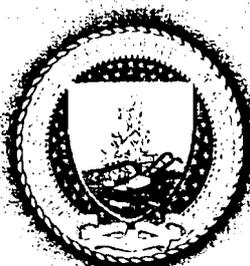
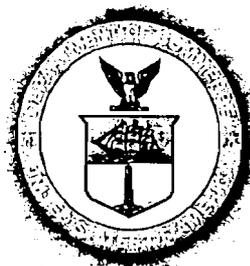


Interagency Review of the Export Licensing Process for Chemical and Biological Commodities

VOLUME I

June 2005



Prepared by the
Offices of Inspector General
of the
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Report No. D-2005-043

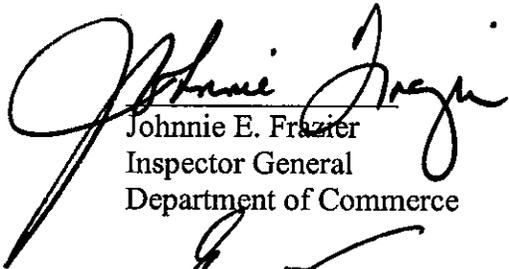
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PREFACE

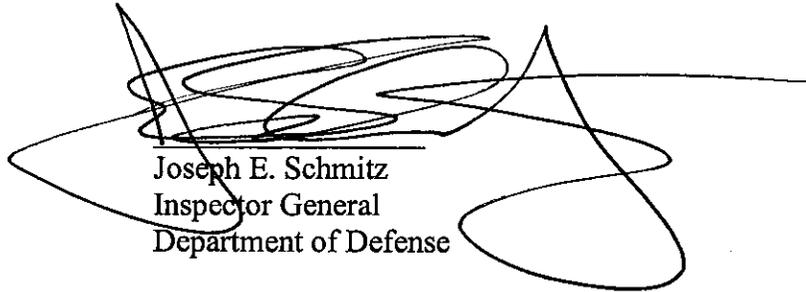
We are providing this interagency report for information and use. This review was conducted as a cooperative effort by the Offices of Inspector General of the Departments of Agriculture, Commerce, Defense, Energy, Homeland Security, and State, and the Central Intelligence Agency in response to Public Law 106-65, "National Defense Authorization Act for FY 2000," section 1402. The Act requires that the Offices of Inspector General provide an annual report to Congress through 2007 on the transfer of militarily sensitive technology to countries and entities of concern. Our report this year focuses on the export licensing process for chemical and biological commodities.

This report addresses issues that impact more than one agency and includes separate appendixes containing the agency-specific reports. The report is in two volumes. Volume I contains the interagency findings and the agency-specific reports issued by the Departments of Commerce, Defense, Energy, State, and Agriculture. Volume II contains the agency-specific report issued by the Department of Homeland Security and a followup report on recommendations in previous years' Offices of Inspector General reports issued under Public Law 106-65. The Central Intelligence Agency report is classified (SECRET//NOFORN); therefore, it is not included as an appendix in this report. The Central Intelligence Agency Office of Inspector General provided unclassified information which was included in the interagency report. There are no interagency recommendations in this year's report; therefore, management comments on the interagency report are not required. However, management comments on agency-specific draft reports were requested from the appropriate officials and, when provided, were considered in the preparation of this report. Management comments provided in response to individual agency reports are included in those reports.

This interagency report is required by Congress and will support Congress and the Administration in shaping the future of Federal export licensing policies and procedures related to the license process for chemical and biological commodities.



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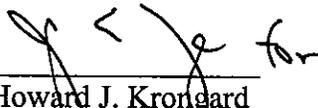
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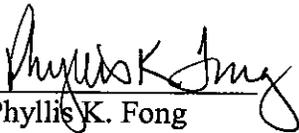
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Report No. D-2005-043

June 10, 2005

**Interagency Review of the Export Licensing Process for
Chemical and Biological Commodities**

Executive Summary

Introduction

Public Law 106-65, "National Defense Authorization Act for FY 2000," section 1402, requires the President to submit an annual report to Congress, each year through 2007, on the transfer of militarily sensitive technology to countries and entities of concern. The National Defense Authorization Act further requires that the Inspectors General of the Departments of Commerce, Defense, Energy, and State, in consultation with the Directors of Central Intelligence and the Federal Bureau of Investigation,¹ conduct an annual review of policies and procedures of the U.S. Government with respect to their adequacy in preventing the export of sensitive technology and technical information to countries and entities of concern. An amendment to section 1402(b), in section 1204 of the National Defense Authorization Act for FY 2001, further requires that the Inspectors General include in the annual report the status or disposition of recommendations set forth in previous annual reports issued under section 1402. This year, to comply with the fifth-year requirement of the Act, the Offices of Inspector General (OIGs) conducted an interagency review of the licensing process for chemical and biological commodities and reviewed the effectiveness of coordination between the various Federal agencies during the export licensing process for these commodities. Because the Department of Homeland Security is also responsible for enforcing Federal export laws, the OIG for that agency participated in this year's review. In addition, because the Departments of Agriculture and Health and Human Services² are also responsible for identifying and controlling chemical and biological agents, the OIGs for these agencies participated in this year's review.

Background

The United States controls the export of dual-use commodities and munitions for national security and foreign policy purposes under the authority of several laws, primarily the Export Administration Act of 1979³ and the Arms Export Control Act of 1976.

¹The Federal Bureau of Investigation does not play an active role in the licensing process for export-controlled technology and therefore did not participate in this interagency review.

²Although the Health and Human Services OIG participated in the interagency review, their agency specific review was not provided for inclusion in the interagency report, and thus that agency is not a signatory.

³Export Administration Act of 1979, as amended, sec. 3; 50 U.S.C. app. sec. 2402(2). Although the Act expired on August 20, 2001, Congress agreed to the President's request to extend existing export regulations under Executive Order 13222, dated August 17, 2001, thereby invoking emergency authority under the International Emergency Economic Powers Act.

Chemical and biological commodities are subject to the licensing requirements contained in the Export Administration Regulations (for dual-use commodities) or the International Traffic in Arms Regulations (for munitions). In FY 2003, 1,803 license applications were submitted to Commerce and 717 license applications were submitted to State for chemical and biological commodities.

Objectives

Our overall objective was to assess whether the current export licensing process can help deter the proliferation of chemical and biological commodities. Specifically, we examined whether current licensing and enforcement practices and procedures were consistent with relevant laws and regulations, as well as established national security and foreign policy objectives, such as those set forth in the Presidential National Strategy to Combat Weapons of Mass Destruction, December 2002. In addition, we assessed the effectiveness of coordination between the various Federal agencies during the export licensing process for these commodities.

Review Results

The interagency review identified four areas covered in this report. Specifically, the report focuses on the review of export licenses and enforcement, export issues for registered entities, updates to the Commerce Control List, and Australia Group denials.

Review of Export Licenses and Enforcement. Although the export license application review process was generally found to be adequate, Commerce OIG, Energy OIG, and Central Intelligence Agency OIG identified areas where improvements were possible. Specifically, Commerce OIG found that the timeliness of reviews could be improved, guidance should be consolidated, the operating committee needs to sustain improvements in timeliness, and that cumulative effect reviews should be performed. Energy OIG found that some Energy licensing officers were unable to access Commerce's export license application database to identify changes to applications. Although the Central Intelligence Agency OIG determined that the timeliness of munitions license application reviews could be improved, the Central Intelligence Agency OIG found that changes to internal administrative procedures resulted in timelier support in the second half of FY 2003. Defense OIG found that the processes used to review export license applications were effective, and State OIG found that the State export licensing process was working as intended. Finally, Homeland Security OIG found that U.S. Customs and Border Protection personnel did not consistently enforce Federal export licensing laws and regulations at all U.S. ports of exit.

Export Issues for Registered Entities. Commerce and Agriculture OIGs found that their agencies could improve the awareness of registered entities of regulations regarding the movement of dangerous biological agents or toxins. Commerce OIG reported that there were 318 entities registered with Animal and Plant Health Inspection Service and/or the Centers for Disease Control and Prevention to possess, use, and transfer the agents and toxins on the Select Agent List. The registered entities are an excellent group for Bureau of Industry and Security to reach and educate about export controls with minimal effort. Agriculture OIG found that researchers at registered entities were not always familiar with or did not always follow Commerce/Bureau of Industry and Security exporting requirements. Specifically, Agriculture OIG found that 1 of the 10 registered entities reviewed had exported a select agent also listed on the Commerce Control List without obtaining the required license from Commerce. In addition, another registered entity exported a biological agent that was subsequently added to the Commerce Control List. This entity was unaware of the export licensing requirement. Overall, the lack of

awareness of exporting regulations could expose the country to potential biological attacks by terrorists.

Update of the Commerce Control List. Commerce OIG found that Bureau of Industry and Security, working with the other U.S. licensing agencies, is responsible for making changes to the Commerce Control List to add any newly controlled dual-use items resulting from changes to the Australia Group list of controlled chemical and biological commodities. The Australia Group is a multilateral regime dedicated to curbing the proliferation of chemical and biological weapons. Prior to 2004, Australia Group changes took, on average, 11 months to be incorporated in the Commerce Control List. However, the changes resulting from the June 2004 Australia Group plenary took just 6 months to implement. This improvement in timeliness of changes to the Commerce Control List should be maintained. Commerce OIG also determined that Bureau of Industry and Security is in the process of adding 25 items from the Animal and Plant Health Inspection Service and Centers for Disease Control and Prevention Select Agent List to the Commerce Control List. The intention is to first pursue multilateral controls for these items, through the Australia Group, and if not successful, pursue unilateral controls. Both Commerce and Defense OIGs believe items from the Animal and Plant Health Inspection Service and Centers for Disease Control and Prevention Select Agent List not currently listed on the Commerce Control List should be added through either multilateral or unilateral controls.

Australia Group Denials. Commerce OIG found a disagreement between Commerce and State regarding the Australia Group denial notification process. State is the lead U.S. representative to the Australia Group and is responsible for submitting license denials to the Australia Group so that potential proliferators cannot “shop around” for items from one country to another. The disagreement between the two agencies centers on three issues: (1) which denials are sent to the Australia Group, (2) the timing of submitting denials to the Australia Group, and (3) whether State should unilaterally rescind prior denials to the Australia Group. Commerce OIG found that the Australia Group policy on the reporting of denials is not explicit, which has led to the current disagreement.

Followup on Prior Interagency Reviews

As required by the National Defense Authorization Act for 2001, as amended, Appendix H (Volume II) provides the status of recommendations from previous years’ reports. Appendix H also discusses the status of interagency OIG recommendations from Report No. D-2002-074, “Interagency Review of Federal Automated Export Licensing Systems,” March 29, 2002, the only interagency report that included interagency recommendations.

Management Comments

There are no interagency recommendations in this year’s report; therefore, management comments on the interagency report are not required. The participating OIGs made specific recommendations relevant to their own agencies. Recommendations, management comments, and OIG responses are included in the separate reports each office issued, which are in Appendix B (Commerce), Appendix C (Defense), Appendix D (Energy), Appendix E (State), Appendix F (Agriculture), and Appendix G (Homeland Security). Appendixes B, C, D, E, and F are in Volume I. Appendixes G and H are in Volume II. The Central Intelligence Agency (CIA) OIG report is classified (SECRET//NOFORN) and, therefore, is not included as an appendix in this report. Please contact the CIA OIG Executive Officer at (703) 874-5368 to request a copy of the CIA report.

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Introduction

Public Law 106-65, “National Defense Authorization Act for FY 2000,” section 1402, “Annual Report on Transfers of Militarily Sensitive Technology to Countries and Entities of Concern,” October 5, 1999, requires that the President submit an annual report to Congress, from 2000 through 2007, on the transfer of militarily sensitive technology to countries and entities of concern. The National Defense Authorization Act further requires that the Inspectors General of the Departments of Commerce, Defense, Energy, and State, in consultation with the Directors of Central Intelligence and the Federal Bureau of Investigation, conduct an annual review of the policies and procedures of the U.S. Government with respect to their adequacy to prevent the illegal export of any sensitive technology and technical information to countries and entities of concern. An amendment to section 1402(b), in section 1204 of the National Defense Authorization Act for FY 2001, further requires that the OIGs include in the annual report the status or disposition of recommendations set forth in previous annual reports issued under section 1402.

To comply with the first-year requirement of the Act, the OIGs conducted agency-specific and interagency reviews of Federal agency compliance with the license requirements for the release of export-controlled technology to foreign nationals⁴ in the United States and U.S. Government efforts to protect against the illicit transfer of U.S. technology through select intelligence, counterintelligence, foreign investment reporting, and enforcement activities. In March 2000, two interagency reports were issued: Report No. D-2000-109, “Interagency Review of the Export Licensing Process for Foreign National Visitors,” and Report No. 00-OIR-05, “Interagency Inspectors General Assessment of Measures to Protect Against the Illicit Transfer of Sensitive Technology (U).”

To meet the second-year requirement of the Act, the OIGs conducted an interagency review to assess policies and procedures for developing, maintaining, and revising the Commerce Control List (CCL) and the U.S. Munitions List.⁵ The interagency report, D-2001-092, “Interagency Review of the CCL and the U.S. Munitions List,” was issued in March 2001. For the third-year requirement of the Act, the OIGs conducted an interagency review of the Federal automation programs that support the export licensing and enforcement process. That interagency report, D-2002-074, “Interagency Review of Federal Automated Export Licensing Systems,” was issued in March 2002.

For the fourth-year requirement of the Act, the OIGs conducted an interagency review of U.S. Government activities to enforce export controls and prevent or

⁴This report’s use of the term “foreign national” encompasses both foreign nationals and foreign persons, as defined by the Export Administration Regulations and the International Traffic in Arms Regulations. The Export Administration Regulations uses the term “foreign national” to refer to any person who is not a permanent resident of the United States or is not a protected individual as defined by the Immigration and Naturalization Act. The International Traffic in Arms Regulations defines a foreign person as “any natural person who is not a lawful permanent resident as defined by 8 U.S. Code 1101(a)(20) or who is not a protected individual as defined by 8 U.S.C. 1324b(a)(3).”

⁵That list includes those items, technologies, and services that are inherently military in character and could, if exported, jeopardize national security or foreign policy interests of the United States.

detect the illegal transfer of militarily sensitive technology to countries and entities of concern. That interagency report, Report No. D-2003-069, “Interagency Review of Federal Export Enforcement Efforts,” was issued in April 2003. For the fifth-year requirement of the Act, the OIGs conducted an interagency review of the release of export-controlled technology to foreign nationals at U.S. academic institutions,⁶ Federal contractors and other private companies, and research facilities.⁷ That interagency report, Report No. D-2004-062, “Interagency Review of Foreign National Access to Export-Controlled Technology in the United States,” was issued in April 2004.

This year, to comply with the sixth-year requirement of the Act, the OIGs conducted an interagency review to assess whether the current export licensing process can help deter the proliferation of chemical and biological commodities. Because the Department of Homeland Security is also responsible for enforcing Federal export laws, the OIG for that agency participated in this year’s review. In addition, because the Department of Agriculture is also responsible for identifying and controlling biological agents and toxins, the OIG for this agency participated in this year’s review.

Background

The United States controls the export of chemical and biological commodities and technologies for national security, foreign policy, antiterrorism, and nonproliferation reasons, under the authority of several laws. The primary legislative authority for controlling the export of goods and technologies that have both commercial and military applications (dual-use items) is the Export Administration Act of 1979,⁸ as amended (appendix 2401, title 50, United States Code). The export of Defense articles and services (munitions) is controlled under authority of the Arms Export Control Act of 1976 (section 2751, title 22, United States Code).

Commerce. Under the Export Administration Act, the Department of Commerce’s Bureau of Industry and Security (BIS) administers the Export Administration Regulations (EAR) by developing export control policies, issuing export licenses, and enforcing the laws and regulations for dual-use exports. BIS was established in 1987 as a separate regulatory agency within the Commerce Department to control dual-use exports. Prior to 1987, the agency was an operating component of Commerce’s International Trade Administration. In FY 2004, BIS had 371 employees and an appropriation of \$69 million.

⁶This report’s use of the term academic institutions includes both universities and other institutions of higher learning.

⁷This term encompasses Government-owned research facilities and Federally Funded Research and Development Centers.

⁸Export Administration Act of 1979, as amended, sec. 3; 50 U.S.C. app. sec. 2402(2). Although the Act expired on August 20, 2001, the Congress agreed to the President’s request to extend existing export regulations under Executive Order 13222, dated August 17, 2001, thereby invoking emergency authority under the International Emergency Economic Powers Act.

BIS has two principal operating units: Export Administration and Export Enforcement. Within Export Administration, two offices are responsible for processing export license applications—the Office of Nonproliferation and Treaty Compliance and the Office of National Security and Technology Transfer Controls. Under the Office of Nonproliferation and Treaty Compliance is the Chemical and Biological Controls Division, which processes export license applications pertaining to chemical and biological commodities, equipment, and software. The Commerce OIG review focused on the activities of the Chemical and Biological Controls Division, which generally handles license applications for items controlled on the CCL in 14 different commodity categories. Most of these items are also subject to controls emanating from the United States' membership in the Australia Group (AG), a multilateral assemblage of countries dedicated to curbing the proliferation of chemical and biological weapons.

Of the 12,296 export license applications BIS received during FY 2003, 1,803 were for chemical and biological commodities. Nearly all of these chemical and biological license applications were reviewed and processed by the Chemical and Biological Controls Division.

Defense. Although the Departments of Commerce and State are responsible for issuing export licenses, the Department of Defense reviews license applications and provides recommendations to those agencies for approval, approval with conditions, or denial of licenses involving dual-use and munitions commodities or technology. The Defense Technology Security Administration (DTSA) serves as the focal point for processing license applications and advises the Under Secretary of Defense for Policy on issues related to the transfer of sensitive technology and the export of dual-use items and munitions. DTSA also assists in developing export control policies and procedures that are necessary to protect U.S. national security interests.

Energy. Energy's Office of Export Control Policy and Cooperation reviews license applications and recommends approval, approval with conditions, or denial of licenses involving nuclear, chemical, biological, and missile dual-use and munitions commodities or technology referred to them by Commerce and State.

State. Under the Arms Export Control Act, State's Bureau of Political-Military Affairs, Directorate of Defense Trade Controls (PM/DDTC) administers the International Traffic in Arms Regulations (ITAR) by developing export control policies, registering companies and academic institutions to export munitions, issuing licenses and compliance provisions, and maintaining the U.S. Munitions List. Various offices within State review munitions export licenses and recommend approval, conditional approval, or disapproval of an applicant's license, including those related to the release of export-controlled technology to foreign nationals in the United States.

Homeland Security. As the enforcement arm at U.S. ports for both State and Commerce, Customs and Border Protection (CBP) does not accept or approve applications for the export of dual-use items or munitions that should be licensed. Instead, CBP is responsible for ensuring that licensable exports, in this case chemical and biological commodities, are processed in accordance with

applicable laws and regulations. CBP uses the Immigration and Customs Enforcement Exodus Command Center as a liaison with State and Commerce to answer questions that may arise as to whether a shipment is licensable and CBP Officers are directed to send any such questions to the Exodus Command Center for resolution.

Central Intelligence Agency. The CIA provides intelligence support to the Department of Commerce on dual-use license applications, and to the Department of State on munitions license applications. CIA analysts review comprehensive intelligence records to provide information to these agencies that will assist them in decisions to approve or deny licenses.

During FY 2003, BIS submitted license applications to the CIA Director of Central Intelligence Center for Weapons Intelligence, Nonproliferation, and Arms Control (WINPAC), some of which were for chemical and biological commodities and technologies. In addition to providing intelligence support to BIS, WINPAC analysts and experts are also actively involved in export licensing advisory and oversight groups.

In FY 2003, the Department of State's PM/DDTC submitted munitions license applications to the Director of Central Intelligence Counterterrorist Center for review.

Agriculture. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Title II, Subtitle B, 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. The Animal and Plant Health Inspection Service (APHIS) was delegated authority to administer the regulations for U.S. Department of Agriculture (USDA). The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 did not address exports. APHIS officials stated that they referred any export license issues to Commerce.

Objectives

Our overall objective was to assess whether the current export licensing process can help deter the proliferation of chemical and biological commodities. Specifically, we examined whether current licensing and enforcement practices and procedures were consistent with relevant laws and regulations, as well as established national security and foreign policy objectives, such as those set forth in the Presidential National Strategy to Combat Weapons of Mass Destruction, December 2002. In addition, we assessed the effectiveness of coordination between the various Federal agencies during the export licensing process for these commodities.

A. Review of Export Licenses and Enforcement

Although the export license application review process was generally found to be adequate, Commerce OIG, Energy OIG, and CIA OIG identified areas where improvements were possible. Specifically, Commerce OIG found that the timeliness of reviews could be improved, guidance for licensing officers should be consolidated, the operating committee needs to sustain improvements in timeliness, and that cumulative effect reviews should be performed. Energy OIG found that some Energy licensing officers were unable to access Commerce's export license application database. Although CIA OIG determined that the timeliness of munitions license application reviews could be improved, CIA OIG found that changes to internal administrative procedures resulted in timelier support in the second half of FY 2003. Defense OIG found that the processes used to review export license applications were effective, and State OIG found that the State export licensing process was working as intended. Finally, Homeland Security OIG found that CBP personnel did not consistently enforce Federal export licensing laws and regulations at all U.S. ports of exit.

Process and Timeliness of Export License Applications

Dual-Use Export Licensing Process. According to Executive Order 12981,⁹ BIS has 9 days to conduct its initial review and refer an application to the Departments of Defense, Energy,¹⁰ and State. Although the Executive Order does not specifically provide a time requirement for CIA review of referred licenses, BIS and CIA have agreed to aim for a 30-day turnaround for CIA input. To determine whether the applicable policies and procedures for each application have been followed, each BIS licensing officer (1) verifies the export control classification number (ECCN) the applicant obtained from the CCL;¹¹ (2) reviews the license requirements and license exceptions for that ECCN; (3) determines the reasonableness of the end use specified by the exporter; (4) documents the licensing history of the exporter, ultimate consignee, or end user(s); (5) documents the reason(s) for not referring a license application to the other agencies (if applicable); and (6) provides a written recommendation on whether to approve or deny the application.

⁹Executive Order 12981—*Administration of Export Controls*, December 5, 1995.

¹⁰Energy provided BIS with a delegation of authority to review chemical and biological export license applications on its behalf. That delegation of authority was rescinded April 15, 2003, after the agency added more licensing officers and decided it had the ability to review all chemical and biological license applications.

¹¹The CCL lists 487 ECCNs for commodities, software, and technology, 14 of which are numbers for chemical and biological commodities.

Under the Executive Order, referral agencies must provide a recommendation to approve or deny the license application to the Secretary of Commerce within 30 days of receipt of the referral and all related required information. To deny an application, the referral agency is required to cite both the statutory and regulatory basis for denial, consistent with the provisions of the Export Administration Act and the EAR. An agency that fails to provide a recommendation within 30 days is considered to be in agreement with the decision of the Secretary of Commerce.

License applications for chemical and biological commodities also undergo review by the Chemical and Biological Weapons Control Group, an interagency body also known as SHIELD.¹² At SHIELD meetings, which are chaired by the Department of State, member agencies review dual-use export license applications related to the possible proliferation of chemical or biological weapons with the goal of resolving differences between agencies and thereby precluding the need to escalate license applications into the formal dispute resolution process.

Commerce OIG took a sample of 90¹³ of the 1,803 chemical and biological license applications received in FY 2003 and compared them against BIS' guidance for reviewing and processing applications. Commerce OIG found that the licensing process is working reasonably well. For example, the average time to process a license application was 43.7 days, which is slightly higher than the 40-day BIS standard or internal goal for processing license applications. However, Commerce OIG noted that 26 of the 82¹⁴ applications had review times of 44 days or more. In addition, Commerce OIG found that Defense, State, and Energy all completed their review of license applications within the 30-day period allowed by the Executive Order, but CIA took more than 30 days to return 16 of the 53 cases referred to it in FY 2003. It should be noted, however, that the 30-day period specified for interagency review in Executive Order 12981 does not apply to the CIA.

Dual-Use Dispute Resolution Process. The interagency dispute resolution process for dual-use licenses provides Commerce, Defense, Energy, and State officials a meaningful opportunity to review and comment on applications. If there is disagreement on whether or not to approve a pending license application after the 30-day review period, the application is referred to a higher-level interagency working group called the Operating Committee (OC). Under Executive Order 12981, the OC has representatives from the Departments of Commerce, Defense, Energy, and State. Non-voting members of the OC include appropriate representatives of WINPAC and the Joint Chiefs of Staff. The OC meets weekly. The Secretary of Commerce appoints the OC Chair who considers the recommendations of the reviewing departments before making a decision.

¹²The SHIELD is made up of working-level representatives from State, Commerce (BIS), DOD, CIA, and Energy.

¹³Commerce OIG removed the one escalated application from the sample of 91 and reviewed it separately as part of its review of the 17 FY 2003 escalated chemical and biological license applications.

¹⁴Eight of 90 applications in Commerce OIG's sample were not included in the analysis. Six applications were returned without action to the exporter, one application was pending at the time of the sample selection, and one was incorrectly included in the sample and was not for a chemical or biological commodity.

The OC Chair has 14 calendar days to consider the positions of the agencies and render a decision. The OC Chair's decision does not have to be based on a majority vote.¹⁵ If any agency disagrees with the OC Chair's decision, it has 5 calendar days to appeal the decision to the Advisory Committee on Export Policy (ACEP).

The ACEP meets monthly and is chaired by the Commerce Assistant Secretary for Export Administration, and includes Assistant Secretary-level representatives from the Departments of Defense, Energy, and State. The ACEP also includes non-voting representatives from WINPAC and the Joint Chiefs of Staff. The ACEP decision is based on a majority vote.

Within 5 days of an ACEP decision, any dissenting department or agency may appeal the majority decision to the Export Administration Review Board. The Secretary of Commerce chairs the Export Administration Review Board, and its members include the Secretaries of Defense, Energy, and State. The Chairman of the Joint Chiefs of Staff and the Director of the CIA are non-voting members of the Export Administration Review Board. The Export Administration Review Board's decision is based on a majority vote. Finally, within 5 days of this decision, any dissenting agency may make a final appeal to the President.

Munitions Export Licensing Process. PM/DDTC is responsible for controlling the export and temporary import of Defense articles and Defense services covered by the U.S. Munitions List. PM/DDTC approval of a license application is required before the export of Defense articles or services. In FY 2003, State received 717 license applications for chemical and biological commodities. These commodities include such items as riot control masks, anthrax biological threat alert test strips, and instantaneous blast grenades.

When the PM/DDTC Compliance Division receives license applications, it screens the parties listed on the submission against a Watch List of persons and entities for eligibility to engage in U.S. Defense trade.

PM/DDTC reviews the license applications against a number of factors, including:

- applicant eligibility,
- foreign policy objectives,
- stated end-use and end-user,
- commodity,
- quantity,

¹⁵Per Executive Order 12981, as amended, one exception to this rule involves “. . . license applications concerning commercial communication satellites and hot-section technologies for the development, production, and overhaul of commercial aircraft engines. . .” For these applications, the OC Chair is to report the “majority vote decision of the OC” rather than his/her decision.

-
- national security interests,
 - regional stability,
 - human rights issues and concerns,
 - multilateral agreements and nonproliferation regimes, and
 - intelligence information.

Current guidelines call for initial action by the licensing officer within 10 days of receiving the case. These actions include Approval, Denial, Returned without Action, or Staffing (referral to other offices or agencies). PM/DDTC refers about 30 percent of the applications to other Department offices as well as other agencies for their comments and recommendations.

Munitions Dispute Resolution Process. Munitions license applications do not have a formal escalation process. The primary concern is to ensure national security. In Executive Order 11958, the President delegated the final decision-making authority for issuing munitions licenses to the State Department.

The following paragraphs describe each OIG's results for the review of its agency's processes and timeliness regarding chemical and biological export license applications.

Commerce Findings. Commerce OIG identified four issues that warrant BIS' attention and improvement:

- Commerce OIG reported that BIS took from 11 to 30 days after interagency approval to review 7 applications, or 8 percent of the sample of 90 applications, in FY 2003. However, Executive Order 12981 and the EAR do not explicitly set time requirements for the completion of license applications approved by the interagency group, but not escalated. The Executive Order and EAR only provide timeframes for escalated cases after the initial interagency referral process is completed. License processing times could potentially be improved if BIS set internal timeframes for closing out applications that do not need to be escalated to the interagency dispute resolution process. Commerce OIG recommended that BIS establish specific timeframes for reviewing and signing off on license applications after approval by the referral agencies.
- Guidance for licensing officers should be consolidated and readily accessible. Commerce OIG found that the guidance cited by licensing officers and BIS management was an assortment of memos and documents issued over an 11-year period, housed in different places within BIS, and not readily accessible to the licensing officers. In addition, the guidance routinely used by the licensing officers is not always detailed enough to provide specific steps for reviewing a license application. Commerce OIG recommended that BIS develop and maintain clear, consolidated, and up-to-date guidance, or an internal operations handbook, to strengthen current

license application review practices and help ensure that they are consistently applied.

- The SHIELD and OC are generally working well, but the OC needs to sustain recent improvements in application timeliness. Commerce OIG found that the SHIELD review helps ensure that the applications escalated for dispute resolution are the result of true disagreement between the agencies. Commerce OIG also found that the OC has improved its time to render decisions in recent years, but still rarely meets the 14-day requirement.¹⁶ In FY 2003, 17 chemical and biological export license applications, or approximately 1 percent of the 1,803 license applications submitted, were escalated to the OC for resolution. The average time for the 17 applications was 51 days in the OC, with 5 applications taking more than 100 days to adjudicate. Commerce OIG did not evaluate OC timeliness for escalated chemical and biological applications after FY 2003 (the period of our review), but timeliness has reportedly improved. For example, according to the BIS FY 2004 Annual Report, the average time to reach a decision on all escalated applications in FY 2004 was 22 days. In FY 2003, with 6 months under the former OC Chair and 6 months with interim chairs, this average was reportedly 45 days.¹⁷ In addition, Commerce OIG reported that all 17 escalated applications were ultimately approved by the OC Chair, and none of the agencies chose to appeal the OC Chair's decisions. Thus, the ACEP did not review any chemical and biological export license applications in FY 2003.
- Cumulative effect reviews are not being performed for chemical and biological export licenses. Cumulative effect reviews examine the impact of proposed exports when added to other past exports to countries and entities of concern. Commerce OIG found that BIS lacks the systems and resources to perform cumulative effect analyses of prior technology transfers made to the end users listed on chemical and biological license applications. In addition, BIS does not receive such assessments from other agencies, including the CIA, during the interagency export license application review process. Commerce OIG reiterated the recommendation from its 1999 report,¹⁸ that BIS work with the intelligence community, including the CIA, DoD, State, and Energy, to develop a method to analyze and track the cumulative effect of dual-use exports to specific countries and regions.

Defense Findings. Defense OIG found that the DoD had an effective process to review export license applications for chemical and biological items. DoD consistently reviewed and referred applications in a timely manner, provided positions on export license applications, and complied with applicable requirements. Despite the lack of a fully automated license application referral process at State or Commerce, DoD met statutory and internal review objectives.

¹⁶Executive Order 12981 states that the OC has 14 days to reach a decision once an application is escalated.

¹⁷Both averages include all escalated applications, not just chemical and biological applications.

¹⁸Commerce OIG Report No. IPE-11488, "Bureau of Export Administration: Improvements Are Needed to Meet the Export Licensing Requirements of the 21st Century," June 18, 1999.

DTSA follows statutorily required timelines¹⁹ for review of dual-use export license applications, which allow up to 30 days for review. DTSA receives dual-use license applications electronically through the Technology Protection System, but DTSA receives supporting data in hard copy by a courier service. A DTSA Tiger Team, composed of representatives from the Licensing, Technical, and Policy Divisions of DTSA, meets each morning to review a synopsis of dual-use license applications to determine which license applications should be referred to DoD Components. DTSA does not refer an application that the Tiger Team determines is standard or repetitive. For non-referred license applications, DTSA records its position through the Technology Protection System. If the application is not standard or repetitive, DTSA refers the application electronically to the appropriate DoD Components through the Technology Protection System and sends the supporting data in hard copy by a courier service. The DoD Components that DTSA might refer applications to are the Army, the Navy, and the Air Force (the Military Departments). DTSA gives the Military Departments 10 days to review the application. Once DTSA receives the Military Departments' comments, a DTSA licensing officer creates a final DoD position and enters it into the Technology Protection System.

Commerce referred 84 of the 91 dual-use export license applications in our sample to DTSA for comment. Commerce returned six of the remaining seven applications to the applicant without action because the applications were incomplete, and Commerce did not refer the seventh application to DoD because it was not considered to be a military item. DTSA met the statutory timeframe for the 84 applications it reviewed, and DTSA personnel stated that they had no outstanding concerns with Commerce's final positions.

DTSA has established informal, internal deadlines for the review of munitions export license applications. DTSA normally allows up to 31 days for DoD review and response to referred applications. DTSA either receives munitions license applications in hard copy by a courier or electronically through the U.S. Exports System from the State Department. Once DTSA receives a license application, they review the application and determine whether it is standard or repetitive and, therefore, does not need to be referred. When DTSA determines that a license application is standard or repetitive, DTSA provides the DoD position to State through U.S. Exports System. If the license application is not standard or repetitive, DTSA refers the application to the Military Departments. This step including the process of providing State the DoD position or referring the application to the Military Departments takes approximately 2 days. Hard copies of the applications and associated technical data are transferred for review by courier service. If the information is available in electronic form, it is also transferred for review through the U.S. Exports System. DTSA allows Military Departments 25 days to review an application and, if that deadline is not met, DTSA can approve a 14-day extension. At the conclusion of the 25 days, it takes DTSA approximately 2 days to create and post the draft DoD position for review and comment by the Military Departments. Military Departments then have

¹⁹Executive Order 12981 states that for dual-use export license applications, a Department or agency shall provide the Secretary of Commerce with a recommendation either to approve or deny the license application within 30 days of receipt of a referral and all required information.

approximately 2 days to dispute the draft position. If there are no comments received from the reviewers, DTSA posts the final DoD position to State.

State referred 57 of the 85 munitions license applications in our sample to DTSA. State did not refer the other 28 applications to DTSA because of the following reasons.

- Eighteen applications were for standard or repetitive items or State considered the technology level of the item to be widespread and not to pose a threat to the United States.
- Ten applications were incomplete and returned to the applicant without action.

DTSA generally met internal deadlines for reviewing the 57 referred munitions export license applications. DTSA took more than 31 days to review 4 of the 57 referred applications; however, we do not consider those instances to be excessive or to reveal an overall weakness with the review process for munitions license applications because they were reviewed in under 45 days, which is still within the allowable 14-day extension. DTSA personnel stated that, for the 57 referred applications, they had no outstanding concerns with State's final positions.

With regard to the dispute resolution process, Defense OIG found that DoD participated in the OC and felt its positions and concerns were considered appropriately. Defense OIG reviewed 18 dual-use export license applications that had been escalated to the OC for review during FY 2003. DTSA personnel stated that DoD had no outstanding issues with the OC or Commerce final positions on those items.

Energy Findings. Energy OIG found that Energy added additional licensing officers, which provided Energy the capability to begin conducting reviews of chemical and biological export license applications in April 2003. Following the events of September 11, 2001, Energy concluded that its "assets should be mobilized to deal with all forms of weapons of mass destruction...[including] chemical and biological weapons." Subsequently, the Energy budget was increased to allow for these additional reviews, and Energy officially requested that Commerce refer chemical and biological export license applications to Energy for review beginning April 15, 2003.

