally, provide the date when the agencies' actions should be completed. If this language will not be included in the Federal Register, please clarify whether language will be included in the Federal Register indicating that directives will be issued by REE to define the responsibility of USDA agencies to design and implement guidelines for fair and timely procedures and for taking agency administrative actions as they relate to research misconduct. Please provide OIG with a time when the directives will be issued and a time when agency actions should be completed.

Also, please provide OIG with clarification of whether the language in the Federal Register notice (Recommendation No. 1) will include a description of how REE will provide oversight to ensure that agencies implement OSTP-compliant procedures or whether language will be included in the Federal Register indicating that directives will be issued to define REE's process to

ensure that agencies implement OSTP-compliant procedures. If directives will be issued, please provide OIG with a time when the directives will be issued.

Section 2. Extramural Research

Finding 2

USDA Has No Guidelines to Identify and Resolve Extramural Research Misconduct Allegations

The Department did not establish an OSTP-compliant research misconduct policy that addresses extramural research misconduct allegations. As such, the Department does not have adequate assurance that extramural research misconduct allegations are identified, that proceedings are thorough and objective, and that Department and public interests are adequately protected.

Each year, USDA awards millions of research dollars to universities and other institutions. USDA agencies do not review extramural research misconduct policies as part of the funding application process in order to determine an institution's ability to address research misconduct allegations. We found that policies outlining USDA oversight of extramural institutions involving research activities are virtually nonexistent.

According to the OSTP Policy, Federal agencies have ultimate oversight authority for federally funded research, while institutions bear primary responsibility to detect and investigate research misconduct. However, agencies may proceed with their own inquiries or investigations at any time, such as when the agency determines that the institution is not prepared to handle an allegation in a manner consistent with the OSTP Policy, or when agency involvement is necessary to protect the public's interests.

The Department does not have a research misconduct policy that addresses allegations and investigations at extramural institutions. Eight agencies did not have research misconduct policies that address allegations and investigations: seven of the eight agencies did not have research misconduct policies at all, and ARS' research misconduct policy did not include critical oversight components for extramural institutions. Only the FS policy, as implemented through an interim directive, was OSTP-compliant.

Inconsistent Misconduct Oversight

Existing Department policies vary, with the result that similar situations may be treated very differently, depending upon which USDA agency is funding research.

On June 10, 2003, ARS added a sentence to its research misconduct policy to address extramural research. The expanded policy⁹ states, "ARS policies and procedures are applicable only if the institution does not have established

⁹ Research Misconduct, Number 129.0 – ARS, June 10, 2003.

policies and procedures regarding research misconduct.” However, the policy does not require ARS to assess an extramural institution’s research misconduct policy to determine if it is adequate. ARS may find itself in the position of relying on an extramural institution’s policy that may not be in the Department’s best interests or may not be compliant with OSTP Policy.

In contrast, FS policy directly addresses the capability of an institution to deal with research misconduct. As a result, a situation may be treated in a vastly different manner by the FS than the way the same situation would be handled by ARS. For example, the FS interim directive calls for allegations of scientific misconduct to be handled in accordance with a well-defined five step process. The general FS policy is for the cooperating research institution to bear primary responsibility for the prevention and detection of research misconduct and for the inquiry, investigation, and adjudication of research misconduct alleged to have occurred in association with their own institution. However, the FS policy allows the FS to proceed with its own inquiry or investigation. Circumstances when the FS may elect not to defer to the research institution may include, but are not limited to the following:

- The FS determines that the institution is not prepared to handle the allegation in a manner consistent with the published Federal policy (65 FR 76260-76264, dated December 6, 2000) [the OSTP policy];
- FS involvement is needed to protect the public interest, including public health and safety; or
- The allegation involves an entity of sufficiently small size (or an individual) that the entity cannot reasonably conduct the investigation itself.

