U.S. Department of Agriculture

Office of Inspector General
Midwest Region

Audit Report

Adequacy of Controls to Prevent the Improper Transfer of Sensitive Technology

Report No. 02601-1-Ch
SEPTEMBER 2005

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL
Washington D.C. 20250

September 30, 2005

REPLY TO
ATTN OF: 02601-1-Ch

TO: Edward B. Knipling
Administrator
Agricultural Research Service

ATTN: Steven M. Helmrich
Division Director
Financial Management Division

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

SUBJECT: Adequacy of Controls to Prevent the Improper Transfer of Sensitive Technology

This report presents the results of our audit of the Adequacy of Controls to Prevent the Improper Transfer of Sensitive Technology. Your agency's response to the draft report, dated September 15, 2005, is included in its entirety as exhibit B, with excerpts and the Office of Inspector General's position incorporated into the relevant sections of the report.

We agree with your management decisions for Recommendations 1, 2, 3, and 5. Please follow your agency's internal procedures in forwarding final action correspondence to the Office of the Chief Financial Officer.

Management decision has not been reached for Recommendations 4, 6, 7, 8, 9, 10 and 11. The Findings and Recommendations sections of the report include a description of the information needed to reach management decisions for these recommendations.

In accordance with the Departmental Regulation 1720-1, please furnish a reply within 60 days describing the corrective actions taken or planned and the timeframes for implementing these recommendations. Please note that the regulation requires a management decision to be reached on all findings and recommendations within a maximum of 6 months from 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 your staff.

Executive Summary

Results in Brief

This report presents the results of our audit of the Agricultural Research Service's (ARS) efforts to prevent the improper transfer of sensitive technology to questionable individuals and entities. Our objective was to evaluate the agency's management controls in this critical area. Specifically, we evaluated controls over the identification, approval, and monitoring of sensitive research, as well as controls to ensure that sensitive knowledge had not been transferred to questionable individuals. We also evaluated the agency's compliance with U.S. Department of Commerce (DOC) deemed export license requirements.

Our audit disclosed that ARS' management controls need enhancement to prevent the transfer of sensitive knowledge to hostile individuals or countries. Of greatest concern, ARS officials have not identified which of its research projects are sensitive or dual use—that is, which projects involve specialized knowledge that could be exploited by questionable individuals, such as bioterrorists. ARS, as well as other Federal agencies, have not identified such research because there are no established Government-wide criteria. The Government's scientific community has recognized this deficiency, and the National Institutes of Health created the National Science Advisory Board for Biosecurity (the Board) to tackle this and other biosecurity issues. The Board is scheduled to convene on June 30, 2005, but has not established timeframes for issuing guidance.

ARS officials, however, cannot afford to wait for the Board's guidance to begin identifying dual-use research and monitoring it appropriately. The danger that the agency will unintentionally provide hostile individuals or groups with unique knowledge—including techniques for manipulating select biological agents—presents too great of a risk to national security. Thus, ARS officials need to immediately establish criteria to define dual-use research projects, to approve those projects in light of their destructive potential, and to monitor those projects on an ongoing basis.

ARS officials also do not check the backgrounds of all non-Government scientists working on research projects involving sensitive knowledge. In fact, ARS was unaware of the number of non-Government scientists currently working on such projects. Our inquiries revealed that at least 130 non-Government scientists, whose backgrounds were unknown, were working on only 10 of the sensitive research projects we reviewed. Agency officials informed us that they had not obtained the detailed personal information necessary to perform security suitability determinations primarily because of concern that non-Government scientists would be deterred from participating in collaborative research. They added that the agency had no policy and

procedures for maintaining the names of all collaborating non-Government scientists. As a result, non-Government scientists with questionable backgrounds may be able to obtain unique knowledge about select biological agents and other sensitive scientific research through collaboration with the agency.

We also found that ARS officials post sensitive information—including the names and locations of scientists working with select agents—on the Internet, where it is easily accessible by the public. We concluded that this practice conflicts with USDA regulations, which require agencies to define, identify, and protect sensitive security information. Our examination of ARS' website and the Current Research Information System, a public database used by ARS, disclosed detailed descriptions of experiments and results for 224 ongoing research projects involving select agents. (There were over 3,400 ongoing research projects as of October 2004.)

The ARS website also included abstracts of scientific manuscripts dealing with dual-use research. Although the scientific community values the open exchange of research information and results, we concluded that some of the technical data that ARS includes online could be manipulated for destructive purposes.

Finally, although ARS scientists routinely share sensitive information with foreign scientists, some from countries of concern, the agency had not applied for deemed export licenses issued by the DOC, which controls the transfer of such information between the United States and other nations. ARS officials had not developed policy and procedures to apply for deemed export licenses for controlled information.

ARS research offers solutions to a variety of agricultural problems, ranging from animal and plant diseases to human nutrition. Unfortunately, while ARS is devoted to pursuing beneficial advances in research, other parties and individuals may be attempting to harness that research for harmful purposes. Thus, in pursuing its valuable scientific work, ARS officials must consider—and work to prevent—the potential negative applications of the specialized knowledge it uses and creates.

Recommendations In Brief

We recommend that ARS officials develop policy and procedures to (1) identify, approve, and monitor dual-use research projects; (2) perform suitability determinations, based on a risk analysis, of non-Government scientists involved in sensitive research projects; and (3) submit deemed export license applications to DOC prior to initiating sensitive research projects with foreign scientists. We also recommend that ARS officials develop criteria for identifying sensitive security information and implement procedures to ensure that this information is not posted on the Internet.

Agency Response

In its response dated September 15, 2005, ARS officials generally agreed with all but three recommendations in the report. We have incorporated applicable portions of ARS' response, along with our position, in the Findings and Recommendations section of the report. The agency's response is included in its entirety as exhibit B of the report.

OIG Position

We generally agree with ARS' response and have reached management decision on four of the recommendations (1, 2, 3, and 5). In order to reach management decision for four of the recommendations (6, 7, 8, and 11), ARS needs to provide timeframes for completion of the corrective actions. We disagreed with ARS' response to three of the recommendations (4, 9, and 10). Management decisions can be reached for these three once we receive the information specified in the report sections *OIG Position*.

Abbreviations Used in This Report

APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
BSL	Biosafety Level
CDC	Centers for Disease Control
CRIS	Current Research Information System
DOC	U.S. Department of Commerce
EAR	Export Administration Regulations
HHS	U.S. Department of Health and Human Services
NIH	National Institutes of Health
NRC	National Research Council
Board	National Science Advisory Board for Biosecurity
OIG	Office of Inspector General
rDNA	Recombinant deoxyribonucleic acid
SSI	Sensitive security information
USDA	U.S. Department of Agriculture

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Background and Objectives

Background

The Agricultural Research Service (ARS) conducts scientific research to develop, and transfer to the public, solutions to agricultural issues of a high national priority. ARS administers its programs through its National offices in Washington, D.C., and Beltsville, Maryland. The National offices and 8 area offices monitor ARS research activities at 11 research centers, 5 human nutrition centers, and 243 laboratories in 113 locations, including Argentina, China, France, and Australia.

