

8. Biological Agents and Associated Equipment, Technology and Software (Sections 742.2, 744.4 and 744.6)

Export Control Program Description And Licensing Policy

The Bureau of Export Administration (BXA) exercises export controls over certain microorganisms and toxins, biological equipment, and technology for their use or disposal in order to further U.S. foreign policy opposing the proliferation and use of biological weapons.¹ These export controls are implemented multilaterally in coordination with the Australia Group (AG), an informal forum of 30 nations cooperating to halt the proliferation of chemical and biological weapons. (See Appendix II for complete list of regime members.) BXA 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).²

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

A. A license is required for the export to all destinations, except Canada, of certain human pathogens, zoonoses, toxins, animal pathogens, genetically modified microorganisms and plant pathogens, and technology for their use and/or disposal.

A license is required to export to specified countries certain dual-use equipment and materials that can be used in the production of biological agents and technology for their production. The countries to which this licensing requirement applies are indicated in Column CB:3 of the Commerce Country Chart, Export Administration Regulations (EAR), Section 738, Supplement No. 1.³

A license or reexport authorization is required for any item subject 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, Section 740, Supplement No. 1).⁴ No U.S. person may knowingly support an export, reexport or transfer covered by these controls. Support could mean any action, including financing, transportation, or freight forwarding. 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, 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. Applications for licenses will be considered 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 an export is deemed to make such a contribution, the application will be denied.

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

A. The Purpose of the Control

The purpose of these controls is to prevent U.S. contribution to, and to support multilateral efforts to control, the proliferation and illegal use of biological weapons. They also provide regulatory authority to control 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 some of the measures directed in Executive Order 12735 of November 16, 1990, and its successor, Executive Order 12938 of November 14, 1994, and the Enhanced Proliferation Control Initiative of December 13, 1990.

These controls are implemented 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 assist the United States in implementing its obligation under the BWC not to assist other countries develop, produce, stockpile, or otherwise acquire or retain biological agents or toxins, weapons, equipment or the means of delivery for hostile purposes or in armed conflict. 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, which prohibits the use 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 the control is likely to achieve the intended foreign policy purpose in light of other factors including availability from other sources of these biological materials and related equipment, technology and software. 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.

While the controlled materials are widely available from other countries, the continuation of these controls reaffirms U.S. opposition to the development, proliferation and use of biological weapons and serves to distance the United States from such activities.

2. **Compatibility with Foreign Policy Objectives.** In extending these 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 in 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 in the AG. Moreover, the United States has a binding international commitment under the BWC to the complete prohibition and elimination of biological weapons. Therefore, these controls are compatible with multilateral efforts to strengthen the BWC to deter noncompliance and to reinforce the global commitment against the proliferation of biological weapons.

3. Reaction of Other Countries. The United States regularly engages in consultation with other countries regarding use of export controls to halt the proliferation of biological weapons. In addition, the AG urges all countries to adopt export controls on microorganisms, equipment technology and software related to the production of biological weapons. Some developing country governments believe that AG export controls discriminate against less industrialized nations by depriving them of goods and assistance in the field of chemical and biological technology. The United States does not agree with this position, which it believes the evidence does not support (see next section, Economic Impact on United States Industry). In international fora the United States has sought to dispel this perception by clarifying the purpose of the controls and demonstrating that very few export requests are denied.

4. Economic Impact on United States Industry. The Secretary has determined that the potential impact of these export controls on the U.S. economic position is minimal as borne out by our export licensing statistics. In FY 1997, the Department approved 418 export license applications for biological agents valued at \$80 million. One export application, worth \$324, was denied. No export license applications for the categories of equipment and materials related to production of controlled biological agents were approved or denied. These statistics also demonstrate that AG export controls do not undermine the legitimate economic or technological development of any country.

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. Because of their size, they can be concealed and transported with ease. Enforcing controls on biological agents and associated equipment brings enforcement personnel into contact with industries, manufacturers and exporters with whom they have had little prior contact until recently.

To meet the challenge of effective enforcement of these proliferation controls, Commerce has redirected resources toward preventive enforcement, and conducts an extensive on-going outreach program to educate appropriate industries about export controls. The program is also designed to increase the industry's awareness of suspicious orders for products or equipment that could be used for biological weapons proliferation. A significant number of investigations have been opened into allegations of illegal activity related to these concerns. In cases when unlicensed shipments of biological materials have already taken place, Commerce has found that investigations and prosecutions can be successfully conducted on the basis of routine

documentation, as in other export control enforcement cases.