Energy OIG found that of a sample of 91 chemical and biological license applications received by Commerce in FY 2003, 36 were referred to Energy for review. (The remaining export license applications received by Commerce were either returned to the applicant without being referred by Commerce to other agencies for review or were originally submitted to Commerce prior to April 15, 2003, when Energy established its chemical and biological export license application review process.) Energy OIG determined that Energy replied to Commerce within the 30-day time frame on all 36 of the license applications referred to Energy for review.

Energy OIG also observed that some Energy licensing officers were unable to access Commerce's unclassified Export Control Automated Support System

(ECASS) export license application database. After Energy downloads referred application information from ECASS, the information is uploaded into Energy's classified Proliferation Information Network System. Because of classification concerns, there is no direct link between ECASS and the Proliferation Information Network System. Accordingly, changes to a case recorded in ECASS after the initial download of the case by Energy would not necessarily be known by Energy officials. Energy OIG learned that updated information on export license applications can be obtained by Energy personnel by either directly contacting Commerce officials or accessing ECASS again. Although an ECASS terminal is located at Energy headquarters, only one Energy licensing officer has password access to ECASS and no licensing officers have been trained in the use of the system. Energy OIG was told that Commerce officials have not responded to Energy's repeated requests for training and password assistance on ECASS. Energy OIG made two recommendations to management designed to enhance Energy's export control review process.

Finally, Energy OIG found that Energy has participated in the SHIELD licensing group since April 2003 and the OC since 1975. Energy OIG determined that for the period covered by our review, Energy participated in each of the SHIELD licensing group meetings, and coordinated with the other group members on all the chemical and biological license applications referred to Energy by Commerce. Energy OIG examined 18 license applications escalated to the OC for review during FY 2003. Energy OIG determined that Energy participated in each of the OC meetings concerning the 18 license applications in the sample; that Energy's votes were recorded; and that Energy coordinated with the other committee members on each of the 18 license applications reviewed by the OC.

CIA Findings. Although a review of a sample of chemical and biological license applications processed during FY 2003 indicated that WINPAC did not always provide BIS with timely intelligence support, WINPAC made administrative changes in its procedures which significantly improved the timeliness of its support in the second half of FY 2003. These administrative changes included tracking the status of license applications from the time they arrived at WINPAC to the time they were returned with intelligence support to BIS. The changes have improved the timeliness of WINPAC's license reviews and enabled WINPAC to keep pace with an increased number of export license applications received in FY 2004. BIS officials and the Chair of the SHIELD working group praised the quality of support received from WINPAC since FY 2003.

During and since FY 2003, some inconsistency existed in the intelligence support that the Director of Central Intelligence Counterterrorist Center was providing to PM/DDTC on munitions applications. The CIA OIG audit identified improvements that could be made, which have the potential of enhancing and improving intelligence support.

Enforcement of Export Licenses

Enforcement Process. Homeland Security's CBP operates at U.S. ports of exit and is responsible for enforcing export control laws and regulations at the ports of exit. However, the export licenses and the regulations that govern licensing and controlling exports are issued by State and Commerce. Homeland Security's U. S. Immigration and Customs Enforcement bureau is the liaison between CBP, State, and Commerce.

Actions that CBP may take to enforce export control laws and regulations are: reviewing hard copy and electronic license and shipment information, physically examining outbound cargo to verify compliance with license conditions and shipping documents filed by exporters, reviewing the Automated Targeting System/Anti-Terrorism and the Automated Export System (AES). Open Shipments Listing for alerts that a shipment may warrant a physical exam or document review, and targeting a shipment for physical exam or document review based on officer judgment.

Homeland Security Findings. Homeland Security OIG found that CBP did not consistently enforce federal export licensing laws and regulations at all U.S. ports of exit. CBP's ability to effectively and efficiently control exports licensed by State and Commerce is limited by inadequate information and staff resources.

Homeland Security OIG also found that CBP did not consistently document the location of State Licenses in its AES. Exporters physically lodge State licenses with CBP at the port where shipments are expected primarily to occur; however, exports may be made through any authorized U.S. port of exit. Such license information is necessary to determine whether an individual shipment is being made in compliance with the associated license conditions. When a port receives notification of an export to be shipped against a license lodged at another port, enforcement personnel must locate the port of lodging and verify the authenticity of the export information to the original license. However, CBP is not required to document the location of State licenses in the AES, which makes it difficult for enforcement personnel at the port of shipping to readily obtain license information. As a result, CBP's ability to enforce State licensed exports in a timely and efficient manner is reduced. Also, CBP needs to improve its enforcement of shipments that have been processed against Commerce licenses.

Homeland Security OIG recommended that the Commissioner of CBP evaluate the Outbound program, including information requirements, staffing needs, and consistency of enforcement practices, and make adjustments necessary to ensure that all of CBP's enforcement responsibilities are accomplished.

B. Export Issues for Registered Entities

Commerce and Agriculture OIGs found that each agency could improve the awareness of registered entities of regulations regarding the movement of dangerous biological agents or toxins. Commerce OIG reported that there were 318 entities registered with APHIS and/or the Centers for Disease Control and Prevention (CDC) to deal in the agents and toxins on the Select Agent List. Agriculture OIG found that researchers at registered entities were not always familiar with or did not always follow Commerce/BIS exporting requirements. Specifically, Agriculture OIG found that 1 of the 10 registered entities reviewed had exported a select agent also on the CCL without obtaining the required license from Commerce. In addition, another registered entity exported a biological agent that was subsequently added to the CCL. This entity was unaware of the export licensing requirement. Overall, the lack of awareness of exporting regulations could expose the country to potential biological attacks by terrorists.

Background

Commerce. A critical component of the BIS mission is outreach to the exporting community to build awareness and compliance with the EAR. BIS holds an annual Update Conference on Export Controls and Policy each October to educate exporters about new policy initiatives and to provide information on export controls through small group sessions that focus on a wide array of topics. BIS complements its Update Conference by providing numerous export control seminars around the country throughout the year. BIS often also targets outreach to specific business and technology sectors.

Agriculture. Even though the Public Health Security and Bioterrorism Preparedness and Response 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 Commerce/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 they are within the United States or being exported to other countries.

Improvements in Outreach to Registered Entities

Commerce Findings. Commerce OIG found that there is an opportunity for BIS to conduct focused outreach to registered entities. Specifically, the USDA's APHIS and the U.S. Department of Health and Human Services' CDC jointly

maintain a list of select agents and toxins that pose a severe threat to livestock, plants, and/or public health.²⁰

Commerce OIG reported that there are 318 entities registered with APHIS and/or CDC to possess, use, and transfer agents and toxins on the Select Agent List. Given both the overlap between the Select Agent List and the CCL, and the “ready made” list of users of select agents and toxins in the hands of APHIS and CDC, this is an excellent group for BIS to reach and educate with minimal effort. Commerce OIG recommended that BIS inform APHIS and CDC registered entities in writing of the need to comply with the EAR and how to apply for an export license if they plan to export controlled items.

Agriculture Findings. Agriculture OIG found that researchers at registered entities were not always familiar with or did not always follow Commerce/BIS exporting requirements. During Agriculture OIG site visits, they found that 1 of the 10 entities (a private research facility) exported Highly Pathogenic Avian Influenza to Hong Kong on two occasions without obtaining the required license from Commerce. Highly Pathogenic Avian Influenza was on both the APHIS Select Agent List and the CCL. The responsible official²¹ at the entity contacted APHIS personnel concerning export requirements prior to the shipments. APHIS personnel and the responsible official discussed both the vaccine strain (no license required) and the virus strain. The responsible official mistakenly concluded that there were no licensing requirements for Highly Pathogenic Avian Influenza. Any violation of either APHIS or Commerce/BIS regulations could expose the country to potential biological attacks by terrorists.

Additionally, Agriculture OIG found that a university exported a biological agent that was on the APHIS list, but not on the CCL, on May 17, 2004. However, the biological agent was added to the CCL effective December 29, 2004. Agriculture OIG contacted the entity on February 1, 2005, to determine whether it was aware that the agent had been added to the CCL. The entity officials were not aware of the addition to the CCL. The entity had not exported any of the pathogen since December 29, 2004.

Agriculture OIG concluded that even though APHIS has no regulatory authority regarding exports, the agency could help its registered entities ensure compliance with all requirements concerning movements of dangerous biological agents by working with Commerce/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 Combat Weapons of Mass Destruction by ensuring that controls are followed to keep dangerous biological materials out of the hands of terrorists. To accomplish this, Agriculture OIG recommended that APHIS work with Commerce/BIS to disseminate up-to-date information to entities registered with APHIS.

²⁰See http://www.aphis.usda.gov/programs/ag_selectagent/ag_bioterr_toxinslist.html for the Select Agent List.

²¹APHIS regulations (7 Code of Federal Regulations (CFR) 331.5 and 9 CFR 121.6) require that registered entities appoint a responsible official for ensuring compliance with the regulations concerning APHIS listed agents or toxins.

C. Updates to the Commerce Control List

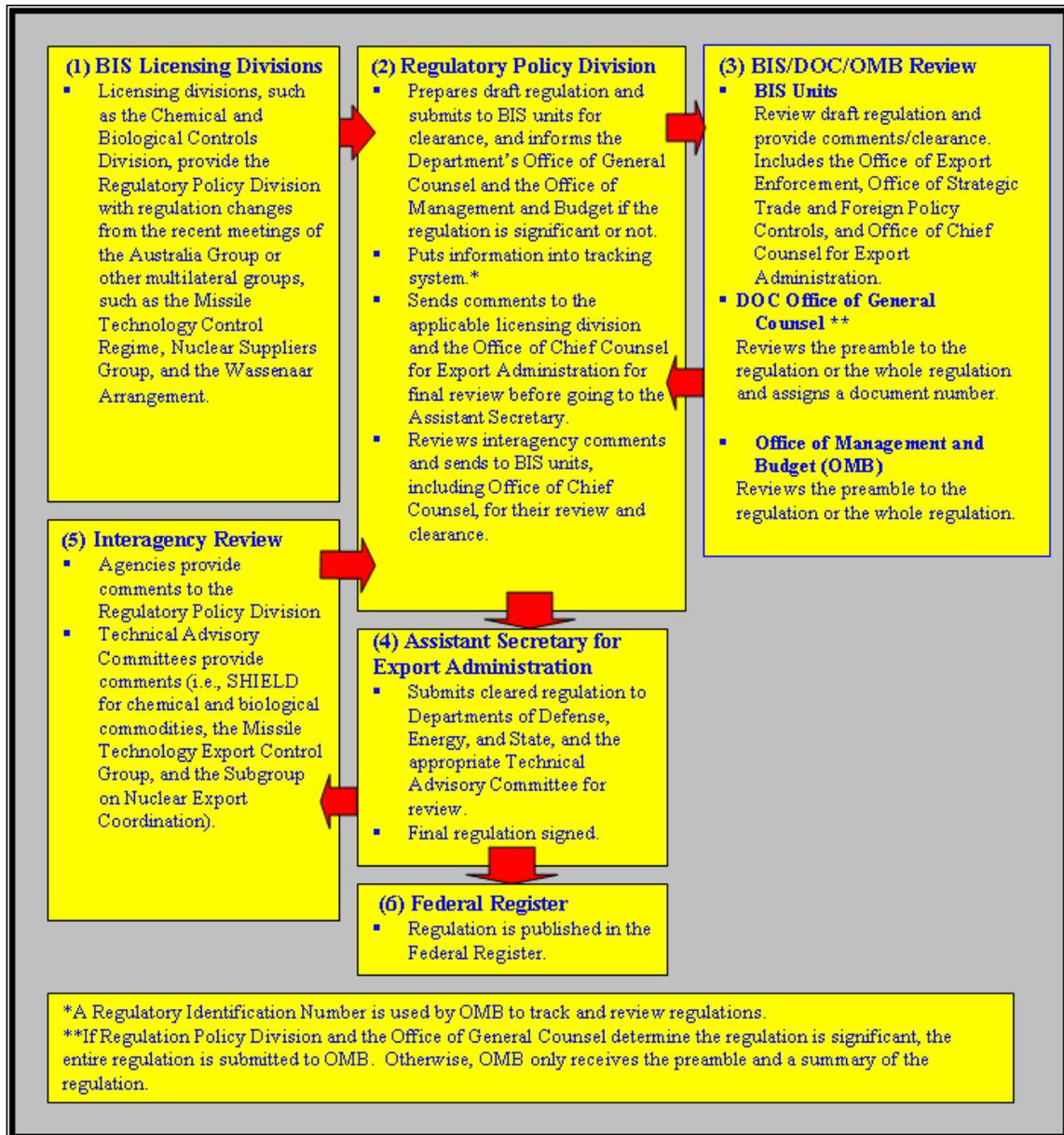
Commerce OIG found that BIS, working with the other U.S. licensing agencies, is responsible for making changes to the CCL to add any newly controlled dual-use items resulting from changes to the AG list of controlled chemical and biological commodities. Prior to 2004, AG changes took, on average, 11 months to be incorporated in the CCL. However, the changes resulting from the June 2004 AG plenary took just 6 months to implement, thereby reducing the overall average to 10 months. This improvement in timeliness of changes to the CCL should be maintained. Commerce OIG also determined that BIS is in the process of adding 25 items from the APHIS and CDC Select Agent List to the CCL. The intention is to first pursue multilateral controls for these items, through the AG, and if not successful, pursue unilateral controls. Defense OIG also reported that BIS is updating the CCL to add the remaining biological agents and toxins from the APHIS and CDC Select Agent List that are not currently controlled for export. Both the Commerce and Defense OIGs believe items from the APHIS and CDC Select Agent List not currently listed on the CCL should be added through either multilateral or unilateral controls.

Background

The AG, established in 1985, is a forum of industrialized countries that cooperates to try to prevent the proliferation of chemical and biological weapons, by coordinating export controls, exchanging information, and performing other diplomatic actions. Each year, after the annual meeting of the AG, U.S. licensing agencies meet to decide how to implement any new control changes. If a new control is added to the AG list, the United States must decide whether it wants to control the item as a dual-use or munitions item. The Department of Commerce is responsible for making changes on the CCL for dual-use items, and the Department of State is responsible for making changes on the U.S. Munitions List for munitions items. The process for making changes to the CCL is outlined in the figure on the next page.

The U.S. regulatory process to make changes to the CCL is more comprehensive than that of other AG members. In addition, the U.S. process requires multiple parties to approve changes before they can be published. All the licensing agencies participate in the AG annual sessions, so they are aware of control changes agreed to by the United States before BIS provides them with the draft regulations to review. But, the need for all agencies to be involved increases the amount of time it takes to get changes published. In addition, all comments and changes from the licensing agencies, Office of Management and Budget, or other BIS offices need to be incorporated by BIS' Regulatory Policy Division and again reviewed by BIS' Chemical and Biological Controls Division and the Office of Chief Counsel before the changes can be published.

BIS Process for Changes to the Commerce Control List



Source: Commerce OIG, based on information from BIS' Regulatory

Updates to the CCL Need to be Made More Quickly

Commerce Findings. After the AG annually recommends new chemical and biological items for control, Commerce OIG found that it takes just over 10 months²² for BIS and the other U.S. licensing agencies to place newly regulated items on the CCL. On three occasions in the last 7 years, the U.S. government failed to publish new AG regulations before the next annual AG meeting (1999, 2000, and 2003). Delays in publishing the latest AG guidelines could cause problems for the U.S. government. In an October 2002 report, the Government Accountability Office²³ recommended agreed-upon changes to control lists should be adopted by all AG members at the same time. If not, the Government Accountability Office said that proliferators could exploit time lags to obtain sensitive technologies by focusing on AG members slowest to incorporate the changes.²⁴ Until an item is actually listed on the CCL, BIS cannot (1) reveal to exporters that it may soon be controlled and (2) stop items from being exported.

Commerce OIG found that BIS does sometimes attempt to legally stall the export of items in the “lag time” between being newly controlled by the AG and inclusion on the CCL. For example, BIS received an application in FY 2003 for a biological item that the AG had marked for control but was not yet listed on the CCL. The exporter submitted an application on February 6, 2003, but the item was not listed on the CCL until June 10, 2003. If BIS had not received the application, the item would have shipped because a license was not required.²⁵ Because the exporter applied for a license, BIS was able to assess the end-user and find negative information. The derogatory information on the end-user led BIS to place the application on Hold Without Action pending publication of the new AG rules in June 2003. The reviewing agencies ultimately rejected the application after the new regulations were published. Such occurrences are rare, though, and BIS officials are concerned about items that have been exported pending the publication of new regulations.

During its review, Commerce OIG found that BIS insisted that it had made all feasible changes to the process of publishing new AG regulations and that the time could not be further reduced. However, BIS managed to publish the latest round of changes in 2004 in only 6 months, which demonstrates that the time can be reduced. BIS told Commerce OIG that it only took 6 months because it needed to quickly restore certain notes covering license requirements that had been inadvertently removed by a BIS rule on July 30, 2004.²⁶ The urgent need to

²²This is the average for the last 7 years; for the 6 years prior to the June 2004 annual AG meeting, the U.S. licensing agencies had taken an average of 11 months to publish the new AG regulations in the Federal Register.

²³The General Accounting Office was renamed the Government Accountability Office in July 2004.

²⁴The United States General Accounting Office, Report No. GAO-03-43, “Nonproliferation: Strategy Needed to Strengthen Multilateral Export Control Regimes,” October 2002.

²⁵According to BIS officials, exporters often file applications for items that are not controlled “just to be safe.”

²⁶BIS wanted to quickly restore these notes in the Federal Register because they contained critical guidance concerning the license requirements for ECCNs 1C355, 1C395, and 1C995. Only one of these ECCNs (1C395) is for chemical or biological commodities.

get these notes restored apparently motivated both BIS and the other agencies to move much more quickly than they usually do.

BIS says publishing changes from the April 2005 AG meeting in the CCL will depend on (1) how quickly BIS receives official notice of the changes; (2) the complexity of the changes; (3) whether there is an effort to add unrelated revisions to the rule; and (4) how quickly Commerce, Defense, and State resolve any comments on the rule. On this issue, Commerce OIG recommended that BIS take appropriate actions to sustain recent improvements in the timeliness of U.S. publication of AG guidelines and rule changes that impact the CCL.

Finally, Commerce OIG found that all but 25 of the items on the Select Agent List are also controlled under the EAR and are on the CCL. In October 2004, after discussions with CDC and APHIS officials, BIS decided to start the process to put the remaining 25 items from the Select Agent List onto the CCL. After interagency review and clearance of the proposal, State submitted the proposal for consideration at the April 2005 AG plenary. Commerce OIG recommended that BIS take appropriate action to pursue multilateral controls on the 25 items now on the Department of Health and Human Services (HHS)/APHIS select Agent List that are not currently controlled for export. If agreement cannot be reached multilaterally, Commerce OIG recommended that BIS evaluate putting the 25 items on the CCL unilaterally.

Defense Findings. DoD uses the CCL to determine which biological items of concern are export controlled and require the filing of an export license application. However, the CCL does not contain 20²⁷ biological agents and toxins identified on the HHS/APHIS Select Agent List that have the potential to pose a threat to animal, plant, and public health and safety. Commerce is currently considering whether the items contained in the HHS/APHIS Select Agent List should be export controlled. It is the opinion of Defense OIG that items listed on the HHS/APHIS Select Agent List should be periodically evaluated for inclusion in the CCL. The Defense OIG recommends that the Deputy Under Secretary of Defense (Technology Security Policy and Counterproliferation), together with the Department of Commerce, undertake an assessment of items on the HHS/APHIS Select Agent List as changes occur to those lists and determine whether any of the listed agents and toxins should be controlled for export purposes by inclusion on the CCL.

²⁷Subsequent information and analysis provided by Commerce OIG expanded the original 20 items identified by the Defense OIG to 25.

D. Australia Group Denials

Commerce OIG found that there is disagreement between Commerce and State regarding the AG denial notification process. State is the lead U.S. representative to the AG and is responsible for submitting license denials to the AG. The disagreement between the two agencies centers on three issues: (1) which denials are sent to the AG, (2) the timing of submitting denials to the AG, and (3) whether State should unilaterally rescind prior denial notices to the AG. Commerce OIG found that the AG policy on the reporting of denials is not explicit, which has led to the current disagreement.

Background

One of the obligations of the 39 AG members is the submittal of license denials to the group so that potential proliferators cannot “shop around” for items from one country to another. AG members have also adopted a “no undercut policy” in which members agree not to approve an identical sale without first consulting with the member that denied an export license. The Department of State, as the lead U.S. representative to the AG, is responsible for submitting license denials to the AG. Commerce OIG found that for various reasons, State is not currently submitting all denials to the AG, which means the AG no undercut policy is not always triggered. State’s rationale for not submitting all denials to the AG is not documented in any way, which leads to confusion.

Denial Notification to the Australia Group Needs To Be More Transparent

Commerce Findings. Commerce OIG reported that BIS believes three changes are necessary in State’s current denial notification process to make it more effective and transparent. First, BIS would like all denials sent to the AG to ensure that the no undercut policy is always triggered. The Department of State now subjectively determines which denials are submitted. Second, BIS believes that State should send denials to the AG at the time that BIS issues its “intent to deny” letter to applicants, rather than after the mandatory 45-day period during which BIS will consider any additional information provided by the exporter to rebut BIS’ decision to deny the application.²⁸ Finally, BIS believes that State should not unilaterally rescind prior denial notices to the AG. Unfortunately, the AG policy on the reporting of denials is not explicit, so State interprets the policy

²⁸According to 15 CFR 750.6, an applicant has 20 days after the date of the intent to deny letter to rebut BIS’ decision and provide additional information showing why the application should be approved. Unless BIS advises the applicant that the bureau has reversed its opinion, the denial becomes final 45 days after the date of the intent to deny letter. The applicant then has 45 days from the date of the final denial to appeal the decision, as outlined in Part 756 of the EAR.

one way and Commerce another, which has led to the current confusion and disagreement.

Commerce OIG recommended that BIS work with the State Department, and the other licensing referral agencies, to develop and implement written procedures for handling the AG denial notification process. The procedures should cover, at a minimum:

- The U.S. policy on submitting denials to the AG;
- When U.S. denial notifications will be sent to the AG—either when the intent to deny letter is sent or after the 45-day rebuttal period has lapsed; and
- How U.S. decisions to rescind prior denial notifications to the AG will be made. This should specify how State will exercise its representation authority and how the other licensing agencies will be involved in the decision making process.

Appendix A. Scope and Methodology

Interagency Scope

The review assessed whether the current export licensing process can help deter the proliferation of chemical and biological commodities. Specifically, we examined whether current licensing and enforcement practices and procedures were consistent with relevant laws and regulations, as well as established national security and foreign policy objectives, such as those set forth in the Presidential National Strategy to Combat Weapons of Mass Destruction, December 2002. In addition, we assessed the effectiveness of coordination between the various Federal agencies during the export licensing process for these commodities. The participating review teams were from Commerce, Defense, Energy, State, Homeland Security, Agriculture, and the Central Intelligence Agency OIGs.

Interagency Methodology

To coordinate the review issues related to the export licensing process for chemical and biological commodities and determine the work to be performed by each OIG team, the eight OIGs formed an interagency working group and held monthly meetings while conducting agency-specific reviews. The interagency working group collectively attended a briefing on the export licensing process for chemical and biological commodities hosted by BIS. The briefing also included presentations from State, Central Intelligence Agency, and Energy. Additionally, the group met with the Chair of the Chemical and Biological Weapons Control Group, an interagency body also known as SHIELD. The review was performed between August 2004 and March 2005.

This report summarizes the work completed by the seven interagency working group members. This report contains six of the individual OIG reports. The seventh report, the CIA OIG report, is classified (SECRET//NOFORN) and is not included as an appendix in this report.

Agency-Specific Methodology

Appendixes B through G contain the agency-specific OIG reports and the methodology used for each review. The information gathered and the analyses performed in developing those reports were used to produce the interagency report.

Commerce OIG Methodology. The Commerce OIG methodology included the following:

Commerce OIG evaluated three types of license applications submitted to BIS in FY 2003 to accomplish the review objectives: (1) a statistically valid sample of 90 regular chemical and biological applications (out of 1,803), (2) all 17 license applications escalated to the OC, and (3) the 25 denied license applications in FY 2003.

To determine the effectiveness of the current export license process and obtain their suggestions for improving the process, Commerce OIG spoke with senior BIS officials and personnel from the following groups: (1) Chemical and Biological Controls Division, (2) Regulatory Policy Division, (3) Office of Nonproliferation and Treaty Compliance, (4) Office of Enforcement Analysis, (5) Office of Exporter Services, and (6) the OC Chair. Commerce OIG also spoke with representatives of other organizations, including (1) the Chairman of the SHIELD at the Department of State about how chemical and biological applications are reviewed and (2) Department of Agriculture officials about chemical and biological items controlled by Agriculture but not listed on the CCL.

Commerce OIG evaluated specific literature during the review including (1) prior Government Accountability Office, Commerce OIG, and interagency OIG reports; (2) the BIS FY 2003 and 2004 Annual Reports; (3) the BIS FY 2003 Foreign Policy Report; (4) BIS procedures for processing license applications; and (5) relevant laws and regulations.

In addition, Commerce OIG followed up on recommendations from prior Commerce OIG reports related to the export licensing process and/or export controls for biological agents.²⁹ Commerce OIG conducted its review from August 12, 2004, through January 21, 2005. On March 9, 2005, Commerce OIG conducted an exit conference with the Acting Under Secretary for Industry and Security and other senior BIS officials to discuss the contents of the Commerce OIG agency specific report.

Defense OIG Methodology. Defense OIG met with DTSA personnel who reviewed export license applications referred by Commerce and State. In addition, Defense OIG met with the Shield chairman to gain an understanding of the Shield process for reviewing dual-use export license applications. Defense OIG also met with the Military Departments' export license application review offices to determine their processes for reviewing applications referred to them by DTSA.

Defense OIG reviewed applicable Executive Orders and Federal laws and regulations, including the Export Administration Act, the Arms Export Control Act, and the associated EAR and ITAR. In addition, Defense OIG evaluated the adequacy of DoD directives, policies, and regulations related to the disclosure and transfer of militarily sensitive and critical technologies to foreign entities from

²⁹Commerce OIG Report No. IRM-6686, "Bureau of Export Administration: Assessing the Effectiveness of Export Controls for Dual-Use Biological Agents," September 1995 and Commerce OIG Report No. IPE-11488, "Bureau of Export Administration: Improvements Are Needed to Meet the Export Licensing Requirements of the 21st Century," June 18, 1999.

1984 through 2004. Defense OIG reviewed those documents to determine DoD responsibilities in the export license application review process.

Defense OIG compared export-controlled items listed in the EAR and ITAR with chemical and biological items listed in multilateral agreements, such as the AG, Chemical Weapons Convention, Comprehensive Nuclear-Test-Ban Treaty, Missile Technology Control Regime, and the Wassenaar Agreement, to identify whether any of those items were not included in the EAR or ITAR. Additionally, Defense OIG compared the items on the USDA Biological Agent List and the HHS Select Agent List with the items controlled by the EAR and the ITAR to determine whether any of those items were not included in the EAR or ITAR.

Energy OIG Methodology. Energy OIG interviewed Federal and contractor Energy officials at Energy headquarters and at the Los Alamos National Laboratory, which operates the database used by Energy to process and review export license applications. Energy OIG reviewed Energy and Commerce documentation for a sample of 108 (original sample of 91 export license applications and 17 additional applications that were escalated to the OC) export license applications for chemical and biological commodities that were submitted to Commerce in FY 2003. This sample was selected by the OIGs interagency working group. Energy OIG also reviewed relevant export control regulations. Energy OIG evaluated Energy's implementation of the "Government Performance and Results Act of 1993" and did not identify any performance measure issues regarding the review of chemical and biological export license applications. Energy OIG followed up on the status of recommendations from prior Energy OIG reviews conducted under the requirements of the FY 2000 National Defense Authorization Act.

State OIG Methodology. State OIG compared the information contained in the applications against PM/DDTC's standard operating procedures for licensing requirements. State OIG reviewed a sample of the 717 license applications for chemical and biological commodities that PM/DDTC received during FY 2003. The State OIG sample identified 85 files randomly selected from the universe (717) of license applications. However, State OIG was unable to review 30 files contained in the sample because PM/DDTC had retired the files to an off-site location, which prevented their timely retrieval. As a result, State OIG reviewed 55 files, with a confidence level of 95 percent (plus or minus 5 percent).

The State OIG examination included a determination as to whether each export request in the files contained the required information necessary to make a licensing decision, including the following:

- license number and expiration date,
- organization requesting the license,
- export item (that is, pocket grenades),
- dollar value of the order,
- shipping company,

-
- destination of items,
 - application review by other bureaus and agencies, and
 - final disposition (that is, approved, denied, etc.).

State OIG interviewed PM/DDTC officials and consulted with OIG officials from the Departments of Commerce, Defense, Energy, Homeland Security, and the CIA. State's OIG Office of Audits, Program Reviews Division conducted this audit from August 2004 through January 2005 in the Washington, D.C. area. State OIG performed this work according to government auditing standards and included such tests and auditing procedures as were considered necessary under the circumstances.

Homeland Security OIG Methodology. Homeland Security OIG conducted an evaluation that:

- Reviewed and analyzed the Department of Homeland Security enforcement practices and its laws and regulations, policies and procedures applicable to the exportation of chemical and biological commodities.
- Assessed CBP and Immigration and Customs Enforcement efforts to coordinate and cooperate with other appropriate Federal agencies involved in export enforcement and licensing processes.
- Assessed CBP export screening efforts at ports of exit.
- Conducted interviews with responsible CBP and Immigration and Customs Enforcement officials and other personnel to determine whether they are compliant with applicable export control laws and regulations as well as their own directives.
- Selected exports for testing at Department of Homeland Security ports of exit to determine whether controls are implemented to enforce the requirements applicable to the export of chemical and biological commodities.

The Homeland Security OIG audit was conducted at locations in Washington, D.C., and at the Seaport of Baltimore, Dulles International Airport, Seaport of Philadelphia, Miami International Airport, Seaport of Beaufort-Morehead City, John F. Kennedy International Airport, Newark International Airport, and Denver International Airport from September 2004 through December 2004. Testing was performed using a statistical sample of Commerce and State license applications provided by the interagency group. To accomplish this review, Homeland Security OIG conducted fieldwork at selected port locations, collected export enforcement procedural information through a survey at the 311 CBP ports of exit; and interviewed officials and personnel at Department of Homeland Security bureaus of CBP, CIS, and Immigration and Customs Enforcement. Homeland Security OIG conducted followup reviews at the bureaus of CBP, CIS, and

Immigration and Customs Enforcement as appropriate on prior recommendations from one Department of Homeland Security and two Treasury reports.

CIA OIG Methodology. The CIA OIG audit focused on evaluating the processes CIA used to assist Federal agencies that are responsible for issuing licenses for exports of chemical and biological commodities. The audit also assessed the exchange of information between CIA and Federal licensing agencies from FY 2003 to the present. To accomplish the audit objectives, the CIA OIG performed the following tasks:

- Interviewed WINPAC and Director of Central Intelligence Counterterrorist Center managers who were responsible in FY 2003 for providing BIS and PM/DDTC, respectively, with intelligence support on license applications.
- Evaluated how WINPAC and Counterterrorist Center analysts communicated with BIS and PM/DDTC, and identified the sources of information used to respond to requests to review export license applications.
- Reviewed applicable laws and regulations, as well as memoranda of understanding between the CIA and other Federal agencies.
- Reviewed a sample of FY 2003 chemical and biological license applications referred to WINPAC by BIS.
- Evaluated the quality and timeliness of intelligence support that CIA provided to Federal licensing agencies.

Agriculture OIG Methodology. Agriculture OIG performed this review as part of an audit of the APHIS Implementation of the Listed Agents or Toxin Regulations – Phase II (Audit No. 33601-3-AT). The work was performed 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.

Agriculture OIG 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 the Department of Commerce when considering which biological agents or toxins to include on the select agent list.

At each of the 10 selected entities, Agriculture OIG 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 the Department of Commerce/BIS to export such biological agents on the CCL (if not, Agriculture OIG determined the reason for not obtaining the license); (3) received guidance concerning biological exports from APHIS, the 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, Agriculture OIG determined whether the entities had the required APHIS permits).

Appendix B. Department of Commerce Report



*U.S. DEPARTMENT OF COMMERCE
Office of Inspector General*



BUREAU OF INDUSTRY AND SECURITY

*The Export Licensing Process for Chemical and
Biological Commodities is Generally Working
Well, But Some Issues Need Resolution*

Final Inspection Report No. IPE-16946—March 2005

PUBLIC RELEASE

Office of Inspections and Program Evaluations



UNITED STATES DEPARTMENT OF COMMERCE
The Inspector General
Washington, D.C. 20230

MAR 31 2005

MEMORANDUM FOR: Peter Lichtenbaum
Acting Under Secretary for Industry and Security

Mark Foulon
Deputy Under Secretary for Industry and Security

FROM: Johnnie E. Frazier

SUBJECT: Final Report: *The Export Licensing Process for Chemical and Biological Commodities is Generally Working Well, But Some Issues Need Resolution* (IPE-16946)

As a follow-up to our March 16, 2005, draft report, attached is a final copy of our sixth report as required by the National Defense Authorization Act for Fiscal Year 2000, as amended. As you know, the act mandates that we issue a report to the Congress on the policies and procedures of the U.S. government with respect to the export of technologies and technical information to countries and entities of concern by March 30 of each year through 2007. This year's report focuses on the export licensing process for chemical and biological commodities.

Our review indicates that the licensing process for chemical and biological commodities is working reasonably well. At the same time, we offer a number of specific recommendations, summarized on pages 48-49, that we believe will improve that process. We are pleased to note that BIS, in its written response to our draft report, indicated agreement with all of our recommendations. We request that you provide us with an action plan addressing the status of the recommendations in our report within 60 calendar days.

We want to thank you and other members of the BIS staff for your assistance and courtesies extended to us during our review. If you would like to discuss this report or the requested action plan, please call me at (202) 482-4661 or Jill Gross, Assistant Inspector General for Inspections and Program Evaluations, at (202) 482-2754.

Attachment



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EXECUTIVE SUMMARY

The Inspectors General of the Departments of Commerce, Defense, Energy, and State, in consultation with the Director of Central Intelligence and the Director of the Federal Bureau of Investigation, are required by the National Defense Authorization Act (NDAA) for Fiscal Year 2000 to conduct an 8-year assessment of the adequacy of current export controls and counterintelligence measures to prevent the acquisition of sensitive U.S. technology and technical information by countries and entities of concern. The NDAA mandates that the Inspectors General report to the Congress no later than March 30 of each year, until 2007.

The United States controls the export of sensitive goods and technologies for national security, foreign policy, antiterrorism, and nonproliferation reasons under the authority of several different laws. The primary legislative authority is the Export Administration Act of 1979, as amended.¹ Under the Act, the Commerce Department's Bureau of Industry and Security (BIS) administers the Export Administration Regulations (EAR) by developing export control policies, issuing export licenses, and enforcing the laws and regulations for dual-use exports.² The EAR contains the Commerce Control List (CCL), which identifies the specific dual-use items subject to control, and the conditions under which those items may be exported. Under Executive Order 12981, as amended, several other agencies—the departments of Defense, State, and Energy—have the authority to review all export license applications and render approval or denial opinions. The Central Intelligence Agency also provides intelligence related to the end-users listed on the license applications.

Of the 15,506 export license applications received by BIS in FY 2004, 2,801 were for chemical and biological commodities listed on the CCL. Most of these items are also subject to controls emanating from the United States' membership in the Australia Group (AG), a multilateral regime dedicated to curbing the proliferation of chemical and biological weapons. The United States is one of 38 member countries and the European Commission³ that make up the Australia Group, which was established in 1985. AG members have adopted controls on chemical weapons precursors; dual-use chemical manufacturing facilities and equipment; biological agents used against humans, animals, and plants; and dual-use biological equipment.