ARS generally performs research on animal and plant diseases and pest problems. This research can include the use of biological agents—living organisms in their microbial form that are generally pathogenic, or disease producing, to some degree. Some of ARS' research projects involve select agents, a group of infectious biological agents that USDA's Animal and Plant Health Inspection Service (APHIS) and the Centers for Disease Control (CDC) have determined most seriously threaten human, animal, and plant health. (See exhibit A.) Some of these pathogens, such as *Bacillus anthracis* (anthrax) and avian influenza virus, are regarded as zoonotic—that is, able to cause disease, even death, in both animals and humans.

Through formal collaborative agreements, ARS scientists frequently share knowledge with research partners from universities, private companies, non-profit organizations, and other countries to solve agricultural issues. ARS scientists also collaborate informally with non-Government scientists on ARS in-house research projects.

The "Dual-use Dilemma"

In 2003, the National Academy of Sciences reported that knowledge generated by biotechnology research, while greatly benefiting society, also poses a threat in that it could be used to create the next generation of biological weapons. The Academy called this the "dual-use dilemma," in which the same knowledge could be used legitimately for human betterment and misused for bioterrorism. The risk is that research results, knowledge, or techniques could facilitate the creation of novel pathogens with unique properties, or the creation of entirely new classes of threat agents.

Export Requirements

ARS research is subject to the U.S. Department of Commerce (DOC) Export Administration Regulations (EAR) for exports to foreign countries, as well as exports to foreign nationals inside the United States. An export is a shipment of materials out of the United States. In addition, any release of technology, including the transfer of technical knowledge, or source code subject to the EAR, to a foreign national, is deemed to be an export to the home country or

countries of the foreign national. A deemed export license may not be required if the research being conducted is "fundamental research." Fundamental research is defined as basic and applied research where the resulting information is published and shared broadly within the scientific community.

The DOC Office of Inspector General (OIG) recently reviewed deemed export applications from several Federal agencies and concluded that there is a lack of understanding regarding the applicability and requirements of export regulations as they apply to deemed exports. This lack of understanding could result in a loss of technology to inappropriate end users. DOC OIG found instances where the Departments of Commerce, Defense, and Transportation may be noncompliant with deemed export regulations. DOC OIG did not include USDA in its review.

Objectives

Our objective was to evaluate agency controls over the transfer of sensitive (dual-use) technology to the public. Specifically, we determined if ARS (1) adequately identified, approved, and monitored sensitive research; (2) identified scientists working on the projects and ensured that sensitive knowledge had not been transferred to unscrupulous individuals; and (3) complied with DOC's deemed export license requirements.

Findings and Recommendations

Section 1. Identifying, Approving, and Monitoring Sensitive Research

Finding 1 — ARS Needs To Identify, Thoroughly Review, and Monitor Dual-Use Research Projects

ARS officials had not identified which of its more than 3,400 ongoing research projects are sensitive, or "dual use," in nature—that is, projects involving specialized knowledge that could be used for both beneficial and harmful purposes. This situation exists because ARS officials had not established criteria to define dual-use research, nor has it developed procedures to identify, approve, and monitor research projects meeting the criteria. As a result, in the course of conducting research intended to benefit society, ARS may be unintentionally providing questionable individuals or groups with knowledge—including techniques for manipulating select biological agents—that could be used for illicit purposes.

Government-wide, no legislation or regulations exist requiring agencies to define, identify, approve, or monitor dual-use research. Developing such requirements is a complicated and controversial matter, as both Government and private sector researchers are concerned that restrictions on the flow of information could impede scientific advancements. Despite these concerns, the scientific community has recognized the need for guidance in this area. The National Institutes of Health (NIH), an agency of the U.S. Department of Health and Human Services (HHS), has convened an advisory board to undertake the task of providing advice, guidance, and leadership regarding biosecurity of dual-use research. However, it could be several years before guidance on dual-use research is available to the scientific community.

Given the heightened security concerns since September 11, 2001, which have been emphasized in numerous recent Presidential Directives, there is an immediate need for ARS to monitor its activities in the critical area of dual-use research.

Lack of Criteria for Identifying Dual-Use Research

In general, the term "dual use" is used to describe research with a legitimate scientific purpose that may be misused to pose a threat to public health or national security. For example, knowledge gleaned from a project intended to develop a vaccine could be used to create a more potent virus. Despite the fact that many of ARS' research projects are potentially dual use—we found 224 such projects during our review of ARS' database—the agency has not developed specific criteria for identifying dual-use research. According to

ARS officials, since the concept of dual-use research is relatively new and NIH is developing guidance, the agency, which represents only a portion of the Federal research community, is reluctant to be at the forefront of such groundbreaking criteria.

ARS officials' hesitation to identify dual-use projects reflects the cautious approach toward dual-use research in the Federal government and in the scientific community at large. In 2003, the National Research Council (NRC), an independent society of scientists that advises the Federal Government, addressed what it termed the "dual-use dilemma" in a report called *Biotechnology Research in an Age of Terrorism.*[1] The NRC report emphasized the pressing need to develop criteria for identifying dual-use research as well as the challenges inherent in doing so. As a starting point, NRC proposed seven types of experiments involving infectious agents and their products that could be considered dual use. Specifically, NRC defined these "experiments of concern" as those that:

1. Demonstrate how to render a vaccine ineffective;
2. Confer resistance to therapeutically useful antibiotics or antiviral agents;
3. Enhance the virulence of a pathogen or render a nonpathogen virulent;
4. Increase transmissibility of a pathogen;
5. Alter the host range of a pathogen;
6. Enable the evasion of diagnostic/detection modalities; or
7. Enable the weaponization of a biological agent or toxin.

Although biological research covers a much broader spectrum of experiments that could be considered dual use, NRC concluded that projects involving infectious agents pose the greatest threat. Some of ARS' research projects involve select agents—a group of infectious agents that APHIS and the CDC have determined most seriously threaten human, animal, and plant health. (See exhibit A.) In fact, we identified 224 ongoing research projects involving select agents, such as avian influenza and bovine spongiform encephalopathy. (See Finding 3.) Scientists we spoke with also confirmed that ARS performs research that would fall under the seven NRC criteria. One scientist stated that his project met the NRC criteria because it involves select agents. Another scientist informed us that the project he was involved with met three of the seven NRC criteria.

The NRC criteria, however, serve only as an initial step in addressing the dual-use dilemma. To further refine the dual-use criteria, NRC recommended establishing a separate board made up of both scientists and policymakers. To that end, NIH formed the National Science Advisory Board for Biosecurity (the Board), on which representatives of fifteen Federal departments and agencies, including ARS, serve as a non-voting participants.