Additionally, the FS interim directive explains that, after reviewing the record of the investigation, the institution’s recommendations to the institution’s adjudicating official, and any corrective actions taken by the research institution, the responsible FS Station Director will take additional oversight or investigative steps, if necessary. Upon completion of the review, the FS Station Director will take appropriate administrative action in accordance with applicable laws, FS and USDA regulations, and policies. When the FS Station Director has made a final determination, she/he will notify the subject of the allegation of the outcome and inform the research institution regarding the Director’s disposition of the case. The FS finding of research misconduct and the FS administrative actions can be appealed pursuant to applicable agency procedures.

The differences in these two policies illustrate the variation in how research misconduct allegations could be handled within the Department. By not developing a Department-wide policy, the USDA is vulnerable to criticism due to the inconsistent approaches each agency takes to process allegations.

Oversight of Extramural Research Misconduct

An incident involving a \$750,000 CSREES award to Michigan State University (MSU) highlights the need for a policy to address extramural research misconduct. A graduate student involved in a study of the bacterium that causes pneumonia in young pigs¹⁰ fabricated results during 2 years of the study and subsequently staged a burglary in an attempt to conceal the misconduct. An MSU investigation eventually revealed that the student's research was fraudulent, as it was all based on the supposed mutation of a specific gene - an alteration that never actually occurred. In August 2003, the graduate student pled guilty to making false statements and mail fraud. He was sentenced to 10 months in prison and ordered to repay \$69,000 in restitution to USDA.

CSREES did not have a research misconduct policy or dedicated staff to independently review MSU's research misconduct policies. Consequently, CSREES has been relying on MSU's adjudication of the allegation. MSU efforts may not fully review institutional practices and recommend any needed improvements in the control environment, which allowed the fraudulent research to proceed undetected for at least 2 years. Also, MSU efforts are not expected to include an assessment of other USDA-funded research conducted by the researcher under investigation at the institution to determine whether the case represents an isolated integrity problem or a pattern of abuse.

Discussions with USDA agency officials led us to conclude that most USDA agencies that fund extramural research were not prepared to review research misconduct policies at extramural institutions. Agencies are responsible to examine extramural institution research misconduct policies and procedures, and determine an institution's ability to adequately resolve research misconduct allegations. Given the difficulties inherent in establishing a review process in nine different agencies (some with very small budgets), the Department should designate a central contact to coordinate performance of the reviews.

Resolution of Extramural Research Misconduct Findings

Due to the lack of a Department-wide, OSTP-compliant policy for extramural research misconduct, USDA agencies do not have a method to pursue restitution initiatives that are in the Department's and public's best interests.

The MSU case demonstrates that the USDA needs to include guidelines for recapturing funds in the administrative actions portion of its Department-wide research misconduct policy. Without such guidance, it is unclear how

¹⁰ *Actinobacillus pleuropneumoniae*

CSREES will resolve the financial aspects of the MSU situation. The \$69,000 restitution due from the graduate student represents only a small portion of USDA's investment in the project. While CSREES has frozen additional funds, it has not attempted to recover the rest of the money already expended on the fraudulent research.

Identification of Extramural Research Misconduct Allegations

Due to the lack of a Department-wide, OSTP-compliant policy for extramural research misconduct, universities and other research institutions do not always report credible allegations to USDA. Consequently, the Department does not have: (1) a valid way to know the extent to which fabrication, falsification, and plagiarism affect USDA extramural research, or (2) an opportunity to participate in the research misconduct investigations and adjudications.

The OSTP Policy requires extramural institutions to notify Federal agencies of a research misconduct allegation if the allegation meets the Federal definition of research misconduct, and if the institution's inquiry into the allegation yields sufficient evidence to proceed to an investigation.

In January 2000, the University of Connecticut (UConn) submitted a funding application to CSREES. Before CSREES processed the application, UConn became aware of an allegation that the application included falsified data. After convening a special review board to investigate the matter, UConn concluded that one of the principal researchers had engaged in research misconduct, and the university withdrew the application from funding consideration. In its finding, the UConn board wrote, "USDA regulations do not require that grantees report alleged misconduct related to proposal submission." Because neither a CSREES nor a Department-wide research misconduct policy existed, the UConn board consulted ARS' research misconduct policy to make its determination. While the ARS policy did not apply to other agencies, the board determined that ARS grantees were not required to report research misconduct allegations. Consequently, UConn did not notify CSREES of the incident.

