U.S. Department of Agriculture

Office of Inspector General
Southeast Region

Audit Report

Review of Export Licensing Process for Animal and Plant Health Inspection Service Listed Agents or Toxins

Report No. 33601-4-AT
March 2005

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

DATE: March 31, 2005

REPLY TO
ATTN OF: 33601-4-At

SUBJECT: Review of Export Licensing Process for Animal and Plant Health Inspection Service Listed Agents or Toxins

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

ATTN: William J. Hudnall
Deputy Administrator for Marketing Regulatory Program
Business Services

This audit was done as part of an interagency review to assess whether the current export licensing process can help deter the proliferation of chemical and biological commodities. Agencies participating in the review included the Offices of Inspectors General from the Departments of Commerce (DOC), Defense, Energy, State, Homeland Security, Health and Human Services, and Agriculture. In performing the reviews, the participating agencies are examining whether current licensing and enforcement practices and procedures are consistent with relevant laws and regulations, and consistent with established national security and foreign policy objectives, such as those set forth in the President's National Strategy to Combat Weapons of Mass Destruction, dated December 2002. The purpose of the reviews also includes an assessment of the effectiveness of coordination between the various Federal agencies during the export licensing process for these commodities. We performed this audit in conjunction with our ongoing Evaluation of the Implementation of the Select Agent or Toxin Regulations by Animal and Plant Health Inspection Service (APHIS) – Phase II (Audit No. 33601-3-AT).

According to APHIS officials, the U.S. Department of Agriculture (USDA) does not have regulatory authority for exports. Consequently, APHIS had neither established controls over exports of animal and plant pathogens, nor coordinated with DOC to establish and implement export control licensing requirements pertaining to select agents. During our review at 10 selected entities registered with APHIS, we found that a private research facility exported Highly Pathogenic Avian Influenza (HPAI) to Hong Kong on two occasions without obtaining the required license from DOC. An entity official stated that they were not aware of the licensing requirement for HPAI.

Even though APHIS has no regulatory authority regarding exports, we concluded that the agency could help registered entities ensure compliance with all requirements concerning movements, including exports of dangerous biological agents or toxins by working with DOC to provide the entities with up-to-date information concerning export licensing requirements. We also concluded APHIS should notify DOC of any changes to the list of agents or toxins that pose a severe threat to animals or plants, and work with that agency to help determine whether the Commerce Control List (CCL)[1] should be updated based on APHIS' changes.

BACKGROUND:

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Title II, Subtitle B,[2] was enacted to enhance controls over dangerous biological agents or toxins. The act requires that the Secretary of Agriculture, through regulations, establish and maintain a list of each biological agent and each toxin that is determined to have the potential to pose a severe threat to animal or plant health, or to animal or plant products. It also required that the Secretary establish procedures to protect animal and plant health, and animal and plant products in the event of a transfer of biological agents. APHIS was delegated authority to administer the regulations for USDA.

On December 11, 2002, the President issued the National Strategy to Combat Weapons of Mass Destruction. The strategy established a comprehensive approach to counter the growing threat from weapons of mass destruction including, among other things, biological weapons. One aspect of the strategy is to strengthen export controls to provide for better nonproliferation measures and prevent terrorists from acquiring such weapons. The United States controls the export of dual-use commodities for national security, foreign policy, and nonproliferation reasons under the authority of several different laws. Dual-use commodities are goods and technology determined to have both civilian and military uses. The primary legislative authority for controlling the export of dual-use commodities is the Export Administration Act of 1979, as amended.[3] Under the act, the DOC's Bureau of Industry and Security (BIS) administers the Export Administration Regulations by developing export control policies, issuing export licenses, and enforcing the laws and regulations for dual-use exports. The 1979 act[4] authorizes BIS to use export controls only after full consideration of the impact on the economy of the United States and only to the extent necessary to restrict the export of (1) goods and technology that would make a significant contribution to the military potential of any other country or combination of countries that would prove detrimental to the national security of the United States, (2) goods and technology where necessary to further significantly the foreign policy[5] of the United States or to fulfill its declared international

[1] The DOC maintains the CCL to identify items subject to export controls.
[2] Also known as "The Agricultural Bioterrorism Protection Act of 2002."
[3] The act expired on August 20, 1994, and was reauthorized by Public Law 106-508 (November 13, 2000) until August 20, 2001. During the lapse, a national emergency declared under Executive Order 12924 (August 19, 1994), and extended by annual Presidential Notices, continued in effect the provisions of the act.
[4] Export Administration Act of 1979, as amended, sec.3; 50 United States Code, app. sec. 2402(2).
[5] According to the act, foreign policy controls expire annually, unless extended by Congress. In order for foreign policy controls to be extended, the President must submit a report to Congress explaining why it is necessary for the United States to continue to control these items.

obligations, and (3) goods where necessary to protect the domestic economy from the excessive drain of scarce materials and to reduce the serious inflationary impact of foreign demand.