[1] The study was sponsored by the Sloan Foundation and the Nuclear Threat Initiative. NRC is the principal operating agency of the National Academy of Sciences and the National Academy of Engineering. It is a private, nonprofit institution that provides scientific advice under a congressional charter.

According to a Board official, the Board's guidance regarding dual-use research will be based on NRC's list of "experiments of concern." However, the Board will not meet until June 30, 2005, and it has yet to establish timeframes for issuing guidance.

The Department has signed a Memorandum of Agreement with HHS, in which it agrees to consider the Board's criteria for identifying dual-use projects once it is developed. In our view, ARS officials should either adopt the Board's criteria or, if the criteria are not acceptable, seek guidance from other authoritative scientific sources, such as the Office of Science and Technology Policy. Until the Board issues criteria, ARS officials need to take action to identify dual-use projects. One way would be to implement the NRC's criteria for the seven "experiments of concern." As an alternative, ARS officials could identify as dual use all projects involving select agents and toxins on the APHIS/CDC list. (See exhibit A.) Focusing on select agents would allow ARS to identify, in a streamlined fashion, projects with the most serious dual-use implications until the Board finalizes Government-wide criteria.

Lack of Approval and Monitoring Procedures for Dual-Use Research

Because ARS officials have no criteria for identifying dual-use research, the approval and monitoring processes do not specifically identify dual-use projects. The Board's charter states that it will develop guidelines for approval and oversight of dual-use research, including publication of dual-use research results. However, ARS officials should take interim steps to ensure that it adequately addresses the unique risks of dual-use research when it approves projects and while they are underway.

Currently, ARS officials review and approve research project proposals based on the scientific merit of the research and whether it supports the agency's mission. As part of the review and approval process, ARS officials need to determine if projects are dual use based on the available criteria, such as the NRC "experiments of concern" or the use of select agents. Once it deems a project "dual use," ARS officials should evaluate the project to determine if the potential benefits of the research outweigh its risk of misuse.

Upon approval of a dual-use project, ARS officials should also consider if scientific manuscripts resulting from the project should undergo additional review prior to publication, in order to prevent release of sensitive information. In some instances, it may be necessary to delay or prohibit publication of research results. To institute these additional controls over dual-use projects, ARS will need to include a biosecurity expert on the review panel to counsel agency managers during the review and approval process.

Once it approves dual-use projects, ARS officials should monitor those projects closely while they are underway to ensure that the research is proceeding according to the original objectives. In the case of dual-use research, departures from the original proposal may present new risks that the approval panel did not foresee. Currently, ARS scientists submit annual reports to agency headquarters detailing the progress of all research projects, including major accomplishments and resulting publications. However, our conclusion is that more frequent reporting is necessary for dual-use research projects. In addition, scientists working on dual-use projects should formally notify ARS headquarters when deviations from the approved objectives or other significant events occur. Headquarters personnel should then verify the reports, determine if any new risks have arisen, and evaluate whether the project should continue.

To maintain accountability for dual-use research, ARS officials need to develop and incorporate these approval and monitoring controls into agency policies. Upon issuance of the Board's guidelines, ARS officials should reevaluate the approval and monitoring procedures for dual-use projects to ensure that they reflect the Board's guidance.

ARS research leads to numerous beneficial discoveries in science and technology, and we recognize the need to avoid undue restrictions on the agency's important work. However, in the interest of national security, ARS must recognize and address the potential negative applications of the scientific knowledge it uses and creates. Identifying, thoroughly reviewing, and monitoring dual-use projects are critical steps in ensuring that ARS research contributes only to the advancement of science, not to terrorist activity.

Recommendation 1

Formalize in agency policies and procedures the criteria for identifying dual-use projects when it is issued by the Board; or seek guidance from other authoritative sources, such as the Office of Science and Technology Policy.

ARS Response

ARS will develop policies and procedures adopting the Board's recommendations when they are issued. If necessary, ARS will engage an office such as the Office of Science and Technology Policy to discuss proposed recommendations and seek guidance on implementation of the Board's recommendations. In the interim, as stated in response to Recommendations 2 and 3, ARS will issue a memorandum by the end of the year that will provide guidance on procedures for the review and monitoring of sensitive research projects which qualify as "experiments of concern," as defined by the National Research Council of the National Academies.

OIG Position

Based on the uncertainty as to the issuance of the Board's recommendations and on ARS' agreement to issue interim guidance using the definitions issued by the National Research Council of the National Academies, we accept ARS' management decision for this recommendation. Final action will be completed once ARS provides the Office of the Chief Financial Officer (OCFO) a copy of the interim guidance.

Recommendation 2

Until the Board develops criteria, establish policies and procedures to identify dual-use research using the NRC criteria; or, alternatively, consider all research projects involving select agents as candidates for the dual-use designation.

ARS Response

Until the Board develops criteria for identifying dual-use research projects, ARS will use interim criteria to define and identify sensitive research projects. The interim criteria will be based upon the seven classes of experiments involving infectious agents and their products, defined as the seven "experiments of concern" by the National Research Council of the National Academies. As stated in response to Recommendation 3, ARS will issue a memorandum by the end of the year.

OIG Position

We accept ARS' management decision on this recommendation. Final action will be completed once ARS provides OCFO a copy of the interim guidance.

Recommendation 3

Develop procedures to evaluate the potential risks of dual-use research projects as part of the approval process, including whether pre-publication review of research results is appropriate.

ARS Response

Until the Board issues guidance, the ARS Administrator is planning to issue a memorandum that will provide guidance on procedures for the review and monitoring of sensitive research projects which qualify as "experiments of concern" under the interim criteria described in the ARS response to Recommendation 2. This memorandum should be issued by the end of the year. When the Board establishes criteria, ARS will develop procedures based on those recommendations.

OIG Position

We accept ARS' management decision for this recommendation. Final action will be completed once ARS provides OCFO a copy of the interim guidance.

Recommendation 4

Require ARS scientists working on dual-use projects to immediately report any significant events or deviations from the approved objectives to headquarters, which should verify the reports and reevaluate the projects as necessary.

ARS Response

ARS currently has procedures which necessitate internal review of all projects when significant deviations from approved project objectives are made to project plans. Significant changes in project/program objectives are documented by the National Program Staff through the issuance of Program Direction and Resource Allocation Memos (PDRAMs). In addition to internal oversight and review of such changes, significant changes may also result in additional external peer review.

OIG Position

We do not accept ARS' management decision for this recommendation. ARS' current procedures do not address deviations that occur during the course of ongoing research. We are concerned that ARS managers will not be made aware of significant events or deviations from approved objectives in a timely manner. At the time of our audit, scientists submitted annual reports to Headquarters, which could be a considerable time after a significant event occurred. We believe that scientists should be required to immediately report such events and that more frequent reporting is necessary. To reach a management decision for this recommendation, ARS needs to address this issue.

Recommendation 5

Develop monitoring procedures for dual-use projects, and ensure that they reflect the Board's guidance, when issued.