To comply with the NDAA's FY 2005 requirement, the Offices of Inspector General⁴ agreed to evaluate the U.S. export licensing process for chemical and biological commodities to determine whether current practices and procedures help deter the proliferation of chemical and biological weapons. Within Commerce, we specifically sought to evaluate BIS' licensing process for chemical and biological commodities to determine whether the process is timely, complies with statutory and regulatory requirements, and takes the cumulative effect of prior technology transfers to end users into consideration during the review of license applications. We also

¹ Although the Act last expired on August 20, 2001, the President extended existing export regulations under Executive Order 13222, dated August 17, 2001, invoking emergency authority under the International Emergency Economic Powers Act.

² Dual-use commodities are goods and technology determined to have both military and commercial uses.

³ The European Commission is the executive body of the European Union—consisting of 25 European countries—whose role is to propose legislation, administer and implement policies, enforce commission law, and negotiate international agreements relating to trade and cooperation.

⁴ This year's review also included the participation of the Offices of Inspector General from the Departments of Agriculture, Health and Human Services, and Homeland Security.

assessed whether data and information are properly shared between the various agencies involved in the export license review process and whether the dispute resolution process between the agencies works. Finally, we looked at BIS' interaction with the AG and its procedures for placing newly controlled items on the CCL. We did not evaluate the overall outcome of the licensing process and whether countries or entities were able to illegally acquire biological or chemical commodities by circumventing the licensing process altogether. Our specific observations are as follows:

Licensing Process for Chemical and Biological Commodities Generally Resulted in Timely Decisions in FY 2003, but Some Improvements Are Needed. We took a sample of 90 of the 1,803 chemical and biological license applications submitted in FY 2003 and compared them against BIS' guidance for reviewing and processing applications. We found that the licensing process is generally resulting in timely decisions. For example, the average time to process a license application was 43.7 days. This is slightly higher than the 40-day BIS standard or internal goal for processing license applications, but we noted that 26 of the 82 applications in our revised sample had review times of 44 days or more.⁵ In addition, Defense, State, and Energy all completed their review of license applications within the 30-day period allowed, but CIA took more than 30 days to return 17 of the 56 cases referred to it in FY 2003. It should be noted, however, that the 30-day period specified for interagency review in Executive Order 12981, as amended, does not apply to the CIA.

Further, license processing times could potentially be improved if BIS set internal timeframes for closing out applications that do not need to be escalated to the interagency dispute resolution process. While neither Executive Order 12981 nor the EAR explicitly set time requirements for the issuance of license applications following the conclusion of the interagency review process where there is no escalation, internal BIS processing timeframes could encourage more timely disposition of such license applications.

In addition to focusing on the timeliness of the licensing process, licensing officers need to follow appropriate policies and procedures in order to ensure proper analysis of export license applications. However, we found that the guidance BIS provides is an assortment of memos and documents issued over an 11-year period, and all are housed in different places within BIS, not readily accessible to the licensing officers. In addition, some of the guidance routinely used by BIS is not very clear. For example, licensing officers are directed to "characterize the end user" on a license application, but the guidance does not provide instruction on what should be included in such descriptions or how the licensing officer should acquire and use this information. BIS should develop and maintain updated, consolidated written guidance, or an internal operations handbook, to formalize current license application review practices. This guidance or handbook should be made accessible to all employees involved in the licensing process (see page 11).

Review of License Applications by the SHIELD Works Reasonably Well, But the Operating Committee Needs to Sustain Recent Improvements in Timeliness. License applications for chemical and biological commodities undergo an additional level of review by

⁵ 8 of the 90 license applications in our sample ultimately could not be included in our analysis for various reasons, as listed in Figure 5 on page 12.

the Chemical and Biological Weapons Control Group, an interagency body also known as SHIELD.⁶ At SHIELD meetings, the member agencies share viewpoints, intelligence information, and clarifications on statutory and regulatory authority to resolve differences on specific license applications. The SHIELD review helps ensure that the applications escalated for dispute resolution are the result of true disagreement between the agencies. Should SHIELD not resolve interagency differences, applications are normally escalated for dispute resolution. Executive Order 12981 states that the Operating Committee—the first of three possible levels of review or appeal in the dispute resolution process—has 14 days to reach a decision once an application is escalated. The Operating Committee has improved its time to render decisions in recent years, but still rarely meets the 14-day requirement. In FY 2003, the average number of days for the committee to reach a decision on chemical and biological license applications was 51. According to BIS, that number was reduced to 22 days for all license applications escalated to the OC in FY 2004. This improvement in the timeliness of OC decisions should be sustained (see page 21).

Cumulative Effect Reviews Are Not Being Performed for Chemical and Biological Export Licenses. Cumulative effect reviews examine the impact of proposed exports when added to other past exports to countries and entities of concern. Approval of a single export license may not result in a significant increase in strategic capability of a country or entity of concern, but approval of multiple licenses combined with diversion of strategic items from other countries, the provision of items not requiring a license, and/or legitimate shipments from foreign suppliers could substantially enhance a country's ability to build a weapon of mass destruction.

BIS may not have sufficient intelligence information to know other commodities acquired by end users, but it could track exports of items controlled by BIS. However, we found that BIS lacks the systems and resources to analyze the cumulative effect of prior technology transfers made to the end users listed on chemical and biological license applications. In addition, BIS does not receive such assessments from other agencies, including the CIA, during the interagency export license application review process. Congress has been concerned for many years that the interagency licensing community lacks an integrated mechanism to conduct cumulative effect analyses of U.S. technology transfers. To address this continuing concern, we reiterate the recommendation from our 1999 report,⁷ that BIS work with the intelligence community, including the CIA, Defense, Energy, and State, to develop a method to analyze and track the cumulative effect of dual-use exports to specific countries and regions. No action has been taken on that earlier recommendation (see page 25).

Recent Improvements in the Timeliness of Changes to the Commerce Control List Need to Be Maintained. The AG generally recommends new chemical and biological items for control on an annual basis. However, BIS, in cooperation with the other U.S. licensing agencies, takes many months to include these newly regulated items on the CCL. During the last 7 years, BIS has taken an average of 10 months to get newly regulated chemical and biological items published on the CCL. BIS and the other licensing agencies cannot disclose such items to U.S. companies and cannot prevent newly regulated items from being exported until the items are published on the CCL. Changes from the AG's June 2004 meeting were published on the CCL

⁶ The SHIELD is made up of working-level representatives from State, Commerce (BIS), DOD, CIA, and Energy.

⁷ U.S. Department of Commerce Office of Inspector General, *Bureau of Export Administration: Improvements Are Needed to Meet the Export Licensing Requirements of the 21st Century*, IPE-11488, June 18, 1999.

in just 6 months. We recommend that BIS take appropriate actions to sustain the recent improvements in the timeliness of U.S. publication of AG guidelines and rule changes that impact the CCL (see page 31).

Denial Notification to the Australia Group Needs to Be More Transparent. One of the obligations of AG membership is the submittal of license denials to the group so that potential proliferators cannot “shop around” for items from one country to another. AG members have also adopted a “no undercut policy” in which members agree not to approve an identical sale without first consulting with the member that first denied an export license. The Department of State, as the lead U.S. representative to the AG, is responsible for submitting license denials to the AG. For various reasons, State is not currently submitting all denials to the AG, which means the AG’s no undercut policy is not always triggered. For example, State only submits denials that involve exports to non-AG countries.

State’s rationale for this “policy” is not documented in any way, which leads to confusion. Since August 2002, Commerce and State have disagreed about the U.S. policy for submitting denials to the AG. Unfortunately, the AG’s policy on the reporting of denials is not detailed, so State interprets the policy one way and Commerce another. Commerce proposes three changes in State’s current practice: (1) send all denials to the AG to ensure that the no undercut policy is always triggered, (2) send the denials to the AG at the time that BIS issues its “intent to deny” letter rather than after the mandatory 45-day period during which BIS will consider any additional information provided by the exporter to rebut BIS’ decision to deny the application, and (3) do not unilaterally rescind prior denials sent to the AG. We recommend that BIS ask the State Department to seek a ruling from the AG Chair on which denials should be sent to the AG and based on the response, work with all the licensing referral agencies to develop and implement a written policy and procedures for handling the AG denial notification process (see page 37).

BIS Outreach Efforts are Mainly Targeted to the Biological Exporting Community and Could Be Expanded. Outreach to the exporting community is a critical component of BIS’ mission to build awareness of and compliance with export controls. BIS has a reasonably robust outreach program to the biological exporting community, but outreach specific to the chemical exporting community has been limited. The only recent outreach dedicated to the chemical exporting community was done by BIS enforcement agents after the September 11th terrorist attacks, when the agents were instructed to visit all chemical manufacturers within their respective regions to inform them of their responsibility to comply with the EAR. Given resource constraints, BIS should explore alternative ways to increase its outreach to the chemical community, such as setting up briefings in Washington, mailings, or piggybacking on outreach done in connection with the Chemical Weapons Convention compliance activities conducted by BIS’ Treaty Compliance Division. BIS should also seize opportunities to conduct outreach to the entities registered with the U.S. Department of Agriculture’s Animal and Plant Health Inspection Service (APHIS) and the U.S. Department of Health and Human Services’ Centers for Disease Control and Prevention (CDC). Registered entities work with select agents and toxins controlled by APHIS and CDC, many of which are also contained on the CCL (see page 42).

BIS’ Export Enforcement Office Needs to Act on the Treaty Compliance Division’s Investigative Referrals. The Treaty Compliance Division (TCD) is the BIS office that helps

ensure U.S. industry compliance with the Chemical Weapons Convention (CWC), among other international treaties. CWC, which took effect on April 29, 1997, affects companies involved in the production, processing, consumption, import, and export of a range of commercial chemicals and precursors. One of the CWC requirements imposed on industry is the submittal of end-use certificates, within 7 days of the date of export, that state the types and quantities of chemicals being exported, the intended end-use for the chemicals, and a certification that the chemicals will be used only for purposes not prohibited by the CWC. Between FY 2002 and 2004, TCD identified 13 instances where companies did not submit the end-use certificates to BIS, as required. TCD staff referred all of the cases of non-compliance to BIS' Office of Export Enforcement (OEE) for investigation and appropriate action. However, TCD told us at the start of our review that to date, no action had been taken against offenders, and it feared that some exporters have gotten the impression that BIS does not enforce the end-use certificate requirement.

We found that OEE had opened 9 investigations on the 12 cases of non-compliance referred by TCD.⁸ OEE had no record of one referral and the referral of two companies in FY 2003 was rolled into open investigations of the same two companies for the same infraction in FY 2002. After closely analyzing the investigations upon our request, OEE officials determined that three cases were closed and of those, two were closed prematurely and would be reopened. For the remaining six cases, no final action had been taken and the cases were still open. OEE should inform TCD of the outcome of investigations, and TCD should track its referrals to OEE so it can follow up if it has not received status reports on investigations after a specified period of time. This information is necessary to help show the other CWC member countries that the U.S. consistently enforces the treaty within its borders (see page 46).

On page 48, we offer specific recommendations to address our concerns.



In a March 30, 2005, written response to our draft report, the Acting Under Secretary for Industry and Security agreed with all our recommendations and provided us with specific comments on the text of the draft report to ensure its accuracy. Where appropriate, we have made changes to the report and recommendations in response to BIS' comments. In addition, we discuss pertinent aspects of the bureau's response after each recommendation in the report. We have asked BIS to provide an action plan, within 60 calendar days, addressing the status of its actions taken to implement the recommendations in our report. The complete response from BIS is included as an appendix to this report (see page 53).

⁸ The 13th referral—for a case of non-compliance in FY 2004—had just been made to OEE at the time of our review, thus OEE had not yet had time to open a case or take any action.

BACKGROUND

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 (EAA) of 1979, as amended.⁹

Under the Act, the Department of Commerce's Bureau of Industry and Security (BIS) administers the Export Administration Regulations (EAR) by developing export control policies, issuing export licenses, and enforcing the laws and regulations for dual-use exports. BIS was established in 1987 as a separate regulatory agency within the Commerce Department to control dual-use exports. Prior to 1987, the agency was an operating component of Commerce's International Trade Administration. In FY 2004, BIS had 371 employees and an appropriation of \$69 million.

BIS organizational structure

BIS has two principal operating units: Export Administration (EA) and Export Enforcement (EE). Within EA, there are two offices with responsibility for processing export license applications—the Office of Nonproliferation and Treaty Compliance and the Office of National Security and Technology Transfer Controls. Under the Office of Nonproliferation and Treaty Compliance is the Chemical and Biological Controls Division (CBCD), which processes export license applications pertaining to chemical and biological commodities, equipment, and software. Our review focused on the activities of CBCD, which generally handles license applications for items controlled on the Commerce Control List (CCL) in 14 different commodity categories. Most of these items are also subject to controls emanating from the United States' membership in the Australia Group (AG), a multilateral assemblage of countries dedicated to curbing the proliferation of chemical and biological weapons. A description of how the CCL is derived can be found on page 4.

The Australia Group

The AG, established in 1985, is a forum of industrialized countries that cooperate in trying to prevent the proliferation of chemical and biological weapons, by coordinating export controls, exchanging information, and performing other diplomatic actions (see Appendix B for list of member countries). The 39 AG members have adopted controls on chemical weapon precursors; dual-use chemical manufacturing facilities and equipment; biological agents used against humans, animals, and plants; and dual-use biological manufacturing facilities and equipment.

The AG operates by consensus, with members agreeing to develop or amend guidelines, procedures, and control lists. The group is not based on treaty obligations, so its members,

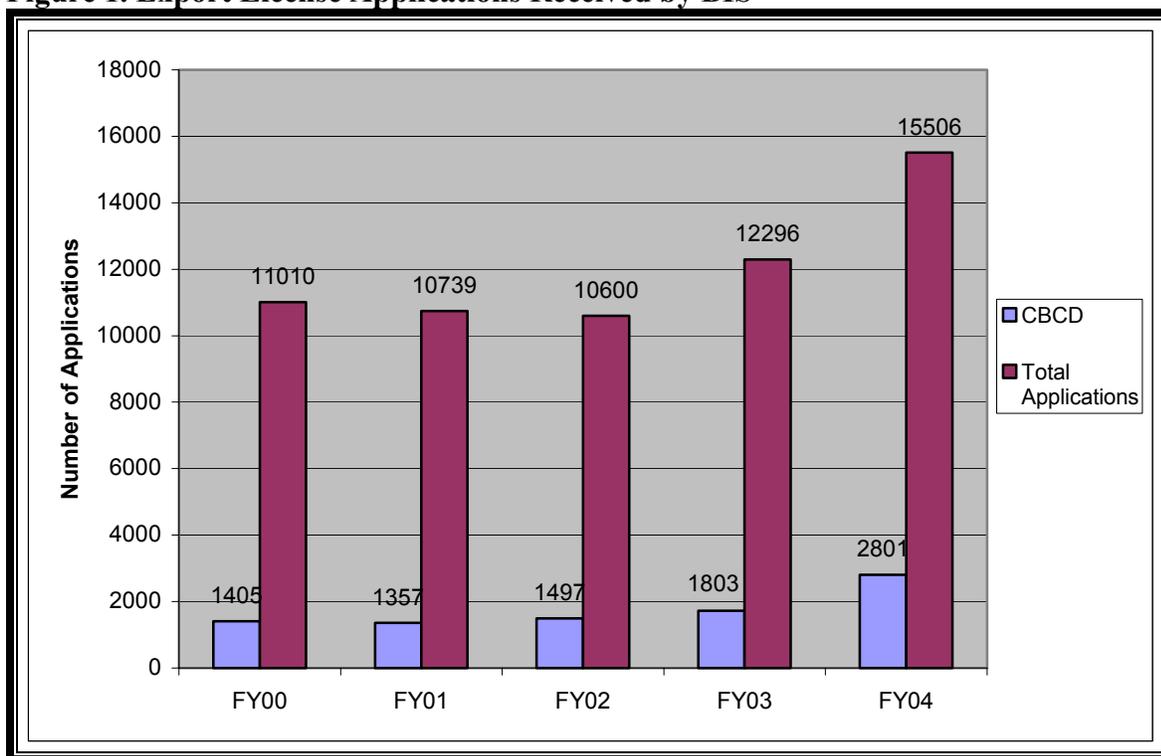
⁹ Export Administration Act of 1979, as amended, sec. 3; 50 U.S.C app. sec. 2402(2). Although the Act expired on August 20, 2001, the Congress agreed to the President's request to extend existing export regulations under Executive Order 13222, dated August 17, 2001, thereby invoking emergency authority under the International Emergency Economic Powers Act.

including the United States, are not bound by international law to abide by its guidelines. Instead, the AG operates under the principle of national discretion, with each member deciding how it will carry out membership obligations. One of the guidelines that members have agreed to is an AG denial notification procedure, whereby members notify the group when a license for a controlled item is denied. AG members have also agreed to a "No Undercut Policy," whereby members agree not to approve an identical export sale without first consulting with the member issuing the denial notification.

BIS export license application review process for chemical and biological commodities

During FY 2004, BIS received 2,801 chemical and biological export license applications, most of which were reviewed and processed by CBCD.¹⁰ Figure 1 (below) illustrates the total number of export license applications received by BIS from FY 2000 through 2004 and the subset processed by CBCD.

Figure 1. Export License Applications Received by BIS



Source: Bureau of Industry and Security

When BIS receives a license application, either manually or electronically, it is entered into the Export Control Automated Support System (ECASS).¹¹ ECASS screens all new applications to determine whether the listed parties have (1) registration numbers in ECASS or need numbers assigned and (2) any "flags" that require the application to be referred to the Office of Export

¹⁰ In FY 2003, a few chemical and biological export license applications were processed by another BIS licensing division. The vast majority, however, were processed by CBCD.

¹¹ ECASS is an unclassified system that processes and stores dual-use export licensing information for BIS headquarters and field offices, the Central Intelligence Agency, and the Departments of Defense, Energy, State, and the Treasury.

Enforcement (OEE).¹² Applications flagged by the system are simultaneously referred to OEE and the licensing officers (LOs) in EA. Unflagged applications are referred only to the LOs for processing.

According to Executive Order 12981,¹³ BIS has 9 days to conduct its initial review. During this review, the LO first verifies the export control classification number (ECCN) the applicant obtained from the CCL. The CCL lists 487 ECCNs for commodities, software, and technology, 14 of which are numbers for chemical and biological commodities (see Figure 2). Each ECCN contains a brief description of the item(s). Some items are subject to the EAR but not specified on the CCL. These are designated as "EAR99."¹⁴

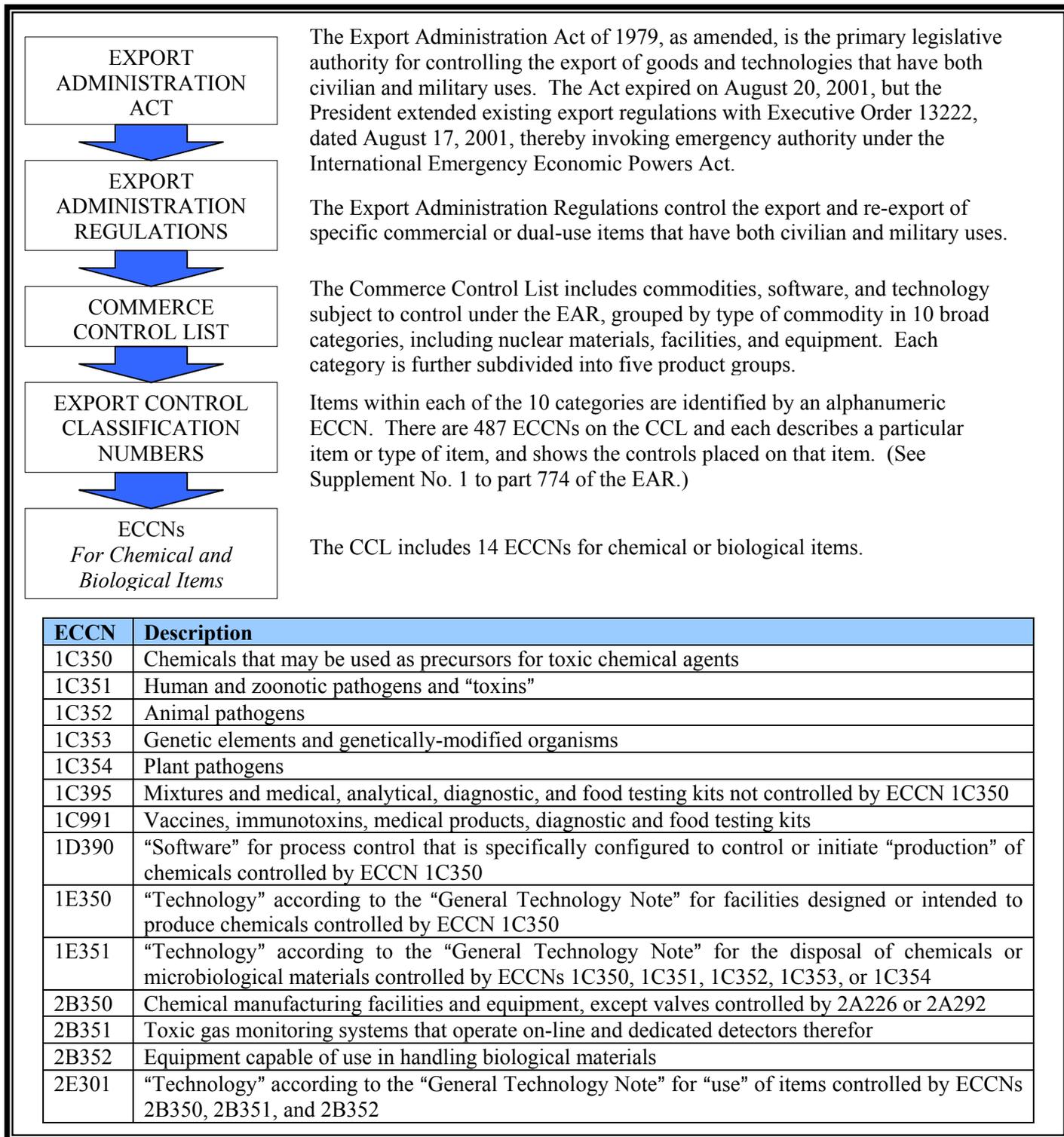
After verifying the ECCN, the LO reviews the license requirements and license exceptions for that ECCN. The LO then (1) determines the reasonableness of the end use specified by the exporter, (2) documents the licensing history of the exporter, (3) documents the licensing history of the ultimate consignee or end user(s), (4) documents the reason(s) for not referring a license application to the other agencies (if applicable), and (5) provides a written recommendation on whether to approve or deny the application. After the LO's review is completed, the application is referred to the Departments of Defense, Energy, and State. BIS also provides the Central Intelligence Agency with the application for review at the same time as the other agencies.

¹² Generally, applications referred to OEE are those involving parties on BIS' watchlist, as they have been identified as warranting increased scrutiny for export license purposes. OEE agents may also put flags on certain parties that they are interested in seeing, such as parties involved in an ongoing investigation.

¹³ Executive Order 12981, as amended—*Administration of Export Controls*, December 5, 1995.

¹⁴ Normally, a license is not required for an item classified as EAR99 unless certain prohibitions apply (e.g., export to an embargoed destination) or there is a concern about the end user or end use.

Figure 2. Export Control Classification Numbers for Chemical and Biological Items



Source: BIS and Office of Inspector General

Referral of export license applications to other agencies

The Export Administration Act of 1979, as amended, authorizes the Secretary of Commerce to issue rules and procedures for processing dual-use export license applications. The Act requires that a determination concerning an export license application be made by the Secretary of Commerce, without referral to any other government department or agency, to the maximum extent possible. However, in December 1995, in response to the need for more transparency in the dual-use export license process, the President issued Executive Order 12981. Specifically, it authorized the Departments of Defense, Energy, and State and the Arms Control and Disarmament Agency¹⁵ to each review any license application received by Commerce. In addition, Executive Order 12981 established mandatory escalation procedures to be followed, when the reviewing agencies disagreed about dual-use export license applications, and defined the time frames for this escalation process. (See Figure 3).

Currently, the Departments of Defense, Energy, and State review all export license applications except applications for which those departments have delegated decision authority to Commerce.¹⁶ BIS also sends all chemical and biological license applications to the Central Intelligence Agency's Weapons Intelligence, Nonproliferation, and Arms Control Center (WINPAC) for an end user review.¹⁷

Under the Executive Order, the referral agencies (Defense, Energy, and State) must provide a recommendation to approve or deny the license application to the Secretary of Commerce within 30 days of receipt of the referral and all related required information. To deny an application, the referral agency is required to cite both the statutory and regulatory basis for denial, consistent with the provisions of the EAA and the EAR. An agency that fails to provide a recommendation within 30 days is deemed to agree with the decision of the Secretary of Commerce.

Most export licenses are issued with conditions that require the exporter to abide by certain restrictions. The conditions are primarily used to control proliferation of the commodity by limiting the end use or restricting access to the commodity to specific end users. There are 55 standard conditions that BIS can place on an export license. When BIS refers the export license application to the other agencies, it attaches a list of recommended conditions for the agency to review. The referral agencies can also recommend additional conditions be placed on the export license before it is issued. If the reviewing agencies disagree on the license application, the application goes to the Operating Committee for resolution.

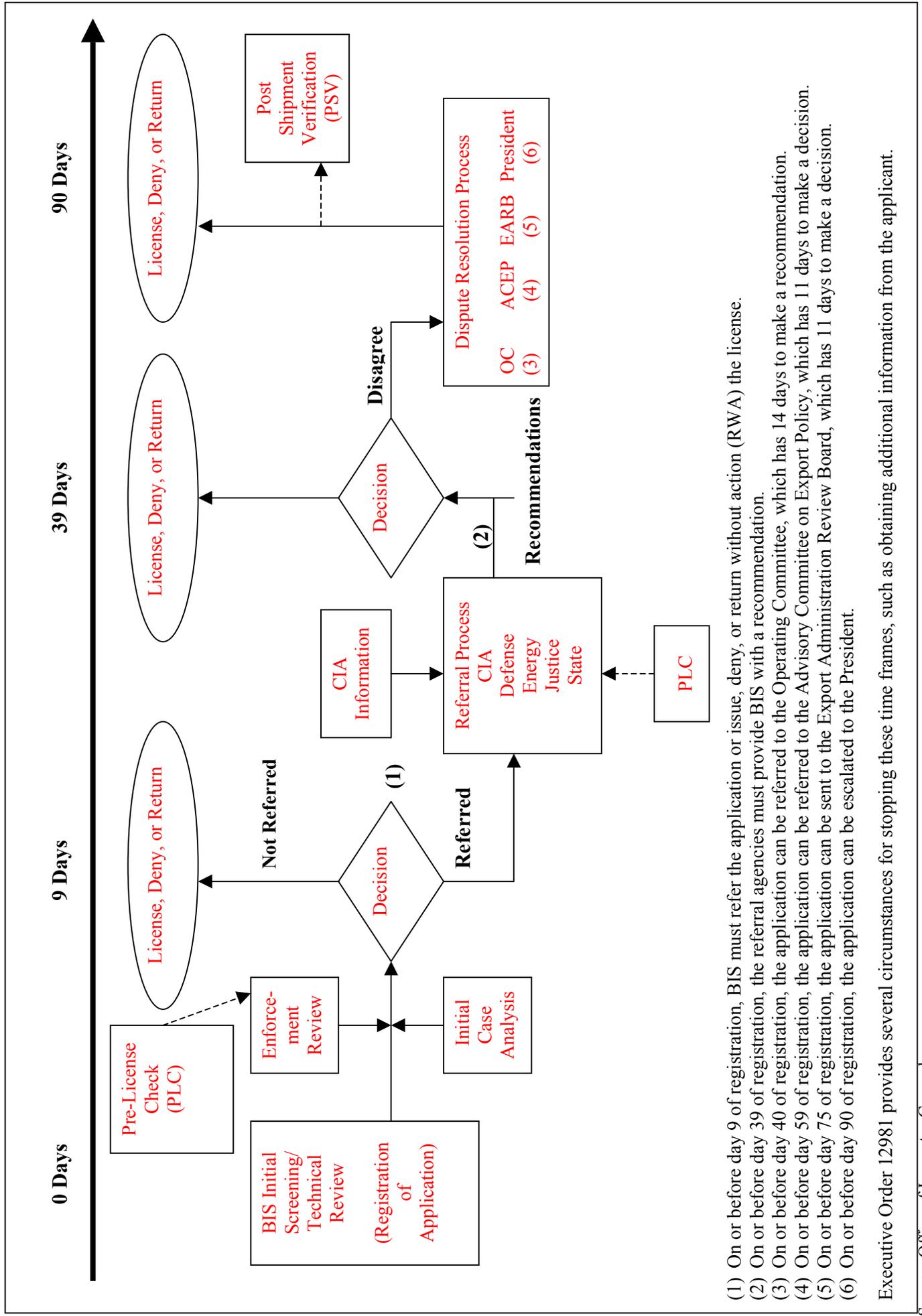
Before an application for a chemical and biological export license application is escalated, any of the reviewing agencies may choose to address a potential proliferation concern on a particular application by discussing the application at the SHIELD interagency working group, which is

¹⁵ The U.S. Arms Control and Disarmament Agency was dissolved on April 1, 1999. Its licensing review function was moved to the State Department.

¹⁶ Energy did not review chemical and biological export license applications until April 2003. It had previously provided BIS with a delegation of authority to review any such applications on its behalf. That delegation of authority was rescinded on April 15, 2003, after the agency added more LOs and decided it had the ability to review all chemical and biological license applications.

¹⁷ In FY 2003, WINPAC did not review all license applications, only those for which an intelligence report on the end user(s) had not been generated for a specific period of time.

Figure 3. Dual-Use Export Licensing Process



(1) On or before day 9 of registration, BIS must refer the application or issue, deny, or return without action (RWA) the license.

(2) On or before day 39 of registration, the referral agencies must provide BIS with a recommendation.

(3) On or before day 40 of registration, the application can be referred to the Operating Committee, which has 14 days to make a recommendation.

(4) On or before day 59 of registration, the application can be referred to the Advisory Committee on Export Policy, which has 11 days to make a decision.

(5) On or before day 75 of registration, the application can be sent to the Export Administration Review Board, which has 11 days to make a decision.

(6) On or before day 90 of registration, the application can be escalated to the President.

Executive Order 12981 provides several circumstances for stopping these time frames, such as obtaining additional information from the applicant.

chaired by the Department of State, and has working-level representatives from Commerce (BIS), DOD, CIA, and Energy.¹⁸ The SHIELD group reviews dual-use export license applications related to the possible proliferation of chemical or biological weapons with the goal of resolving differences between agencies and thereby precluding the need to escalate license applications into the formal dispute resolution process.

Dispute resolution process

If there is disagreement on whether or not to approve a pending license application after the 30-day review period, the application is referred to a higher-level interagency working group called the Operating Committee (OC). Under Executive Order 12981, the OC has representatives from the Departments of Commerce, Defense, Energy, and State. Non-voting members of the OC include appropriate representatives of WINPAC and the Joint Chiefs of Staff. The OC meets weekly. The Secretary of Commerce appoints the OC chairman who considers the recommendations of the reviewing departments before making a decision. The OC chair's decision does not have to be based on a majority vote.¹⁹

Within 5 days of the OC chair's decision, a reviewing department may appeal or escalate the decision to the Advisory Committee on Export Policy (ACEP). The ACEP meets monthly if there are applications to decide and is chaired by the Commerce Assistant Secretary for Export Administration, and includes Assistant Secretary-level representatives from the Departments of Defense, Energy, and State. The ACEP also includes non-voting representatives from WINPAC and the Joint Chiefs of Staff. The ACEP's decision is based on a majority vote.

Within 5 days of an ACEP decision, any dissenting department or agency may appeal the majority decision to the Export Administration Review Board (EARB). The Secretary of Commerce chairs the EARB, and its members include the Secretaries of Defense, Energy, and State. The Chairman of the Joint Chiefs of Staff and the Director of the Central Intelligence Agency are non-voting members of the EARB. The EARB's decision is based on a majority vote. Finally, within 5 days of this decision, any dissenting agency may make a final appeal to the President.

End use checks

End use checks are an important component of the export licensing process. They help determine if the end users or intermediary consignees are suitable to receive sensitive U.S. items and technology and will likely comply with appropriate end use conditions and retransfer restrictions. End use checks consist of pre-license checks (PLCs), which are conducted to obtain information about a foreign end user or intermediary consignee before the approval of a license application, and post shipment verifications (PSVs), which are conducted after goods have been shipped. PSVs help determine whether the licensed item or technology was received and is

¹⁸ SHIELD does not serve as an acronym for any phrase. The group uses all capital letters for its name, which is why it is presented as such in this report.

¹⁹ Per Executive Order 12981, as amended, one exception to this rule involves "...license applications concerning commercial communication satellites and hot-section technologies for the development, production, and overhaul of commercial aircraft engines. . ." For these applications, the chair of the OC is to report the "majority vote decision of the OC" rather than his/her decision.

being used appropriately by the party named on the license or shipper's export declaration (SED) or whether it was diverted to an unauthorized end user.

End-use checks (PLCs and PSVs) are conducted by BIS export control attachés (stationed in Hong Kong, Abu Dhabi, Beijing, Moscow, and New Delhi), by BIS special agents traveling in two-person Sentinel Teams,²⁰ or where these options are not available or not economical, by U.S. Commercial Service or State personnel stationed in the country where the end-use check is conducted. Any of the departments (Commerce, Defense, Energy, or State) authorized under Executive Order 12981, as amended, to make recommendations on export license applications can request an end-use check.

Chemical Weapons Convention and the Treaty Compliance Division

The U.S. is party to several international arms control, disarmament, and nonproliferation agreements, including the Chemical Weapons Convention (CWC), an international treaty that bans the development, production, stockpiling, or use of chemical weapons by its signatories and provides a verification regime to ensure compliance with its nonproliferation terms. The treaty affects companies involved in the production, processing, consumption, import, and/or export of a range of commercial chemicals and precursors. The CWC entered into force on April 29, 1997, and currently 167 countries are state parties to the convention. Of the 50 chemicals on the CCL that are subject to AG controls, 30 are CWC chemicals.

For these 30 chemicals, there are additional requirements placed on exporters to ensure compliance with the CWC. For example, in addition to obtaining an export license for a chemical, the CWC might also require the exporter to file an end-use certificate—a document provided by the country of destination stating what the chemical will be used for, who the end-user is, and certifying that it will be used only for purposes not prohibited by the CWC. The additional obligations on exporters, as required by the CWC, vary depending on the chemical and the country to which it is being exported. BIS' Treaty Compliance Division (TCD) is responsible for ensuring that U.S. industry is in compliance with the CWC. As such, TCD assists U.S. companies in (1) submitting annual declarations, end-use certificates, and other reports to both BIS and the Organization for the Prohibition of Chemical Weapons,²¹ (2) preparing for on-site inspections, and (3) making determinations on whether chemicals are subject to CWC reporting requirements.

TCD is also responsible for strengthening international cooperation with the Biological Weapons Convention (BWC), which prohibits developing, producing, stockpiling, or otherwise acquiring or retaining biological agents or toxins for non-peaceful purposes. The BWC entered into force in 1975 and 153 countries are state parties to the convention.

²⁰ Prior to late 2004, the BIS end use check program was called the Safeguard Verification Program.

²¹ The Organization for the Prohibition of Chemical Weapons is the international body created to implement the CWC.