While this case was resolved before CSREES obligated funds, it highlights the need to require extramural institutions to report all misconduct allegations to the funding agency. In light of UConn's nondisclosure, the Department did not participate in the investigation and adjudication process. However, the Department of Health and Human Services (DHHS), to which UConn had submitted related applications, did assign its Office of Research Integrity, Public Health Service (PHS) to analyze the case as part of an oversight review. PHS agreed with the UConn board's research misconduct finding and further concluded that the fabricated material could have misled funding reviewers and the scientific community about the related research.

Ultimately, the accused researcher voluntarily agreed for a period of 5 years: (1) that he would be excluded from serving in any advisory capacity to PHS, (2) that any institution that submits a grant application to PHS involving the researcher's participation must include a plan for supervising his duties, and (3) that any employing institution must certify that data provided by the researcher is based on actual experiments or legitimately derived. The researcher was not similarly limited from participating in USDA-funded activities.

Recommendation No. 3

Assign a specific person or group to be accountable for overseeing extramural institution research misconduct policies and procedures, to include the objective of determining the institution's ability to adequately resolve research misconduct allegations.

Departmental Response. REE will assign a person to coordinate research misconduct across the USDA for both intramural and extramural research. All USDA research organizations will announce their policies for adequately resolving research misconduct allegations.

OIG Position. We concur with the intent of the proposed actions. To reach management decision, please provide details of who will be assigned to coordinate oversight of intramural and extramural research misconduct, as well as the planned date for the assignment.

Additionally, please provide OIG with clarification of how the designated person will ensure that all USDA research organizations have announced their policies for adequately resolving research misconduct allegations and how, if misconduct allegations arise, the person will monitor and determine the institution's ability to adequately resolve research misconduct allegations. If this information will not be included in the Federal Register notice (Recommendation No. 1), please clarify whether directives will be issued to define how the designated person will ensure that all USDA research organizations have announced their policies for adequately resolving research misconduct allegations and how, if misconduct allegations arise, the person will monitor and determine the institution's ability to adequately resolve research misconduct allegations, and provide OIG with a time when the directives will be issued.

Recommendation No. 4

Require extramural research institutions to report all allegations of research misconduct involving USDA funded projects to the USDA. Include this requirement in the Department-wide policy described in Recommendation No. 1.

Departmental Response. USDA concurs with the recommendation and will include this recommendation in the general guidelines specified in the response to Recommendations Nos. 1 and 2. Within 3 months of acceptance of management decision, REE will publish a Federal Register notice incorporating the general guidelines requiring extramural research institutions to report all allegations of research misconduct involving USDA-funded project to USDA.

OIG Position. We accept the management decision. For acceptance of final action, provide the OCFO/PAD a copy of the Federal Register notice.

Recommendation No. 5

Develop and implement extramural guidelines for USDA agency oversight and involvement in the investigation, adjudication, and recapture of funds when it is in the best interests of the Department and public. Include this requirement in the Department-wide policy described in Recommendation No. 1.

Departmental Response. USDA concurs with the recommendation. USDA will develop general guidance for the investigation of research misconduct allegations.

OIG Position. We concur with the intent of the proposed actions. To reach management decision, please provide details of how the Department will provide guidance for investigation and adjudication and a date when the direction will be issued.

In addition, please provide OIG with clarification of whether the cost recovery language in the management response will be included in the Federal Register notice (Recommendation No. 1) or whether specific language will be included in each agency's guidelines that should be completed 9 months after the Federal Register notice.

Scope and Methodology

Our audit was conducted between October 2002 and September 2003. We updated the results as needed to reflect current conditions. We performed fieldwork at the headquarters offices of ARS, CSREES, and FS; conducted telephone interviews with APHIS and ERS staff; and reviewed correspondence regarding AMS research misconduct. For FAS, GIPSA and NASS, we made telephone inquiries, and reviewed information available on the Internet, and other documentation.