ARS Response

ARS' line management and the National Program Staff will be involved in developing procedures which will reflect the Board's guidance upon issuance. In response to Recommendation 3, ARS described its approach to developing interim procedures. ARS stated that the interim guidance should be issued by the end of the year.

OIG Position

We accept ARS' management decision for this recommendation. Final action will be completed once ARS provides OCFO a copy of the interim guidance.

In the scientific community, free and open exchange of information among scientists is considered essential to advances in research. For this reason, ARS posts research descriptions and results, including those involving sensitive information about select agents and toxins, on the Internet, which conflicts with Departmental regulations that require agencies to safeguard sensitive information. ARS collaborates with many non-Government scientists, particularly scientists in universities and research centers with expertise in areas related to ARS projects and programs. ARS encourages non-Government scientists to collaborate in joint research projects, some of which could involve sensitive information. In conjunction with some collaborative projects, ARS officials do not look into the backgrounds of all non-Government scientists. Some agency officials believe that requiring such checks would deter scientists from contributing to ARS research. In addition, ARS officials do not have policies and procedures for maintaining the names of non-Government scientists and, therefore, was unaware of how many were collaborating on research projects.

We agree that unnecessary barriers over the exchange of scientific information could impede the progress of beneficial research. However, sharing knowledge about sensitive research, which could be used by questionable individuals for illicit purposes, is an even greater danger.

Finding 2 ARS Does Not Check All Non-Government Scientists for Security Suitability

ARS officials do not check the backgrounds of all non-Government scientists that collaborate on ARS research projects involving sensitive knowledge, nor is the agency aware of how many such scientists are involved in those projects. Agency officials informed us that they had not obtained the detailed personal information necessary to perform security suitability determinations because of concern that non-Government scientists would be deterred from collaborating on research projects, and because of the considerable time and expense of performing extensive suitability determinations. As a result, non-Government scientists with questionable backgrounds may be able to obtain unique knowledge about select biological agents and other sensitive scientific research through participation in agency projects.

ARS officials lack policies and procedures for maintaining the names of non-Government scientists participating on research projects, and for obtaining other information necessary to determine security suitability. Also, ARS officials check the background of non-Government scientists only when they

will physically enter an agency facility, such as a BSL-3 laboratory. In these instances, ARS officials perform a security suitability determination based on the perceived level of risk for the position; as the level of risk increases, so does the depth of the background review. For example, a National Agency Check with Inquiry might be appropriate for an individual with little or no access to sensitive areas of a facility. For individuals with access to more sensitive areas, ARS officials would perform either a Limited Background Investigation or a Background Investigation. (See the Glossary of Terms for a description of these suitability determinations.)

ARS scientists work with non-Government scientists in numerous types of collaborative research projects. For all types of projects, researchers working at different locations share with each other the details of their experiments, findings, and conclusions. In most instances, sharing information with non-Government scientists is not a concern because the project does not involve dual-use research. However, some ARS research involves select biological agents and other types of experimentation that could be used for illicit/harmful purposes. In these instances, information should not be shared with non-Government scientists whose backgrounds are unknown. An agency official informed us that it is not uncommon for ARS scientists and non-Government scientists to agree to pursue collaboration after meeting at scientific symposiums and conferences. Thus, in some instances, ARS scientists may know very little about the background of individuals they will be working with on a project.

In fact, agency officials were unable to provide us with the number of non-Government scientists collaborating on ARS research projects. To gain an approximate idea of how many non-Government scientists were participating in ARS research, we interviewed scientists involved with the 10 sensitive research projects included in our review. Our inquiries disclosed that, on those 10 projects, ARS scientists were working with at least 130 non-Government scientists. (This number is based solely on the scientists' recollection and willingness to provide the names of non-Government scientists. The exact number could be higher or lower because it is based on anecdotal information from a portion of ARS scientists on each project.) ARS officials confirmed that this number was typical for agency research projects. Since ARS is involved in at least 224 projects that could be dual use in nature (see Finding 3), the number of non-Government scientists working with ARS on sensitive projects could be significant.

We also found that some of the non-Government scientists working on the sensitive projects in our review were from countries of concern, a DOC distinction for countries where caution should be used in sharing information. (See Finding 4.) Determining the security suitability of these scientists would reduce the risk that sensitive information will be shared with questionable individuals.

Some ARS officials agreed with our assessment, but expressed concern that requiring non-Government scientists to submit personal information for suitability determinations would deter them from collaborating on research projects. They stated that non-Government scientists are reluctant to undergo extensive background investigations in order to be involved in collaborative research. ARS officials also stated that performing suitability determinations could be costly and time consuming, especially with the number of non-Government scientists working on research projects.

Numerous types of checks can be performed to determine the security suitability of non-Government scientists. For projects involving sensitive research, ARS officials need to develop criteria and procedures for deciding the appropriate type of suitability determination to be performed on non-Government scientists. The criteria should equate the level of risk to the appropriate security suitability determination. For example, a non-Government scientist whose involvement in a project will be minimal, and will not include access to sensitive information, may not pose a serious risk and would not need a suitability determination. In contrast, a non-Government scientist who will have access to unique knowledge related to a select biological agent may need a comprehensive background investigation. The type of analysis currently performed for individuals gaining access to ARS facilities may be sufficient for non-Government scientists working on agency research from distant locations.

The issue of suitability determinations is particularly troubling to ARS officials, and the scientific community at large, because it could cause delays in completing research within desired timeframes. However, ARS' current policy, which limits suitability determinations of non-Government scientists to those who will have physical access to ARS facilities, is not enough. While it is critical to prevent questionable individuals from obtaining select agents such as *Bacillus anthracis*, avian influenza virus, and exotic Newcastle disease, the unique knowledge of how to manipulate those pathogens may pose the greatest danger.

Recommendation 6

Develop policy and procedures for obtaining personal information from all non-Government scientists involved in sensitive research projects in order to perform security suitability determinations.

ARS Response

ARS will work with the Office of the General Counsel to develop the most effective and appropriate approach for obtaining personal information for all non-government scientists working on sensitive research projects as defined by ARS interim guidance.

OIG Position

We agree with ARS' proposed corrective action. To reach management decision, ARS needs to provide a timeframe for completion of this action.

Recommendation 7

Maintain a list of all participating non-Government scientists for each sensitive research project.

ARS Response

ARS will develop a centralized system, with management oversight, to maintain and periodically review a roster of all non-government scientists working on sensitive research projects defined by ARS interim guidance.

OIG Position

We agree with ARS' proposed corrective action. To reach management decision, ARS needs to provide timeframes for the development and implementation of the centralized system and procedures to conduct periodic reviews.

Recommendation 8

Develop and implement policy and procedures for establishing, based on risk factors, appropriate security suitability determinations for all non-Government scientists involved in sensitive research projects.

ARS Response

ARS will develop policies and procedures to address both the risk factors and the appropriate security suitability requirements for non-government scientists involved in sensitive research projects defined by ARS interim guidance. These procedures will be reviewed by the Office of the General Counsel.