OBJECTIVES, SCOPE, AND METHODOLOGY

The Inspectors General of the Departments of Commerce, Defense, Energy, and State, in consultation with the Director of Central Intelligence and the Director of the Federal Bureau of Investigation, are required by the National Defense Authorization Act (NDAA) for Fiscal Year 2000, to conduct eight annual assessments of the adequacy of current export controls and counterintelligence measures to protect against the acquisition of sensitive U.S. technology and technical information by countries and entities of concern.²² This is the sixth review under the NDAA requirement.²³ The Commerce Office of Inspector General (OIG) conducted this program evaluation in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency in 1993, and under authority of the Inspector General Act of 1978, as amended, and Department Organization Order 10-13, dated May 22, 1980, as amended.

Our objectives were to review the adequacy of BIS' export licensing process to determine whether it helps deter the proliferation of chemical and biological weapons and prevents the acquisition of sensitive U.S. technology or technical information by countries or entities of concern. We did not evaluate the overall outcome of the licensing process and whether countries or entities were able to illegally acquire biological or chemical commodities by circumventing the licensing process altogether.

Our scope included determining whether BIS (1) reviews license applications within regulatory timeframes; (2) properly submits license applications to the other licensing agencies; (3) adequately manages the interagency dispute resolution process; (4) processes each license application using information from PLCs and records of exporter compliance with prior license conditions, and analyzing the cumulative effect of proposed and prior chemical and biological technology transfers; (5) properly submits denied applications to the AG; (6) incorporates new AG regulations into the CCL in a timely manner; and (7) performs outreach about export controls for chemical and biological commodities to the exporting community. Our methodology included the following:

- **Statistical analysis.** We evaluated three types of license applications submitted to BIS in FY 2003 to accomplish the tasks listed above: (1) a statistically valid sample of 90 regular chemical and biological applications (out of 1,803), (2) all 17 license applications escalated to the OC, and (3) the 23 denied license applications in FY 2003.
- **Interviews.** To determine the effectiveness of the current export license process and obtain their suggestions for improving the process, we spoke with BIS personnel from the following groups: (1) Office of Nonproliferation and Treaty Compliance, including the Chemical and Biological Controls Division, (2) Regulatory Policy Division, (3) Office of Enforcement Analysis, (4) Office of Exporter Services, and (5) the Operating Committee Chair. We also spoke with representatives of other organizations, including (1) the Chairman of the SHIELD²⁴ at the Department of State about how chemical and

²² The Offices of Inspector General from the Departments of Agriculture, Health and Human Services, and Homeland Security also participated in this review.

²³ See Appendix C for a list of the reports resulting from the five previous reviews.

²⁴ The SHIELD is discussed on pages 5 and 21.

biological applications are reviewed and (2) Department of Agriculture officials about chemical and biological items controlled by Agriculture but not listed on the CCL.

- **Literature review.** We evaluated specific literature during our review including (1) prior Government Accountability Office (GAO), Commerce OIG, and interagency OIG reports, (2) the BIS FY 2003 and 2004 Annual Reports, (3) the BIS FY 2003 Foreign Policy Report, (4) BIS procedures for processing license applications, and (5) relevant laws and regulations.

In addition, we followed up on our recommendations from prior Commerce OIG reports related to the export licensing process and/or export controls for biological agents.²⁵

To coordinate the review of interagency issues and determine the work to be performed by each OIG team, the eight OIGs involved in this year's review formed an interagency working group and held monthly meetings during the review. The eight OIGs decided that each would issue a report on the findings of its agency review, and all eight would contribute to and approve a consolidated report on crosscutting issues. We conducted our review from August 12, 2004, through January 21, 2005. On March 9, 2005, we conducted an exit conference with the Acting Under Secretary for Industry and Security and other senior BIS officials to discuss the contents of this report.

²⁵ U.S. Department of Commerce Office of Inspector General, *Bureau of Export Administration: Assessing the Effectiveness of Export Controls for Dual-Use Biological Agents*, RM-6686, September 1995, and U.S. Department of Commerce Office of Inspector General, *Bureau of Export Administration: Improvements Are Needed to Meet the Export Licensing Requirements of the 21st Century*, IPE-11488, June 18, 1999.

OBSERVATIONS AND CONCLUSIONS

I. Licensing Process for Chemical and Biological Commodities Generally Resulted in Timely Decisions in FY 2003, but Some Improvements Are Needed

Proper analysis of individual export license applications is critical to ensure that appropriate export policies and procedures are followed. We looked at a sample of chemical and biological license applications submitted in FY 2003 and found that the licensing process is generally resulting in timely decisions. We found that while Executive Order 12981 and the EAR provide specific time limits for interagency processing and resolution of disputes involving dual use license applications, they do not explicitly address a time requirement for the completion of a license application that is approved by the interagency group and not escalated. At present, LOs have no time requirement—and could take up to the 90 days allowed under the Executive Order—for processing license applications once they are returned from interagency review. With no objection from the interagency group, the license application may be returned to BIS on the 40th day after registration of the completed license application, with no Executive Order required action for another 50 days.

Finally, license processing guidance should be consolidated and readily accessible to LOs. The guidance for reviewing export license applications cited by LOs and BIS management was an assortment of memos and documents issued over an 11-year period. This guidance is housed in different places within BIS and not readily accessible to the LOs. In addition, the guidance that is routinely used by BIS is not always detailed enough to provide specific steps for reviewing a license application. Clear, complete, and consolidated guidance is needed to formalize current license application review practices and ensure that they are consistently applied.

A. Review of FY 2003 license applications shows the licensing process is working reasonably well

Based on information received from BIS, 1,803 license applications were processed for chemical and biological commodities in FY 2003. We reviewed a statistical sample of 5 percent of those cases, or a total of 90 license applications. In addition, we requested information on the 17 escalated license applications referred to the OC in FY 2003 and the 23 denied applications in FY 2003 for a total of 130 license applications reviewed.

As shown in Figure 4, we divided the license applications into four categories: (1) “Vanilla”²⁶ when they appeared to be complete with few, if any, questions from the interagency group, (2) “Outliers”, a term we used to describe the applications that were returned without action, pending at the time of our sample selection, or incorrectly included in our sample, (3) “Escalated” when the applications were referred to the OC due to interagency disagreement, and (4) “Denied” when the applications were denied. The escalated applications are discussed in more detail in Chapter II of this report (see page 21). With regard to the denied applications, we determined that BIS and the other licensing agencies had appropriately denied the applications, in accordance with the criteria set forth in the EAR. Also, BIS was generally timely in its issuance of the final denial decisions after the applicants’ mandatory 45-day appeal period had

²⁶ Vanilla is a term used by BIS and the other licensing agencies to describe a straightforward license application.

concluded. We found no significant problems with the denied applications and, in fact, these applications indicate that the export licensing process for chemical and biological commodities is working as intended.

Figure 4. License Applications Reviewed

Type of application	Number of applications	Percent of total
Vanilla	82	63%
Outliers	8	6%
Escalated	17	13%
Denied	23	18%
Total	130	100%

Source: OIG

Figure 5 explains why the 8 outlier applications noted above were excluded from our analysis.

Figure 5. Outlier License Applications Excluded from Analysis

Description	Number	Reason
Returned without action (RWA) ²⁷	6	Average days to process 26; no data available for comparative purposes other than total days from BIS receipt to RWA issuance.
Pending	1	Application was in pending status at time of sample selection.
Handcuffs to Norway	1	Was not a chemical or biological commodity and was incorrectly included in the list of applications from which the sample was selected.
Total	8	

Source: OIG

Our in-depth analysis of the remaining 82 license applications identified some issues that require BIS' overall attention.

Analysis of license applications found most were processed in a timely manner

Our calculation of the total days to process a license application was based on information contained in the referral history section of BIS license applications. Total days were calculated from the date of receipt of the license application until the day reviewing staff completed final signoff. Total days were then adjusted for the number of days a license application was placed in hold without action (HWA) status, if any.²⁸ In our review of the 82 license applications, we

²⁷ RWA is used to return a license application to the applicant if the applicant has failed within 20 days to provide additional information that BIS has requested in order to process the application. RWA can also be used if (1) during initial evaluation of an application, an LO determines that a license is not required, (2) the applicant requests the application be returned, or (3) the items are not under Department of Commerce jurisdiction.

²⁸ License applications can be put on HWA when BIS is (1) waiting on information from an exporter, (2) at the direction of a division or office director, or (3) in accordance with Executive Order 12981.

found the average time to refer the application to the interagency group was 3.6 days with only one case taking longer than the 9-day requirement.

The average time to process these license applications from receipt to the completion of interagency review was 43.7 days. Although this average time was reasonably close to the 40-day BIS standard or internal goal for processing license applications, we found that 34 cases, or 41 percent, took longer than 40 days. Eight of those license applications took between 41 and 43 days to process. We did not assess these further since they were within 1-3 days of meeting the BIS standard or internal goal. However, Figure 6 provides a breakdown of the reasons for delay in the remaining 26 license applications (32 percent) with review times of 44 days or more.

Figure 6. Reasons for License Processing Times That Exceeded 44 Days²⁹

Reason for delay	Total license applications
Waiting for CIA information	13
Delayed in CBCD 11-34 days after interagency approval	7
Waiting for CIA and OEE information	3
Waiting for OEE information	3
Total	26

Source: OIG

Interagency and OEE processing of license applications is generally timely

In our review of the 82 license applications, we found that all interagency referrals to the departments of Defense, State, and Energy were returned to BIS within the 30-day requirement. It took 23.3 days on average for information on 56 cases referred to the CIA during FY 2003 to be returned to BIS. A total of 17 of those license applications sent to CIA, or 30 percent, took longer than the 30-day requirement.³⁰

In applications referred to OEE, the total days to receive OEE's comments averaged 10.3 days, although 14 applications, or 27 percent, were greater than OEE's self-imposed 6-day requirement³¹ for reviewing license applications. A summary chart follows on the next page.

²⁹ License processing times ranged from 45 to 112 days after HWA time was deducted.

³⁰ Defense, State, and Energy each have 30 days, concurrently, to review referred licenses. While Executive Order 12981 does not specifically provide a time requirement for CIA's review of referred licenses, BIS and CIA have agreed to aim for a 30-day turnaround for CIA's input. The time requirement for OEE review is 6 days. The goal for completing the initial overall review is 39 days (9 days to interagency referral and 30 days for interagency [including CIA] review).

³¹ The 6-day requirement was contained in the performance plans of OEE analysts, but was not drawn from any overall BIS guidance or by direction of the Executive Order. This 6-day requirement is different, and preceded, the new requirement put in place in July 2004 and discussed in detail on pages 14-15.

Figure 7. Review of License Applications

Reviewer	Total applications reviewed	Average actual days to review	Applications over review time requirement	Percent of total over review time requirement
Defense	82	7.2	0	0
State	82	20.3	0	0
Energy	34	26.8	0	0
CIA	56	23.3	17	30%
OEE	52	10.3	14	27%

Source: OIG

Changes in WINPAC management and subsequent enhancements resulted in improved processing time

We found the processing time of license applications referred to CIA improved noticeably in the latter half of FY 2003. According to the CIA OIG, there was a change in WINPAC management in April 2003. A system was subsequently established allowing management to track applications through the review process and to identify and deal with any delays. [REDACTED]

Time allotted for OEE review of applications has changed recently

OEE reviewed 52 of the license applications in our sample. As noted in Figure 7 above, 14 of those applications took longer than OEE's self-imposed 6-day requirement to review, ranging from 7 to 62 days. According to OEE, reasons for delay included:

Figure 8: Reasons For OEE Delay

Completion of PLCs
Countersigning cases ³²
Completion of PSVs
Pending PSV
Balancing routine cases against more difficult cases in the docket
Investigating applicant and/or consignee

Source: OIG

BIS' Under Secretary determined in July 2004³³ that a new process for reviewing license applications was needed to reduce or eliminate the delays cited above. As a result, he required EA and OEE to reach a unified BIS position on license applications within the 9-day Executive Order timeframe before referring applications to the other agencies. Specifically, OEE must now

³² All license applications are reviewed for accuracy and countersigned by a senior manager before final approval.

³³ Memorandum from Kenneth I. Juster to Peter Lichtenbaum and Julie Myers, *Process for Reaching a Unified BIS Position on Licensing Applications*, July 16, 2004.

submit its recommendations to EA within 6 days of receiving applications, including the reason why PLCs or other actions are warranted. If OEE and EA disagree on an application, the EE and EA directors or the Under Secretary must resolve the disagreement before the 9-day requirement and referral to the other licensing agencies. If OEE requests a PLC for an application, the Under Secretary has established a certain number of days for the foreign posts and/or BIS attaché to complete the PLC.³⁴ In addition, a pending PLC or other OEE flag on an application could delay actual issuance of a license after interagency approval.

Delays in CBCD processing of license applications were not always easily explained

Seven license applications, or 8 percent, were delayed by CBCD from 11 to 30 days after interagency approval, as shown in Figure 9.

Figure 9. Delays in CBCD after interagency approval

Application No.	Total Days to Approval	Days in CBCD
1	70	20
2	58	30
3	52	20
4	51	23
5	47	15
6	45	13
7	45	11

Source: OIG

We asked CBCD management to explain the delays. However, it was difficult for CBCD management to explain all seven cases, as some of the LOs that processed these applications have since left BIS and the records in ECASS are not detailed enough to always reconstruct what happened in the processing of an application. As a general explanation for delays, CBCD management noted that in very rare cases a license application might remain in the countersigner's queue for more than a week. Occasionally, they reported, the countersigner may need to send the license applications back to the LO for clarification of conditions, insertion of inadvertently excluded caveats, or for correction. In other cases, a policy change may make it impossible to countersign an application until CBCD senior management and/or BIS senior management take action—this was definitely the case for two of the seven applications above and, according to CBCD officials, possibly for another two as well. For example, after a meeting between Commerce and Defense, CBCD agreed to include a condition on all CBCD export licenses limiting the end-use to that stated on the license application. This agreement necessitated halting all approvals until the proper language could be worked out.

One senior LO emphasized that sometimes BIS will hold onto an application for a few days past an application's return from the 30-day review by the referral agencies in hopes that the case can be resolved rather than having to refer it to the OC. The senior LO noted that LOs are given the

³⁴ BIS' Under Secretary specified the following three timeframes for PLCs: (1) most PLCs would be completed in 14 days or less, (2) PLCs in countries without a BIS attaché would be completed in 28 days or less, and (3) PLCs in China would be completed in 60 days or less. BIS management will intervene if these timeframes are exceeded.

leeway to use their professional judgment if a case is close to being resolved and permission for extension is not requested from BIS management. The OC Chair said that he prefers that LOs and division directors try to work out issues with their counterparts at the referral agencies before escalating a license application. He said it helps avoid unnecessary escalations even if this means taking a few extra days.

B. Ninety-day time frame does not provide for prompt processing of “non-escalated” license applications

Although Executive Order 12981 and the EAR specify time requirements for the initial license application review, interagency review, and a total processing time for *escalated* license applications, neither includes a specific time requirement for completing a license application that is *approved* by the interagency group during the initial interagency review process.

The 90-calendar day timeframe for the review of license applications from their receipt in BIS is realistic if referral is made to the Operating Committee (OC), Advisory Committee on Export Policy (ACEP), and Export Administration Review Board (EARB), but no guidance is provided to LOs to encourage the timely disposition of license applications that are approved without escalation to the OC. In fact, if these applications are received back from the referral agencies on the 40th day after receipt of a license application, BIS has an additional 50 calendar days to review and sign off on the license application, and finally to notify the applicant, without violating the requirements of the EAR. This could result in unnecessary expense to the exporter and possibly the end user since the shipment of the affected goods would be delayed pending receipt of the approved license.

CBCD staff and other BIS officials agree that Executive Order 12981 and the EAR do not specifically address timeframes for the processing of applications with interagency agreement. However, they say their mandate is to process applications as quickly as possible after interagency agreement is reached and that BIS would never take an additional 50 calendar days to review and sign off on a license application. As mentioned previously, in most cases, BIS is processing applications in a timely manner. The average for vanilla cases was 43.7 days in FY 2003, meaning that CBCD took just a few days after interagency agreement to finalize applications. But, as noted in Figure 9, seven license applications were delayed in CBCD between 11-30 days after interagency approval until final sign off. Even though all seven cases were completed within the overall specified 90-day timeframe, it is difficult to determine whether CBCD was timely in the processing of these applications because there is no specific criteria to use to judge their performance.

Recommendation

BIS should establish specific timeframes for reviewing and signing off on license applications after approval by the referral agencies.



BIS, in its response to our draft report, agreed with this recommendation.

C. License processing guidance should be consolidated and readily accessible to licensing officers

During our review, we asked the five current LOs in CBCD what criteria they use to process, place an application in HWA status, and/or eventually approve or deny chemical and biological commodity applications. All five LOs referred us to an 8-point analysis memorandum. In addition, BIS management referred us to this same memorandum as the criteria used in the review of license applications. This one-page memorandum issued by the Director of the BIS Office of Exporter Services, dated April 20, 1994, outlines information that should be provided in the LO's analysis, prior to referral to the interagency group. (See Figure 10).

Figure 10. Criteria Used in the Review of Export License Applications

APR 20 1994

UNITED STATES DEPARTMENT OF COMMERCE
Bureau of Export Administration
Washington, D.C. 20230

MEMORANDUM FOR ALL LICENSING OFFICERS

FROM: [REDACTED]

SUBJECT: Case Analysis

[REDACTED]

Accordingly, in order to ensure sufficient analysis is evidenced for all applications, effective immediately, Licensing Officers will be required to address each of the following points in every LOA case file:

1. Recommendation.
2. Reiteration of the ECCNs with the subparagraph when necessary, and the applicable reason(s) for control, clearly identifying the items requested, and any General License eligibility, if applicable.
3. Characterization of the end users including type and relationship with applicant, if any (e.g., motel, bank, U.S. subsidiary, etc.).
4. Specify the number of end users, and highlight any data of particular importance, especially the reasonableness of the end-use.
5. State whether or not the application of conditions is appropriate, and if so, identify the specific conditions the Department of Commerce would suggest.
6. Brief background statement, highlighting licensing history involving the applicant and/or item, previous working group consultations (e.g., MTEC, Shield, SNEC, OC) issues of interest, and any precedent setting aspects of the proposed transaction.
7. Identify why a particular referral was not made (e.g., in instances where the entry is controlled for more than one reason, but the particular item is not). Agencies must be able to discern why another agency was not consulted.
8. Licensing Officer, telephone, and facsimile numbers.

[REDACTED]

Source: BIS, Office of Export Administration.

While providing a basic framework for analysis, the 8-point memorandum was written prior to the issuance of Executive Order 12981 on December 5, 1995. In addition, since Export Administration Act discussions were still underway on the date of the memorandum's issuance, it speculates on the final changes to be made in the Act and their subsequent impact on the LO's review of license applications. These are the appropriate areas that LOs should focus on during reviews, but guidance on how to accomplish these objectives is lacking. For instance, the third item tells the LO to "characterize the end user," but it does not say how the LO should acquire the information beyond what was submitted by the applicant (e.g., researching the entity on the Internet) or what types of questions the LO should ask exporters or end users in specific markets. The fifth item tells LOs to identify any special conditions that Commerce suggests should be placed on a license, but it does not indicate the criteria the LO should use in making that decision. Such information would be especially helpful to the referral agencies as they do their own license reviews.

Additional guidance was found, but is not being used

To supplement the 8-point analysis memorandum, CBCD issued specific guidance for LOs as a reference for reviewing export license applications for biological and chemical commodities. CBCD's guidance provides some additional instructions to that in the 1994 memorandum. For example, the guidance states that "university" is not a complete description of an end user unless the LO specifies the school or laboratory within the university. CBCD's guidance also requires that LO notes³⁵ include supporting documentation for any decision made as a result of contacts with various individuals and organizations. CBCD also created a "Commodity Classification and License Determination Guide" to assist LOs in determining the appropriate ECCN for items controlled for chemical and biological weapon proliferation reasons. In the absence of comprehensive policies and procedures for all LOs, we compliment CBCD for creating useful reference materials for LOs to use during their license application analysis. However, we are not sure if LOs are using this guidance since when we asked them for the criteria used for their review of license applications, LOs did not make reference to it. We knew about the CBCD guidance only because it was discussed in our 1999 report.³⁶ When we asked for a copy of the CBCD guidelines, one LO stated that it was saved in an old version of word processing software and was not accessible to him.

On March 31, 1999, EA officials implemented new procedures that emphasized the importance of obtaining sufficient information before processing a license application and identified the types of facts and details that must be documented in LO notes. Once again, however, when asked for the criteria used to review license applications, LOs did not refer to this newer guidance. We knew to ask for a copy only because it was mentioned in our 1999 report.

The Licensing Officers Operating Manual has been discontinued and planned electronic library has not been developed

In our 1999 report, we noted that the policy and procedures used by LOs varied. At that point, we noted that the Licensing Officers Operating Manual (LOOM), dated October 1, 1995, had

³⁵ The electronic data file for license applications includes a section for the LO to include comments and notes of importance for additional consideration by reviewers.

³⁶ U.S. Department of Commerce Office of Inspector General, *Bureau of Export Administration: Improvements Are Needed to Meet the Export Licensing Requirements of the 21st Century*, IPE-11488, June 18, 1999.

become an assortment of outdated or superceded documents and was not user friendly. We also reported that the contents of individual LOs' operating manuals varied.³⁷ EA officials said after the LOOM was modified, in 1995, per Executive Order 12981, it was not updated again for almost a year-and-a-half because of resource constraints. Subsequent to our 1999 review, the LOOM was discontinued.

BIS officials also told us in 1999 they would explore the creation of an electronic library to store new policies and procedures. The library was envisioned to include an on-line LO manual and policies and procedures for commodity classifications, license application analysis, license determinations, country-specific policies, referral policies, and record keeping. During this review, we learned from EA staff that the electronic library was only partially developed, and a lack of funding and resources prevented its actual implementation.

Conclusions

According to our interviews with LOs in CBCD, they primarily rely on the April 1994 8-point analysis memorandum to review export license applications. During our review we found that there is other BIS guidance, such as the CBCD specific guidelines, the March 1999 additional guidance, and the criteria for when HWA/RWA can be applied, which LOs clearly are not aware of and/or are not using. Given how difficult it was for us to find the official BIS guidance (beyond the 8-point analysis memorandum) for the review of export license applications, it certainly cannot be easy for busy LOs to find it either. Furthermore, the project that would have centralized such guidance in an electronic library was not completed and the handbook that previously kept all guidance in one place, the LOOM, is outdated and no longer in use.

Given BIS' important regulatory role as the licensing agency for dual-use exports, guidance for the processing of license applications should be better managed. To ensure that all LOs, including new ones, have clear and complete guidance for processing cases, BIS should develop and maintain updated, consolidated, and comprehensive written guidance or an internal operations handbook, to formalize license application review practices. This guidance or handbook should be readily accessible to all employees involved in the licensing process. EA should also develop a long-term plan for maintaining the guidance and/or handbook, including responsibility for ensuring it is kept up-to-date.

³⁷ The OIG team conducting the 1999 review also had difficulty getting a complete up-to-date LO manual. On November 20, 1998, we were provided a copy of the operating manual from the Director of the Office of Exporter Services, who informed us that it was a complete and updated copy. However, in March 1999, we learned that several key sections of the operating manual, such as case analysis, were missing from our copy. On March 25, 1999, the Office of Exporter Services provided us with the missing sections.

Recommendation

Develop and maintain clear, consolidated, and up-to-date guidance, or an internal operations handbook, to strengthen current license application review practices and help ensure that they are consistently applied.



In responding to our draft report, BIS stated that it agreed with this recommendation.

II. Review of License Applications by the SHIELD Works Reasonably Well, But the Operating Committee Needs to Sustain Recent Improvements in Timeliness

License applications for chemical and biological commodities have the benefit of an additional level of review by the Chemical and Biological Weapons Control Group, an interagency working group also known as SHIELD. At the SHIELD meetings, the member agencies share viewpoints, intelligence information, and clarifications on statutory and regulatory authority to help resolve differences and prevent the need to escalate applications to the OC. SHIELD helps ensure that applications are escalated to the OC only because of true disagreement between the agencies. We found that OC was not timely in its decisions on FY 2003 escalated chemical and biological license applications. Specifically, there were 17 applications escalated in FY 2003, and the average time to reach a decision was 51 days in the OC. Times for the current OC Chair to make a decision on escalated applications reportedly improved in FY 2004. This improvement in the timeliness of OC decisions should be sustained.

A. The SHIELD review process ensures that chemical and biological license applications are appropriately vetted before escalation to the Operating Committee

SHIELD is chaired by a Department of State employee in State's Office of Chemical, Biological, and Missile Nonproliferation. Currently, the group meets weekly and is made up of working-level representatives from State, Commerce (BIS), DOD, CIA, and Energy. Each week, SHIELD reviews chemical and biological license applications that are between 16 and 22 days old³⁸ to help ensure that U.S. exports do not contribute to chemical and biological weapon programs of concern. Because of the volume of chemical and biological license applications, SHIELD does not discuss all applications at its meetings. However, all applications are available to be discussed should an agency want to. Generally, applications that do not involve concern or disagreement are not put on the SHIELD agenda. Applications that are difficult to decide or that lack consensus among the member agencies are put on the agenda for a more intense review and discussion.

When reviewing chemical and biological license applications, SHIELD (1) attempts to determine the legitimacy of the end user through intelligence reports; (2) reviews the end user's web site and other information to determine the bona fides of the end user; (3) identifies and may review previously approved licenses to the same end user; (4) determines that the item and end use match; (5) evaluates other agency recommendations, and (6) requests either a PLC or PSV, if necessary. The dialogue and information sharing between the agencies usually result in a consensus opinion either to approve (with conditions) or deny an application. Each agency puts its opinion into ECASS, and BIS proceeds to either issue or deny the license application. In cases where agencies have differing recommendations, the application is escalated to the OC.

During FY 2003, SHIELD met once every three weeks and was chaired by a different State employee than the current chair. By meeting every three weeks, SHIELD was not able to review all of the applications—only those that a member agency asked to be put on the agenda were

³⁸ Between 16 and 22 days since the applications were referred by BIS to the other agencies. The benefit of this timeframe is that by 16 days, agencies have had an opportunity to review the application and determine which applications might need to be reviewed/discussed in depth. Additionally, if an application is 22 days old and requires discussion at a second SHIELD meeting, there is still time to do so before the 30-calendar day requirement for interagency review has been reached.

discussed. Further, because of the 30-day deadline for interagency review and the occasional timing issues in scheduling SHIELD meetings, such as holidays or other conflicts, some applications that might have benefited from the interagency discussion at SHIELD were not reviewed by the working group. As a result, some applications were escalated to the OC unnecessarily because the 30-day time limit had been reached before the case made it to SHIELD. The current OC chair said he saw applications escalated in 2003 that did not involve meaningful interagency disagreement and that could have been resolved through a discussion between agencies or by obtaining additional documentation from the exporter.

The current SHIELD chairman took over in July 2003, but he did not change to weekly meetings until March 2004, after it had become clear that more frequent meetings were necessary for all applications to be appropriately vetted. The OC chair said he has seen an improvement in the types of escalated chemical and biological cases since SHIELD started reviewing all applications. Applications being escalated now center on true disagreement between the agencies and are appropriate for the OC.

B. Recent Operating Committee changes should result in more timely decisions

The OC has representatives from State, Commerce, DOD, and Energy, all of whom are empowered to vote and make decisions of behalf of their respective agencies. The CIA is a non-voting member of the OC and provides necessary intelligence information to the committee. The OC meets once a week the first three weeks of each month. The Advisory Committee on Export Policy (ACEP) meets once during the last week of the month, but only when it has applications that have been escalated to it. Per Executive Order 12981, the OC Chair has 14 calendar days to consider the positions of the agencies and render a decision. Should any agency disagree with the OC Chair's decision, it has 5 calendar days to appeal the decision to the ACEP.³⁹

OC was not timely in its decisions on FY 2003 escalated chemical and biological license applications

In FY 2003, 17 chemical and biological export license applications, or approximately 1 percent of the 1,803 license applications submitted, were escalated to the OC for resolution. Many of the escalated applications involved chemicals being exported for use by the Chinese semiconductor industry. There is a concern among some of the agencies that such chemicals are at risk of diversion to chemical and biological weapons programs. The OC Chair speculates that there might be fewer chemical and biological export license applications escalated in the future because of the understanding on end-use visit cooperation between the U.S. Department of Commerce and the Ministry of Commerce of the People's Republic of China. Under the new understanding reached in April 2004, end-use checks should be easier to conduct, and as a result, the U.S. government should get increased insight into where chemicals being exported to China are ending up and what they are being used for. Assuming the end-use checks do not raise further questions about the end users and end use, fewer such applications may need to be escalated in the future.

BIS officials told us the new understanding is working and end-use checks are being conducted without the delays and problems previously encountered. One of the FY 2003 applications

³⁹ For background information on the escalation process, the OC, and the ACEP, see pages 5-7.

escalated to and approved by the OC Chair, contingent on a favorable PLC, did not result in a license being issued shortly after the OC Chair's decision, as is the usual course of events. Instead, it was pending from August 2003 until December 2004, when a PLC of the end-user in China was finally completed as a direct result of the new understanding. The license was finally issued in December 2004.

All 17 of the escalated applications were ultimately approved by the OC Chair, and none of the agencies chose to appeal the OC Chair's decisions. Thus, the ACEP did not review any chemical and biological export license applications in FY 2003. In assessing the timeliness of the OC's work, we found the OC's 14-calendar day deadline was not met for any of the 17 escalated applications. The average time for the 17 applications was 51 days in the OC, with 5 applications taking more than 100 days to adjudicate. In 3 of these 5 extreme cases, the documentation shows the then OC Chair took no action for an extended period of time. For the other 2 applications, the OC was waiting on a PLC and did not use the HWA option to stop the clock.

The 14-calendar day requirement appears to be quite difficult to meet. An OC decision could be reached in 10 days as long as the OC Chair and the members have all the information needed to make a decision at the first meeting where the application appears on the agenda. But frequently a second meeting is necessary to discuss the application and in FY 2003, the former OC Chair routinely did not ask for agency votes or make decisions until the second meeting that an application was on the OC agenda. Should an application be escalated around the time of the ACEP meeting (the week the OC does not meet), it could be 14 days before it is even put on the OC agenda for discussion. We believe a more realistic standard is 21 days for the OC Chair to render a decision.⁴⁰ However, in FY 2003, even using our revised standard, OC decisions were still not close to being timely—51 days versus our more realistic standard of 21.

Changes made by the current OC Chair should improve timeliness

The current OC Chair has implemented some changes to help reach the Executive Order requirement of 14 days. The former OC Chair left the position effective April 1, 2003. The current OC Chair assumed the position on November 1, 2003, after a 7-month period with two successive interim chairs. The changes the current chair has instituted were put in place after the period of our review. Thus, we did not review the data to verify recent reported gains in timeliness.

The current OC Chair's first change was to require agencies to come to the OC meetings ready to discuss in depth and vote on an application the first time it was on the agenda—making it theoretically possible to meet the 14-day requirement for an OC decision. If the members have enough information, they can vote and the OC Chair can make a decision immediately. Previously, applications were not routinely voted on until the second meeting they were on the agenda. The new chair also has declared he will not wait longer than three weeks to obtain documentation needed from an exporter. Should an exporter not submit the documentation by the time the three weeks are up, the chair will RWA the application. According to the current

⁴⁰ Making a change from 14 days to 21 for the OC to reach a decision would require a change to the Executive Order. Given the intricacies involved in taking such an action, we do not advocate BIS pursuing a change in the Executive Order for this reason alone.

chair, the former chair was more lenient in waiting for documentation before using the RWA option.

We did not evaluate OC timeliness for escalated chemical and biological applications after FY 2003 (the period of our review), but timeliness has reportedly improved. For example, according to the BIS FY 2004 Annual Report, the average time to reach a decision on all escalated applications in FY 2004 was 22 days. In FY 2003, with 6 months under the former OC Chair and 6 months with interim chairs, this average was reportedly 45 days.⁴¹ BIS should work to sustain this significant improvement in the timeliness of OC decisions through continuing attention to fine tuning the process and implementing improvements such as those put in place by the current OC Chair.

⁴¹ Both averages include all escalated applications, not just chemical and biological applications.

III. Cumulative Effect Reviews Are Not Being Performed for Chemical and Biological Export Licenses

Cumulative effect reviews look at the impact of proposed exports when added to other past exports to countries and entities of concern. Approval of a single export license may not result in a significant increase in strategic capability of a country or entity of concern, but approval of multiple licenses combined with diversion of strategic items from other countries, the provision of unlicensed items, and/or legitimate shipments from foreign suppliers could improve a country's ability to build a weapon of mass destruction. BIS may not have sufficient intelligence data to know all commodities acquired by end users, but it should trace historical patterns and exports of items it controls.

BIS had seven LOs reviewing 1,803 chemical and biological license applications in FY 2003.⁴² These LOs never determined the cumulative effect of prior technology transfers made to the end-users listed on those license applications. LOs said their long-term institutional knowledge of goods and technologies exported to end-users must substitute for cumulative effect analyses, because BIS lacks the systems and resources to perform such reviews. Additionally, BIS does not receive cumulative effect assessments from other agencies during the interagency license application review process.

A. Congress and others have emphasized the importance of cumulative effect analyses

In numerous reports and Congressional hearings, members of Congress and others have shown interest in the use of cumulative effect analysis to enhance the export control process.

- In June 1999, Inspectors General from the Departments of Commerce, Defense, Energy, State, and the Treasury, and the CIA, testified that additional cumulative effect analyses would improve the license application process.⁴³ The Deputy Inspector General for the Department of State said assessment of the cumulative effect issue required resources and coordination from various federal export licensing departments and agencies and congressional direction. To date, no such assessment has been conducted. The Department of Commerce IG recommended in June 1999 that BIS work with the intelligence community, including CIA, Defense, and Energy, to develop a method to analyze and track the cumulative effect of dual-use exports to specific countries and regions. As of March 2005, this mechanism had not been developed.
- In April 2001, a congressionally funded study⁴⁴ recommended that the Bush Administration employ a shared information management system for processing license applications that would be responsive to current business cycles and allow analysis of cross-cutting issues and cumulative effects. The study group, chaired by four members of Congress,⁴⁵ recommended: (1) increasing appropriations for U.S. intelligence services

⁴² There were seven LOs in CBCD FY 2003. Three have since left, but, according to BIS, only one has been replaced to date due to budget constraints. As a result, there are currently only 5 LOs in CBCD.

⁴³ Hearing Before the Committee on Governmental Affairs, United States Senate, June 23, 1999.

⁴⁴ The Henry L. Stimson Center and the Europe Program of the Center for Strategic and International Studies, *Study Group on Enhancing Multilateral Export Controls For U.S. National Security, Final Report*, April 2001.

⁴⁵ The Study Group was chaired by four members of Congress: Senator Michael B. Enzi (R-WY), Senator Jeff Bingaman (D-NM), Congressman Christopher Cox (R-CA), and Congressman Howard L. Berman (D-CA).

to enhance monitoring and analysis of technology transfers and (2) enhancing intra-industry cooperation to manage and share information on compliance measures, suspect end-users, and patterns of technology transfer.

- In February 2002, the GAO found that the Executive Branch does not have a sound analytical basis for justifying the current export controls on semiconductor manufacturing equipment to China. Specifically, it said that U.S. agencies had not assessed the foreign availability and cumulative effects on U.S. national security interests of exporting such equipment to China.⁴⁶ GAO recommended that the Departments of Commerce, Defense, and State complete this analysis and update policy and develop new controls, if appropriate, for protecting U.S. security interests.