C. Consultation with Industry

BXA recognizes the need to consider the issue of U.S. industry's competitiveness while administering these controls in a manner that will achieve nonproliferation objectives. Throughout 1997 BXA worked closely with various industry associations, including the Pharmaceutical Manufacturers Association (PhRMA), the Biotechnology Industry Organization, and the Animal Health Institute. BXA engaged in numerous discussions with industry to identify areas of concern to industry, seek technical advice and obtain industry views as to measures that could be used to strengthen the BWC. Finally, the Materials Technical Advisory Committee includes a biotechnology subgroup to provide the technical input needed to understand the potential impact of proposed measures on industry. This industry advisory group is playing an important role in the development and implementation of export controls for biological agents, equipment and technology as well as in its efforts to strengthen the BWC.

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 29 other countries in the AG. The AG held its annual session October 6-9, 1997, in Paris during which the members addressed a range of export control issues

South Korea is the most recent member of the AG, joining in February 1997. The United States continues to urge key non-AG countries to adopt AG biological controls. We have been working closely with Bulgaria, Russia and Ukraine to set up an export control system, including an enforcement mechanism, that will include AG-listed biological items.

The BWC, which entered into force in 1975, is an international arms control agreement among 140 nations that bans the development, production, stockpiling, or otherwise acquiring or retaining biological agents or toxins that have no justification for prophylactic, protective or other peaceful purposes, and prohibits assisting other countries in acquiring such items. A multilateral Ad Hoc Group has been established to develop a legally binding protocol to strengthen the effectiveness of the BWC. This group is working to define elements that could be included in the protocol. Elements under consideration include mandatory data declarations, on-site inspections, enhanced information exchange, and a permanent BWC international oversight organization.

E. Alternative Means

The United States continues to address the problem of the proliferation of biological weapons 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. Some of the following are examples of additional means that have been and will continue to be used in an attempt to curb the use and spread of biological weapons:

- o 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), places additional shipping and handling requirements on laboratory facilities that transfer or receive select infectious agents capable of causing substantial harm to human health.
- o 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.
- o Trilateral US/UK/Russian Statement: In September 1992, the United States, 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.
- o Biological Weapons Convention - An Ad Hoc Group continues to develop a protocol to strengthen the effectiveness and build confidence in compliance with 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, Bulgaria, India, Indonesia, Iran, Jordan, Mexico, China (PRC), Senegal, Singapore, Taiwan, and Thailand and related AG-controlled equipment items available in Brazil, Bulgaria, Hong Kong, India, Israel, Malaysia, Pakistan, PRC, 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. *Anti-terrorism controls also apply to exports of these items to terrorist-supporting destinations as designated by the Secretary of State.*
2. *The treaty was signed in 1972 and ratified by the United States in 1975.*

3. *As of the date of submission of this report, the countries in the Commerce Country Chart CB column 3 included Afghanistan, Armenia, Azerbaijan, Bahrain, Belarus, Bulgaria, Burma, China (PRC), Egypt, Georgia, India, Israel, Jordan, Kazakhstan, Kuwait, Kyrgyzstan, Lebanon, Moldova, Mongolia, Oman, Pakistan, Qatar, Russia, St. Kitts & Nevis, Saudi Arabia, Syria, Taiwan, Tajikistan, Turkmenistan, the Ukraine, the United Arab Emirates, Uzbekistan, Vietnam, and Yemen.*

4. *As of the date of submission of this report, the countries in Country Group D:3 included Afghanistan, Armenia, Azerbaijan, Bahrain, Belarus, Bulgaria, Burma, China (PRC), Cuba, Egypt, Georgia, India, Iran, Iraq, Israel, Jordan, Kazakhstan, Kuwait, Kyrgyzstan, Lebanon, Libya, Moldova, Mongolia, North Korea, Oman, Pakistan, Qatar, Russia, Saudi Arabia, Syria, Taiwan, Tajikistan, Turkmenistan, the Ukraine, the United Arab Emirates, Uzbekistan, Vietnam, and Yemen.*