OIG Position

We agree with ARS' proposed corrective action. To reach management decision, ARS needs to provide timeframes for the development and implementation of the policies and procedures.

Finding 3 ARS Makes Sensitive Research Information Available to the Public on the Internet

ARS posts sensitive information—including the names of scientists working with select agents—on its Internet website, where it is easily accessible to the public. This practice conflicts with Departmental regulations[2], which require agencies to define, identify, and protect sensitive security information (SSI). However, ARS officials have not established policy and procedures to comply with these requirements. As a result, knowledge about sensitive research, particularly projects involving select agents and toxins, can be readily obtained by questionable individuals and used for subversive activities.

Departmental regulations[2] require agencies to establish criteria for identifying, and to implement security measures to protect, SSI—unclassified information of a sensitive nature that, if publicly disclosed, could have a harmful impact on public health and safety. Based on this definition, information about select agents and toxins and other potential dual-use research could be classified as SSI.

We found that ARS officials have not defined SSI or developed sufficient criteria for what can and cannot be released on its Internet website or the Current Research Information System (CRIS) database, a publicly available resource maintained by the Cooperative State Research, Education, and Extension Service, another USDA agency. According to agency officials, ARS scientists are required to take annual biosecurity awareness training. Scientists working on individual research projects use their judgment to decide if material is appropriate to post online.

Although the scientific community values the open exchange of research information and results, we concluded that some of the technical data that ARS includes online could be manipulated for harmful/destructive purposes and should not be readily available to the public. This issue was addressed by a White House memorandum dated March 19, 2002, which emphasized each agency's "obligation to safeguard Government records…that could reasonably be expected to assist in the development or use of weapons of mass destruction."

We found, however, that the ARS website and the CRIS database included detailed descriptions of 224 ongoing research projects that involve select agents. (There were over 3,400 ongoing research projects as of October 2004.) For example, numerous projects involved avian influenza virus, a

[2] Department Regulation 3440-2, Section 8 (a and c), dated January 30, 2003.

select agent that is known to be zoonotic and has a 72-percent mortality rate in humans. The details of these projects—including descriptions of conditions that promote the transition of non-pathogenic strains to highly pathogenic strains—were posted on ARS' website. According to the seven NRC criteria, these projects would be considered "experiments of concern" because they could be used to "enhance the virulence of a pathogen or render a nonpathogen virulent."

The ARS website also included abstracts of scientific manuscripts dealing with dual-use research. The website cited the journals where specific details of the experiments, and results of those experiments, were published by the research team.

We also found that, while Departmental regulations[3] cite "information that could result in physical risk to individuals" as an example of SSI, ARS did not exclude the names of scientists working with select agents from its website or the CRIS database. All of the 224 research projects we identified as involving select agents listed the names of the scientists working on the projects, and the locations where the research was being performed. By identifying the names and locations of scientists working with select agents, ARS may unintentionally make those researchers a target for hostile individuals attempting to gain access to or knowledge of a select agent.

ARS officials issued a memorandum dated April 28, 2003, directing that all projects containing select agent names in the objective or approach section of the project summary be removed from the Internet. The memorandum also instructed ARS officials to remove detailed descriptions of researchers' expertise involving select agents and detailed descriptions of laboratory techniques used to investigate sensitive research areas. According to ARS officials, the agency identified over 200 project listings on the ARS website that contained such information. However, they removed the information from only 7 of the more than 200 listings. None of the numerous ARS officials we interviewed could explain why the agency had not fully complied with the memorandum's instructions. According to ARS staff, an official no longer with the agency determined that the select agent information specified in the memorandum was not sensitive and did not need to be removed from the ARS website. However, we could not substantiate those statements.

ARS officials informed us that they are currently in the process of developing criteria for identifying SSI. However, they were unable to provide a timeframe for developing the criteria and implementing security procedures to comply with Departmental regulations.

[3] Departmental Regulations 3440-2, Section 6 (b), dated January 30, 2003.

Recommendation 9

Remove from the Internet all information regarding select agents, the names of individuals authorized to use them, and the location where they could be found.

ARS Response

It is ARS' view that the benefit of having information on select agents available to the public on the Internet, in many cases, outweighs the risk of having such information accessible to a minority segment of the public that might misuse the information. In addition, regardless of whether the information is publicly available on the Internet, it is still likely to be readily available through scientific literature. In those instances where ARS judges that the dangers outweigh the benefits, ARS will not release such information on the Internet. As the Board develops additional guidelines, ARS will take whatever steps are needed to be in compliance with the Board's guidance.

OIG Position

We do not accept management decision for this recommendation. While we agree that the scientific community values the open exchange of research information, we do not believe ARS should be making this type of sensitive information readily available on the Internet. We believe that the disclosure of this type of sensitive information, particularly when it pertains to select agents, goes against the intent of the Public Health Security and Bioterrrorism Preparedness and Response Act of 2002 (Public Law 107-188) to protect such information from those who might use it for the "wrong" purpose. The Act specifically forbids Federal agencies from disclosing any information submitted under the Act. That non-disclosure provision includes information that would identify the select agents involved or the identity or location of the person possessing the select agents; this information is comparable to what ARS currently makes publicly available on the Internet. To reach a management decision, we need to know when the criteria for removal of this information from the Internet will be developed and implemented in agency policy.

Recommendation 10

Develop criteria for identifying SSI and implement procedures to ensure this information is not included on the Internet.

ARS Response

ARS will continue to make every effort to ensure that sensitive security information (SSI) is not included on the Internet. However, this effort will be consistent with guidance from the Board and the standard operating procedure of the academic community working in this area. The effort also

will be guided by the availability of such information elsewhere and from other sources. Even if such information is not included by ARS on the Internet, it may be readily available in published literature, from other Internet sources, and from abstracting services and databases.

OIG Position

The response did not address the recommendation. Therefore, we cannot reach management decision for this recommendation. To reach a management decision, ARS needs to develop criteria for identifying SSI, and implementing security features for complying with Departmental regulations restricting information that can be placed on the Internet.

Finding 4 — ARS Shares Sensitive Information with Foreign Scientists Without Applying for Deemed Export Licenses

Although ARS scientists routinely share sensitive information with foreign scientists, some from countries of concern, the agency had not applied for deemed export licenses issued by DOC, which controls the transfer of such information between the U.S. and other nations. ARS officials have not developed policy and procedures to apply for the deemed export licenses because agency officials incorrectly assumed that since they intend to publish all research results, they were not subject to DOC deemed export requirements. In fact, certain "controlled" information ARS uses to conduct some experiments is subject to deemed export license regulations, regardless of whether ARS plans to publish the research results. Furthermore, once ARS officials begin identifying dual-use research, some research results may not be published at all. Until it takes steps to comply with deemed export regulations, ARS may be providing foreign countries with sensitive dual-use information, such as methods for manipulating select agents.