The Australia Group was established in 1985 as a forum of industrialized countries that cooperate in curbing the proliferation of chemical and biological weapons, by coordinating export controls, exchanging information, and performing other diplomatic actions. The 38 Australia Group members have adopted controls on chemical weapons precursors; dual-use chemical manufacturing facilities and equipment; biological agents used against humans, animals, and plants; dual-use biological equipment, and related equipment. The United States, using the CCL, regulates all items controlled by the Australia Group.

OBJECTIVE:

The objectives of our review were to (1) evaluate USDA's controls to ensure that export licensing requirements are complied with by entities that are registered to possess and use any of USDA-defined select agents or toxins or that possess and export any agent on the CCL and (2) evaluate USDA's coordination with DOC regarding establishment and implementation of export control licensing requirements as they pertain to select agents or toxins.

SCOPE AND METHODOLOGY:

We performed this review as part of our audit of APHIS' Implementation of the Listed Agents or Toxin Regulations – Phase II (Audit No. 33601-3-AT). We performed work at APHIS Headquarters in Riverdale, Maryland, and at 10 entities, selected as part of the Phase II audit, that were registered with APHIS to possess listed agents or toxins. Fieldwork was performed from November 1, 2004, to February 1, 2005. The audit was performed in accordance with generally accepted government audit standards.

We interviewed APHIS Headquarters officials to determine (1) what controls, if any, the agency has over exporting biological agents or toxins and (2) what efforts APHIS had made to coordinate with DOC when considering which biological agents or toxins to include on the select agent list.

At each of the 10 selected entities, we determined whether the entity (1) has ever exported any of the biological agents on the CCL; (2) applied for and received an export license from DOC/BIS to export such biological agents on the CCL (if not, we determined the reason for not obtaining the license); (3) received guidance concerning biological exports from APHIS, the Centers for Disease Control and Prevention (CDC) or any other Federal agency; and (4) exported any biological agents or toxins that were on the APHIS or CDC lists, but were not on the CCL (if so, we determined if the entities had the required APHIS permits).

FINDINGS:

We found that APHIS had not established controls over exports of animal and plant pathogens, including select agents or toxins on the CCL because the agency did not believe it had regulatory authority for exports. APHIS regulations require that listed biological agents or toxins may only be imported or transferred interstate/intrastate by individuals or entities registered to possess, use, or transfer the particular agent or toxin, and must be authorized by either APHIS or CDC. The Agricultural Bioterrorism Protection Act of 2002 did not address exports. APHIS officials said that they referred any exporting license issues to DOC.

Even though the Agricultural Bioterrorism Protection Act of 2002 does not address exports of dangerous biological agents or toxins posing a severe risk to animals or plants, it does share a common goal with the National Strategy to Combat Weapons of Mass Destruction. Both the act and the Strategy are intended to keep dangerous biological materials out of the hands of terrorists. APHIS regulations control the movement of the dangerous biological agents or toxins into and through the United States, whereas DOC/BIS controls exports of such agents or toxins. Researchers must be aware of and comply with all regulations regarding the movement of dangerous biological material whether within the United States or exports to other countries. Any violation of either APHIS or DOC/BIS regulations could expose the country to potential biological attacks by terrorists.

We found that researchers at registered entities were not always familiar with or did not always follow DOC/BIS exporting requirements. During our site visits, we found that 2 of the 10 entities exported biological agents that were on both the APHIS Select Agent List and the CCL. One of the two entities exporting agents on both lists had obtained the required DOC license, the other had not. We also found that a third entity exported an agent on the APHIS list but not on the CCL at the time of our review. However, the biological agent exported by the third entity was added to the CCL on December 29, 2004, after our review of the entity. The following describes the conditions we found at the three entities.

