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CHAPTER 7

Biological Agents and Associated Equipment and Technical Data (Sections 742.2, 744.4 and 744.6)

Export Control Program Description And Licensing Policy

The United States exercises export controls over certain microorganisms, toxins, biological equipment, and related technology to further U.S. foreign policy opposing the proliferation and illegal use of biological weapons. The United States implements these export controls multilaterally in coordination with the Australia Group (AG), an informal forum of 33 nations cooperating to halt the proliferation of chemical and biological weapons. The United States also participates in international efforts to effect a total ban on biological weapons in compliance with the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (BWC).[1]

Licensing Requirements and Policy

The licensing requirements for biological agents, related equipment, and technology as specified on the Commerce Control List (CCL) are:

A. The United States requires a license for the export to all destinations, except Canada, of certain human pathogens, zoonoses, toxins, animal pathogens, genetically modified microorganisms and plant pathogens, and the technology for their production and/or disposal.

The United States requires a license for the export to specified countries of certain dual-use equipment and materials that can be used in the production of biological agents, and the technology that can be used in their production. The countries to which this licensing requirement applies are those indicated in Column CB:3 of the Commerce Country Chart, Export Administration Regulations (EAR), Supplement No. 1 to Part 738, as well as the embargoed destinations identified in EAR Part 746.

The United States requires a license for the export of any item subject to the EAR when the exporter knows that it will be used in the design, development, production, stockpiling or use of biological weapons in, or by, specified countries (Country Group D:3, EAR, Supplement No. 1 to Part 740).

BXA may inform the exporter or reexporter that a license is required due to an unacceptable risk that the items will be used in, or diverted to, a biological weapons project anywhere in the world.

No U.S. person may export, reexport, or transfer any item without a license when that person knows the item will be used in the design, development, production, stockpiling or use of biological weapons in, or by, a country listed in Country Group D:3. No U.S. person may knowingly support such an export, reexport, or transfer without a license. "Support" is defined as action, including financing, transportation, or freight forwarding, that facilitates the export, reexport, or transfer. Additionally, no U.S. person may, without a license, perform any contract service or employment knowing that it will directly assist in the design, development, production, stockpiling, or use of biological weapons in, or by, a country listed in Country Group D:3.

B. BXA will consider applications for licenses on a case-by-case basis to determine whether the export would make a material contribution to the design, development, production, stockpiling, or use of biological weapons. When BXA determines that an export is deemed to make such a contribution, the application is denied.

Analysis of Control as Required by Section 6(f) of The Act

A. The Purpose of the Control

The controls described above are to prevent any U.S. contribution to the proliferation and illegal use of biological weapons, and to support multilaterally coordinated control efforts. The controls also provide the regulatory authority to stop the export of any item from the United States when there is a significant risk that it will be used for biological weapons purposes. The controls implement certain measures directed in Executive Order 12735 of November 16, 1990, its successor, Executive Order 12938 of November 14, 1994, and the Enhanced Proliferation Control Initiative of December 13, 1990.

The United States implements these controls in coordination with the AG. The AG works to accomplish this objective through the harmonization of export controls, the exchange of information, and other diplomatic means. In addition, these controls demonstrate the United States' commitment to its obligation under the BWC not to develop, produce, stockpile, acquire or retain biological agents, weapons, equipment or the means of delivery for warfare purposes. The controls also advance the goals of the 1925 Geneva Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or other Gases and of Bacteriological Methods of Warfare (Geneva Protocol), prohibiting the first use in wartime of chemical or biological weapons.

B. Considerations and/or Determinations of the Secretary of Commerce

1. Probability of Achieving the Intended Foreign Policy Purpose. The Secretary has determined that these controls are likely to achieve their intended foreign policy purpose despite the existence of factors, including availability of these items from other sources, that challenge that achievement. These controls affirm U.S. opposition to the development, proliferation and use of biological weapons and serve to distance the United States from such activities.

2. Compatibility with Foreign Policy Objectives. In extending the current controls, the Secretary has determined that the controls are compatible with the foreign policy objectives of the United States. The United States has a strong interest in remaining at the forefront of international efforts to stem the proliferation of biological weapons. These controls are compatible with the multilateral export controls for biological materials agreed to by the AG. Moreover, the United States has a binding international commitment under the BWC and the Geneva Protocol to prohibit and eliminate biological weapons, and to not assist anyone in biological warfare activities.

3. Reaction of Other Countries. The Secretary has determined that the reaction of other countries to these controls by the United States is not likely to render the controls ineffective in achieving the intended foreign policy purpose or to be counterproductive to U.S. foreign policy interests. The United States continues to discuss chemical and biological export controls with countries outside of the AG to advance the goals of nonproliferation. Some of these countries claim that the controls could hinder their right, under Article X of the BWC, to participate in the fullest possible exchange of equipment, materials and technology for the agents and toxins for peaceful purposes. The United States does not believe that the evidence supports this position (see next section, Economic Impact on U.S. Industry). In international fora, the United States has sought to dispel this false perception by clarifying the purpose of the controls and by demonstrating that the United States denies very few export requests. All AG members have ratified both the CWC and the BWC, and support the full implementation of both treaties.

4. Economic Impact on U.S. Industry. The Secretary has determined that the potential impact of these export controls on U.S. industry is not significant. In FY 2001, BXA received 563 license applications, valued at $21.3 million, for the export or reexport of biological agents. Of these, BXA approved 460 applications, denied 1 application, and returned without action 54 applications. Forty-eight applications were still pending at the close of FY 2001.