DOC's Export Administration Regulations[4] (EAR) outline the requirements for deemed export licenses. Under the EAR, specific unpublished information necessary for the development, production, or use of a product is considered "controlled"—for example, unpublished information related to the use of a select agent[5] [6]. DOC officials also consider the home country of the foreign scientist when determining the need for a deemed export license. DOC has identified seven "countries of concern," or the nations that pose the greatest threat of misusing controlled information. These countries include Iran, Syria, and China.

According to the EAR, a deemed export license is not required if the research being conducted is "fundamental"—that is, basic and applied research whose results are typically published and shared broadly within the scientific community. However, according to DOC officials, all fundamental research is not exempt from deemed export license requirements. The fundamental research exception applies only to information that *arises during* or *results from* the research (emphasis added). The exception does not apply if controlled information is used as an input to the research, regardless of whether the results will be published.

[4] Title 15, Code of Federal Regulations, Chapter 7, Section 734.1, Part (a), dated December 9, 2004.
[5] Title 15, Code of Federal Regulations, Chapter 7, Section 772.1, dated March 10, 2005.
[6] Title 15, Code of Federal Regulations, Chapter 7, Supplement No. 2, Section 774, Part 1, dated July 30, 2004.

Export Licenses Needed for Research Using Controlled Information

Of the 10 ARS research projects we reviewed, 8 used select agent information, some of which may have been previously unpublished, as inputs. In 5 of those projects, there were eight foreign scientists, two of whom were from countries of concern, working in ARS facilities. ARS officials had not applied for deemed export licenses for any of the five projects.

Based on our concern that ARS could be improperly sharing information with foreign scientists, we informed DOC officials that the projects in our sample used select agents and involved foreign scientists. Upon hearing this, a DOC official said that a deemed export license might have been required in each case. Although the official cautioned that multiple factors determine if a deemed export license is needed, ARS officials may have been required to submit the projects for DOC review based on the nature of the projects and the foreign scientists' home countries.

The number of foreign scientists involved in the projects we reviewed is not atypical for ARS research. ARS officials informed us that the agency frequently works with scientists from countries of concern. For example, ARS collaborates extensively with Chinese scientists on disease research that, in some instances, involves the use of select agents. Despite the agency's substantial involvement with foreign collaborators, we learned that ARS officials had not applied for deemed export licenses for any of the joint research involving controlled information it conducts with foreign scientists.

ARS officials told us that, because the agency intends to publish all of its research results, ARS projects are considered "fundamental research" and are therefore exempt from deemed export requirements. However, in the EAR, the fundamental research exemption does not apply to controlled information used in the course of conducting research. ARS officials need to develop a formal policy and procedures for submitting research projects involving controlled information to DOC for deemed export licenses.

ARS officials, through the Office of Technology Transfer, work with the DOC on export license requirements of the EAR, relating to the transfer of select agent materials to foreign countries. According to ARS officials, nine export license requests for materials have been submitted since March 2003. Eight have been approved, and one judged to be unnecessary. Several additional applications are in preparation for submission to DOC. ARS officials have developed policies and procedures for these types of export licenses. The modification of these policies and procedures could be used for deemed export requirements.

Research Designated as Dual Use May Require an Export License

Once ARS officials begin identifying and monitoring dual-use projects, as discussed in Finding 1, some research results may not be published, making those projects subject to deemed export requirements. For instance, ARS scientists could be involved in research resulting in a scientific breakthrough that is sensitive in nature. If ARS managers decide not to publish the results, and there are foreign scientists involved in the project, it will be too late to obtain a deemed export license and prevent the transfer of potentially dangerous knowledge.

To date, ARS officials have operated under the assumption that all of its projects are exempt from deemed export requirements, overlooking the fact that controlled information used in the course of research is subject to the EAR. As the agency begins to identify dual-use research, and place restrictions on publishing results, more ARS projects will likely require deemed export licenses. In an environment of heightened national security concerns, ARS officials need to enhance its current policy and procedures for submitting those projects to DOC so that deemed export determinations can be made prior to giving foreign scientists access to sensitive information.

Recommendation 11

Implement policy and procedures for submitting deemed export applications to DOC prior to initiating dual-use research projects, and projects with controlled information, involving foreign scientists working either in an ARS facility or from another location.

ARS Response

ARS is developing policy and procedures on deemed export licenses and is working directly with the Department of Commerce (DOC) and with other Federal agencies on a task group to address common issues on deemed export policy, including proposed changes to the requirements. The Agency will develop and implement interim guidance on obtaining deemed export licenses. This guidance will be updated when final deemed export requirements are issued by the DOC and when the Board's recommendations are issued.

OIG Position

We agree with ARS' proposed corrective action. To reach management decision, ARS needs to provide a timeframe for the development and implementation of the interim guidance on obtaining deemed export licenses.

Scope and Methodology

Our audit was conducted at the ARS National Offices in Washington, D.C., and Beltsville, MD, and at three research facilities located in Beltsville, MD; Ames, IA; and Athens, GA. We selected these sites based on the number of potential dual-use research projects. We conducted our fieldwork from December 2004 through April 2005.

To gain knowledge about laws, regulations, and guidance related to dual-use research, we interviewed officials from USDA and NIH. We also reviewed the National Academy of Sciences report, "*Biotechnology Research in an Age of Terrorism*," issued in October 2003.

To determine if ARS was adequately identifying, approving, and monitoring dual-use research, we reviewed agency policies and procedures. We also judgmentally selected for in-depth reviews 10 ongoing research projects (from 3,431 as of October 2004) that we judged to be dual use in nature. (See exhibit B.) We considered the use of select agents as a key factor in identifying potential dual-use research projects. The 10 selected projects were located at the 3 ARS facilities listed above.

To determine if ARS was ensuring that dual-use technology was not inappropriately disseminated to the public, we evaluated information related to the 3,431 ongoing USDA research projects that was available on the CRIS Internet database. We also reviewed 1,043 abstracts of manuscripts dealing with rDNA that were available on ARS' website. (The search engine for these manuscripts did not allow us to obtain a universe number.)

To accomplish our objectives, we performed the following procedures:

- Reviewed applicable laws, regulations, and guidance concerning the transfer of sensitive (dual-use) technology to the public;
- Reviewed ARS' policies, procedures, and administrative controls related to identifying, approving, and monitoring projects involving dual-use research;
- Examined files and other agency records, including information posted on the Internet, for selected research projects;
- Interviewed agency scientists and officials responsible for performing research and monitoring the activities of collaborating scientists; and
- Interviewed officials from the NIH and DOC.

We conducted our audit in accordance with generally accepted Government auditing standards.