In addition, Congress has been concerned for many years that the interagency licensing community lacks an integrated mechanism to conduct cumulative effect analyses of dual-use and/or munitions technology transfers. Despite a recommendation from the Commerce OIG in 1999⁴⁷ and a National Defense Authorization Act for Fiscal Year 2000 requirement that the Secretary of Defense assess the cumulative impact of licenses granted by the U.S. for exports to countries and entities of concern, neither BIS nor any of the other licensing agencies has determined how cumulative effect reviews can be performed in an effective and efficient manner. Until this happens, cumulative effect information cannot be factored into the export license review process for chemical and biological commodities.

B. BIS lacks the systems and resources to perform cumulative effect analyses

The seven LOs in CBCD reviewed the 90 applications in our sample of FY 2003 chemical and biological export license applications, in accordance with BIS' 8-point analysis memorandum (see page 17). The 8-point memorandum, the CBCD LOs' analysis of the bona fides and licensing history of individual end-users and the appropriateness of the end-uses, and input from the intelligence community provide the primary information on likelihood of proper use or diversion. Cumulative effect analysis can supplement this information. The current five LOs⁴⁸ told us they do not consider the cumulative effect of prior and proposed exports to individual foreign countries and end users because: (1) BIS' current licensing process does not require LOs to perform cumulative effect reviews, (2) BIS' licensing system cannot input or receive information to perform cumulative effect reviews, and (3) BIS' LOs have not been trained to perform cumulative effect reviews.

BIS licensing process does not require cumulative effect reviews

Current procedures do not require BIS LOs to consider the cumulative effect of prior and proposed exports to individual foreign countries and end users. We found that the five LOs were following the 1994 8-point analysis memorandum. LOs said that the 8-point analysis requirements and the license review process, as a whole, are designed to process many

⁴⁶ The General Accounting Office, *Export Controls, Issues to Consider in Authorizing a New Export Administration Act*, February 28, 2002.

⁴⁷ U.S. Department of Commerce Office of Inspector General, *Bureau of Export Administration: Improvements Are Needed to Meet the Export Licensing Requirements of the 21st Century*, IPE-11488, June 18, 1999.

⁴⁸ BIS lost three LOs in FY 2003, but recently hired a fifth LO to process chemical and biological applications.

applications in a limited time period and not to perform cumulative effect analyses or determine if multiple exports to any one country or countries could result in weapons of mass destruction.

The 8-points do not require LOs to analyze an applicant's entire licensing history. The guidance states that LOs should prepare a "brief background statement, highlighting licensing history involving the applicant, and/or item, previous working group consultations, and any precedent setting aspects of the proposed transaction." LOs typically identify some prior licenses for an applicant, but they primarily consider diversion issues including the bona fides of consignees and end users. They sometimes identify all prior licenses for an exporter, consignee, and/or end user, but only to document how many licenses have been approved. Although BIS expanded its license application guidance in 1999, the new guidance still does not require LOs to perform cumulative effect analyses. LOs include only the previous licensing history of approvals/denials for item(s) and/or consignees as appropriate.

Even if the five LOs wanted to perform cumulative effect analyses, it is unlikely that they would have the time to do so because CBCD receives too many applications to perform such reviews under current circumstances. From FY 2001 to 2004, the number of chemical and biological license applications was 1,357, 1,497, 1,803, and 2,801 respectively. In addition, the division has received an increasing number of commodity classifications⁴⁹ from FY 2001 to 2004: 160, 991, 488, and 903 respectively. Because of the application and commodity classifications increases, the division is now sending approximately 20 percent of applications it receives to two other BIS divisions for processing. And, with only five LOs in the division, no meaningful cumulative effect analyses can be done.

BIS licensing system cannot input or receive cumulative effect information

BIS currently uses ECASS, which was developed in 1984, to process applications, but it is not suited for the current era of license processing. Today's licensing systems need advanced query capabilities, expanded text capabilities, modern interfaces, online access to exporter technical specifications, and access to outside commercial databases. ECASS lacks all of these functions. One LO emphasized the need for databases of foreign end-users, such as the international Dun and Bradstreet database. But, ECASS cannot read or download such databases. Thus, LOs must search information and databases off-line.

LOs also complain about ECASS containing multiple codes for some exporters, consignees, and end users, making it difficult to ensure that all prior licensing history is available. Specifically, over the years, BIS has created multiple ECASS codes for some applicants, consignees, and end users. For example, "ABC Corp." may also be coded as "ABC Corporation," forcing LOs to spend precious time searching and analyzing multiple codes and licenses. Unless LOs perform time-consuming analyses of prior licenses, they cannot determine how much of each commodity has been exported to specific consignees and end users.

One LO also said a sophisticated licensing system should include access to the actual shipments of dual-use chemical and biological commodities, as well as shipments of chemical and biological commodities on the U.S. Munitions List and foreign military and third-country sales. Currently, LOs do not have access to such information. For example, export licenses are valid

⁴⁹ BIS receives requests from companies to classify commodities, technology, or software included on the CCL.

for two years, but LOs do not know whether items listed on a license have ever actually been shipped. Currently, BIS does not request shipment information from exporters, consignees, and/or end-users unless specifically requested in license conditions.

The U.S. Customs and Border Protection (CBP) collects information on shipments made under munitions licenses issued by the State Department, but it does not do so on dual-use licenses issued by the Commerce Department. To receive such information, CBP would have to continually determine what dual-use commodities have been shipped to foreign countries under Commerce licenses. However, BIS does not require CBP to continually monitor the activity under Commerce licenses. BIS holds exporters responsible for keeping track of controlled shipments and ensuring that license limits are not exceeded during the two-year life of the license. LOs emphasized that if better shipment information and software were available, they could perform trend analyses of technology transfers.

The lack of information on actual shipments is not a new problem. For many years, federal agencies responsible for enforcing U.S. export laws and compiling U.S. trade statistics could not obtain accurate and timely data on exports. In 1999, in an attempt to correct the problem, the U.S. Customs Service, predecessor to CBP, and the Bureau of the Census established the Automated Export System (AES) to allow exporting companies to electronically enter data on shipments and provide information to help detect export violations. In 2002, BIS had discussions with CBP and Census, about providing shipment information to BIS and other interagency personnel. CBP and Census told BIS in 2002 that shipment information could be provided, but that software development and resources from all parties would be required to provide such information. More recently, in 2004, BIS enforcement personnel have obtained access to CBP's Automated Targeting System (ATS), which now allows them the capability to search AES for shipments to specific countries. This is a major improvement for enforcement of license applications, but it could also help LOs in their review of license applications by providing them with information on previous shipments. Therefore, we recommend that BIS assess the feasibility of providing LOs with the information housed in ATS and AES.

BIS LOs are not trained to perform cumulative effect analyses

The LOs in CBCD said even if they had more time per application and a sophisticated licensing system, they would need comprehensive training to perform cumulative effect reviews. They noted that CIA/WINPAC has a training school that teaches comprehensive license application review techniques. The LOs told us that they would benefit from such training. CIA/WINPAC officials agree that BIS LOs could benefit from selected training such as trend analyses, but they said BIS would need to obtain top-secret clearances for its five LOs to attend CIA training. A BIS official said that under current fiscal restraints, such clearances would be prohibitively costly.

Recommendation

Assess the feasibility of providing LOs with the information housed in the Automated Targeting System and Automated Export System for use in their review of license applications.



In the Acting Under Secretary's March 30, 2005, response to our draft report, the bureau stated that it agreed with this recommendation. BIS also said that, to date, the bureau has not been appropriated funds by Congress to conduct cumulative effect analyses.

C. Licensing referral agencies are not performing cumulative effect analyses

During congressional testimony on June 23, 1999, both the Chairman and Ranking Minority Member of the Senate Committee on Governmental Affairs expressed grave concern that the licensing community does not consider the cumulative effect of all technology transfers and identify a country or purchaser seeking components for a weapon of mass destruction, though each commodity might be benign by itself.⁵⁰ However, BIS and CIA have emphasized that such analyses are not currently feasible because all the available data sources cannot be quickly consolidated or are not available when processing chemical and biological export license applications. Although one licensing agency performs limited cumulative effect analyses of some chemical and biological license applications, the federal government lacks an integrated capability to analyze all license applications and exports to different countries.

Licensing agencies perform limited cumulative effect analyses

Probably the agency considered most likely to perform cumulative effect analyses is CIA/WINPAC, which is charged with collecting and analyzing intelligence information. However, in practice, CIA simply screens all chemical and biological export license applications and only provides intelligence on those applications that might have some proliferation concerns. CIA officials told us that their role is to provide intelligence and not to perform cumulative effect analyses.

The Department of Energy does perform some limited cumulative effect analyses. Energy's seven laboratories conduct limited cumulative effect assessments for nuclear dual-use exports, but there is no coordinated effort to conduct such assessments for all commodities. The Department of Defense has a congressionally mandated requirement to perform annual assessments of the total effect of transfers of goods, munitions, services, and technology on U.S. security, but it has yet to perform such reviews.⁵¹ Notwithstanding the lack of comprehensive cumulative effect analyses, both BIS and CIA officials stated that all chemical and biological license applications are thoroughly reviewed, including the bona fides of all end users, and that current intelligence is brought to bear on all applications.

⁵⁰ Hearing Before the Committee on Governmental Affairs, United States Senate, *The Inspectors General Report on the Export-Control Process for Dual-Use and Munitions List Commodities*, June 23, 1999.

⁵¹ National Defense Authorization Act for Fiscal Year 2000, section 1402.

A major factor hindering cumulative effect analyses by the licensing agencies is outdated automated systems. In a March 2002 report, the interagency OIG team found that the dual-use export licensing process involves multiple automated systems owned and operated by different federal licensing agencies.⁵² Many of those systems are ineffective for the present era of export license processing because they have varying security standards and rely on cumbersome manual and paper-based processes. There is no comprehensive database of export information to help federal agencies assess the cumulative effect of multiple exports. Thus, we must reiterate our recommendation, first offered in our 1999 report, that BIS work with the intelligence community, including CIA, Defense, State, and Energy, to develop a method to analyze and track the cumulative effect of dual-use exports to specific countries and regions of concern.

Recommendation

Work with the intelligence community to develop a method to analyze and track the cumulative effect of dual-use exports to countries and entities of concern.



BIS, in its response to our draft report, agreed with this recommendation. The bureau also stated that chemical and biological license applications are thoroughly reviewed, including the bona fides of all end users, and that current intelligence is brought to bear on all applications, notwithstanding the lack of comprehensive cumulative effect analyses.

⁵² *Interagency Review of Federal Automated Export Licensing Systems*, prepared by the Offices of Inspector General of the Departments of Commerce, Defense, Energy, State, and Treasury, March 29, 2002.

IV. Recent Improvements in the Timeliness of Changes to the Commerce Control List Need to Be Maintained

The Australia Group annually recommends new chemical and biological items for control, but it takes months for BIS and the other U.S. licensing agencies to place newly regulated items on the CCL. As a member of multilateral organizations, the U.S. is obligated to implement decisions in a reasonable time period. However, BIS and the other licensing agencies cannot disclose newly regulated items to U.S. companies or prevent them from being exported until the new regulations are issued.

In March 2001, we recommended that BIS review its clearance process and work with the other licensing agencies to publish new regulations faster.⁵³ The Under Secretary for Export Administration agreed with our recommendation. BIS completed an evaluation of its regulatory review process in late 2001, creating an internal database to track regulations still under review. BIS now sends a follow-up memorandum to a licensing agency if its response regarding regulations referred for interagency review is overdue. BIS officials believed the 2001 changes would expedite the review of regulations, including those implementing the AG changes. Although these changes did not impact the amount of time taken to publish the 2002 and 2003 changes, in 2004 the changes took only 6 months to publish. Specifically, prior to 2004, U.S. agencies averaged 11 months to get items newly regulated by the AG published in the CCL. However, changes from the AG's June 2004 meeting only took six months to get published in the CCL, bringing the average down to 10 months.⁵⁴ In the future, BIS should build on its 2004 performance and continue to publish the AG changes more quickly.

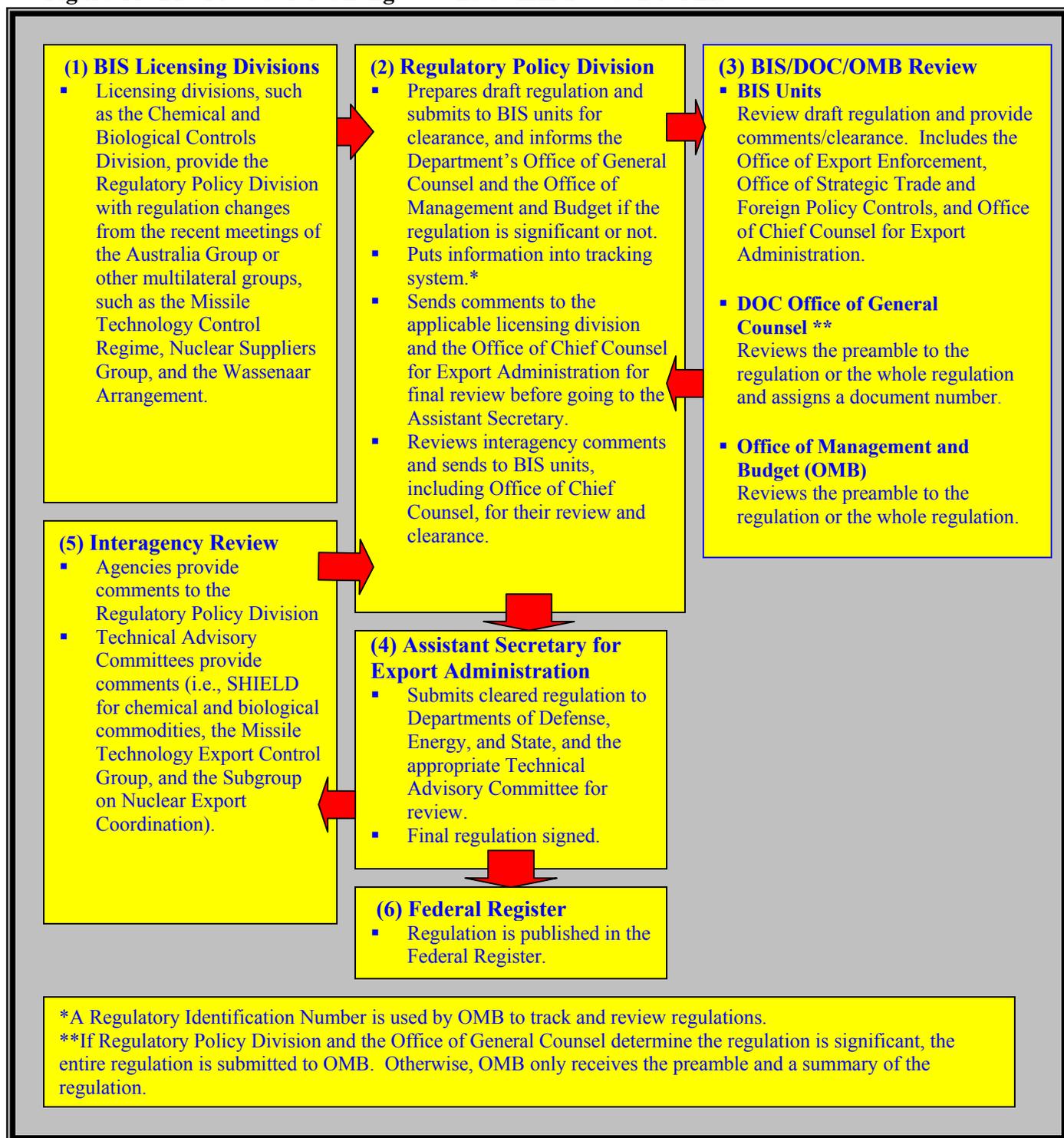
A. Updating the CCL with chemical and biological items is too time consuming

Each year after the annual meeting of the AG, U.S. licensing agencies meet to decide how to implement any new control changes. For example, if a new control is added to the AG list, the U.S. must decide whether it wants to control the item as a dual-use or munitions item. The Department of Commerce is responsible for making changes on the CCL for dual-use items, and the Department of State is responsible for making changes on the U.S. Munitions List (USML) for munitions items. Figure 11 on the next page documents the process used by BIS to implement control regulation changes to the CCL.

⁵³ U.S. Department of Commerce Office of Inspector General, *Management of the Commerce Control List and Related Processes Should be Improved*, IPE-13744, March 23, 2001.

⁵⁴ The AG held its annual meeting from June 7-10, 2004, and the new regulations were published on December 29, 2004.

Figure 11: BIS Process for Changes to the Commerce Control List



Source: OIG, based on information from BIS' Regulatory Policy Division

There is no deadline to publish annual AG changes other than the timeframe listed by BIS' Regulatory Policy Division, which allows 3 months to issue draft regulations to the interagency licensing groups after AG changes are received. However, the publication of new AG regulations has averaged just over 10 months for the last seven years. On three occasions in the

last 7 years, the U.S. Government failed to publish new AG regulations before the next annual AG meeting (1999, 2000, and 2003).

Publication of new AG regulations takes time because of the regulatory process and the need for interagency review

BIS officials cited several reasons for the time it takes to publish new AG regulations. First, time may elapse between the end of the AG plenary and the official posting of the control list changes. This will delay the beginning of the process for formal interagency clearance of the implementing regulation. Second, according to BIS, the U.S. regulatory process is more comprehensive than that of other members. U.S. regulatory requirements to make changes to the CCL, such as the need to publish Federal Register notices, are simply much more complicated and time consuming than those of other countries.

The U.S. interagency process requires that multiple parties must approve changes before they can be published. All the licensing agencies participate in the AG annual sessions, so they are aware of control changes agreed to by the U.S. before BIS provides them with the draft regulations to review. But, BIS officials said the current process is time consuming because other agencies (State and Defense) are allowed to review and comment on the changes. The need for these agencies to be involved increases the amount of time it takes to get changes published. Finally, all comments and changes from the licensing agencies, OMB, or other BIS offices need to be incorporated by the Regulatory Policy Division and again reviewed by CBCD and the Office of Chief Counsel before the changes can be published.

B. Delays in publishing Australia Group guidelines could cause problems

Delays in publishing the latest AG guidelines could cause problems for the U.S. government. In an October 2002 report, GAO recommended agreed-upon changes to control lists should be adopted by all AG members at the same time. If not, proliferators could exploit time lags to obtain sensitive technologies by focusing on AG members slowest to incorporate the changes.⁵⁵ While agreement on timing for implementation among AG members would be ideal, it is unlikely due to members' national discretion in undertaking AG commitments.

Until an item is listed on the CCL, BIS cannot reveal to exporters that it may soon be controlled. The information contained in the reporting cable prepared after AG meetings is classified, so the very mention to an exporter that an item is soon to be controlled could be perceived as improperly revealing classified information. Changes are not considered public information until they are listed on the AG web site.

Even then, BIS has little ability to stop items from being exported until they are added to the CCL. In most cases, the newly regulated items do not require a license and can be shipped at will until they are listed on the CCL. For example, in 2003, AG members agreed to add 12 new viruses to the list of AG-controlled human and zoonotic pathogens described in ECCN 1C351. BIS did not add them to the CCL until 9 ½ months later, during which time U.S. exporters could have legally shipped these items without a license. Because exporters were not required to have

⁵⁵ The United States General Accounting Office, *Nonproliferation: Strategy Needed to Strengthen Multilateral Export Control Regimes*, GAO-03-43, October 2002.

an export license to ship the items, BIS has no way of knowing whether any shipments were made.

BIS does sometimes attempt to legally stall the export of items in the “lag time” between being newly controlled by the AG and inclusion on the CCL. For example, BIS received an application in FY 2003 for a biological item that the AG had marked for control but was not yet listed on the CCL. The exporter submitted an application on February 6, 2003, and the item was not listed on the CCL until June 10, 2003. If BIS had not received the application, the item would have been shipped because a license was not required.⁵⁶ But, because the exporter applied for a license, BIS was able to assess the end-user and it found negative information. Because of the derogatory information on the end-user, BIS placed the application on HWA pending publication of the new AG rules in June 2003 in order to obtain and issue a regime-based denial so that the AG no undercut obligations would be implemented on a multilateral basis. Denials based on unilateral controls do not invoke such obligations. The reviewing agencies ultimately rejected the application after the new regulations were published. Such lucky occurrences are rare, though, and BIS officials are concerned about items that have been exported pending the publication of new regulations.

Catch-all controls may prevent unlisted chemical and biological items from being exported

As stated above, the “lag time” between when the AG newly controls items and when those same items are actually published on the CCL can be lengthy. One mechanism to potentially mitigate this problem is “catch-all” controls. In December 1990, the U.S. government announced the Enhanced Proliferation Control Initiative (EPCI) to implement catch-all controls to prevent common use items, such as test equipment, decontrolled machine tools, certain steels, and electronic parts from being exported to foreign countries that want to acquire the capability to develop, produce, stockpile, deliver, or use nuclear, missile, chemical, or biological weapons.⁵⁷

The EAR requires exporters to obtain an export license for all items, even those not on the CCL, when the exporter “knows” or “is informed” that the goods and technology will be used in connection with WMD activities. To help exporters with the first criterion—knowledge that an item is being sought for proliferation reasons—BIS established guidelines to help exporters “know” or “have reason to know” whether an item will be used directly or indirectly in a nuclear, missile, chemical, or biological weapons program and whether “catch-all” controls are applicable. Specifically, BIS’ “Know Your Customer” and “Red Flags” guidelines⁵⁸ provide tips to help exporters scrutinize the parties and proposed end use listed on an application. This may include looking for signs that the consignee may not be legitimate, such as an order placed for a high performance computer going to a small bakery.

For the second criterion, the EAR requires an exporter to obtain a license if the exporter “is informed” by the Department of Commerce that there is a serious risk of diversion. The Department informs exporters through letters in response to exporter requests for information about the end-use or end-user associated with a proposed transaction. The Department also

⁵⁶ According to BIS officials, exporters often file applications for items that are not controlled “just to be safe.”

⁵⁷ Statement by White House Press Secretary Fitzwater on the President’s Export Control Initiatives, December 13, 1990. EPCI continued controls set up by Executive Order 12735, *Chemical and Biological Weapons Proliferation*, November 16, 1990.

⁵⁸ Export Administration Regulations, Part 732, Supplement No. 3.

informs exporters through a list of entities and items considered to be at serious risk for diversion. The Department publishes the names, items, and restrictions placed on entities in the Federal Register and the EAR. The Department requires exporters to assess the nature and activities of their potential customers, and they are advised to contact the Department if they have any concern with the identity or activities of end-users.

GAO and BIS are concerned that the catch-all controls are not consistently implemented and not easily enforced. GAO found in 2002 that countries implement catch-all controls differently, possibly impacting the controls' effectiveness in stopping proliferation.⁵⁹ Specifically, GAO stated that some countries must show that an exporter had absolute knowledge that an export would support proliferation activities before they can require a license or prosecute a violation of law. As a result, some exporters may have had a reason to know about certain end uses or end users, but not absolute knowledge, and exported goods without a license that might have been used in connection with WMD activities. However, the U.S. needs to show only that an exporter knew or suspected that an export would support proliferation activities to require a license or to prosecute a violation of law. As for BIS, it stated in a 2001 report that different countries' standards complicate detecting, investigating, and prosecuting cases under the "knowing" standard set by the EPCI catch-all provision.⁶⁰

Conclusions

During our review, BIS personnel were adamant that the bureau had made all feasible changes to the process of publishing new AG regulations and that the time could not be further reduced. The average time to publish new AG regulations has been 10 months for the last 7 years, but BIS managed to publish the latest round of changes in 2004 in only 6 months, which demonstrates that the time can be reduced.⁶¹ We hope such a change is not an anomaly and can be replicated. BIS told us it only took 6 months because it needed to quickly restore certain notes covering license requirements that had been inadvertently removed by a BIS rule on July 30, 2004.⁶² The urgent need to get these notes restored apparently motivated both BIS and the other agencies to move much more quickly than they usually do.

BIS says publishing changes from the April 2005 AG meeting in the CCL will depend on (1) how quickly BIS receives official notice of the changes, (2) the complexity of the changes, (3) whether there is an effort to add unrelated revisions to the rule, and (4) how quickly Commerce, Defense, and State resolve any comments on the rule.

⁵⁹ The United States General Accounting Office, *Nonproliferation: Strategy Needed to Strengthen Multilateral Export Control Regimes*, October 2002, page 19-20.

⁶⁰ U.S. Department of Commerce, *Foreign Policy Report*, 2001.

⁶¹ For the six years prior to the June 2004 annual AG meeting, the U.S. licensing agencies had taken an average of 11 months to publish the new AG regulations in the Federal Register.

⁶² BIS wanted to quickly restore these notes in the Federal Register because they contained critical guidance concerning the license requirements for ECCNs 1C355, 1C395, and 1C995. Only one of these ECCNs (1C395) is for chemical or biological commodities.

Recommendation

Take appropriate actions to sustain recent improvements in the timeliness of U.S. publication of Australia Group guidelines and rule changes that impact the Commerce Control List.



The bureau's response to our draft report stated agreement with this recommendation. Further, BIS stated that its FY 2005 Regulations Calendar has the AG changes (resulting from the April 2005 AG plenary) scheduled to be sent for interagency review one month after official notification of the regime list changes. BIS notes that the regulation will need to be cleared by State and Defense and, prior to publication, OMB must approve the regulation.

V. Denial Notification to the Australia Group Needs to Be More Transparent

One of the obligations of AG membership is the submittal of license denials to the group so that potential proliferators cannot “shop around” from one country to another for items. AG members have also adopted a “no undercut” policy in which members agree not to approve an identical sale without first consulting with the member that first issued the license denial.

Since August 2002, Commerce and the State Department have disagreed about the U.S. policy and practices for submitting denials to the AG. State, as the lead representative to the AG, is responsible for submitting the U.S.’s denials to the AG. BIS believes three changes would be useful to make the denial notification process more effective and transparent. First, BIS would like all denials sent to the AG to ensure that the no undercut policy is always triggered. The Department of State now subjectively determines which denials are submitted. Second, BIS believes that State should send denials to the AG at the time that BIS issues its “intent to deny” letter to applicants, rather than after the mandatory 45-day period during which BIS will consider any additional information provided by the exporter to rebut BIS’ decision to deny the application.⁶³ Finally, BIS believes that State should not unilaterally rescind prior denials to the AG. Unfortunately, the AG’s policy on the reporting of denials is not explicit, so State and Commerce have different views on how it should be implemented. The process of submitting U.S. export license denials to the AG should be more transparent and written policies and procedures are needed for the process.

BIS wants all denials sent to the Australia Group

When one of the 39 AG members denies a license for an AG-controlled item, the other 38 members have agreed not to approve essentially identical applications without consulting the member that issued the original denial. The AG’s “no undercut” policy, which includes the reporting of denials, helps identify end users who shop from country to country for chemical and biological commodities. The “no undercut” policy was established in 1993 to promote compliance with regime commitments, provide members with information on questionable license applications, and help better monitor export trends.

The policy depends on the cooperation of AG members to be effective.⁶⁴ However, the AG Handbook implies, but does not specifically state, that members should submit all denials in a timely manner, which allows members to interpret the policy as they wish. The AG Handbook does provide specific criteria and a format for denials, but adopting the policy is a matter of national choice by each AG member.

As the lead U.S. representative to the AG, the State Department is responsible for submitting license denials to the AG. Yet, State does not currently submit all denials to the AG. Instead, it examines each denial on a case-by-case basis and determines whether to send the denial to the AG. For example, State only submits denials that involve exports to non-AG countries. State’s

⁶³ According to 15 CFR 750.6, an applicant has 20 days after the date of the intent to deny letter to rebut BIS’ decision and provide additional information showing why the application should be approved. Unless BIS advises the applicant that the bureau has reversed its opinion, the denial becomes final 45 days after the date of the intent to deny letter. The applicant then has 45 days from the date of the final denial to appeal the decision, as outlined in Part 756 of the EAR.

⁶⁴ AG members are not legally bound to comply with AG policies.

rationale for this “policy” is not documented in any way. Since August 2002, Commerce and State have disagreed about the U.S. policy for submitting denials to the AG. This disagreement over the interpretation of AG policy has prevented development of a consistent and transparent U.S. process for ensuring American compliance with the AG’s nonproliferation goals.

BIS acknowledges that the AG Handbook does not specifically state that all denials should be sent to the AG, but it also does not state that some denials can be kept from the AG, depending on a member country’s preference. We agree that the AG Handbook is somewhat ambiguous. BIS’ position is all denials, including denials to companies in AG member countries, should be submitted to the AG. Specifically, AG member countries should be alerted to end users in their countries who shop from country to country for chemical and biological commodities. Thus, while BIS does not challenge State’s authority to make such decisions, it disagrees with State’s application of that authority.

To better understand State’s position on the denial notification process, we spoke to officials in State’s Office of Chemical, Biological, and Missile Nonproliferation. They said the process is better than it was in 2002, when State was criticized by GAO for not providing any denials to the AG between 1996 and 2001.⁶⁵ State officials center their position around their belief that AG policy language allows member countries to submit denials at their discretion, including whether to submit (1) all denials, (2) denials for companies in AG member countries, and (3) denials while end users are under review. State stated that it did not send 10 of the 23 denials for chemical and biological commodities in FY 2003 to the AG for these reasons.

On the other hand, BIS told us that State should have sent 6 of the 10 denials it did not send in FY 2003 to the AG and 1 to the Missile Technology Control Regime, another international export control consortium devoted to stemming the proliferation of delivery systems for nuclear, chemical, and biological weapons. BIS officials agree that State did not need to send the other three denials to the AG, because two were to end users already under investigation by BIS⁶⁶ and the third was an application returned to the applicant. Figure 12 shows the specific details for the 6 denials Commerce believes State should have sent to the AG.

Figure 12: 6 Additional Denials That BIS Believes Should Have Been Sent to the AG in FY 2003

- 1. Three Cases**—State unilaterally and incorrectly (according to BIS) classified three cases as non-chemical and/or biological proliferation related denials and did not send the denials.
- 2. Two Cases**—Two cases involved companies (end users) in AG member countries, which State told us they do not send to the AG.⁶⁷ BIS officials disagree with this policy.
- 3. One Case**—In the final case, State declined to send the denial based on high-level intelligence. BIS officials contend the denial still should have been sent to the AG.

Source: OIG and BIS

⁶⁵ General Accounting Office, *Nonproliferation: Strategy Needed to Strengthen Multilateral Export Control Regimes*, October 2002 (GAO-03-43). GAO was recently renamed the Government Accountability Office.

⁶⁶ The licensing agencies decided to not send multiple notifications for the same denied end user.

⁶⁷ State believes it is AG policy not to send to the AG any denials involving companies in AG member countries. We could find no support for State’s assertion.

BIS wants all denials sent to the Australia Group at the time applicants are informed

BIS also believes that State should send denials to the AG at the time BIS issues an intent to deny and not after the expiration of the 45-day period during which BIS will consider any additional information provided by the exporter to rebut BIS' decision to deny the application. Currently, State sends denials after the 45 days has elapsed. In August 2002, Commerce's Assistant Secretary for Export Administration wrote to his counterpart at State asserting that license application denials should be provided to three⁶⁸ of the four multilateral organizations when Commerce issues its intent to deny letter to an applicant.⁶⁹

The Assistant Secretary's letter stated that the AG's no undercut policy is negated if AG member countries are not aware of U.S. denials shortly after the denial decision has been made, and U.S. business interests suffer if end users approach foreign competitors to purchase commodities that the U.S. declined to license for export. Commerce's position is that companies in all member countries should compete for international sales on a fair and equal basis. Furthermore, if the U.S. had serious concerns about proliferation and decided to deny a license, other AG members should know about the U.S.'s denial before they are approached by the same foreign buyer. If the U.S. waits 45 days to notify AG members, it may be too late to prevent a sale from another source.

In September 2002, State's Acting Assistant Secretary for Nonproliferation responded to Commerce's August 2002 letter and outlined a three-step process to improve U.S. implementation of the AG's no undercut policy. Figure 13 describes the three steps proposed by State.

Figure 13: Department of State's Proposed Steps to Improve the No Undercut Policy

- 1. If exporters relinquish their appeal rights**—As part of the Intent to Deny process, exporters could relinquish their appeal rights to denials so that the international organizations are promptly notified, companies in member countries compete equally for international sales, and the negative consequences of denials overturned on appeal are avoided.
- 2. If exporters do not relinquish their appeal rights**—State would promptly issue a “denial based on inquiry” notification to export control organizations and follow-up with a full denial when the denial goes final. (State officials said “denials based on inquiry” are not subject to the no undercut policy, but the prompt issuance of such tentative export license denials would allow member countries to get information sooner. They believe few member countries would permit an essentially identical transfer, even though they are not compelled to deny it “based on inquiry.”)
- 3. Reserve the right to issue intent to deny letters**—State would submit license application denials to member countries at the intent to deny stage in cases with compelling reasons or those cases not addressed by steps 1 and 2.

Source: Department of State letter to BIS, September 23, 2002.

As of March 2005, neither State nor Commerce had implemented State's proposed procedure. BIS officials rejected Step 1 because they believe the appeal process cannot be legally waived, but BIS officials never formally communicated this to the State Department. More than two

⁶⁸ The Australia Group, the Missile Technology Control Regime, and the Nuclear Suppliers Group have a no undercut policy while the Wassenaar Arrangement does not.

⁶⁹ GAO recommended in its October 2002 report that the Secretary of State report U.S. denials of all export licenses when the exporter is issued the intent to deny letter.

years have passed with no resolution of this interagency impasse. Commerce and State need to immediately reopen discussion on this policy and reach agreement on when denials and notices of “denial based on inquiry” or appeal will be sent to the AG.

BIS wants State to not unilaterally rescind prior denial notices to the AG

BIS officials assert it is also inappropriate for State to unilaterally reverse a license denial decision, without first obtaining the concurrence of the agencies involved in the application review process. BIS officials say that State essentially rescinded a prior denial in 2004 without Commerce clearance. A U.S. company had applied for a license to export to a company in a non-AG country, but was denied the license.⁷⁰ State followed AG policy and notified the AG Chair of the denial. But, in accordance with the no undercut policy, an AG member country contacted the U.S. (State) to discuss the denial and ask for information on the company in the non-AG country. This AG member country reportedly wanted to abide by the no undercut policy, because one of its companies had applied for a license for the same goods to the same company in the same non-AG country.

After being asked for its opinion on the company in the non-AG country, State decided that the company in the non-AG country did not pose any proliferation concerns. Despite the fact that licensing agencies, including State,⁷¹ had denied a U.S. export license for goods being sent to this company, BIS told us that the company in the AG member country would be allowed to export goods to the company in the non-AG country because of State’s unilateral decision not to object. Because of State’s reversal, BIS personnel contacted the U.S. company that had originally been denied the license and suggested that the company could reapply, if interested.

We asked both BIS and State for any written procedures for rescinding prior denial notices to the AG. Neither agency was able to provide any documentation. State officials said that the agency controls the rescinding of prior denials to the AG for “foreign policy” reasons. Neither the AG guidelines nor the EAR addresses the issue of rescinding prior denials to the AG. We note further that State would have the opportunity to approve or vote to deny an export for foreign policy reasons during the regular interagency license approval process. In addition, BIS and State disagreed on whether this AG denial notification process is linked to the formal escalation process for export licenses, as outlined in Executive Order 12981. While State believes that CBCD can escalate any State decision to rescind a prior denial to upper BIS management for discussion with their counterparts at State, CBCD believes escalation is difficult without a documented process.

With regard to the case discussed above, State personnel said that the decision was discussed with BIS, DOD, and Energy. However, because there was a quick turnaround placed on the inquiry from the other country, State moved quickly to reply. Thus, while BIS was informed both verbally and in writing of State’s decision, there was reportedly little time to debate the decision. State said that BIS did verbally disagree with State’s decision to rescind the denial notification, but that it received nothing in writing from BIS before or after it released its formal reply on this case. State remarked that CBCD also did not escalate the issue to upper BIS

⁷⁰ The license was not denied simply because the company was located in a non-AG country, but because there were concerns about the company listed as the end-user.