- One of the entities possessed five export licenses for exporting five agents on both the CCL and APHIS listed agents or toxins. The entity, a Federal laboratory, had developed standard operating procedures (SOP) for shipping biological agents to ensure compliance with the various regulations designed to reduce the risk of transmitting diseases to humans or animals through accidental exposure and to minimize the threat of the use of biological weapons by terrorists. The SOP provided detailed information regarding requirements for domestic and international shipments of biological materials, including references to the applicable regulations. Included in the SOP was a shipping checklist to aid authorized individuals in ensuring that all applicable laws and regulations were followed when shipping biological agents or toxins. The checklist included steps to determine whether the biological agent or toxin was a select agent, what APHIS or CDC permits were required, and whether the pathogen was listed on the CCL and required an export certificate.

- Another entity, a private research facility, exported HPAI to Hong Kong on two occasions without obtaining the required license from DOC. An entity official stated that they were not aware of the licensing requirement for HPAI. Although the responsible official (RO)[6] at the entity contacted APHIS personnel concerning export requirements prior to the shipments, an apparent miscommunication led him to believe there were no licensing requirements for HPAI. In a telephone conversation with an APHIS official on May 10, 2004, the RO discussed shipments of vaccine strains outside of the United States. The official told the RO that there were no DOC or Department of Transportation restrictions for exporting the vaccine. However, the APHIS official was not sure whether there were any restrictions regarding the export of APHIS listed agents or toxins. On May 11, 2004, the RO spoke with another official concerning exports of the HPAI virus, not the vaccine. The second APHIS official stated that APHIS had no restrictions on exporting the agent, and that only DOC regulated such exports. Based on the two conversations, the RO mistakenly concluded that there were no DOC restrictions on exporting the HPAI virus, and so informed the researcher[7]. The researcher shipped the virus to a researcher in Hong Kong on June 4, 2004, and again on August 16, 2004, without the required DOC license. HPAI is an extremely infectious and fatal disease for chickens. Once established, the disease can spread rapidly from flock to flock. In some instances, strains of HPAI viruses can be infectious to people. In 1997 a limited outbreak of one strain of HPAI infected 18 people, 6 of whom died.[8]

- We found that a third entity, a university, had exported Ralstonia solanacearum, race 3, biovar 2, to Australia on May 17, 2004. This is a bacterial plant pathogen that infects numerous plants, including tomatoes, eggplant, and peppers. It is also a major concern to the potato industry because the disease survives well in cold temperatures and renders potatoes unmarketable.[9] The entity had the required APHIS permits for transportation to the port of departure. However, at that time there were no DOC exporting requirements for the plant pathogen. On December 29, 2004, the plant pathogen was added to the CCL. We contacted the entity on February 1, 2005 to determine whether they were aware that the agent had been added to the list. The entity officials were not aware of the addition to the CCL, and said that neither APHIS nor DOC had provided any information concerning the update to the list. The entity had not exported any of the pathogen since December 29, 2004.

We concluded that even though APHIS has no regulatory authority regarding exports, the agency could help their registered entities ensure compliance with all requirements concerning movements of dangerous biological agents by working with DOC/BIS to keep the entities up-to-date on export licensing requirements. This would help accomplish goals of both the Agricultural Bioterrorism Protection Act of 2002 and the President's National Strategy to

[6] APHIS regulations (7 Code of Federal Regulations (CFR) 331.5 and 9 CFR 121.6) require that registered entities appoint a RO who is responsible for ensuring compliance with the regulations concerning APHIS listed agents or toxins.
[7] The vaccine strain does not require a license, but a license is required for the virus.
[8] Background data taken from APHIS' Factsheet, entitled "Highly Pathogenic Avian Influenza," issued March 2004.
[9] Background data taken from APHIS' Factsheet, entitled "Detection of Ralstonia solanacearum race 3, biovar 2 in the United States," issued March 2003.

Combat Weapons of Mass Destruction by ensuring controls are followed to keep dangerous biological materials out of the hands of terrorists. Therefore, we are recommending that APHIS work with DOC/BIS to disseminate up-to-date information to entities registered with APHIS.