HHS NON-OVERLAP SELECT AGENTS AND TOXINS

- ☐ Crimean-Congo haemorrhagic fever virus
- ☐ *Coccidioides posadasii*
- ☐ Ebola viruses
- ☐ Cercopithecine herpesvirus 1 (Herpes B virus)
- ☐ Lassa fever virus
- ☐ Marburg virus
- ☐ Monkeypox virus
- ☐ *Rickettsia prowazekii*
- ☐ *Rickettsia rickettsii*

South American haemorrhagic fever viruses

- ☐ Junin
- ☐ Machupo
- ☐ Sabia
- ☐ Flexal
- ☐ Guanarito

Tick-borne encephalitis complex (flavi) viruses

- ☐ Central European tick-borne encephalitis
- ☐ Far Eastern tick-borne encephalitis
- ☐ Russian spring and summer encephalitis
- ☐ Kyasanur forest disease
- ☐ Omsk hemorrhagic fever

- ☐ Variola major virus (Smallpox virus)
- ☐ Variola minor virus (Alastrim)
- ☐ *Yersinia pestis*
- ☐ Abrin
- ☐ Conotoxins
- ☐ Diacetoxyscirpenol
- ☐ Ricin
- ☐ Saxitoxin
- ☐ Shiga-like ribosome inactivating proteins
- ☐ Tetrodotoxin

HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS/ SELECT AGENTS (OVERLAP AGENTS)

- ☐ *Bacillus anthracis*
- ☐ *Brucella abortus*
- ☐ *Brucella melitensis*
- ☐ *Brucella suis*
- ☐ *Burkholderia mallei* (formerly *Pseudomonas mallei*)
- ☐ *Burkholderia pseudomallei* (formerly *Pseudomonas pseudomallei*)
- ☐ Botulinum neurotoxin producing species of *Clostridium*
- ☐ *Coccidioides immitis*
- ☐ *Coxiella burnetii*
- ☐ Eastern equine encephalitis virus
- ☐ Hendra virus
- ☐ *Francisella tularensis*
- ☐ Nipah Virus
- ☐ Rift Valley fever virus
- ☐ Venezuelan equine encephalitis virus
- ☐ Botulinum neurotoxin
- ☐ *Clostridium perfringens* epsilon toxin
- ☐ Shigatoxin
- ☐ Staphylococcal enterotoxin
- ☐ T-2 toxin

USDA HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS (NON-OVERLAP AGENTS AND TOXINS)

- ☐ Akabane virus
- ☐ African swine fever virus
- ☐ African horse sickness virus
- ☐ Avian influenza virus (highly pathogenic)
- ☐ Blue tongue virus (Exotic)
- ☐ Bovine spongiform encephalopathy agent
- ☐ Camel pox virus
- ☐ Classical swine fever virus
- ☐ *Cowdria ruminantium* (Heartwater)
- ☐ Foot and mouth disease virus
- ☐ Goat pox virus
- ☐ Lumpy skin disease virus
- ☐ Japanese encephalitis virus
- ☐ Malignant catarrhal fever virus (Exotic)
- ☐ Menangle virus
- ☐ *Mycoplasma capricolum*/ M.F38/*M. mycoides capri*
- ☐ *Mycoplasma mycoides mycoides*
- ☐ Newcastle disease virus (VVND)
- ☐ Peste Des Petits Ruminants virus
- ☐ Rinderpest virus
- ☐ Sheep pox virus
- ☐ Swine vesicular disease virus
- ☐ Vesicular stomatitis virus (Exotic)

LISTED PLANT PATHOGENS

- ☐ *Liberobacter africanus*
- ☐ *Liberobacter asiaticus*
- ☐ *Peronosclerospora philippinensis*
- ☐ *Phakopsora pachyrhizi*
- ☐ Plum Pox Potyvirus
- ☐ *Ralstonia solanacearum* race 3, biovar 2
- ☐ *Schlerophthora rayssiae* var *zeae*
- ☐ *Synchytrium endobioticum*
- ☐ *Xanthomonas oryzae*
- ☐ *Xylella fastidiosa* (citrus variegated chlorosis strain)

USDA

United States Department of Agriculture

Research, Education, and Economics
Agricultural Research Service

SEP 15 2005

SUBJECT: Response to Recommendations in the Official Draft Report "Adequacy of Controls to Prevent the Improper Transfer of Sensitive Technology" (02601-1-Ch)

TO: Robert W. Young
Assistant Inspector General for Audit

FROM: Edward B. Knipling
Administrator

This memorandum responds to the official draft of the audit report "Adequacy of Controls to Prevent the Improper Transfer of Sensitive Technology," as transmitted to me by your August 15, 2005, memorandum." ARS appreciates the opportunity to respond to the recommendations included in the official draft. If you have any questions, please contact Jeff Hayes, Acting Director of the ARS Office of Homeland Security, on (202) 720-3778.

Recommendation 1

Formalize in agency policies and procedures the criteria for identifying dual-use projects when it is issued by the Board; or seek guidance from other authoritative sources, such as the Office of Science and Technology Policy.

ARS Response

ARS looks to the recommendations of the National Science Advisory Board for Biosecurity (NSABB) to provide guidance in identifying dual-use projects. Through participation on the Board, ARS will be working with other members of the NSABB from academia, industry, and the Federal government to define and identify dual-use research and to develop balanced strategies and criteria for oversight of such dual-use research. ARS will develop policies and procedures adopting the Board's recommendations when they are issued. If necessary, ARS will engage an office such as the Office of Science and Technology Policy to discuss proposed recommendations and seek guidance on implementation of the Board's recommendations.

ars

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Recommendation 2

Until the Board develops criteria, establish policies and procedures to identify dual-use research using the NRC criteria; or, alternatively, consider all research projects involving select agents as candidates for the dual-use designation.

ARS Response

Until the Board develops criteria for identifying dual-use research projects, ARS will use interim criteria to define and identify sensitive research projects. The interim criteria will be based upon the seven classes of experiments involving infectious agents and their products, defined as the seven "experiments of concern" by the National Research Council of the National Academies.

Recommendation 3

Develop procedures to evaluate the potential risks of dual-use research projects as part of the approval process, including whether pre-publication review of research results is appropriate.

ARS Response

A central challenge to the NSABB is developing a strategy and criteria for oversight of dual-use research. Recommendation 3 presents the same challenge to ARS. At this time, while awaiting guidance and direction from the Board, ARS is planning an interim approach which will include a memorandum from the ARS Administrator to senior executive leadership and management officials of ARS and to all Agency scientists and research leaders. This memorandum will provide guidance on procedures for the review and monitoring of sensitive research projects which qualify as "experiments of concern" under the interim criteria described in the ARS response to Recommendation 2. The Administrator's memorandum should be issued by the end of the year. When the NSABB completes its strategy and criteria, ARS will develop procedures based on those recommendations.

Recommendation 4

Require ARS scientists working on dual-use projects to immediately report any significant events or deviations from the approved objectives to headquarters, which should verify the reports and reevaluate the projects as necessary.

ARS Response

ARS currently has procedures which necessitate internal review of all projects when significant deviations from approved project objectives are made to project plans. Significant changes in project/program objectives are documented by the National Program Staff through the issuance of Program Direction and Resource Allocation Memos (PDRAMs). In addition to internal oversight and review of such changes, significant changes may also result in additional external peer review.