⁷¹ State had denied the license “due to risk of diversion to end-users/programs of concern.”

management. To avoid similar disagreements in the future, BIS and State and the other referral agencies should jointly develop written procedures on the handling of such notices.

Recommendation

Work with the State Department, and the other licensing referral agencies, to develop and implement written procedures for handling the AG denial notification process. The procedures should cover, at a minimum:

- the U.S. policy on submitting denials to the AG,
- when U.S. denial notifications will be sent to the AG—either when the intent to deny letter is sent or after the 45-day rebuttal period has lapsed, and
- how U.S. decisions to rescind prior denial notifications to the AG will be made. This should specify how State will exercise its representation authority and how the other licensing agencies will be involved in the decision making process.



BIS, in responding to our draft report, stated that it agreed with this recommendation.

VI. BIS Outreach Efforts Are Mainly Targeted to the Biological Exporting Community and Could Be Expanded

A critical component of BIS' mission is outreach to the exporting community to build awareness and compliance with the EAR. BIS holds an annual Update Conference on Export Controls and Policy each October to educate exporters about new policy initiatives and to provide information on export controls through small group sessions that focus on a wide array of topics. The Update Conference is complemented by numerous BIS export control seminars held around the country throughout the year. Often it is necessary to target outreach to specific business and technology sectors. We found BIS has expanded its efforts to reach the biological exporting community, but it has not been as successful in reaching the chemical exporting community. In addition, BIS has an opportunity to reach out to the 318 entities registered with the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) and the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (CDC). These entities work with select agents and toxins that pose a severe threat to livestock, plants, and/or public health, many of which are also listed on the CCL.

A. BIS outreach efforts to the chemical community need to be expanded

In recent years, CBCD has concentrated its outreach on the biological exporting community. Since 2002, staff members in CBCD have given presentations at the annual meetings of the American Biological Safety Association, the Biotechnology Industry Organization, the American Society for Microbiology, the Federal Laboratory Consortium for Technology Transfer, and the Animal Health Institute—Biologics Section. In May 2004, CBCD hosted an in-house presentation for biological exporters covering nonproliferation controls on biological commodities. Outreach to the chemical exporting community has been in conjunction with outreach to the biological exporting community, such as a presentation at the Licensing Executives Society Meeting in December 2003 and an in-house seminar for other federal agencies covering nonproliferation controls on biological and chemical items in April 2003. We should note that after the September 11, 2001, terrorist attacks, agents from OEE were instructed to visit all chemical manufacturers within their respective regions to inform them of their responsibility to comply with the EAR. However, this type of outreach has not been duplicated since.

The director of the Office of Nonproliferation and Treaty Compliance said there is a reason for the disparity between outreach done to the biological exporting community and outreach done to the chemical community. The biological exporting community usually exports small, financially insignificant amounts that are not typically viewed by the exporters as commercial transactions and not regarded as subject to export controls. But according to this BIS official, chemical exporters tend to be large companies with significant experience in exporting. These firms usually have offices or staff that regularly handle export control and compliance matters because the industry is so heavily regulated. The director feels that scarce resources for outreach efforts need to be directed where the greatest need lies, which he believes is in the biological community. Another licensing official also emphasized that BIS gives extra attention to the biological community because of greater proliferation concerns involving biological commodities, which can be readily reproduced and diverted.

CBCD staff mentioned scarce resources several times as the reason why outreach to the chemical community is limited. For example, one of the LOs in CBCD was invited to speak about export controls at the American Chemical Society's annual meeting in 2004, but he could not attend because BIS did not make funding available for him to attend. The director of the Office of Nonproliferation and Treaty Compliance told us that even if sufficient budgetary resources were available to pay for travel expenses to do outreach, right now he cannot send CBCD staff out of the office for outreach activities because export license applications will sit unprocessed for the period of time that they are gone. As it is, 20 percent of incoming chemical and biological license applications are being reviewed and processed by other divisions because of staffing shortages in CBCD.⁷²

According to BIS' director of administration, the agency has \$68.779 million to spend on its programs in FY 2005. This was a small decrease of \$240,000 from FY 2004, when available funding was \$69.019 million. Funding in FY 2003 was \$72.189 million, so BIS's budget was reduced by \$3.170 million between FY 2003 and FY 2004. While BIS has experienced a series of declining budgets, BIS management has not arranged the budgetary resources it does have to fund more outreach to the chemical exporting community. While outreach to the biological exporting community is probably a higher priority, outreach done with the chemical community in recent years has been limited, except for OEE's outreach after the September 11th terrorist attacks and outreach done by the Treaty Compliance Division on the Chemical Weapons Convention. Lower cost options to extend BIS' outreach to the chemical community are possible.

Recommendation

Explore ways to do more outreach to the chemical exporting community, including lower cost outreach alternatives, such as setting up briefings in Washington, mailings, or piggybacking on outreach done in connection with CWC compliance activities conducted by BIS' Treaty Compliance Division.



BIS, in its response to our draft report, agreed with this recommendation. Specifically, BIS said it will explore ways to increase outreach to the chemical exporting community consistent with available resources and chemical licensing and policy matters requiring attention. BIS also stated that it has an extensive general outreach program in which the chemical industry can participate.

B. There is an opportunity for focused outreach to registered entities

APHIS and the CDC jointly maintain a list of select agents and toxins that pose a severe threat to livestock, plants, and/or public health.⁷³ Currently, all but 25 of the items on the Select Agent List are also controlled under the EAR and are on the CCL. In October 2004, staff in CBCD, based on discussions with CDC and APHIS officials, decided to draft an AG proposal to put the remaining 25 items from the Select Agent List on the AG control list and then the CCL.

⁷² In FY 2004, CBCD lost 3 LOs. One was replaced in October 2004, however there are still two vacancies.

⁷³ See http://www.aphis.usda.gov/programs/ag_selectagent/ag_bioterr_toxinslist.html for the Select Agent List.

CBCD staff shared this proposal with the Materials Technical Advisory Committee at its February 2005 meeting. After interagency review and concurrence, State submitted this proposal for consideration at the April 2005 AG plenary. If this proposal is made to the AG, but not adopted, BIS will evaluate whether to unilaterally place these 25 items on the CCL.

Note that even without the 25 items on the CCL, there still is a high level of overlap between the Select Agent List and the CCL. APHIS and CDC are responsible for tracking U.S. entities that deal in the agents and toxins on the Select Agent List. The Public Health Security and Bioterrorism Preparedness Response Act of 2002, P.L. 107-188, which was signed into law by the President on June 12, 2002, requires that entities, such as private, state, and federal research laboratories, universities, and vaccine companies, that possess, use, or transfer agents or toxins on the Select Agent List register with the appropriate federal agency (APHIS for livestock and plant pathogens or toxins and CDC for agents or toxins deemed a severe threat to public health). Currently, 318 entities are registered with APHIS and/or CDC. The registered entities fall in the following general categories:

Figure 14. Registered Entities

31%	State and Local Government
30%	Academia
17%	Federal Government
11%	Commercial (For Profit)
10%	Private (Non Profit)
1%	Other

Source: HHS OIG, January 2005

Discussions with officials at APHIS, as well as work done by the OIGs at the U.S. Department of Agriculture and U.S. Department of Health and Human Services, reveal that APHIS and CDC may not be adequately educating the registered entities about the need to obtain export licenses for select agents subject to the CCL and shipped outside the United States. The OIG at Agriculture found two instances of a registered entity shipping a CCL-controlled item to Hong Kong without an export license. They also found that APHIS does not tell its registered entities about export license requirements unless specifically asked. In such cases, APHIS does refer the entities to BIS. The OIG at Health and Human Services did not do an in-depth inspection of registered entities, but it did note that guidance provided by CDC to the entities lacks information about exporting requirements and how to obtain an export license from BIS.

Given both the overlap between the Select Agent List and the CCL, and the “ready made” list of users of select agents and toxins in the hands of APHIS and CDC, this appears to be an excellent group for BIS to reach and educate with minimal effort. BIS should work with APHIS and the CDC to obtain a list of their registered entities and develop a way to inform each entity of (1) the need to comply with the EAR, (2) how to apply for an export license, and (3) contact information for BIS staff should the letter recipients have questions about export licensing requirements.

Recommendations

Pursue multilateral controls on the 25 items now on the HHS/APHIS Select Agent List that are not currently controlled for export. If agreement cannot be reached multilaterally, evaluate putting the 25 items on the CCL unilaterally.

Inform APHIS and CDC registered entities in writing of the need to comply with the EAR and how to apply for an export license if they plan to export controlled items.



In the Acting Under Secretary's March 30, 2005, response to our draft report, the bureau stated that it agreed with these recommendations. For the first recommendation, BIS suggested a modification to reflect the bureau's plan to first petition the AG to control the 25 agents on the Select Agent List that are not currently on the CCL. If the AG does not add the items to its control list, BIS will consider imposing unilateral controls. The recommendation was changed in accordance with BIS' suggestion. For the second recommendation, BIS stated that it has already contacted both APHIS and CDC in order to begin the outreach process to their registered entities. Additionally, BIS stated that CDC's Select Agent website now cites Commerce's export controls on biological agents and APHIS recently requested, and was provided, website citations for BIS to use on its website.

VII. BIS' Export Enforcement Office Needs to Act on the Treaty Compliance Division's Investigative Referrals

BIS' Treaty Compliance Division (TCD) is responsible for assisting U.S. industry in complying with international arms control, disarmament, and non-proliferation agreements and helping to ensure industry compliance. One of the primary agreements the division administers is the Chemical Weapons Convention (CWC), an international treaty that affects companies involved in the production, processing, consumption, import, and export of a range of commercial chemicals and precursors. TCD has referred 13 instances of non-compliance with CWC requirements to OEE for investigation in FYs 2002 through 2004. However, to date, TCD has received no feedback from OEE regarding the referrals, nor has any action been taken against the alleged offenders.

The CWC took effect on April 29, 1997. Currently, 167 countries are state parties to the convention. The CWC contains several requirements for U.S. industry,⁷⁴ such as submitting annual declarations to TCD for certain activities related to chemicals controlled by the CWC. In addition, export licenses may be required to export certain CWC-controlled chemicals, particularly to countries that are not parties to the CWC. In some cases, an end-use certificate is required. End-use certificates are issued directly or approved by the government of the importing destination. When required, end-use certificates must be submitted to BIS within 7 days of the date of export and must state:

- the types and quantities of chemicals being exported;
- their specific end-use(s);
- that the chemicals will be used only for purposes not prohibited by the CWC;
- the name(s) and complete address(es) of end-user(s); and
- that the chemicals will not be transferred to other end-user(s) or end-use(s).

According to TCD, 10 companies did not submit the required end-use certificates in FY 2002. There were two instances of non-compliance with the end-use certificate requirement in FY 2003 and one in FY 2004. TCD staff referred all of the cases of non-compliance to OEE for investigation and appropriate action. However, to date, BIS has taken no action against any of the alleged non-compliant companies. TCD is concerned that this has created the impression among exporters that BIS does not enforce the end-use certificate requirements.

TCD officials are troubled that no sanctions have been applied against any of the companies that did not submit end-use certificates because it reflects poorly on the U.S.'s commitment to enforce CWC provisions. TCD officials noted that the U.S. had worked closely with the Organization for the Prohibition of Chemical Weapons, the international body created to implement the CWC, to set up compliance programs for other CWC members and TCD has worked diligently to be a model for compliance itself. TCD officials are concerned that even though industry compliance has improved, if exporters believe that there is no consequence to not filing the end-use certificates, they may be more lax in the future.

⁷⁴ These requirements are contained in the CWC Provisions of the EAR.
http://www.cwc.gov/Regulations/cwc_ear_provisions.html

We reviewed the 12 referrals TCD made to OEE in FYs 2002 and 2003⁷⁵ and found that OEE had actually initiated nine investigations. OEE had no record of one referral and the referral of two companies in FY 2003 was rolled into open investigations of the same two companies for the same infraction in FY 2002. Six of the nine investigations were still underway, and three were closed without action. Our inquiry into the status of the investigations spurred OEE to take a closer look at the closed referrals, and after examination, OEE officials decided to reopen two of the three closed cases. In addition, OEE has taken further action on the open investigations, including site visits to two companies in December 2004 and January 2005. Given the time intensive nature of the investigations, OEE officials do not have estimates of when these cases will be concluded, but criminal charges will not be filed in the cases because of the nature of the alleged infractions. The more likely penalty would either be a warning letter or an administrative charge that might include a civil fine.

Regardless of the penalties ultimately handed out to companies who have not filed the required end-use certificates, TCD should be informed of any final enforcement actions taken on its referrals so it can (1) educate industry about the consequences of failing to file end-use certificates and (2) demonstrate to the Organization for the Prohibition of Chemical Weapons that the United States has a robust compliance program that includes enforcing CWC requirements through punitive measures. This can be done without publicly disclosing any company-specific or sensitive information. Additionally, TCD should also track its referrals of non-compliant companies so it can follow up with OEE should TCD not be informed in a timely manner of the outcome of the investigations opened as a result of the division's referrals.

Recommendations

Direct OEE to inform TCD of the outcome of the CWC-related investigations upon completion so information can be shared with the chemical exporting community and the Organization for the Prohibition of Chemical Weapons.

Ensure that TCD builds a system to track CWC investigative referrals so it can follow up if OEE has not provided the status of the investigations in a specified period of time.



BIS' response to our draft report stated agreement with these recommendations. For the first recommendation, BIS stated that OEE has designated a senior Special Agent as program manager for CWC-related enforcement. The program manager will forward referrals from TCD to the field for action and share case results with TCD at the appropriate point in OEE's investigation. For the second recommendation, BIS pointed out that the number of referrals is small, an observation with which we agree. However, we still believe that TCD could benefit from tracking its referrals to OEE to ensure the division obtains feedback on the status of the investigations.

⁷⁵ The referral for FY 2004 had just been made to OEE at the time of our review, thus OEE had not yet had time to take any action.

SUMMARY OF RECOMMENDATIONS

We recommend that the Acting Under Secretary for Industry and Security ensure that the following actions are taken:

1. Establish specific timeframes for reviewing and signing off on license applications after approval by the referral agencies (see page 11).
2. Develop and maintain clear, consolidated, and up-to-date guidance, or an internal operations handbook, to strengthen current license application review practices and help ensure that they are consistently applied (see page 11).
3. Assess the feasibility of providing LOs with the information housed in the Automated Targeting System and Automated Export System for use in their review of license applications (see page 25).
4. Work with the intelligence community to develop a method to analyze and track the cumulative effect of dual-use exports to countries and entities of concern (see page 25).
5. Take appropriate actions to sustain recent improvements in the timeliness of U.S. publication of Australia Group guidelines and rule changes that impact the Commerce Control List (see page 31).
6. Work with the State Department, and the other licensing referral agencies, to develop and implement written procedures for handling the AG denial notification process. The procedures should cover, at a minimum:
 - the U.S. policy on submitting denials to the AG,
 - when U.S. denial notifications will be sent to the AG—either when the intent to deny letter is sent or after the 45-day rebuttal period has lapsed, and
 - how U.S. decisions to rescind prior denial notifications to the AG will be made. This should specify how State will exercise its representation authority and how the other licensing agencies will be involved in the decision making process (see page 37).
7. Explore ways to do more outreach to the chemical exporting community, including lower cost outreach alternatives, such as setting up briefings in Washington, mailings, or piggybacking on outreach done in connection with CWC compliance activities conducted by BIS' Treaty Compliance Division (see page 42).
8. Pursue multilateral controls on the 25 items now on the HHS/APHIS Select Agent List that are not currently controlled for export. If agreement cannot be reached multilaterally, evaluate putting the 25 items on the CCL unilaterally (see page 42).
9. Inform APHIS and CDC registered entities in writing of the need to comply with the EAR and how to apply for an export license if they plan to export controlled items (see page 42).

10. Direct OEE to inform TCD of the outcome of the CWC-related investigations upon completion so information can be shared with the chemical exporting community and the Organization for the Prohibition of Chemical Weapons (see page 46).
11. Ensure that TCD builds a system to track CWC investigative referrals so it can follow up if OEE has not provided the status of the investigations in a specified period of time (see page 46).

APPENDIXES

Appendix A

List of Acronyms

ACEP	Advisory Committee on Export Policy
AES	Automated Export System
AG	Australia Group
APHIS	Animal and Plant Health Inspection Service
BIS	Bureau of Industry and Security
BWC	Biological Weapons Convention
CBCD	Chemical and Biological Controls Division
CCL	Commerce Control List
CDC	Centers for Disease Control and Prevention
CIA	Central Intelligence Agency
CBP	U.S. Customs and Border Protection
CWC	Chemical Weapons Convention
EA	Export Administration
EAA	Export Administration Act
EAR	Export Administration Regulations
EARB	Export Administration Review Board
ECASS	Export Control Automated Support System
ECCN	Export Control Classification Number
EE	Export Enforcement
FY	Fiscal Year
GAO	Government Accountability Office
HWA	Hold Without Action
LO	Licensing Officer
LOOM	Licensing Officers Operating Manual
MTCR	Missile Technology Control Regime
MTEC	Missile Technology Export Control Group
NDAA	National Defense Authorization Act
NSG	Nuclear Suppliers Group
OC	Operating Committee
OEE	Office of Export Enforcement
OIG	Office of Inspector General
OMB	Office of Management and Budget
PLC	Pre-License Check
PSV	Post Shipment Verification
RWA	Return Without Action
SED	Shipper's Export Declaration
TCD	Treaty Compliance Division
US&FCS	United States and Foreign Commercial Service
WINPAC	Weapons Intelligence, Nonproliferation, and Arms Control Center

Appendix B

Australia Group Members

Argentina	European Commission	Republic of Korea	Romania
Australia	Finland	Latvia	Slovak Republic
Austria	France	Lithuania	Slovenia
Belgium	Germany	Luxembourg	Spain
Bulgaria	Greece	Malta	Sweden
Canada	Hungary	Netherlands	Switzerland
Republic of Cyprus	Iceland	New Zealand	Republic of Turkey
Czech Republic	Ireland	Norway	United Kingdom
Denmark	Italy	Poland	United States
Estonia	Japan	Portugal	

Appendix C

List of Previous Commerce and Interagency Office of Inspector General Reports, Completed Pursuant to the National Defense Authorization Act For 2000

March 2000—(1) *Improvements Are Needed in Programs Designed to Protect Against the Transfer of Sensitive Technologies to Countries of Concern*, U.S. Department of Commerce Office of Inspector General, IPE-12454-1, (2) *Interagency Inspector General Assessment of Measures to Protect Against the Illicit Transfer of Sensitive Technology*, conducted by the Offices of Inspector General at the Departments of Commerce, Defense, Energy, State, and the Treasury, and the Central Intelligence Agency, 00-OIR-06, and (3) *Interagency Review of the Export Licensing Process for Foreign National Visitors*, conducted by the Offices of Inspector General at the Departments of Commerce, Defense, Energy, and State, D-2000-109.

March 2001—(1) *Management of Commerce Control List and Related Processes Should be Improved*, U.S. Department of Commerce Office of Inspector General, IPE-13744 and (2) *Interagency Review of the Commerce Control List and the U.S. Munitions List*, conducted by the Offices of Inspector General at the Departments of Commerce, Defense, Energy, and State, D-2001-092.

February 2002— *BXA Needs to Strengthen Its ECASS Modernization Efforts to Ensure Long-Term Success of the Project*, U.S. Department of Commerce Office of Inspector General, IPE-14270.

March 2002—*Interagency Review of Federal Automated Export Licensing Systems*, conducted by the Offices of Inspector General at the Departments of Commerce, Defense, Energy, State, and the Treasury, D-2002-074.

March 2003— *Improvements Are Needed to Better Enforce Dual-Use Export Control Laws*, U.S. Department of Commerce Office of Inspector General, IPE-15155.

April 2003—*Interagency Review of Federal Export Enforcement Efforts*, conducted by the Offices of Inspector General at the Departments of Commerce, Defense, State, and the Treasury, and the Central Intelligence Agency and the U.S. Postal Service, D-2003-069.

March 2004—*Deemed Export Controls May Not Stop the Transfer of Sensitive Technology to Foreign Nationals in the U.S.*, U.S. Department of Commerce Office of Inspector General, IPE-16176.

April 2004—*Interagency Review of Foreign National Access to Export-Controlled Technology in the United States*, conducted by the Offices of Inspector General at the Departments of Commerce, Defense, Energy, Homeland Security, and State, and the Central Intelligence Agency, D-2004-062.

Appendix D

Agency Response to Draft Report



UNITED STATES DEPARTMENT OF COMMERCE
Under Secretary for Industry and Security
Washington, D.C. 20230

March 30, 2005

MEMORANDUM FOR JILL GROSS

OFFICE OF INSPECTOR GENERAL

FROM:

Peter Lichtenbaum, Acting 

SUBJECT:

Audit Report No. IPE-116946/March 2005

Draft Report Date: March 16, 2005

Audited Entity: Bureau of Industry and Security

Attached are the Bureau of Industry and Security's comments on the Office of Inspector General's draft report entitled: The Export Licensing Process for Chemical and Biological Commodities is Generally Working Well, But Some Issues Need Resolution, Report No. IPE-16946, March 2005. We appreciate the work you and your staff put into this report.

If you have any questions regarding our submission, please call me at (202) 482-5491.

Attachment

BIS Comments to IG Draft Report



**BUREAU OF INDUSTRY AND SECURITY COMMENTS:
The Export Licensing Process for Chemical and Biological Commodities is Generally Working Well, But Some Issues Need Resolution, Report No. IPE-16946, March 2005.**

Part I contains BIS's comments on specific recommendations in the report. Part II contains comments on the text of the report to ensure its accuracy.

Part I – Response to IG Recommendations

Recommendation 1: *“Establish specific timeframes for reviewing and signing off on license applications after approval by the referral agencies (see page 11).”*

Response: Agree.

Recommendation 2: *“Develop and maintain clear, consolidated, and up-to-date guidance, or an internal operations handbook, to strengthen current license application review practices and help ensure that they are consistently applied (see page 11).”*

Response: Agree.

Recommendation 3: *“Assess the feasibility of providing LOs with the information housed in the Automated Targeting System and Automated Export System for use in their review of license applications (see page 24).”*

Response: Agree.

Recommendation 4: *“Work with the intelligence community to develop a method to analyze and track the cumulative effect of dual-use exports to countries and entities of concern (see page 24).”*

Response: Agree.

Recommendation 5: *“Take appropriate actions to sustain recent improvements in the timeliness of U.S. publication of Australia Group guidelines and rule changes that impact the Commerce Control List (see page 29).”*

Response: Agree. BIS's Fiscal Year 2005 Regulations Calendar has the Australia Group regulation scheduled to be sent for interagency review one month after official notification of the regime list changes. It should be noted, however, that the regulation will need to be cleared by the Departments of State and Defense and, prior to publication, the Office of Management and Budget must approve the regulation.

Recommendation 6: “Work with the State Department, and the other licensing referral agencies to develop and implement written procedures for handling the AG denial notification process.

The procedures should cover, at a minimum:

- the U.S. policy on submitting denials to the AG,
- when U.S. denial notifications are sent to the AG – either when the intent to deny letter is sent or after the 45-day rebuttal period has lapsed, and
- how U.S. decisions to rescind prior denial notifications to the AG will be made. This should specify how State will exercise its representation authority and how the other licensing agencies will be involved in the decision making process (see page 34).”

Response: Agree.

Recommendation 7: “Explore ways to do more outreach to the chemical exporting community, including lower cost outreach alternatives, such as setting up briefings in Washington, mailings, or piggybacking on outreach done in connection with CWC compliance activities conducted by BIS’ Treaty Compliance Division (see page 39).”

Response: Agree. BIS will explore ways to increase outreach to the chemical exporting community consistent with available resources and chemical licensing and policy matters requiring attention.

Recommendation 8: “Modify the CCL to add the 25 items now on the HHS/APHIS Select Agent List that are not currently controlled for export (see page 39).”

Response: Agree but suggest modifying the recommendation to read: “Modify the CCL to add the 25 items now on the HHS/APHIS Select Agent List that are not currently controlled for export following addition of these items to the AG control list. If the AG does not agree to control these items at the 2005 plenary, consider imposing unilateral controls on them (see page 39).” The United States has proposed that the AG control these agents. If the AG does not add these items to its control list, BIS will consider imposing unilateral controls.

Recommendation 9: “Inform APHIS and CDC registered entities in writing of the need to comply with the EAR and how to apply for an export license if they plan to export controlled items (see page 39).”

Response: Agree. BIS has already contacted these agencies in order to begin the outreach process to their registered entities regarding the regulation and control of the export of their commodities. CDC’s Select Agent website currently references to Commerce’s export controls on biological agents. APHIS also recently requested, and received, website citations for Commerce’s export controls on biological agents.

Recommendation 10: *“Direct OEE to inform TCD of the outcome of the CWC-related investigations upon completion so information can be shared with the chemical exporting community and the Organization for the Prohibition of Chemical Weapons (see page 43.)”*

Response: Agree. OEE has designated a senior Special Agent as program manager for CWC-related enforcement. The Program Manager will forward referrals from TCD to the field for action and share case results with TCD at the appropriate point in OEE’s investigation.

Recommendation 11: *“Ensure that TCD builds a system to track CWC investigative referrals so it can follow up if OEE has not provided the status of the investigations in a specified period of time (see page 43.)”*

Response: Agree. We note that the number of these referrals is small.

Part II – Comments on the Report Text

Page i, 2nd full para., revise 4th sentence to read: *“The EAR contains the Commerce Control List (CCL), which identifies the specific dual-use items subject to control, and specifies the conditions under which those items may be exported.”*

Page i, 2nd full para., revise 2nd to last sentence to read: *“Under Executive Order 12981, as amended, several other agencies . . . “*

Page ii, carryover paragraph. The portion of the paragraph carried from page i beginning with “Although Congress is interested in whether . . .” should be deleted or revised.

Comment: As noted in the beginning of the paragraph on page i, the review focused on various aspects of export licensing process (timeliness, adherence to statutory and regulatory requirements, etc.) for items controlled for chemical and biological (CB) weapons proliferation reasons. The review did not seek to actually evaluate the outcome of that licensing process. Thus, the scope of the review selected by the Office of Inspector General (OIG) could not have provided a definitive assessment of whether the export licensing process is helping to prevent the acquisition of sensitive U.S. technology by countries or entities of concern. Given this, the report should not state “. . . we were unable to make a definitive assessment on that point [whether the export licensing process is helping prevent illicit procurement of sensitive technologies] from this review.” The second part of this paragraph – from “Although Congress . . .” through “. . . by circumventing that process altogether.” should either be deleted or revised to note that the review did not seek to evaluate whether the export licensing process is helping to deter illicit acquisition of items controlled for chemical and biological (CB) weapons proliferation reasons.

Page ii, 1st full para., after 5th sentence: *“In addition, Defense, State, and Energy all completed . . .”* add the following sentence: *“The 30-day period specified for interagency review in Executive Order 12981, as amended does not apply to the CIA.”*

Page ii, 1st full para., revise 6th through 9th sentences to read follows: *“License processing times could potentially be improved somewhat if BIS set internal time frames for the closing out license applications that do not need to be escalated to interagency dispute resolution process because neither Executive Order 12981 nor the EAR explicitly set time requirements for the issuance of license applications following conclusion of the interagency review process where there is no escalation.”*

Comment: The report does not provide the analysis to demonstrate that this is a systemic problem causing significant delays in the issuance of CB license applications.

Page iii, 3rd full para., in 2nd to last sentence, revise to read: *“To address this continuing concern, we reiterate the recommendation from our 1999 report, that BIS work with the intelligence community, including CIA, Defense, Energy, and State to develop a method to analyze and track the cumulative effect of dual-use exports to specific countries and regions.”* Add “State” to list of agencies that should participate in this effort.

Page iv, carryover paragraph, last two sentences, delete “a new record” from the second to the last sentence and revise the last sentence to read: *“BIS has told us it will continue its efforts to publish regulations implementing multilateral regime changes, including AG changes, in shorter time frames and we recommend . . .”*

Page iv, 2nd full para., in 3rd sentence, item 2, revise to read: *“Commerce proposes three changes in State’s current practice: . . . (2) send the denials to the AG at the time that BIS issues its “intent to deny” letter rather than at the end of the 45-day appeal period, . . .”*

Comment: Exporters may “rebut” an Intent to Deny letter and “appeal” a final denial.

Page iv, last para., 2nd sentence, revise to read: *“BIS has a reasonably robust . . . , but outreach specific to the chemical exporting community has been limited.”*

Comment: BIS has an extensive general outreach program in which the chemical industry can participate. The OIG did not review the number of chemical companies participating in BIS’s general seminars.

Page 1, 2nd para., 1st sentence, revise to read: *“Currently, the Departments of Defense, Energy, and State review all export license applications except applications for which those departments have delegated decision authority to Commerce.”*

Page 1, 2nd para., last sentence, revise to read: *“In FY 2004, BIS had 371 employees and an appropriation of \$69 million.”*

Page 5, 3rd full para., 1st sentence, revise to read: *“Under the Executive Order, the referral departments (Defense, Energy, and State) must provide a recommendation to approve or deny the license application to the Secretary of Commerce within 30 days of receipt of the referral and all related required information.”*

Page 5, 4th para., 3rd sentence, revise to read: *“There are 55 standard conditions that BIS can place on an export license.”*

Page 5, 4th para., last sentence, revise to read: *“If the reviewing agencies disagree on the license application, the application goes to the Operating Committee for resolution.”*

Page 5, last para., 1st sentence, revise to read: *“Before an application for a chemical and biological export license is escalated, any of the reviewing agencies may choose to address a potential proliferation concern on a particular application by discussing the application at the SHIELD interagency working group, which is [continued to page 6] chaired by State, and has working-level representatives from Commerce (BIS), Defense, CIA, and Energy.”*

Page 6, chart, add note to read: *“Executive Order 12981 provides several circumstances for stopping these time frames, such as obtaining additional information from the applicant.”*

Page 7, 2nd full paragraph, 2nd sentence, revise to read: “The ACEP meets monthly if there are applications to decide and is chaired by . . .”

Page 8, 1st full para., revise to read: “End-use checks (PLCs and PSVs) are conducted by BIS export control attaches (stationed in Abu Dhabi, Beijing, Hong Kong, Moscow, and New Delhi), by BIS special agents traveling in two-person Sentinel Teams, or where these options are not available or not economical, by Commercial Service or State personnel stationed in the country where the end-use check is conducted. Any of the departments (Commerce, Defense, Energy, or State) authorized under Executive Order 12981, as amended, to make recommendations on export license applications can request an end-use check.”

Page 8, 3rd full para., last sentence, revise to read: “As such, TCD assists U.S. companies in (1) submitting annual declarations, end-use certificates, and other reports to both BIS and the Organization for the Prohibition of Chemical Weapons, (2) preparing for on-site inspections, and (3) making determinations on whether chemicals are subject to CWC reporting requirements.”

Comment: All chemicals are subject to Article 1 of the CWC if used to develop chemical weapons. TCD’s responsibility here, however, is not in making determinations on what chemicals are subject to the CWC, rather in making determinations on what chemicals are subject to CWC reporting requirements.

Page 9, 2nd para., portion beginning with “However, while did review . . .”, delete or revise as noted above.

Page 9, last bullet, “Interviews”, revise to read. To determine the effectiveness of the current export license process and obtain their suggestions for improving the process, we spoke with BIS personnel from the following groups: (1) Office of Nonproliferation and Treaty Compliance, including the Chemical and Biological Controls Division, (2) Regulatory Policy Division, (3) Office of [continued on page 10] Enforcement Analysis, (4) Office of Exporter Services, and (5) the Operating Committee Chair.”

Page 12, first sentence after Figure 5, revise to read as follows: “Our in-depth analysis of the remaining 82 license applications identified some issues that require BIS’s overall attention.

Comment: The findings identified procedural issues.

Page 12, footnote 28, revise to read: “License applications can be put on HWA in accordance with Executive Order 12981.”

Comment: Executive Order 12981 sets forth the circumstances for HWA of applications sent to the reviewing departments (Defense, Energy, and State) for recommendations.

Page 13, footnote 30, last sentence, revise to read: “The goal for completing the initial overall review is 39 days (9 days to refer interagency and 30 days for interagency (including CIA)) review.”

Page 15, 1st full paragraph, add new last sentence to read: *“In addition, a pending PLC or other EE flag on an application could delay actual issuance of a license after interagency approval.”*

Page 16, 3rd full para., last sentence, revise to read: *“Even though all seven cases were completed within the overall specified 90 day time frame, it is difficult to determine whether CBCD was timely in the processing of these applications because there was no specific data on the delays to review and no specific criteria to use to judge their performance.”*

Page 18, last paragraph, delete.

Comment: This paragraph should be deleted because it overlooks the fundamental issue – that the Export Administration Regulations (EAR) set forth the circumstances for holding a license application without action (HWA) or returning a license application without action (RWA). As stated in the definition of Hold Without Action in Part 772 of the EAR, Section 750.4 describes the circumstances under which license applications may be put on HWA. The definition of Return Without Action in Part 772 enumerates the circumstances for returning a license application without action. The OIG did not attempt to determine whether the licensing officers apply the criteria set forth in the EAR.

Page 20, 3rd full para., last sentence, revise to read: *“In cases where agencies have differing recommendations, the application is escalated to the OC.”*

Comment: As previously noted, BIS is the escalating party when cases are referred to the OC.

Page 21, last para., 4th and 6th sentences, revise to read: *“The OC Chair speculates that there might be fewer chemical and biological export license applications escalated in the future because of the understanding on end-use visit cooperation between the U.S. Department of Commerce and the Ministry of Commerce of the People’s Republic of China. Under the new understanding reached in April 2004, . . .”*

Page 22, carryover para., replace “agreement” with “understanding.”

Page 24 - 25, subpart A, revise to note: *“Congress has not appropriated funds to BIS to conduct cumulative effect analysis.”*

Page 24, footnote 42, second sentence, revise to read: *“Three have since left, but only one has been replaced to date due to budget constraints.”*

Page 25, subpart B, 1st para., add after the 1st sentence: *“The 8-point memorandum, the CBCD LOs’ analyses of the bona fides and licensing history of individual end-users and the appropriateness of the end-uses, and input from the intelligence community provides the primary information on likelihood of proper use or diversion. Cumulative effect analysis can supplement this information.”*

Comment: CBC LOs provide to the interagency application reviewing community an analysis of

the bona fides and licensing history of individual end-users as well as an analysis of the appropriateness of the commodity's proposed end-use.

Page 27, 3rd para., last sentence, revise to read: *"A BIS official said that under current fiscal restraints such clearances would be prohibitively costly given the isolated training for which they would be needed. BIS would welcome the resources in order to allow its staff to procure such clearances to gain such CIA/WINPAC training opportunities, as well as the resources necessary to develop additional related in-house tools such as secure databases."*

Page 28, 2nd para., last sentence, revise to read: *"Both BIS and CIA officials stated that all chemical and biological license applications are thoroughly reviewed, including the bona fides of all end users, and that current intelligence is brought to bear on all applications, notwithstanding the lack of comprehensive cumulative effect analyses."*

Page 29, 2nd para., 5th sentence, revise to read: *"BIS officials believed that the 2001 changes would expedite the review of regulations, including those implementing the AG changes. Although these changes did not impact the amount of time needed to publish the 2002 and 2003 changes, in 2004 the changes took only 6 months to publish. In the future, . . . BIS officials reported that they plan to send the regulation implementing the 2005 AG changes for interagency review within one month of receiving official notification of the regime changes."*

Comment: The revision more precisely reflects the current situation and planned 2005 schedule.