Of the 54 agents or toxins on APHIS' list (23 animal pathogens, 21 overlap pathogens, and 10 plant pathogens), 16 are not on the CCL (7 animal pathogens, 1 overlap pathogens, and 8 plant pathogens). Based on discussions with APHIS officials in October 2004, DOC officials decided to take action to put the remaining 16 animal and plant pathogens onto the CCL. However, APHIS has not established a protocol to coordinate future additions/deletions to the CCL with DOC. In addition to the initial list of biological agents or toxins posing a severe risk to animal or plants, published by APHIS on August 12, 2002, the Agricultural Bioterrorism Protection Act of 2002 requires that the list be reviewed biennially, or more often if needed, and revised. Because APHIS has been tasked with periodically reviewing and updating the list of agents or toxins posing a severe threat to animal or plant health, or animal or plant products, we are recommending that the agency notify DOC/BIS of any changes to the list and discuss the potential need to also update the CCL.

RECOMMENDATION 1:

Work with DOC/BIS to disseminate, and keep current, CCL export requirements to registered entities to help ensure that all controls regarding movement of biological agents or toxins that pose a severe threat to animals and plants are followed.

AGENCY RESPONSE:

In its March 29, 2005 (see exhibit A), response, the agency stated:

> *APHIS will work with the * * * [DOC] and its * * * BIS to disseminate, and keep current, the * * * [CCL] export requirements to registered entities, to help ensure that all controls regarding movement of biological agents or toxins that pose a severe threat to animals and plants are followed. We will investigate adding a " * * * [DOC], BIS" hyperlink to our Select Agent Program website.*

OIG POSITION:

In order to reach management decision, please describe the process by which APHIS will coordinate with DOC to disseminate and keep current the CCL export requirements to registered entities, and the estimated timeframes for implementing the process.

RECOMMENDATION 2:

Notify DOC/BIS of changes to the list of agents or toxins posing a severe risk to animals or plants, and work with that agency to help determine whether the CCL should be updated based on APHIS changes.

AGENCY RESPONSE:

In its March 29, 2005 (see exhibit A), response, the agency stated:

> *APHIS will notify the * * * [DOC] and BIS of changes to the list of agents or toxins posing a severe risk to animals or plants. We will continue to work with the * * * [DOC] and BIS to determine whether the * * * [CCL] should be updated based on our periodical review and/or changes.*

OIG POSITION:

In order to reach management decision, please provide information describing the process (e.g., memorandum of understanding or coordinating procedures) that will be established to coordinate with DOC regarding updates of APHIS' listed agents or toxins, and the estimated timeframes for implementing the process.

In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the corrective action taken or planned and the timeframes for implementation. Please note that the regulation requires management decision to be reached on the finding and recommendation within a maximum of 6 months from report issuance, and final action be taken within 1 year of management decision.

We appreciate the courtesies and cooperation extended to our staff during this review.

/S/
ROBERT W. YOUNG
Assistant Inspector General
for Audit

EXHIBIT A- AGENCY RESPONSE

USDA

MAR 29 2005

United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Washington, DC 20250

TO: Robert W. Young
Assistant Inspector General
for Audit

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

SUBJECT: APHIS' Response to OIG Report, "Review of Export Licensing Process for Animal and Plant Health Inspection Service Listed Agents or Toxins" (Report No. 33601-4-AT)

Thank you for the opportunity for the Animal and Plant Health Inspection Service (APHIS) to comment on the above report. As APHIS officials have stated, and as your report has identified, APHIS does not have regulatory authority regarding the exports of biological agents. Your report contained two recommendations for APHIS to undertake regarding the exports of biological agents.

In response to Recommendation #1, APHIS will work with the Department of Commerce and its Bureau of Industry and Security (BIS) to disseminate, and keep current, the Commerce Control List export requirements to registered entities, to help ensure that all controls regarding movement of biological agents or toxins that pose a severe threat to animals and plants are followed. We will investigate adding a "Department of Commerce, BIS" hyperlink to our Select Agent Program website.

In response to Recommendation #2, APHIS will notify the Department of Commerce and BIS of changes to the list of agents or toxins posing a severe risk to animals or plants. We will continue to work with the Department of Commerce and BIS to determine whether the Commerce Control List should be updated based on our periodical review and/or changes.

We appreciate the opportunity to respond to the findings and recommendations identified by this review. We will further continue a cooperative working environment with the Department of Commerce and its Bureau of Industry and Security to further ensure that the list of agents or toxins posing a severe threat to animal or plant health is minimized.

Informational copies of this report have been distributed to:

Administrator, APHIS (9)
ATTN: Agency Liaison Officer
Government Accountability Office (1)
Office of Management and Budget (1)
Office of the Chief Financial Officer (1)
Director, Planning and Accountability Division