Recommendation 5

Develop monitoring procedures for dual-use projects, and ensure that they reflect the Board's guidance, when issued.

ARS Response

ARS line management (Research Leaders and Area Directors) and the National Program Staff will be involved in developing procedures which will reflect the NSABB guidance upon issuance. The response to Recommendation 3 describes our approach to developing interim procedures.

Recommendation 6

Develop policy and procedures for obtaining personal information from all non-Government scientists involved in sensitive research projects in order to perform suitability determinations.

ARS Response

ARS will work with the Office of General Counsel to develop the most effective and appropriate approach for obtaining personal information for all non-government scientists working on sensitive research projects as defined by ARS interim guidance. The significant increase in the financial costs for such an expanded program will need to be borne by the research program.

Recommendation 7

Maintain a list of all participating non-Government scientists for each sensitive research project.

ARS Response

ARS will develop a centralized system, with management oversight, to maintain and periodically review a roster of all non-government scientists working on sensitive research projects defined by ARS interim guidance.

Recommendation 8

Develop and implement policy and procedures for establishing, based on risk factors, appropriate security suitability determinations for all non-Government scientists involved in sensitive research projects.

ARS Response

Based on a number of position sensitivity factors, ARS currently has a progressive system of suitability reviews in place. In recent years, the agency has expended over $1,000,000 to execute these security suitability determinations.

Policies and procedures will be developed to address both the risk factors and the appropriate security suitability requirements for non-government scientists involved in sensitive research projects defined by ARS interim guidance. These procedures will be reviewed by the Office of General Counsel.

Recommendation 9

Remove from the Internet all information regarding select agents, the names of individuals authorized to use them, and the location where they could be found.

ARS Response

To remove all information relating to select agents from the internet would, in essence, remove from the broader research community all of the Agency's research information and progress in these critical areas. ARS will continue to monitor all information that it makes available on the internet and is aware of the need to protect individuals and property. However, as a publicly funded research agency, it is the Agency's view that the benefit of having information on select agents available to the public on the internet, in many cases, outweighs the risk of having such information accessible to a minority segment of the public that might misuse the information. In addition, regardless of whether the information is publicly available on the internet, it is still likely to be readily available through the scientific literature. Certainly, ARS does not want to stand in the way of the legitimate use of such information by the broader research community and industry for purposes of furthering research on counter-terrorism. In those instances where ARS judges that the dangers may outweigh the benefits, ARS will not release such information on the internet. As the NSABB develops additional guidelines, ARS will take whatever steps are needed to be in compliance with the Board's guidance.

Recommendation 10

Develop criteria for identifying SSI and implement procedures to ensure this information is not included on the Internet.

ARS Response

ARS will continue to make every effort to ensure that sensitive security information (SSI) is not included on the internet. However, this effort will be consistent with guidance from the NSABB and the standard operating procedures of the academic community working in this area. The effort also will be guided by the availability of such information elsewhere and from other sources. Even if such information is not included by ARS on the internet, it may be readily available in published literature, from other internet sources, and from abstracting services and databases such as PubMed and AGRICOLA.

Recommendation 11

Implement policy and procedures for submitted deemed export applications to DOC prior to initiating dual-use research projects, and projects with controlled information, involving foreign scientists working either in an ARS facility or from another location.

ARS Response

ARS has established procedures to secure export licenses when they are required and is developing policy and procedures on deemed export licenses. As part of this process, the Agency is working directly with the Department of Commerce (DOC) and with other Federal agencies on the Task Group on Export Controls for Science and Technology. The Task Group, established by the Office of Science and Technology, is addressing common issues on deemed export policy, particularly issues surrounding the changes to deemed export requirements proposed by the DOC earlier this year. At this time, the Agency plans to develop and implement interim guidance on obtaining deemed export licenses. The interim guidance will be updated when final deemed export requirements are issued by the DOC and when the NSABB recommendations are issued.

cc:
A. Betschart
J. Bradley
J. Hayes
S. Helmrich
C. Rexroad

Glossary of Terms

Applied research	Original investigation undertaken to acquire new knowledge and directed primarily toward a specific practical aim or objective.
Background Investigation	This is a more in-depth version of the Limited Background Investigation (LBI) since the personal investigation coverage is the most recent five to seven years. This investigation is required of those going into "high risk" public trust positions.
Basic research	Experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular use in view.
Biosafety levels	Combinations of laboratory practices and techniques, safety equipment, and laboratory facilities appropriate for the operations performed and are based on the potential hazards imposed by the agents used and for the laboratory function and activity. Biosafety Level 4 provides the most stringent conditions, Biosafety Level 1 the least stringent.
Biotechnology	The application of biological research techniques to the development of products that improve human health, animal health, and Agriculture.
Bioterrorism	The use of biological agents, such as pathogenic organisms or agricultural pests, for terrorist purposes.
Collaborate	To work together, especially in a joint intellectual effort.
Deemed export	Any release of technology or source code subject to the EAR to a foreign national is deemed to be an export to the home country or countries of the foreign national.
Dual-use technology	Research involving specialized knowledge that has both a legitimate, intended use and the potential to be used for illicit/harmful purposes.
Fundamental research	The DOC term for basic and applied research where the resulting information is published and shared broadly within the scientific community.

Limited Background Investigation	This investigation includes a National Agency Check and Inquiries (NACI), personal subject interview, and personal interviews by an investigator of subject's background during the most recent three years.
National Agency Check (NAC)	An integral part of all background investigations, consisting of searches of the Office of Personnel Management Security/Suitability/Investigations Index, the Defense Clearance and Investigations Index, the Federal Bureau of Investigations Identification Division's name and fingerprint files, and other files or indices when necessary.
National Agency Check And Inquiries	The basic and minimum investigation required on all new Federal employees consisting of a NAC with written inquiries and searches of records covering specific areas of an individual's background during the past 5 years (inquiries sent to current and past employers, schools attended, references, and local law enforcement authorities).
Pathogen	Any disease-producing organism.
Recombinant Deoxyribonucleic Acid (rDNA)	Genetically engineered DNA prepared by transplanting or splicing genes from one species into the cells of a host organism of a different species. Such DNA becomes part of the host's genetic makeup and is replicated.
Select biological agents	A group of infectious agents, established by APHIS and CDC, that most seriously threaten human, animal, and plant health.
Sensitive security information	Unclassified information of a sensitive nature that, if publicly disclosed, could have a harmful impact on public health and safety.
Suitability determination	Decision made on the level of security clearance granted to an individual based on background information.
Toxin	Any of a group of poisonous, usually unstable, compounds generated by microorganisms, plants, or animals.
Zoonotic	Type of pathogen that can cause disease and death in both humans and animals.

Informational copies of this report have been distributed to:

Administrator, ARS
Agency Liaison Officer (6)
General Accountability Officer (1)
Office of the Chief Financial Officer
Director, Planning and Accountability Division (1)