5. Enforcement of Control. Enforcing controls on biological weapons materials poses problems similar to the enforcement of chemical controls, but with additional difficulties. Biological materials are

microscopic organisms that require technical expertise and specialized facilities to identify and to handle them. Because of their size, biological agents can often be concealed and transported with ease.

To meet the challenge of effective enforcement of these proliferation controls, BXA has redirected resources toward preventive enforcement. Enforcement personnel conduct an extensive, on-going outreach program to educate industry about export controls. The program is also designed to increase industry's awareness of suspect orders for products or equipment that could be used for biological weapons proliferation. As a result, a significant number of investigations have been opened into allegations of illegal activity. In cases where unlicensed shipments of biological materials have already taken place, BXA has found that, as in other export control enforcement cases, commercial shipping documentation can form the basis for successful investigations and prosecutions.

C. Consultation with Industry

Exporters of biological products include commercial firms, as well as academic and government entities. The Department of Commerce maintains ongoing interaction with individual exporters, Technical Advisory Committees (TACs), and trade associations to discuss proposed export transactions and marketing plans to facilitate the thorough, yet prompt, review of export license applications. Through the TACs, BXA keeps industry representatives abreast of licensing proposals for items on the control list and gives them the opportunity to provide technical input.

Throughout CY 2001, BXA kept the Materials TAC informed of the status of negotiations on a Protocol to strengthen the BWC. In July 2001, the United States rejected the draft BWC Protocol set forth by Ambassador Tibor Toth, Chairman of the BWC Ad Hoc Group, in charge of development of the Protocol. The United States views the draft Protocol as ineffective in promoting U.S. nonproliferation and arms control objectives. As an alternative approach, the United States began work on a package of other proposals to strengthen the BWC. During the reporting period, BXA representatives participated in briefings on these BWC issues for trade associations such as the Pharmaceutical Research and Manufacturers of America, the Biotechnology Industry Organization, and the Animal Health Institute.

On November 7, 2001, the Department of Commerce, via the *Federal Register* and the BXA Web page, solicited comments from industry on the effectiveness of foreign policy-based export controls. No comments were received specific to the controls described in this chapter. A more detailed review of the comments is available in Appendix I.

D. Consultation with Other Countries

Recognizing that multilateral coordination of export controls and enforcement actions is the most effective means of restricting proliferation activities, the United States coordinates its controls on biological items with other countries in the AG. At the annual AG plenary (October 1-4, 2001), two U.S. proposals were adopted.

The first proposal liberalizes controls on medical and diagnostic kits containing controlled chemicals and the second proposal imposes controls on critical components that can be used to upgrade freely exported equipment to the functional equivalent of a controlled item. The AG also welcomed Bulgaria as a member. The United States continues to address the problem of biological weapons proliferation through a variety of international fora and urges other AG members to pursue export control cooperation with non-members on a bilateral or regional basis.

During 2001, as noted above, international negotiations to strengthen the BWC continued. The BWC, which entered into force in 1975, is an international arms control agreement among 140 nations. As an alternative to the Protocol suggested by Ambassador Tibor Toth, the
United States is now pursuing various alternative means to strengthen the BWC including agreements by BWC adherents to enact national criminal legislation, enhanced efforts on global disease surveillance, and the establishment of biosafety standards. There will be another meeting in late 2002 to discuss the next steps in the international effort to strengthen the BWC.

E. Alternative Means

The United States continues to address the problem of biological weapons proliferation on a number of fronts. Direct negotiations with countries intent on acquiring biological weapons are not likely to prevent the use of U.S.-origin materials in such activities; neither are such negotiations likely to affect the behavior of these countries.

Alternative means to curtail the acquisition and development of biological warfare capabilities, such as diplomatic negotiations, do not obviate the need for controls. The following examples demonstrate additional means that have been, and will continue to be, used in an attempt to curb the use and spread of biological weapons:

- U.S. Legislation: Regulations issued by the Public Health Service (42 CFR Part 72) pursuant to the "The Antiterrorism and Effective Death Penalty Act of 1996" (Sec. 511 of Pub. L.104-

132) place additional shipping and handling requirements on laboratory facilities that transfer or receive select infectious agents capable of causing substantial harm to human health.

- The Chemical and Biological Weapons Control and Warfare Elimination Act of 1991 (Title III, Pub. L.102-182) provides for the imposition of sanctions on foreign persons and countries for certain kinds of chemical and biological weapons-related activity. To date, no sanctions have been imposed for biological weapons-related activities.

- Trilateral US/UK/Russian Statement: In September 1992, the United States, the United Kingdom, and Russia confirmed their commitment to full compliance with the BWC and agreed to a number of steps including data exchanges, visits to sites, and further consultations to enhance cooperation and confidence.

- BWC: The United States continues to pursue options that will strengthen the BWC.

F. Foreign Availability

Past reviews conducted by BXA identified the availability of AG-controlled viruses and bacteria in the non-AG countries of Brazil, India, Indonesia, Iran, Jordan, Mexico, the People's Republic of China, Senegal, Singapore, Taiwan, and Thailand and the availability of AG-controlled equipment items in - Brazil, Hong Kong, India, Israel, Malaysia, Pakistan, the People's Republic of China, Russia, Saudi Arabia, Singapore, South Africa, Taiwan, and Ukraine. Most of this equipment has application in the food processing and pharmaceutical industries. Many of the countries listed above are parties to the BWC, and BXA is working with other U.S. agencies as part of ongoing international efforts to strengthen the effectiveness of this Convention.

ENDNOTES

1. *The Treaty was signed in 1972 and ratified by the United States in 1975.*