We judgmentally selected ARS, CSREES, and FS for review based on their roles in a research misconduct policy implementation meeting held in August 2001. We selected AMS, APHIS, ERS, FAS, GIPSA, and NASS for review based on their research funding as reported in the USDA Budget Authority by Appropriation for Research, Development, and Education.

We reviewed the Federal OSTP Research Misconduct Policy to gain an understanding of its requirements. We interviewed agency officials and analyzed documentation and records to determine the status of the Department's research misconduct policy and the reasons the policy had not been implemented.

We interviewed agency officials and analyzed documentation to determine whether individual agency research misconduct policies and procedures that agencies relied upon complied with the OSTP Policy. We also obtained and reviewed research misconduct allegations from 1998 through April 2003 to determine whether selected agencies properly reported matters to OIG or handled them according to the OSTP Policy (for allegations occurring after December 6, 2001).

The audit was conducted in accordance with generally accepted Government auditing standards.

Exhibit A — Departmental Response from the Research, Education and Economics

Exhibit A - Page 1 of 5



United States
Department of
Agriculture

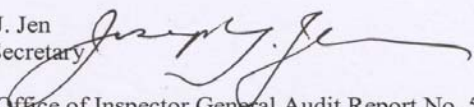
Research
Education
Economics

Office
of the Under
Secretary

Room 216W
Jamie L. Whitten Building
Washington, DC 20250-0110

MAR 25 2005

TO: Robert W. Young
Assistant Inspector General for Audit
USDA Office of Inspector General

FROM: Joseph J. Jen
Under Secretary 

SUBJECT: USDA Office of Inspector General Audit Report No. 50099-11-HY:
Implementation of the Federal Research Misconduct Policy in the
U.S. Department of Agriculture

A response to the above audit was submitted on January 28, 2005. Included in the response was an Appendix that we now wish to retract. A revised response is attached. If you have any questions, please contact Dr. Deborah Sheely, Scientific Integrity Officer for the Cooperative State Research, Education, and Extension Service at (202) 401-1294 or via e-mail at dsheely@csrees.usda.gov.

Attachment

**Response to Office of Inspector General Audit Report (No. SOO99-11-Hy) on
"Implementation of the Federal Research Misconduct Policy in the U.S. Department
of Agriculture"**

General comments:

The USDA has carefully read and evaluated the audit report. It should be noted that research misconduct in the USDA, whether in intramural laboratories or through Federal assistance grants made to outside entities, is rare. This rarity does not diminish the need to develop more uniform and consistent policies to deal with and manage misconduct cases that do arise and to implement the OSTP guidelines. Thus, the recommendations of the report are important in advancing the Department's ability to effectively and consistently manage these cases and meet Federal requirements. However, the rarity of such cases and the unique circumstances from which these cases may arise in various USDA agencies with distinct and independent administrative procedures also means centralized infrastructural changes created to deal with research misconduct at the Department level likely would be cost-prohibitive and counter productive. While oversight and coordination should be centralized, procedures for the investigation and adjudication of cases should be vested to the Agency which is responsible for administration of the research award under which the misconduct arose.

In addition, the audit report implies that the OSTP guidelines only pertain to extramural research. In fact, the OSTP guidelines state " the term 'research institution' is defined to include all organizations using Federal funds for research, including, for example, colleges and universities, intramural Federal research laboratories, Federally funded research development centers, national user facilities, industrial laboratories, or other research institutions... agency policies and procedures with regard to intramural as well as extramural programs must conform to the policy described in this document." Thus, within our USDA response, both intramural and extramural research is discussed to promote conformity with the OSTP guidelines throughout the USDA.

Recommendation No.1

Coordinate and develop a department-wide, OSTP-compliant research misconduct policy. Include specific guidelines as provided in Section 2, Recommendation Nos. 4 and 5.

Agency Response:

The USDA agrees with this recommendation that a Department-wide research misconduct policy that is compliant with OSTP guidelines be developed.

1. REE will serve as the coordinating body for research misconduct within the Department and will assign a specific person or group within the Office of the Undersecretary to be accountable for coordinating research misconduct policies and procedures.
2. Within 3 months of acceptance of these management decisions, REE will publish a Federal Register notice which accepts the OSTP definition of research misconduct as the USDA definition. CSREES will take the lead on preparation and publication of the Federal Register notice.

