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

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Export Control Program Description And Licensing Policy

The Bureau of Export Administration (BXA) exercises export controls over certain microorganisms and toxins and biological equipment and related technology, to further U.S. foreign policy opposing the proliferation and use of biological weapons. The United States implements these export controls multilaterally in coordination with the Australia Group (AG), an informal forum of 30 nations cooperating to halt the proliferation of chemical an 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).

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 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 technology that can be used in their production. The countries to which this licensing requirement applies are indicated in Column CB:3 of the Commerce Country Chart, Export Administration Regulations, 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 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, Export Administration Regulations, 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 that the item will be used in the design, development, production, stockpiling or use of chemical 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 means any action, including financing, transportation, or freight forwarding, that facilitates the export, reexport or transfer.

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. The United Sates 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 the United States determines that an export is deemed to make such a contribution, we will deny the application.

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

A. The Purpose of the Control

These controls are to prevent U.S. contribution to the proliferation and 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, and 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, a forum of thirty nations that cooperate to halt the spread of chemical and biological weapons. 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[1] not to develop, produce, stockpile, acquire or retain biological agents, weapons, equipment or the means of delivery for warfare purposes and not in any way assist such activities. 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, to prohibit 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 even in light of other factors, including availability of these items from other sources. These controls continue to affirm 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 by the AG. Moreover, the United States has a binding international commitment under the BWC and the Geneva Protocol to the complete prohibition and elimination of all biological weapons and to their nonproliferation.

3. Reaction of Other Countries. Some non-aligned countries - those which are party to the BWC and the Chemical Weapons Convention (CWC), but not the AG - have voiced opposition to the AG's export controls incorrectly claiming they discriminate against developing countries. Countries claim to be concerned 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. In international fora, the U.S. Government has sought to dispel this perception by clarifying the purpose of the controls.

4. Economic Impact on U.S. Industry. The Secretary has determined that the potential impact of these export controls on the U.S. position is minimal. In FY 1998, BXA received 509 license applications, valued at $85 million, for the export or reexport of biological agents. Of these, the United States approved 484 applications, denied two applications and RWA'd 17 applications. In addition, the actual trade in these controlled commodities is significantly greater than the value of the license applications because U.S. exporters may export biological equipment to selected countries without a license.

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, the biological agents can be concealed and transported with ease.

To meet the challenge of effective enforcement of these proliferation controls, Commerce has redirected resources towards preventive enforcement. Enforcement personnel have recently begun conducting 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 are successfully conducted on the basis of routine documentation, as in other export control enforcement cases.

C. Consultation with Industry

On October 13, 1998, the Department of Commerce, via the *Federal Register*, solicited comments from Industry on the effectiveness of export policy. In general, the comments indicated that Industry does not feel that unilateral sanctions are effective. A more detailed review of the comments is available in Appendix I.

Exporters of biological products include commercial firms as well as academic and government entities. BXA maintains ongoing interaction with individual exporters, the Commerce chartered Technical Advisory Committees, and trade associations on proposed export transactions and marketing plans to facilitate thorough, yet prompt, review of export license applications. Through the Technical Advisory Committees, BXA keeps industry representatives abreast of AG proposals for items on the control list and gives them the opportunity to provide technical input. The Materials Technical Advisory Committee restructured its agenda in 1998 to allow for speedy, meaningful responses to the U.S. delegation negotiating a protocol to the BWC in Geneva. In addition, trade associations, such as the Pharmaceutical Manufacturers Association, the Biotechnology Industry Organization and the Animal Health Institute have been supportive of BXA's efforts to develop a protocol that will not endanger confidential business information.

D. Consultation with Other Countries

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.

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. At the annual AG plenary, held last October 12-15, 1998, members reviewed export controls on certain biological agents and toxins and biological equipment items.

The U.S. continues to urge key non-AG countries to adopt AG biological export controls. In 1998, BXA interacted with several of the Newly Independent States, including Russia, to raise awareness about the problems of proliferation and the need to develop export control systems that support nonproliferation goals.

In addition, during 1998, there was further discussion on completing a protocol to the BWC. The BWC, which entered into force in 1975, is an international arms control agreement among 140 nations that bans the development, production, stockpiling, acquisition, or retention of biological agents or toxins that have no justification for prophylactic, protective or other peaceful purposes. Discussions on a protocol included 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 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. 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), places 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, United Kingdom and Russia confirmed their commitment to full compliance with the Biological Weapons Convention and agreed to a number of steps including data exchanges, visits to sites, and further consultations to enhance cooperation and confidence.**

- **Biological Weapons Convention - An Ad Hoc Group continues to work 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, 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.

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ENDNOTES

1. *The full title of the BWC is the "Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction. The treaty was signed in 1972 and ratified by the United States in 1975.*