Page 31, 1st full para., revise to read: *"BIS officials cited several reasons for the time it takes to publish new AG regulations. First, time may elapse between the end of the AG plenary and the official posting of the control list changes. This will delay the beginning of the process for formal interagency clearance of the implementing regulation. Second, according to BIS, the U.S. regulatory process . . ."*

Page 31, 2nd para., 3rd sentence, revise by striking Energy and CIA from parenthetical.
Comment: Energy and CIA do not review AG regulations.

Page 31, subpart B, 1st para., add after last sentence: *"While agreement on timing for implementation among AG members would be ideal, it is unlikely due to members' national discretion in undertaking AG commitments."*

Comment: It would be difficult for the State Department, as U.S. delegation chair to the Australia Group (AG), to request this type of simultaneous implementation from the AG, as each member will want to retain the right to implement AG guidelines at their national discretion. BIS will continue efforts to expedite implementation of regulations incorporating AG guidelines.

Page 32, 1st para., 6th sentence, revise to read: *"Because of the derogatory information on the end-user, BIS placed the application on HWA pending publication of the new AG rules in June 2003 in order to obtain and issue a regime-based denial so that the AG no undercut obligations would be implemented on a multilateral basis. Denials based on unilateral controls do not*



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invoke such obligations.”

Page 33, Conclusions, 1st para., 1st sentence: This does not reflect the view of BIS management. BIS’s 2005 Regulations Calendar, circulated to the reviewing departments in December 2004, has scheduled interagency review of the regulation implementing the 2005 AG changes one month after receiving official notification of the changes.

Page 33, Conclusions, 2nd para., revise to read: *“BIS says publishing changes . . . will depend on (1) how quickly BIS receives the official notice of the changes, (2) the complexity of the changes, (3) whether there is an effort to add unrelated revisions to the rule, and (4) how quickly Commerce, Defense, and State resolve any comments on the rule.*

Page 34, 2nd para., 3rd sentence, revise to read: *“BIS believes three changes would be useful to make the denial notification process more effective and transparent.”*

Page 34, 2nd para., 2nd to last sentence, revise to read: *“Unfortunately, the AG’s policy on the reporting of denials is not explicit, so State and Commerce have different views on how it should be implemented.”*

Page 35, 1st full para., last sentence, delete.

Comment: BIS has not challenged the Department of State’s authority to make such decisions, although we disagree with State’s application of that authority.

Page 37, 3rd full para., 4th sentence, revise to read: *“Neither the AG guidelines nor the EAR address the issue of rescinding prior denials to the AG.*

Pages 40, last para., pages 40 -41, revise to read: *“In October 2004, staff in CBCD based on discussions with CDC and APHIS officials, decided to draft an AG proposal to put the remaining 25 items from the Select Agent List on the AG control list and then the CCL.”*

Page 40, para. continuing onto the top of page 41: Strike the paragraph on unilateral controls.

Page 41, 1st para., revise to read: *“CBCD shared this proposal with the Materials Technical Advisory Committee at its February 2005 meeting. After interagency review and concurrence, State submitted this proposal for consideration at the April AG plenary. If this proposal is made to the AG but not adopted, BIS will evaluate whether to place unilateral controls on these items.”*

Page 42, Recommendations, revise to read: *“Pursue multilateral controls on the 25 items now on the HHS/APHIS Select Agent List that are not currently controlled for export.*

Inform APHIS and CDC . . .

Appendix C. Department of Defense Report

March, 30, 2005



Export Controls

Controls Over the Export Licensing
Process for Chemical and Biological
Items

(D-2005-042)

Department of Defense
Office of the Inspector General

Quality

Integrity

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Acronyms

AECA	Arms Export Control Act
CCL	Commerce Control List
DTSA	Defense Technology Security Administration
EAA	Export Administration Act
EAR	Export Administration Regulations
HHS	Department of Health and Human Services
ITAR	International Traffic in Arms Regulations
TPS	Technology Protection System
USDA	U.S. Department of Agriculture
USML	U.S. Munitions List
USXPORTS	U.S. Export System



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March 30, 2005

MEMORANDUM FOR DEPUTY UNDER SECRETARY OF DEFENSE
(TECHNOLOGY SECURITY POLICY AND
COUNTERPROLIFERATION)

SUBJECT: Report on Controls Over the Export Licensing Process for Chemical
and Biological Items (Report No. D-2005-042)

We are providing this report for information and use. We conducted the audit in response to Public Law 106-65, "National Defense Authorization Act for Fiscal Year 2000," Section 1402, "Annual Report on Transfers of Militarily Sensitive Technology to Countries and Entities of Concern." We considered management comments on a draft of this report in preparing the final report. The complete text of the comments is in the Management Comments section of the report.

Comments on the draft of this report conformed to the requirements of DoD Directive 7650.3 and left no unresolved issues. Therefore, no additional comments are required.

We appreciate the courtesies extended to the staff. Questions should be directed to Mr. Robert F. Prinzbach at (703) 604-8907 (DSN 664-8907) or to Mr. Brett A. Mansfield at (703) 604-9646 (DSN 664-9646). See Appendix D for the report distribution. The team members are listed inside the back cover.

Robert K. West

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Deputy Inspector General
for Auditing

Department of Defense Office of Inspector General

Report Number D-2005-042

March 30, 2005

(Project No. D2004-D000LG-0232)

Controls Over the Export Licensing Process for Chemical and Biological Items

Executive Summary

Who Should Read This Report and Why? Civil service employees and uniformed officers responsible for controlling the release of chemical and biological items for reasons of national security or U.S. foreign policy should read this report. The report discusses the effectiveness of the DoD review process for export license applications and updates to Federal export regulations to prevent the proliferation of items that could pose a threat to public health and safety.

Background. Public Law 106-65, “National Defense Authorization Act for FY 2000,” section 1402, “Annual Report on Transfers of Militarily Sensitive Technology to Countries and Entities of Concern,” October 5, 1999, requires that the Inspectors General of the Departments of Commerce, Defense, Energy, and State, in consultation with the Director of Central Intelligence and the Director of the Federal Bureau of Investigation, conduct annual reviews of controls over the transfer of militarily sensitive technology to countries and entities of concern. These annual reviews are summarized in an interagency report to Congress.

The U.S. Government restricts the export of chemical and biological items to foreign entities through the Department of Commerce’s Export Administration Regulations and the Department of State’s International Traffic in Arms Regulations (the Federal export regulations). Both the Department of Commerce and the Department of State consult with other Federal agencies, including DoD, during the review of export license applications. Within DoD, the Deputy Under Secretary of Defense (Technology Security Policy and Counterproliferation) is responsible for export control and nonproliferation policies and, as the Director of the Defense Technology Security Administration, is responsible for coordinating license application reviews and providing the overall DoD position on export license applications to Commerce and State, as appropriate.

The United States unilaterally controls biological items through the Bioterrorism Act, which directs the Departments of Agriculture and Health and Human Services to identify biological agents and toxins that could be used in acts of terrorism or other illegal acts and to establish and enforce safeguards and security measures to restrict access to those agents and toxins. These controls apply to the importation, use, and transfer of those items within the United States. They do not control the export of such items.

Results. DoD had an effective process to review export license applications for chemical and biological items. DoD management controls over the licensing process were adequate in that DoD consistently reviewed applications in a timely manner and the controls were in compliance with applicable requirements (see finding A).

DoD uses the Federal export regulations to determine which chemical and biological items require a license for export (export-controlled items). However, the Commerce Control List does not contain 20 biological agents and toxins identified on the U.S. Department of Agriculture and the Department of Health and Human Services lists that have the potential to pose a threat to animal, plant, and public health and safety. The Department of Commerce is currently considering whether the items contained in the U.S. Department of Agriculture and Department of Health and Human Services lists should be export controlled. We recommend that the Deputy Under Secretary of Defense (Technology Security Policy and Counterproliferation), together with the Department of Commerce, undertake an assessment of items on the U.S. Department of Agriculture List of Biological Agents and Toxins and the Department of Health and Human Services List of Select Agents and Toxins as changes occur to those lists and determine whether any of the listed agents and toxins should be controlled for export purposes by inclusion on the Commerce Control List (see finding B).

Management Comments and Audit Response. The Deputy Under Secretary of Defense (Technology Security Policy and Counterproliferation) concurred with the audit findings and the recommendation. However, she stated that the section of the draft report labeled “Munitions Export License Applications” was not entirely accurate. Based on her comments, we made revisions to the “Munitions Export License Applications” section of the report to better reflect the process used by Defense Technology Security Administration to process and refer munitions export license applications. Management comments are responsive, and no additional comments are required. See the Finding sections of the report for a discussion of management comments and the Management Comments section of the report for the complete text of the comments.

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This audit was performed to meet the requirement of Public Law 106-65, “National Defense Authorization Act for FY 2000,” section 1402, “Annual Report on Transfers of Militarily Sensitive Technology to Countries and Entities of Concern,” October 5, 1999, which states:

“(a) ANNUAL REPORT. – Not later than March 30 of each year beginning in the year 2000 and ending in the year 2007, the President shall transmit to Congress a report on transfers to countries and entities of concern during the preceding calendar year of the most significant categories of United States technologies and technical information with potential military applications.

“(b) CONTENTS OF REPORT. – The report required by subsection (a) shall include, at a minimum, the following:

* * * * *

“(3) An audit by the Inspectors General of the Departments of Defense, State, Commerce, and Energy, in consultation with the Director of Central Intelligence and the Director of the Federal Bureau of Investigation, of the policies and procedures of the United States Government with respect to the export of technologies and technical information referred to in subsection (a) to countries and entities of concern.”

This report addresses the DoD portion of the required FY 2005 interagency review. An interagency report will also be issued.

Background

The United States unilaterally controls the export of certain goods and technologies for national security, foreign policy, or nonproliferation reasons under the authority of several different laws. The primary legislative authority for controlling the export of goods and technologies that have civilian and military application (dual-use) is the Export Administration Act (EAA) of 1979, as amended (title 50, United States Code, section 2401).¹ The Export Administration Regulations (EAR) state that the EAA gives authority to the Secretary of Commerce to issue rules and procedures for the export of dual-use items. The export of goods and technologies that have only military use (munitions items) is controlled under the authority of the Arms Export Control Act (AECA) (Public Law 90-629). The AECA authorizes the President to control the export of munitions items.

¹ The EAA expired in August 1994. However, the President, under the authority of the International Emergency Economic Powers Act (50 U.S.C. 1702), continued the provision of the EAA through Executive Orders 12924 and 13222, “Continuation of Export Control Regulations,” August 19, 1994, and August 17, 2001, respectively. Each year thereafter, and most recently on August 6, 2004, the President issued a notice, “Continuation of Emergency Regarding Export Control Regulations,” continuing the emergency declared by Executive Order 13222.

The United States restricts the export of chemical and biological items to foreign entities through two Federal export regulations: the EAR, maintained by the Department of Commerce (Commerce), and the International Traffic in Arms Regulations (ITAR), maintained by the Department of State (State). For this report, goods and technologies that are listed in Federal export regulations as requiring a license for export are referred to as export-controlled items. Both Commerce and State may consult with other Federal agencies (referral agencies), including DoD, on export-controlled items.

Department of Commerce. The Commerce Bureau of Industry and Security controls the export of dual-use items using the authority provided in the EAA. The EAR implements the EAA requirements for executing the export licensing process for dual-use items and contains the Commerce Control List (CCL) that identifies dual-use items—goods and technologies, including software—that are subject to the process as well as the conditions under which they may be exported. The term “dual-use” is used to distinguish EAR-controlled items that can be used both in military and other strategic uses and in commercial applications. CCL Category 1, “Materials, Chemicals, Microorganisms, and Toxins,” controls chemical and biological protective and detection equipment and components not specifically designed for military use. Category 1 also controls chemical agents, precursors for toxic chemical agents, human pathogens and toxins, and Chemical Weapons Convention schedule 2 and 3 chemicals. Software and technology specifically designed or modified to develop, produce, or use Category 1 items are also export-controlled items. This report uses the term “chemical and biological items” to refer to all items listed under Category 1.

Department of State. The State Office of Defense Trade Controls is responsible for controlling the export of defense-related articles and services, approving or denying export license applications, ensuring compliance with the AECA, and registering persons and contractors. The ITAR implements the AECA and contains the U.S. Munitions List (USML), which identifies export-controlled defense-related articles, services, and related technical data as well as the conditions under which they may be exported. USML Category 14, “Toxicological Agents and Equipment and Radiological Equipment” controls nerve agents, vesicant agents, incapacitating agents, riot control agents, defoliants, medical countermeasures, and modeling or simulation test facilities. In addition, Category 14 controls technical data and defensive services. Components, parts, accessories, tools, and equipment specifically designed or modified for the production of those munitions are also export-controlled items. This report’s use of the term “chemical and biological items” also includes all items listed under Category 14.

Department of Defense. Within DoD, the Deputy Under Secretary of Defense (Technology Security Policy and Counterproliferation), under the direction, authority, and control of the Under Secretary of Defense for Policy, is responsible for the development and issuance of export control and nonproliferation policies. The Deputy Under Secretary also serves as the Director of the Defense Technology Security Administration (DTSA) and is responsible for coordinating license application reviews and providing to Commerce and State, as appropriate, the overall DoD position on export license applications. According to Draft Directive 5105.72, “Defense Technology Security Administration (DTSA),”

DTSA is the receiving point for all export license applications and develops DoD positions on those applications. The Director, DTSA is also responsible for supporting the activities of other DoD Components and Federal agencies to restrain the flow of sensitive defense-related technology, goods, services, and munitions.

Export Licenses. To be exported from the United States, all items listed on either the CCL or the USML must have an approved license or a specific license exception. U.S. entities are generally required to obtain an export license before providing foreign nationals access to software or technology that is subject to export licensing requirements. The need for an export license or license exception is determined by the type of item being exported, the country of final destination, and the end use of the item. Information about consignees, end users, and end uses must be included in the application. Because of recent proliferation concerns, the export of even the most basic items may require an export license if the end use is for nuclear, missile, biological, or chemical research, development, or production. Commerce and State may issue licenses with conditions that require the exporter to abide by certain restrictions. The referral agencies can also recommend that conditions be placed on an export license before it is issued.

Objectives

Our overall audit objective was to evaluate whether the DoD export licensing review process helped deter the proliferation of chemical and biological commodities. We assessed the effectiveness of the DoD export licensing review process to ensure that lethal chemical and biological items were not exported to countries and entities of concern. Specifically, we determined whether DoD received, and how DoD assessed, export license applications for chemical and biological items. We also reviewed the management control program as it related to the overall objective. We deferred an announced objective of determining whether DoD facilities with chemical and biological items were in compliance with Federal export laws and regulations. See Appendix A for a discussion of the scope and methodology and our review of the management control program. See Appendix B for prior coverage related to the objectives.

A. DoD Review Process for Export License Applications

DoD had an effective process to review export license applications for chemical and biological items. DoD consistently reviewed and referred applications in a timely manner, provided positions on export license applications, and was in compliance with applicable requirements. Despite the lack of a fully automated license application referral process at State or Commerce, DoD met statutory and internal review objectives.

DoD Role in the Export License Application Review Process

DTSA is the DoD focal point and is responsible for coordinating and reviewing export license applications received from Commerce and State. DTSA is required to develop DoD positions on export license applications consistent with national security objectives and to process applications expeditiously, making full use of automation and other efficiencies. As required by Executive Order 12981, DTSA participates in the review of dual-use export license applications.

Dual-Use Export License Applications. DTSA follows statutorily required timelines² for review of dual-use export license applications, which allow up to 30 days for review. DTSA receives dual-use license applications electronically through the Technology Protection System (TPS), but DTSA receives supporting data in hard copy via a courier service. A DTSA Tiger Team, composed of representatives from the Licensing, Technical, and Policy Divisions of DTSA, meets each morning to review a synopsis of dual-use license applications to determine which license applications should be referred to DoD Components. DTSA does not refer an application that the Tiger Team determines is standard or repetitive. For non-referred license applications, DTSA records its position through TPS. If the application is not standard or repetitive, DTSA refers the application electronically to the appropriate DoD Components via TPS and sends the supporting data in hard copy via a courier service. The DoD Components that DTSA might refer applications to are the Army, the Navy, and the Air Force (the Military Departments). DTSA gives the Military Departments 10 days to review the application. Once DTSA receives the Military Departments' comments, a DTSA licensing officer creates a final DoD position and enters it into TPS.

Dual-use license applications are also reviewed at an interagency "Shield" meeting. Chaired by State, Shield is an informal interagency working group with representation from Commerce, the Central Intelligence Agency, DoD, and the Department of Energy. Shield meetings provide a forum for discussing different opinions on license applications. Shield facilitates the review of dual-use license applications for chemical and biological items by meeting once a week and reviewing all dual-use license applications that are 16 to 22 days old. Shield

² Executive Order 12981 states that for dual-use export license applications, a Department or agency shall provide the Secretary of Commerce with a recommendation either to approve or deny the license application within 30 days of receipt of a referral and all required information.

focuses on applications of concern and attempts to resolve issues. Shield escalates applications to the Operating Committee³ if issues cannot be resolved. The Operating Committee considers the agencies' positions on unresolved dual-use export license applications and determines whether to permit the export.

Munitions Export License Applications. DTSA has established informal, internal deadlines for the review of munitions export license applications. DTSA normally allows up to 31 days for DoD review and response to referred applications. DTSA either receives munitions license applications in hard copy via a courier or electronically through the U.S. Exports System (USXPORTS) from the State Department. Once DTSA receives a license application, they review the application and determine whether it is standard or repetitive and, therefore, does not need to be referred. If DTSA determines that a license application is standard or repetitive, DTSA provides the DoD position to State through USXPORTS. If the license application is not standard or repetitive, DTSA refers the application to the Military Departments. This step including the process of providing State the DoD position or referring the application to the Military Departments takes approximately 2 days. Hard copies of the applications and associated technical data are transferred for review via courier service. If the information is available in electronic form, it is also transferred for review via USXPORTS. DTSA allows Military Departments 25 days to review an application and, if that deadline is not met, DTSA can approve a 14-day extension. At the conclusion of the 25 days, it takes DTSA approximately 2 days to create and post the draft DoD position for review and comment by the Military Departments. Military Departments then have approximately 2 days to dispute the draft position. If there are no comments received from the reviewers, DTSA posts the final DoD position to State.

Military Department Referrals. For both dual-use and munitions license applications, the Military Departments refer the license applications to program managers, technical experts, or other appropriate personnel for comment.

The Deputy Assistant Secretary of the Army (Defense Exports and Cooperation) sent a memorandum to DTSA on July 23, 2003, that deferred the Army position on dual-use export license applications to the judgment and expertise of DTSA for the development of positions. The Deputy Assistant Secretary initiated that action after an internal review found that the Army's interests were equally served regardless of whether the Army or DTSA reviewed the applications. However, the memorandum also states that dual-use license applications considered by DTSA to be of particular importance could still be referred and would be appropriately reviewed. Army personnel stated that they review approximately 150 chemical or biological export license applications per year. Navy and Air Force personnel stated that they review approximately 20 or fewer chemical or biological license applications per year for each of their respective Departments.

³ Executive Order 12981 states that the Secretary of Commerce appoints the Chair of the Operating Committee and he or she will consider the recommendations of the reviewing Departments and agencies and make the final decision concerning the proposed export.

DoD Review of Export License Applications

We obtained a list of all chemical and biological export license applications received by Commerce and State during FY 2003. Those lists showed that Commerce had received 1,803 dual-use export license applications and that State had received 717 munitions export license applications for chemical or biological items. We reviewed random samples of 91 of the 1,803 dual-use applications and 85 of the 717 munitions applications.

Dual-Use Export License Applications. Commerce referred 84 of the 91 dual-use export license applications in our sample to DTSA for comment. Commerce returned six of the remaining seven applications to the applicant without action because the applications were incomplete, and Commerce did not refer the seventh application to DoD because it was not considered to be a military item. DTSA met the statutory timeframe for the 84 applications it reviewed, and DTSA personnel stated that they had no outstanding concerns with Commerce's final positions.

In addition, we reviewed 18 dual-use export license applications from the Commerce list that had been escalated to the Operating Committee. DTSA personnel stated that DoD had no outstanding issues with the Operating Committee's or Commerce's final positions.

Munitions Export License Applications. State referred 57 of the 85 munitions license applications in our sample to DTSA. State did not refer the other 28 applications to DTSA because of the following reasons.

- Eighteen applications were for standard or repetitive items or State considered the technology level of the item to be widespread and not to pose a threat to the United States.
- Ten applications were incomplete and returned to the applicant without action.

DTSA generally met internal deadlines for reviewing the 57 referred munitions export license applications. DTSA took more than 31 days to review 4 of the 57 referred applications; however, we do not consider those instances to be excessive or to reveal an overall weakness with the review process for munitions license applications because they were reviewed in under 45 days, which is still within the allowable 14-day extension. DTSA personnel stated that, for the 57 referred applications, they had no outstanding concerns with State's final positions.

Automation of the Export Licensing Process. DoD was generally timely in its reviews of both dual-use and munitions export licenses. However, DTSA and Military Department personnel stated that the application review process would be more efficient if all license applications and supporting data were provided electronically. Specifically, the use of a courier service to deliver supporting data to DTSA and Military Departments adds at least 3 days of processing time for both dual-use and munitions export license applications. If Commerce and State referred supporting data electronically with the applications, DTSA and Military

Departments could reduce their review time by at least 3 days for some applications. However, DTSA consistently met statutory and internal deadlines despite the lack of a fully automated license application process; therefore, we are not making a recommendation to fully automate the process. Additionally, DTSA does not control how it receives supporting data; Commerce and State would need to take actions to ensure that all supporting data were sent to DTSA electronically by their Departments.

Conclusion

DTSA and the Military Departments were effective in meeting their statutorily required and internal deadlines and contributed to the dual-use and munitions export license application review process. We attribute much of the success of the process to the spirit of cooperation exhibited by the personnel of DTSA and the Military Departments.

Management Comments on the Finding

Management Comments. The Deputy Under Secretary of Defense (Technology Security Policy and Counterproliferation) concurred with the audit finding. However, she stated that the paragraph of the draft report labeled “Munitions Export License Applications” was not entirely accurate. She provided alternate language for this section of the report.

Audit Response. As a result of management comments by the Deputy Under Secretary of Defense (Technology Security Policy and Counterproliferation), we made revisions to the “Munitions Export License Applications” paragraph of the report to better reflect the process used by DTSA to process and refer munitions export license applications.

B. Biological Items of Concern Not Currently Export Controlled

DoD uses the Commerce Control List (CCL) to determine which biological items of concern are export controlled and require the filing of an export license application. However, the CCL does not contain 20 biological agents and toxins identified on the U.S. Department of Agriculture (USDA) and the Department of Health and Human Services (HHS) lists that have the potential to pose a threat to animal, plant, and public health and safety. Commerce is currently considering whether the items contained in the USDA and HHS lists should be export controlled. It is our opinion that items listed on the USDA and HHS lists should be periodically evaluated for inclusion in the CCL.

Established Legislative Authority

The United States controls chemical and biological items through legislation and by implementing regulations. The AECA and the EAA are the legislative authority for the EAR and the ITAR. The EAR and the ITAR are the Federal export regulations that identify the chemical and biological items of concern that require export control. Also, Public Law 107-188, "Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (Bioterrorism Act), directs the USDA and HHS to establish and enforce safeguards and security measures to restrict access to biological agents and toxins that could be used in acts of terrorism or for any other criminal purpose. USDA is required to establish and maintain a list of and controls for biological agents and toxins that have the potential to pose a threat to animal or plant health or to animal or plant products. HHS is required to establish and maintain a list of and controls for biological agents and toxins that have the potential to pose a threat to public health and safety.

Biological Items of Concern Not Export Controlled

As a result of the Bioterrorism Act, USDA and HHS published regulations on the possession, use, and transfer of chemical and biological items listed in those regulations. The regulations went into effect on February 11, 2003, and February 7, 2003, respectively.

Both regulations establish requirements regarding the possession and use of the listed agents, their importation, and their transfer within the United States. The USDA regulation does not address the establishment of export controls. The HHS regulation states that it does not set export controls because regulating exports is the responsibility of Commerce.

The USDA and HHS lists, in effect since February 2003, included 20 items that were not included on the CCL as of February 2005. Specifically, the CCL did not include:

-
- 15 biological agents on the USDA Biological Agent List;
 - 1 biological agent on both the USDA Biological Agent List and the HHS Select Agent List; and
 - 4 biological agents on the HHS Select Agent List.

See Appendix C for a table showing the 20 biological agents and the particular lists they are on.

DoD Control of Biological Items

DoD Directive 2040.2 requires the Under Secretary of Defense for Policy to prepare technology transfer control policy. In addition, the Directive requires DoD Components to manage transfers of technology, goods, services, and munitions consistent with U.S. foreign policy and national security objectives.

DoD, like all U.S. entities, uses the Federal export regulations to determine which chemical and biological items require a license for export (export-controlled items).

Annual Report to Congress on Export Policies and Procedures

To meet the intent of the “National Defense Authorization Act for FY 2000” the Offices of the Inspectors General of the Departments of Commerce, Defense, Energy, and State, in consultation with the Director of Central Intelligence and the Director of the Federal Bureau of Investigation, established guidelines for conducting annual reviews of controls over the transfer of militarily sensitive technology to countries and entities of concern. The participating Offices of Inspectors General signed a memorandum of understanding which stated that the agencies would develop an agreed upon approach to address each year’s review of controls over the transfer of militarily sensitive technology to countries and entities of concern. Each Office of Inspector General agreed to issue an agency specific report and work together to issue an interagency report to Congress outlining the combined findings and recommendations.

In discussions with the Commerce Office of Inspector General’s representative to the interagency working group, subsequent to the draft report, we were notified that Commerce will address the issue of updating the CCL with items listed on the USDA and HHS lists. This issue will also be addressed in the Commerce specific and interagency reports. As a result, we made revisions to our draft finding to reflect the actions planned by Commerce to expand the CCL.

Recommendation and Management Comments

B. We recommend that the Deputy Under Secretary of Defense (Technology Security Policy and Counterproliferation), together with the Department of Commerce, undertake an assessment of items on the U.S. Department of Agriculture List of Biological Agents and Toxins and the Department of Health and Human Services List of Select Agents and Toxins as changes occur to those lists and determine whether any of the listed agents and toxins should be controlled for export purposes by inclusion on the Commerce Control List.

Management Comments. The Deputy Under Secretary (Technology Security Policy and Counterproliferation) concurred with the draft finding and recommendation.

Appendix A. Scope and Methodology

We reviewed applicable Executive Orders and Federal laws and regulations, including the EAA, the AECA, and the associated EAR and ITAR. In addition, we evaluated the adequacy of DoD directives, policies, and regulations related to the disclosure and transfer of militarily sensitive and critical technologies to foreign entities from 1984 through 2004. We reviewed those documents to determine DoD responsibilities in the export license application review process.

We compared export-controlled items listed in the EAR and ITAR with chemical and biological items listed in multilateral agreements, such as the Australia Group, Chemical Weapons Convention, Comprehensive Nuclear-Test-Ban Treaty, Missile Technology Control Regime, and the Wassenaar Agreement, to identify whether any of those items were not included in the EAR or ITAR. Additionally, we compared the items on the USDA Biological Agent List and the HHS Select Agent List with the items controlled by the EAR and the ITAR to determine whether any of those items were not included in the EAR or ITAR.

During our audit, we interviewed personnel from the following offices: the Office of the Under Secretary of Defense for Intelligence; the Office of the Assistant to the Secretary of Defense (Chemical and Biological Defense); the Office of the Deputy Under Secretary of Defense (Technology Security Policy and Counterproliferation); the Plans & Policy Directorate (J-5) and the Force Structure, Resources, and Assessment Directorate (J-8), Joint Staff; the Joint Program Executive Office (Chemical and Biological Defense); the Office of the Deputy Assistant Secretary of the Army (Defense Exports and Cooperation); the Navy International Programs Office, Export License Division; the Deputy Under Secretary of the Air Force (Foreign Disclosure and Technology Transfer Division); the Defense Security Service; DTSA; and the Defense Threat Reduction Agency. At each location we discussed the export license application review process and the role and responsibilities for each office.

We performed this audit from September 2004 through February 2005 in accordance with generally accepted government auditing standards. Our scope was limited due to time and resource constraints. Specifically, we did not address the announced objective of determining whether DoD facilities with chemical and biological items were in compliance with Federal export laws and regulations.

We met with DTSA personnel who reviewed export license applications referred by Commerce and State, and we reviewed the automated systems used in the license review process. In addition, we met with the Shield chairperson to gain an understanding of the Shield process for reviewing dual-use export license applications. We also met with the Military Departments' export license application review offices to determine their processes for reviewing applications referred to them by DTSA.

To determine the effectiveness of the DoD export license application review process to ensure that lethal chemical and biological commodities were not exported to countries and entities of concern, we reviewed two random samples of applications—91 dual-use and 85 munitions export license applications. We

reviewed the samples to determine whether the export license applications were referred to DTSA and the Military Departments. To determine whether DoD received, and how DoD assessed, chemical and biological export license applications, we reconciled the export license applications in our samples with DTSA records and reviewed the rationale for each non-referral. We then compared actual processing times for referred applications with the statutory and internal deadlines for timeliness. We also compared the DoD final position with the final Commerce or State position, identified discrepancies, and inquired about those discrepancies.

For our samples, we obtained lists from Commerce and State of all chemical or biological export license applications they received during FY 2003. Those lists showed that Commerce had received 1,803 dual-use export license applications and that State had received 717 munitions export license applications for chemical or biological items. We used a sampling plan designed by the DoD Office of Inspector General's Quantitative Methods Division to randomly select export license applications from those lists for review.

Use of Computer-Processed Data. We relied on computer-processed data from the Commerce Export Control Automated Support System, USXPORTS, and TPS. We compared summarized or detailed data contained within those automated export licensing systems and reconciled differences. We did not find any errors that would preclude our use of the computer-processed data to meet the audit objectives or would change the conclusions in this report. Based on our comparison, we concluded that the system controls were adequate for our purposes in conducting this audit.

Use of Technical Assistance. We received technical assistance from the DoD Office of Inspector General's Quantitative Methods Division, which designed the sampling plan for our random samples taken from the lists of dual-use and munitions export license applications received by Commerce and State, respectively, during FY 2003. The sampling plan was designed with a 95 percent confidence level and a 10 percent precision level. We also received technical assistance from DTSA and Commerce during the course of this audit. Specifically, DTSA and Commerce personnel reviewed our comparison of the CCL and the USML with the multilateral agreement and unilateral regulations to determine whether our conclusions were accurate.

Management Control Program Review

DoD Directive 5010.38, "Management Control (MC) Program," August 26, 1996, and DoD Instruction 5010.40, "Management Control (MC) Program Procedures," August 28, 1996, require DoD organizations to implement a comprehensive system of management controls that provides reasonable assurance that programs are operating as intended and to evaluate the adequacy of the controls.

Scope of the Review of the Management Control Program. We evaluated the controls over the DoD export license review process for lethal chemical and biological items. Specifically, we reviewed the adequacy of the policies and

procedures that the Office of the Deputy Under Secretary of Defense (Technology Security Policy and Counterproliferation) had for preventing the transfer of lethal chemical and biological items to countries and entities of concern. We also reviewed the adequacy of DTSA management controls over referred dual-use and munitions export license applications. Because we did not identify a material weakness, we did not assess management's self-evaluation.

Adequacy of Management Controls. The Office of the Deputy Under Secretary of Defense (Technology Security Policy and Counterproliferation) and DTSA management controls were adequate in that we identified no material management control weakness.

Appendix B. Prior Coverage

During the last 6 years, the Government Accountability Office (GAO) and the Department of Defense Inspector General (DoD IG) have conducted multiple reviews discussing the adequacy of export controls. Unrestricted GAO reports can be accessed over the Internet at <http://www.gao.gov>. Unrestricted DoD IG reports can be accessed at <http://www.dodig.mil/audit/reports>. The following previous reports are of particular relevance to the subject matter in this report.