Recommendation No.2

Coordinate and develop an effective management oversight process for agency implementation of the Department-wide OSTP-compliant research misconduct policy.

Agency Response:

The USDA agrees with the concept of a centralized body for **coordinating** OSTP-compliant research misconduct policies across the Agency.

1. REE will have general oversight and serve as the coordinating body for research misconduct within the Department. As such, USDA research agencies will report all research misconduct cases to the REE Office of the Undersecretary for oversight.
2. Within the Federal Register announcement cited above, language will be included stating that USDA will follow the OSTP Federal Policy to define the responsibility of USDA agencies in designing and implementing guidelines for fair and timely procedures and for taking agency administrative actions as they relate to research misconduct. Such generalities will include a statement that: 1) Federal agencies have ultimate oversight authority for Federally funded research, but research institutions bear primary responsibility for prevention and detection of research misconduct, and for the inquiry, investigation, and adjudication of allegation of research misconduct; 2) identifies the multiple phases of an investigation; and 3) describes the policy to separate the adjudication and investigation phases.

Implementation of the Federal Policy will be the responsibility of each USDA agency, which, if not already in place, will develop, announce and execute procedures appropriate to its own organizational structure within 9 months of the above-mentioned Federal Register announcement.

3. When formulating USDA agency research misconduct policies and procedures, the agencies will consult with REE. REE will be responsible to ensure that each agency has conformed to OSTP guidance and that among agencies there is, to the extent practical, consistent policies and procedures, particularly for extramural research where non-Federal entities must be subjected to equitable treatment through standardized procedures across the USDA.
4. Some USDA agencies may adopt procedures and guidelines developed by other USDA agencies or seek assistance from larger agencies with more expertise in the administration of research misconduct actions.

Recommendation No.3

Assign a specific person or group to be accountable for overseeing extramural institution research misconduct policies and procedures, to include the objective of determining the institution's ability to adequately resolve research misconduct allegations.

Agency Response:

As stated in the response to Recommendation No. 1, REE will assign a person to coordinate research misconduct across the USDA for both intramural and extramural research. All USDA research organizations will announce their policies for adequately resolving research misconduct allegations. The USDA will not embark on a separate and centralized exercise to determine that all institutions have the ability to adequately resolve research misconduct allegations because of the impracticality of doing so. Instead, the USDA will rely on institutional assurances until such time as a research misconduct allegation arises. Federal assistance policies require that institutions assure that procedures are in place to investigate research misconduct allegations as part of the terms and conditions for accepting an award (see the Federal Demonstration Partnership National Policy Requirements. At <http://thefdp.org>) The USDA, like other Federal granting agencies, does not require separate submission of assurances, only the agreement that such assurances are in place by way of signature at the time of application submission and through acceptance of award terms and conditions.

Recommendation No.4

Require extramural research institutions to report all allegations of research misconduct involving USDA-funded projects to the USDA. Include this requirement in the Department-wide policy described in Recommendation No. 1.

Agency Response:

The USDA agrees with this comment and will put this requirement in its general guidelines as in recommendation 1 and 2. Agencies supporting extramural research will provide contact information for reporting research misconduct in terms and conditions applied to awards, and intramural agencies will announce, through standard means to its employees, how research misconduct should be reported.

Recommendation No.5

Develop and implement extramural guidelines for USDA agency oversight and involvement in the investigation, adjudication, recapture of funds when it is in the best interests of the Department and public. Include this requirement in the Department-wide policy described in Recommendation No. 1.

Agency Response:

As stated in each of the other recommendations, USDA will develop general guidance for the investigation of research misconduct allegations. If the resulting investigation determines the fraudulent or inappropriate use of USDA funds, the USDA will use its well established policies for recovering funds where necessary. The OSTP guidelines do not include guidance as to cost recovery and state simply that an agency take appropriate administration action in accordance with applicable laws or regulations. In announcing its implementation guidance, each USDA agency will state that recovery of funds, where appropriate, is one of a number of potential administrative actions that could result from a proven case of research misconduct.