GAO

GAO Report No. GAO-01-528, “Export Controls: State and Commerce Department License Review Times are Similar,” June 14, 2001

DoD IG

DoD IG Report No. D-2004-061, “Export Controls: Export-Controlled Technology at Contractor, University, and Federally Funded Research and Development Center Facilities,” March 25, 2004

DoD IG Report No. D2003-070, “Export Controls: DoD Involvement in Export Enforcement Activities,” March 28, 2003

DoD IG Report No. D-2003-021, “Security: Export Controls Over Biological Agents (U),” November 12, 2002

DoD IG Report No. D-2002-039, “Automation of the DoD Export License Application Review Process,” January 15, 2002

DoD IG Report No. D-2001-088, “DoD Involvement in the Review and Revision of the Commerce Control List and the U.S. Munitions List,” March 23, 2001

DoD IG Report No. D-2000-110, “Export Licensing at DoD Research Facilities,” March 24, 2000

DoD IG Report No. 99-186, “Review of the DoD Export Licensing Processes for Dual-Use Commodities and Munitions,” June 18, 1999

Interagency Reviews

Inspectors General of the Departments of Commerce, Defense, Energy, Homeland Security, and State and the Central Intelligence Agency Report No. D-2004-062, "Interagency Review of Foreign National Access to Export-Controlled Technology in the United States," April 16, 2004

Inspectors General of the Departments of Commerce, Defense, State, and the Treasury; the Central Intelligence Agency; and the United States Postal Service Report No. D-2003-069, "Interagency Review of Federal Export Enforcement Efforts," April 18, 2003

Inspectors General of the Departments of Commerce, Defense, Energy, State, and the Treasury Report No. D-2002-074, "Interagency Review of Federal Automated Export Licensing Systems," March 29, 2002

Inspectors General of the Departments of Commerce, Defense, Energy, and State Report No. D-2001-092, "Interagency Review of the Commerce Control List and the U.S. Munitions List," March 23, 2001

Inspectors General of the Departments of Commerce, Defense, Energy, and State Report No. D-2000-109, "Interagency Review of the Export Licensing Process for Foreign National Visitors," March 24, 2000

Inspectors General of the Departments of Commerce, Defense, Energy, State, and the Treasury and the Central Intelligence Agency Report No. 99-187, "Interagency Review of the Export Licensing Processes for Dual-Use Commodities and Munitions," June 18, 1999

Appendix C. Biological Agents Not Included on the Commerce Control List

<u>Chemical and Biological Agent</u>	<u>USDA Biological Agent List</u>	<u>HHS Select Agent List</u>
Akabane virus	✓	
Bovine spongiform encephalopathy agent	✓	
Camel pox virus	✓	
Central European tick-borne encephalitis		✓
Cercopithecine herpesvirus 1 (Herpes B virus)		✓
Coccidioides immitis	✓	✓
Coccidioides posadasii		✓
Cowdria ruminantium (Heartwater)	✓	
Far Eastern tick-borne encephalitis		✓
Liberobacter africanus	✓	
Liberobacter asiaticus	✓	
Malignant catarrhal fever virus (Exotic)	✓	
Menangle virus	✓	
Mycoplasma capricolum/ M.F38/M. mycoides Capri	✓	
Peronosclerospora philippinensis	✓	
Phakopsora pachyrhizi	✓	
Plum Pox Potyvirus	✓	
Sclerophthora rayssiae var zeaе	✓	
Synchytrium endobioticum	✓	
Xylella fastidiosa (citrusBacillus anthracis variegated chlorosis strain)	✓	

Appendix D. Report Distribution

Office of the Secretary of Defense

Under Secretary of Defense for Acquisition, Technology, and Logistics
Deputy Under Secretary of Defense (Science and Technology)
Under Secretary of Defense for Policy
Under Secretary of Defense (Comptroller)/Chief Financial Officer
Deputy Chief Financial Officer
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Under Secretary of Defense for Intelligence
Assistant to the Secretary of Defense (Nuclear and Chemical and Biological Defense Programs)
Director, Program Analysis and Evaluation
Deputy Under Secretary of Defense (Technology Security Policy and Counterproliferation)

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Department of the Navy

Naval Inspector General
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Department of the Air Force

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Inspector General, Department of Commerce
Inspector General, Department of Energy
Inspector General, Department of Health and Human Services
Inspector General, Department of Homeland Security
Inspector General, Department of State
Inspector General, Central Intelligence Agency

Congressional Committees and Subcommittees, Chairman and Ranking Minority Member

Senate Committee on Appropriations
Senate Subcommittee on Defense, Committee on Appropriations
Senate Committee on Armed Services
Senate Committee on Governmental Affairs
Senate Select Committee on Intelligence
Senate Committee on Foreign Relations
House Committee on Appropriations
House Subcommittee on Defense, Committee on Appropriations
House Committee on Armed Services
House Committee on Government Reform
House Subcommittee on Government Efficiency and Financial Management, Committee on Government Reform
House Subcommittee on National Security, Emerging Threats, and International Relations, Committee on Government Reform
House Subcommittee on Technology, Information Policy, Intergovernmental Relations, and the Census, Committee on Government Reform
House Committee on International Relations
House Permanent Select Committee on Intelligence

Deputy Under Secretary of Defense (Technology Security Policy and Counterproliferation) Comments

Final Report
Reference



POLICY

OFFICE OF THE UNDER SECRETARY OF DEFENSE
2000 DEFENSE PENTAGON
WASHINGTON, DC 20301-2000

MAR 17 2005

MEMORANDUM FOR THE DEPUTY INSPECTOR GENERAL FOR AUDITING,
READINESS AND LOGISTICS SUPPORT, OFFICE OF THE
INSPECTOR GENERAL, DEPARTMENT OF DEFENSE

SUBJECT: Comments on Draft of DoD/IG Audit Report, "Controls over the Licensing
Process for Biological and Chemical Commodities" (Proj. # D2004LG-
0232)

We concur with the findings and the recommendation contained in this report, with the exception of the findings in the section labeled "Munitions Export License Applications" on page 5, which is not entirely accurate. We recommend that the language of that section be revised as follows (in line-in/line-out format):

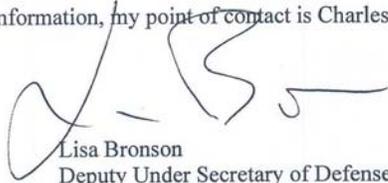
Munitions Export License Applications. DTSA has established informal, internal deadlines for the review of munitions export license applications. DTSA allows up to 31 days for DoD's review of an application. DTSA receives approximately 90% of the munitions license applications in hard copy via a courier from the State Department. The other 10% are received electronically through the automated U.S. Export System (USXPORTS), but normally receives hard copy supporting data via a courier service. Once DTSA receives a license application, it takes approximately 2 days to review the application and determine whether it is standard or repetitive and, therefore, does not need to be referred. it is reviewed the same day by the prescreening team and a determination is made on the requirement for external staffing. If DTSA determines that a license is standard or repetitive, DTSA provides the DoD position to State through USXPORTS at that time. If the license application is not standard or repetitive, DTSA refers the application electronically to the appropriate Military Departments via USXPORTS and sends the supporting data either electronically via USXPORTS or in hard copy via courier service. Approximately one third of the cases are processed without the need for external staffing to the Military Departments. If the information is available in electronic form, it is transferred for review via USXPORTS. Hard copies of the applications and associated technical data are staffed via courier service. DTSA allows the Military Departments 25 days to review an application and, if that deadline is not met, DTSA can approve a 14-day extension. When sufficient information is available to craft a position, DTSA releases a draft DoD position for review and comment by the reviewers, within 2 days of receiving comments from the Military Departments. The final DoD position is released to State Department 2 days later if there are no comments received from the

Revised

~~reviewers. Military Departments have approximately 2 days to dispute the draft position before DTSA sends the final DoD position to State.~~

We also note that the Department of State is circulating a draft paper which proposes adding to the Australia Group Core List (Control List) the 25 "Select Agents" that are not currently Australia Group controlled, but which are found on the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention and U.S. Department of Agriculture's Animal and Plant Health Inspection Service lists.

Should you require further information, my point of contact is Charles B. Shotwell, (703) 325-3784.



Lisa Bronson
Deputy Under Secretary of Defense,
Technology Security Policy and
Counterproliferation

Team Members

The Department of Defense Office of the Deputy Inspector General for Auditing, Readiness and Logistics Support prepared this report. Personnel of the Department of Defense Office of Inspector General who contributed to the report are listed below.

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Ronald L. Rembold

Appendix D. Department of Energy Report



U.S. Department of Energy
Office of Inspector General
Office of Inspections and Special Inquiries

Inspection Report

The Department of Energy's Review of
Chemical and Biological Export License
Applications

DOE/IG-0682

March 2005



Department of Energy

Washington, DC 20585

March 24, 2005

MEMORANDUM FOR THE SECRETARY

FROM:

Greg Friedman
Gregory H. Friedman
Inspector General

SUBJECT:

INFORMATION: Inspection Report on "The Department of Energy's Review of Chemical and Biological Export License Applications"

BACKGROUND

The Fiscal Year 2000 National Defense Authorization Act provides that the President shall annually submit to Congress a report by the Inspectors General of the Departments of Energy, Commerce, State, and Defense of the policies and procedures of the United States Government with respect to the export of technologies and technical information with potential military application to countries and entities of concern. Exports of chemical and biological commodities from the United States are receiving increased scrutiny as a result of heightened national security concerns regarding the possible proliferation of weapons of mass destruction using these materials. Therefore, for 2005, an interagency working group comprised of the Inspectors General for the above agencies, as well as the Department of Homeland Security and the Central Intelligence Agency, examined the process for reviewing chemical and biological export license applications.

The specific objective of our inspection was to determine if the Department of Energy's export license review process is assisting the Government in its efforts to deter the proliferation of chemical and biological commodities that could be used in weapons of mass destruction. Additionally, we reviewed the status of recommendations set forth in our previous reports on the general subject of the Department of Energy's export control program.

RESULTS OF INSPECTION

We concluded that the Department of Energy's export license review process is appropriately assisting the Government in its efforts to deter the proliferation of chemical and biological commodities that could be used in weapons of mass destruction. Specifically, we found that: (1) the Department added additional licensing officers, which provided the necessary capability to begin conducting reviews in April 2003 of chemical and biological export license applications; (2) reviews of chemical and biological export license applications by Departmental officials complied with the 30-day review requirement; and (3) Departmental officials appropriately coordinated with other Federal agencies regarding the Department's review of chemical and biological export license applications. These were positive accomplishments, in our judgment. However, we did find that some Department of Energy licensing officers were



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unable to effectively access the export license application database maintained by the Department of Commerce. These were technical difficulties that had the potential to negatively impact the work of the Department's licensing officers. This matter was referred to the Department of Commerce Inspector General for coordination as a matter of mutual interest.

Regarding the status of recommendations set forth in previous Department of Energy Office of Inspector General reports on annual export control reviews conducted pursuant to the Fiscal Year 2000 National Defense Authorization Act, we determined that 12 of the 13 recommendations have been closed. Details regarding the recommendations can be found in Appendix B of the report.

We made two recommendations to management designed to enhance the Department of Energy's export control review process.

MANAGEMENT REACTION

Management agreed with our recommendations and will implement corrective actions. Management's comments are provided in their entirety in Appendix D of the report. We found management's comments to be responsive to our recommendations.

Attachment

cc: Deputy Secretary
Administrator, National Nuclear Security Administration
Under Secretary for Energy, Science and Environment
Director, Office of Program Liaison and Financial Analysis (ME-100)
Director, Policy and Internal Controls Management (NA-66)

THE DEPARTMENT OF ENERGY'S REVIEW OF CHEMICAL AND BIOLOGICAL EXPORT LICENSE APPLICATIONS

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Overview

INTRODUCTION AND OBJECTIVES

The National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2000 provides that beginning in the year 2000 and ending in the year 2007, the President shall annually submit to Congress a report by the Inspectors General of, at a minimum, the Departments of Energy (Energy), Commerce (Commerce), Defense (Defense), and State (State) of the policies and procedures of the United States Government with respect to the export of technologies and technical information with potential military application to countries and entities of concern. The NDAA for FY 2001 also requires the Inspectors General to include in each annual report the status of the implementation or disposition of recommendations that were set forth in previous annual reports.

Exports of chemical and biological commodities from the United States are receiving increased scrutiny as a result of heightened national security concerns regarding the possible proliferation of weapons of mass destruction using these materials. Therefore, an interagency working group comprised of representatives from the Offices of Inspectors General (OIGs) for Energy, Commerce, Defense, State, the Department of Homeland Security, and the Central Intelligence Agency (CIA) selected the process for reviewing chemical and biological export license applications as the topic for its 2005 review.

The objective of our inspection was to determine if Energy's export license review process is assisting the Government in its efforts to deter the proliferation of chemical and biological commodities that could be used in weapons of mass destruction. To accomplish this objective, we examined:

- Energy's role in reviewing export license applications for chemical and biological commodities;
- Adherence by Energy officials to relevant laws and regulations governing such reviews; and
- Coordination by Energy officials with other Federal agencies.

Additionally, we reviewed the status of recommendations set forth in previous Energy OIG reports on annual export control reviews conducted pursuant to the NDAA for FY 2000.

OBSERVATIONS AND CONCLUSIONS

We concluded that Energy's export license review process is assisting the Government in its efforts to deter the proliferation of chemical and biological commodities that could be used in weapons of mass destruction. Specifically, we found that:

- Energy added additional licensing officers, which provided Energy the capability to begin conducting reviews of chemical and biological export license applications in April 2003;
- Reviews of chemical and biological export license applications by Energy officials complied with the 30-day review requirement; and
- Energy officials appropriately coordinated with other Federal agencies regarding Energy's review of chemical and biological export license applications. However, some Energy licensing officers were unable to access Commerce's export license application database.

Regarding the status of recommendations set forth in previous Energy OIG reports on annual export control reviews conducted pursuant to the NDAA for FY 2000, we determined that 12 of the 13 recommendations have been closed. Details regarding the recommendations can be found in Appendix B.

The Energy OIG has conducted a number of reviews related to the topic of export controls. A listing of these reports is contained in Appendix C.

Details of Findings

BACKGROUND

The principal legislative authorities governing the export control of nuclear-related, dual-use¹ items are the Export Administration Act (EAA) of 1979 and the Nuclear Non-Proliferation Act of 1978. The provisions of the EAA have been updated by Executive Order, most recently by Executive Order 12981, “Administration of Export Controls,” dated December 5, 1995. Executive Order 12981 grants the Secretary of Commerce the authority to refer export license applications to other agencies for review and gives agencies such as Energy the authority to look at any export license application submitted to Commerce. To implement the EAA, Commerce issues the Export Administration Regulations (EAR), which includes controls over nuclear-related items. Because Energy’s national laboratories are the primary source for expertise on nuclear-related items for the Federal Government, nuclear-related items identified for export controls by the EAR have traditionally been referred to Energy for review. Within Energy, these reviews are coordinated by licensing officers within the National Nuclear Security Administration’s (NNSA’s) Office of Export Control Policy and Cooperation.

State administers export controls on all munitions pursuant to the International Traffic in Arms Regulations and reviews the pertinent export license applications, including those for chemical and biological munitions. Although State may refer export license applications for munitions commodities to Energy for review, there is no formal mechanism regarding such referrals. To date, State has not requested that Energy review export license applications for chemical and biological munitions.

ENERGY EXPORT LICENSE REVIEWS

We found that Energy added additional licensing officers, which provided Energy the capability to begin conducting reviews of chemical and biological export license applications in April 2003. Energy’s national laboratories have expertise in many areas, including chemical and biological matters. Following the events of September 11, 2001, Energy concluded that its “assets should be mobilized to deal with all forms of weapons of mass destruction...[including] chemical and biological weapons.” Pursuant to this review, the NNSA budget was increased to allow for these additional reviews, and Energy officially requested that Commerce refer chemical and biological export license applications to Energy for review beginning April 15, 2003.

¹ Some controlled commodities are designated as “dual-use,” that is, goods and technologies that have both civilian and military uses. The U.S. Government designates some dual-use commodities as “nuclear dual-use” items, which are controlled for nuclear nonproliferation purposes.

COMPLIANCE

We found that reviews of chemical and biological export license applications by Energy officials complied with the requirement to review export license applications within 30 days.

Executive Order 12981 states that Energy has 30 days to review a referred application and provide a recommendation to Commerce regarding approval or denial of the license application. Of a sample of 91 chemical and biological license applications received by Commerce in FY 2003,² 36 were referred to Energy for review. (The remaining export license applications received by Commerce were either returned to the applicant without being referred by Commerce to other agencies for review or were received by Commerce prior to April 15, 2003, when Energy established its chemical and biological export license application review process.) We determined that Energy replied to Commerce within the 30-day time frame on all 36 of the license applications referred to Energy for review.

**INTERAGENCY
COORDINATION**

We found that Energy officials appropriately coordinated with other Federal agencies regarding Energy's review of chemical and biological export license applications. However, some Energy officials were unable to access Commerce's export license application database.

**SHIELD Licensing
Group**

There are two interagency groups that can resolve disputes among Federal agencies regarding approval of export license applications; the SHIELD licensing group and the Operating Committee. Energy became a member of the SHIELD licensing group in April 2003, joining with State, Defense, Commerce, and CIA. The SHIELD licensing group reviews export license applications involving items controlled for chemical and biological weapons reasons and recommends whether an application should be approved or disapproved. If the members of the SHIELD licensing group cannot reach agreement on disposition of an application, the application is referred to the Operating Committee for further review. We determined that for the period covered by our review, Energy participated in each of the SHIELD licensing group meetings, and coordinated with the other group members on

² The OIG interagency group examined a sample, developed by a Defense statistician, of 91 chemical and biological related export license applications from a total of 1,803 applications received by Commerce in FY 2003. Additionally, the OIG interagency group examined all the license applications from FY 2003 that were escalated to the Operating Committee for resolution, meaning one or more Federal agencies recommended denial after their initial review of the export license application. (The function of the Operating Committee is discussed in the next section of this report.) The total number of escalated license applications was 18, which included one export license application already reported in the initial sample of 91. Therefore, a total sample of 108 license applications was reviewed by the OIG interagency group.

all the chemical and biological license applications referred to Energy by Commerce.

Operating Committee

Energy has been a member of the Operating Committee since it was established in 1975. The Operating Committee includes senior officials from Energy, Commerce, Defense, and State, which are voting members, and the CIA, which is a non-voting member. The Operating Committee members are higher level agency officials than those in the SHIELD licensing group. We examined a sample of 18 license applications escalated to the Operating Committee for review during FY 2003. The 18 license applications were part of the 108 license applications reviewed by the OIG interagency working group. We determined that Energy participated in each of the Operating Committee meetings concerning the 18 license applications in our sample; that Energy's votes were recorded; and that Energy coordinated with the other committee members on each of the 18 license applications reviewed by the Operating Committee.

ECASS Access

During our review, we observed that some Energy licensing officers were unable to access Commerce's export license application database. All chemical and biological license applications, in addition to nuclear-related applications, are referred to Energy from Commerce via Commerce's unclassified electronic Export Control Automated Support System (ECASS). After Energy downloads the application information from ECASS, the information is uploaded into Energy's classified Proliferation Information Network System (PINS). The case (application) is then assigned by an Energy licensing officer to one or more Energy national laboratories for review. Because of classification concerns, there is no direct link between ECASS and PINS. Accordingly, changes to a case recorded in ECASS after the initial download of the case by Energy would not necessarily be known by Energy officials.

Updated information on export license applications can be obtained by Energy personnel by either directly contacting Commerce officials or accessing ECASS again. Although an ECASS terminal is located at Energy headquarters, only one Energy licensing officer has password access to ECASS and no licensing officers have been trained in the use of the system. We were told that Commerce officials have not responded to Energy's repeated requests for training and password assistance on ECASS.

RECOMMENDATIONS

We recommend that the Deputy Administrator, Defense Nuclear Nonproliferation, take appropriate action to ensure that Energy licensing officers:

1. Have access to the Department of Commerce's Export Control Automated Support System; and
2. Are properly trained in the use of this system.

**MANAGEMENT
COMMENTS**

Management agreed with our recommendations and will implement corrective actions. Management's comments are provided in their entirety in Appendix D.

**INSPECTOR
COMMENTS**

We found management's comments to be responsive to our recommendations. We coordinated our recommendations regarding Commerce's Export Control Automated Support System with the Commerce OIG.

Appendix A

SCOPE AND METHODOLOGY

We interviewed Federal and contractor Energy officials at Energy headquarters and the Los Alamos National Laboratory, which operates the database used by Energy to process and review export license applications. We reviewed Energy and Commerce documentation for a sample of 108 export license applications for chemical and biological commodities that were submitted to Commerce in FY 2003. This sample was selected by the Offices of Inspectors General interagency working group. We also reviewed relevant export control regulations.

As part of our review, we evaluated Energy's implementation of the "Government Performance and Results Act of 1993." We did not identify any performance measure issues regarding the review of chemical and biological export license applications.

This inspection was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency.

Appendix B

STATUS OF RECOMMENDATIONS FROM PRIOR NATIONAL DEFENSE AUTHORIZATION ACT REPORTS

Section 1204 of the NDAA for Fiscal Year (FY) 2001 amended Section 1402(b) of the NDAA for FY 2000 to require the specified Offices of Inspectors General (OIGs) to include in each annual report the status of the implementation or other disposition of recommendations that have been set forth in previous annual reports under Section 1402(b). To date, five reports have been completed by the Energy OIG under this requirement. Two reports: “Inspection of Status of Recommendations from the Office of Inspector General’s March 2000 and December 2001 Export Control Reviews,” INS-L-03-07, May 2003, and “Inspection of the Department of Energy’s Role in the Commerce Control List and the U.S. Munitions List,” INS-O-01-03, March 2001, did not contain recommendations. The following is the status of the recommendations from the other reports. Of 13 total recommendations, 12 have been closed.

“Contractor Compliance with Deemed Export Controls,” DOE/IG-0645, April 2004:

Recommendation 1. We recommended that the Director, Office of Security and Safety Performance Assurance, expedite issuance of a draft unclassified foreign visits and assignments Order 142.X that addresses training requirements and responsibilities for hosts of foreign nationals.

Energy management reported that the Office of Security has incorporated all required changes into DOE Order 142.3, “Unclassified Foreign Visits and Assignments Program,” which was approved on June 18, 2004. This Order includes the principal roles and responsibilities for hosts of foreign national visitors and assignees. The Energy OIG determined that DOE Order 142.3 includes training requirements and responsibilities for hosts of foreign nationals.

The Energy OIG agreed to close this recommendation.

Recommendation 2. We recommended that the Deputy Administrator, Defense Nuclear Nonproliferation, ensure that export control guidance, including deemed export guidance, is disseminated and is being consistently implemented throughout the Energy complex.

Energy management reported that the National Nuclear Security Administration (NNSA) expects to issue a new edition of the Energy “Guidelines on Export Control and Nonproliferation,” updating and expanding the version of the Guidelines last issued in 1999. Proposals from nonproliferation and export control/technology transfer experts at Energy headquarters and several national laboratories have been collected and are undergoing final review. The new edition is to be formally issued under a cover letter from the Deputy Administrator for Defense Nuclear Nonproliferation reminding all Energy and NNSA elements of their export control responsibilities and noting export control resources available to the field. It will incorporate changes in relevant legislation and regulations, insights gained from dealing with various issues, and expanded and more detailed discussion of problematic issues, such as “deemed exports.” In addition, NNSA continues to develop an Internal Self-Assessment plan, and has not to date received a response to its survey from the Office of Science laboratories.

The Energy OIG determined that this recommendation should remain open until all corrective actions are completed.

**“Inspection of the Department of Energy’s Automated Export Control System,”
DOE/IG-0533, December 2001:**

Recommendation 1. We recommended that the Assistant Deputy Administrator for Arms Control and Nonproliferation coordinate with Commerce and Treasury to ensure access by Energy to information within the Automated Export System regarding the purchase and/or shipment of commodities under an approved export license, and develop guidelines for Energy’s access to the information.

Energy management reported that NNSA has taken actions as far as its cognizant authority allows. All remaining actions are contingent on other Government agencies. NNSA recommended that the interagency OIG group involved with export controls make specific recommendations to individual agencies in order to effect change. While actions are not completed, NNSA can no longer report meaningful status.

The Energy OIG agreed to close this recommendation. The Energy OIG will continue to follow up on these issues through the interagency OIG group.

Recommendation 2a. We recommended that the Assistant Deputy Administrator for Arms Control and Nonproliferation coordinate with State to improve communications regarding review of export license applications for munitions commodities.

Energy management reported that NNSA has taken actions as far as its cognizant authority allows. All remaining actions are contingent on other Government agencies. NNSA recommended that the interagency OIG group involved with export controls make specific recommendations to individual agencies in order to effect change. While actions are not completed, NNSA can no longer report meaningful status.

The Energy OIG agreed to close this recommendation. The Energy OIG will continue to follow up on these issues through the interagency OIG group.

Recommendation 2b. We recommended that the Assistant Deputy Administrator for Arms Control and Nonproliferation coordinate with State to ensure access by Energy to information maintained by State regarding final disposition (i.e., approval/denial of license applications and the purchase and/or shipment of commodities) of export license applications and develop guidelines for Energy’s access to the information.

Energy management reported that NNSA has taken actions as far as its cognizant authority allows. All remaining actions are contingent on other Government agencies. NNSA recommended that the interagency OIG group involved with export controls make specific recommendations to individual agencies in order to effect change. While actions are not completed, NNSA can no longer report meaningful status.

The Energy OIG agreed to close this recommendation. The Energy OIG will continue to follow up on these issues through the interagency OIG group.

“Inspection of the Department of Energy’s Export License Process for Foreign National Visits and Assignments,” DOE/IG-0465, March 2000:

Recommendation 1. We recommended that the Acting Deputy Administrator for Defense Nuclear Nonproliferation ensure that senior Energy officials work with senior Commerce officials to assure clear, concise, and reliable guidance is obtained in a timely manner from Commerce regarding the circumstances under which a foreign national’s visit or assignment to an Energy site would require an export license.

Energy management was advised by the Commerce Assistant Secretary for Export Administration that extensive guidance regarding compliance with the deemed export rule was available on the Commerce website and that Commerce would continue and strengthen its outreach training programs for Energy’s National Laboratories.

The Energy OIG agreed to close this recommendation.

Recommendation 2. We recommended that the Director, Office of Security and Emergency Operations, ensure that a proposed revision of the Energy Notice concerning unclassified foreign visits and assignments includes the principal roles and responsibilities for hosts of foreign national visitors and assignees.

Energy management reported that the Office of Security has incorporated all required changes into DOE Order 142.3, “Unclassified Foreign Visits and Assignments Program,” which was approved on June 18, 2004. This Order includes the principal roles and responsibilities for hosts of foreign national visitors and assignees.

The Energy OIG agreed to close this recommendation.

Recommendation 3. We recommended that the Director, Office of Security and Emergency Operations, include a requirement for Energy and Energy contractor officials to enter required foreign national visit and assignment information in the Foreign Access Records Management System, or a designated central data base, in a complete and timely manner.

Energy management reported that a new Energy-wide information system, the Foreign Access Centralized Tracking System (FACTS), was developed and implemented. Energy further advised that Draft Order 142.X includes a requirement for Energy sites to enter required foreign national visit and assignment information into FACTS in a complete and timely manner.

Because Energy management’s corrective action addressed usage of FACTS by all Energy Federal and contractor employees, the Energy OIG previously agreed to close this recommendation and track this issue under recommendation 8.

Recommendation 4. We recommended that the Manager of Energy’s Oak Ridge Operations Office ensure that requests for foreign national visits and assignments at the Oak Ridge site are reviewed by the Y-12 National Security Program Office to assist in identifying those foreign nationals who may require an export license in conjunction with the visit or assignment.

Energy management reported that to ensure requests for foreign national visits and assignments at the Oak Ridge National Laboratory receive appropriate export license consideration, Oak Ridge National Laboratory initiated a system of reviews. Under the system, requests are reviewed by five separate disciplines (Cyber Security, Export Control, Classification, Counterintelligence, and Security). In addition, requests associated with concerns are referred for resolution to the Non-citizen Access Review Committee. Energy management further reported that while each of the reviews can involve the National Security Program Office, the Oak Ridge National Laboratory Export Control Officer is responsible for referring requests to the National Security Program Office as necessary.

The Energy OIG agreed to close this recommendation.

Recommendation 5. We recommended that the Director, Office of Security and Emergency Operations, ensure that the requirements in the revised Energy Notice for unclassified foreign national visits and assignments are clearly identified and assigned to responsible officials or organizations.

Energy management reported that the Office of Security has incorporated all required changes into DOE Order 142.3, “Unclassified Foreign Visits and Assignments Program,” which was approved on June 18, 2004. This Order includes clear identification of requirements for foreign national visits and assignments, and identifies responsible officials and organizations.

The Energy OIG agreed to close this recommendation.

Recommendation 6. We recommended that the Acting Deputy Administrator for Defense Nuclear Nonproliferation ensure that guidance issued by the Office of Nuclear Transfer and Supplier Policy to advise hosts of their responsibilities regarding foreign nationals includes the appropriate level of oversight to be provided by the host during the period of the visit or assignment.

Energy management reported that the Office of Security has incorporated all required changes into DOE Order 142.3, “Unclassified Foreign Visits and Assignments Program,” which was approved on June 18, 2004. This Order includes the principal roles and responsibilities for hosts of foreign national visitors and assignees.

The Energy OIG agreed to close this recommendation.

Recommendation 7. We recommended that the Director, Office of Security and Emergency Operations, revise the Energy policy regarding foreign national visits and assignments to ensure that Energy sites are maintaining consistent information about foreign nationals visiting or assigned to work at the site.

Energy management reported that the Office of Security has incorporated all required changes into DOE Order 142.3, "Unclassified Foreign Visits and Assignments Program," which was approved on June 18, 2004. This Order includes the requirement for documentation in FACTS for all visit and assignment requests in a timely manner.

The Energy OIG agreed to close this recommendation.

Recommendation 8. We recommended that the Director, Office of Security and Emergency Operations, require that all Energy sites with foreign national visitors or assignees enter information regarding the visits or assignments into the Foreign Access Records Management System, or a designated central Energy database.

Energy management reported that the Office of Security has incorporated all required changes into DOE Order 142.3, "Unclassified Foreign Visits and Assignments Program," which was approved on June 18, 2004. This Order includes the requirement that all sites having foreign national visitors or assignees are required to enter information regarding the visits and assignments into FACTS.

The Energy OIG agreed to close this recommendation.

Appendix C

PRIOR EXPORT CONTROL RELATED REPORTS

- “Contractor Compliance with Deemed Export Controls,” DOE/IG-0645, April 2004;
- “Safeguards Over Sensitive Technology,” DOE/IG-0635, January 2004;
- “Inspection of Status of Recommendations from the Office of Inspector General’s March 2000 and December 2001 Export Control Reviews,” INS-L-03-07, May 2003;
- “The Department’s Unclassified Foreign Visits and Assignments Program,” DOE/IG-0579, December 2002;
- “Follow-up Inspection of the Department of Energy’s Export Licensing Process for Foreign National Visits and Assignments,” INS-L-02-06, June 2002;
- “Inspection of the Department of Energy’s Automated Export Control System,” DOE/IG-0533, December 2001;
- “Inspection of the Department of Energy’s Role in the Commerce Control List and the U.S. Munitions List,” INS-O-01-03, March 2001;
- “Inspection of the Department of Energy’s Export License Process for Foreign National Visits and Assignments,” DOE/IG-0465, March 2000;
- “The Department of Energy’s Export Licensing Process for Dual-Use and Munitions Commodities,” DOE/IG-0445, May 1999; and
- “Report on Inspection of the Department’s Export Licensing Process for Dual-Use and Munitions Commodities,” DOE/IG-0331, August 1993.



Department of Energy
National Nuclear Security Administration
Washington, DC 20585



March 18, 2005

MEMORANDUM FOR Alfred K. Walter
Assistant Inspector General
for Inspections and Special Inquiries

FROM: Michael C. Kane 
Associate Administrator
for Management and Administration

SUBJECT: Comments to IG Draft Inspection Report on Review of
Chem/Bio Export License Applications; S04IS025

The National Nuclear Security Administration (NNSA) appreciates the opportunity to have reviewed the Inspector General's (IG) draft inspection report: "The Department of Energy's Review of Chemical and Biological Export License Applications." NNSA understands that the IG conducted this inspection to determine if the export license review process is assisting the Government in its efforts to deter the proliferation of chemical and biological commodities that could be used in weapons of mass destruction.

NNSA acknowledges the IG's conclusion that the subject review process is, in fact, assisting the Government in the efforts to deter the proliferation of chemical and biological commodities. We agree that there does need to be improved access to the Department of Commerce's system and we will continue to pursue that increased access. In the interim, we will ensure that system training is conducted to a broader audience to allow more of our licensing officers access to Commerce's system.

NNSA has one comment related to report accuracy. Page 5 of the report refers to the Operating Committee as having been established by an Executive Order. Rather the Operating Committee was established by a Department of Commerce departmental order in 1975 and the Executive Order (12981 of 1995) re-affirmed the existence of the Operating Committee.

Should you have any questions about this response, please contact Richard Speidel, Director, Policy and Internal Controls Management. He may be contacted at 202-586-5009.

cc: Paul Longworth, Deputy Administrator for Defense Nuclear Nonproliferation
Karen Boardman, Director, Service Center

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5. Please include your name and telephone number so that we may contact you should we have any questions about your comments.

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Appendix E. Department of State Report

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United States Department of State
and the Broadcasting Board of Governors
Office of Inspector General

Report of Audit

Export Licensing of Chemical and Biological Commodities

Report Number AUD/PR-05-29, April 2005

IMPORTANT NOTICE

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SUMMARY

The September 11, 2001, terrorists' attacks against the United States renewed attention to the importance of U.S. export controls to further our nonproliferation and other national security goals. The Department of State (Department) registers and licenses U.S. companies and universities to participate in the export of defense articles and defense services on the U.S. Munitions List (USML). The Directorate of Defense Trade Controls, Bureau of Political-Military Affairs (PM/DDTC), in accordance with the Arms Export Control Act (AECA)¹ and the International Traffic in Arms Regulations (ITAR),² is charged with controlling the export and temporary import of defense articles and defense services covered by the USML. It has among its primary missions taking final action on license applications for defense trade exports, including chemical and biological commodities and equipment, and handling matters related to defense trade compliance, enforcement, and reporting.

The Office of Inspector General (OIG) conducted an audit of the Department's export licensing process used to help deter the proliferation of chemical and biological weapons of mass destruction (WMD). This audit was initiated in response to Section 1402 of the National Defense Authorization Act (NDAA) for Fiscal Year 2000.³

OIG found that the export licensing process is working as intended and that the Department consistently executed its export licensing responsibilities in regard to chemical and biological commodities in accordance with established policies and procedures.

OIG provided a draft copy of this report to the Bureau of Political-Military Affairs. The bureau reviewed the draft and did not provide any comments.

¹22 U.S.C. 2778-2780.

²22 C.F.R. Parts 120-130.

³Pub. L. No. 106-65.

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BACKGROUND

NDAA requires audits by the Inspectors General of the Departments of Commerce, Defense, Energy, and State, in consultation with the Director of Central Intelligence and the Director of the Federal Bureau of Investigation. The audits focus on the most significant categories of U. S. technologies and technical information with potential military applications.

Nuclear, biological, and chemical WMD in the possession of hostile states and terrorists represent one of the greatest security challenges facing the United States. Sound export controls and licensing operations are essential to preventing the spread of dangerous WMD technologies.

PM/DDTC is responsible for controlling the export and temporary import of defense articles and defense services covered by the USML. PM/DDTC approval of a license application is required before the export of defense articles or services. In FY 2003, the Department received 717 license applications for chemical and biological commodities. These commodities include such items as riot control masks, anthrax biological threat alert test strips, and instantaneous blast grenades.

PM/DDTC reviews the license applications against a number of factors, including:

- applicant eligibility,
- foreign policy objectives,
- stated end-use and end user,
- commodity
- quantity,
- national security interests,
- regional stability,

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- human rights issues and concerns,
- multilateral agreements and nonproliferation regimes, and
- intelligence information.

PM/DDTC refers about 30 percent of the applications to other Department offices as well as other agencies (e.g., Department of Defense) for their comments and recommendations.

The last time that OIG reported on the licensing process was in a June 1999 report, *Export Licensing* (99CI-018). OIG found that, overall, the export licensing process was working as intended and that the Department consistently executed its export licensing responsibilities in accordance with established policies and procedures.

PM/DDTC has had several notable accomplishments since OIG's 1999 review, including an expedited licensing process for coalition forces deployed to Afghanistan and Iraq and a special process for arms transfers to Iraq after the transfer of sovereignty.

OBJECTIVES, SCOPE, AND METHODOLOGY

OIG's objective was to analyze the files of selected chemical and biological commodities to determine if the Department executed licensing responsibilities in accordance with established policies and procedures.

OIG compared the information contained in the applications against PM/DDTC's standard operating procedures for licensing requirements. OIG reviewed a sample of the 717 license applications for chemical and biological commodities that PM/DDTC received during FY 2003. OIG's original sample identified 85 files randomly selected from the universe (717) of license applications. However, OIG was unable to review 30 files contained in the sample because PM/DDTC had retired the files to an off-site location, which prevented their timely retrieval. As a result, OIG reviewed 55 files, with a confidence level of 95 percent (plus or minus 5 percent).

OIG's examination⁴ included a determination as to whether each export request in the files contained the required information necessary to make a licensing decision, including the following:

- license number and expiration date,
- organization requesting the license,
- export item (i.e., pocket grenades),
- dollar value of the order,
- shipping company,
- destination of items,

⁴ Some parts of OIG's examination contained classified and or sensitive information, which is omitted from this report.

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- application review by other bureaus and agencies, and
- final disposition (i.e., approved, denied, etc.).

OIG interviewed PM/DDTC officials and consulted with OIG officials from the Departments of Commerce, Defense, Energy, Homeland Security, and the Central Intelligence Agency. OIG's Office of Audits, Program Reviews Division conducted this audit from August 2004 through January 2005 in the Washington, D.C., area. OIG performed this work according to government auditing standards and included such tests and auditing procedures as were considered necessary under the circumstances.

RESULTS

From the review of 55 cases, OIG found that PM/DDTC adhered to its export licensing process. OIG found that the export licensing process is working as intended and that the Department consistently executed its export licensing responsibilities in regard to chemical and biological commodities in accordance with established policies and procedures.

OIG verified that PM/DDTC had initially screened all license applications to establish that the company submitting the application, commodity involved, the intended user, and the importing country were eligible to receive an export license. OIG also confirmed the eligibility of each shipping company for export control purposes.

OIG confirmed that PM/DDTC tracked interagency and intra-agency referrals to ensure it received their responses in a timely manner. PM/DDTC considered information provided in the referrals in making its licensing decisions and in all cases accepted the respondents' recommendations. In addition, PM/DDTC did not make any licensing decisions before receipt of the requested information.

Finally, the conclusions reached by PM/DDTC personnel were fully supported by file documentation.

Appendix F. Department of Agriculture Report



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 act⁴ 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 policy⁵ 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 researcher⁷. 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



MAR 29 2005

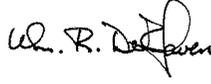
United States
Department of
Agriculture

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.



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ATTN: Agency Liaison Officer

Government Accountability Office (1)

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Director, Planning and Accountability Division