Order Code RS21422
Updated January 22, 2004

Dual-Use Biological Equipment: Difficulties in Domestic Regulation

Dana A. Shea
Analyst in Science and Technology Policy
Resources, Science, and Industry Division

Summary

Dual-use technologies, technologies with both civilian and military use, are often cited as lowering technical barriers to terrorist development of chemical and biological weapons. Export of these technologies is regulated through both domestic law and international agreement, but domestic sales are not. Dual-use biological equipment, whose military use includes the production of biological weapons, is employed in many different civilian and commercial applications, including academic research and the pharmaceutical, medical, and manufacturing industries. Consequently, regulating such equipment might have a marked economic impact and prove to be infeasible. Possible approaches to controlling this equipment include voluntary self-regulation and use of industry best practices by suppliers, licensing of equipment purchasers, registration of equipment, and application of civil penalties to suppliers for inappropriate end-use of equipment. This report will not be updated.

Introduction

A question in the current debate over chemical and biological terrorism is: how well do current United States policies limit opportunities to terrorist groups for acquisition of such weapons? The domestic purchase and use of "dual-use" biological equipment,[1] such as fermenters, centrifuges, and other equipment, is one area suggested as potentially providing opportunities for terrorist, biological weapons development. Dual-use equipment has both legitimate civilian and military use. Regulating international sale of dual-use equipment is used as a nonproliferation policy tool. Similar regulation of domestic sales has not been employed. This report will discuss the difficulties of applying domestic controls on dual-use biological equipment and the potential advantages and disadvantages of doing so.

[1] The phrase dual-use biological equipment, for the purposes of this report, describes dual-use equipment which could be employed to develop biological weapon agents.

The anthrax mailings of September and October 2001 challenged the belief that a nation-state-level weapons program was a prerequisite for the production of high quality biological weapons. Modern advances in dual-use biological equipment may have significantly lowered technological barriers previously thought to impede individuals or small groups wishing to obtain biological weapons.[2] Advanced dual-use biological equipment may allow biological weapons manufacture in smaller facilities, which may be more difficult to detect.[3] Many experts had thought that the requirements of technical skills and education, specialized equipment, and a pathogen source would provide significant barriers to terrorist groups.[4] Although experts are divided, some believe that an individual or a small, autonomous terrorist group may have been able to manufacture and disseminate the anthrax spores used in the 2001 attacks.[5] They suggest anthrax spores might have been developed through the use of dual-use biological equipment by creating a private laboratory to grow biological weapons.[6]

The USA PATRIOT Act (P.L. 107-56) limited individual access to biological agents, and required researchers working with restricted biological agents, and facilities which possess, transfer, or use such agents, to register with the federal government and develop appropriate safeguards to prevent illegal access to said agents. Restricted persons, including persons from any of the terrorism-sponsoring nations, are forbidden access. This act did not impose similar controls on dual-use biological technologies.

What Is Dual-Use Biological Equipment?

Dual-use items range from the sophisticated, such as equipment designed to chemically alter uranium compounds, to the mundane, such as high-voltage capacitors. Dual-use biological equipment includes fermenters, centrifuges, sterilizers, and biological safety equipment. This equipment is found in civilian settings, such as academic and industrial research laboratories, teaching facilities, and hospitals, and in such activities as brewing.

While some dual-use technologies have narrow applicability, others are ubiquitous. In general, dual-use biological equipment is fairly widespread and there is a large commercial trade in such equipment. Many laboratory or production sites contain

---

[2] For an overview of the impact of technological advances on acquisition of biological weapons, see Richard A. Falkenrath, Robert D. Newman, and Bradley A. Thayer, *America's Achilles Heel*, (Cambridge MA: MIT Press) 1998.

[3] For example, it has been reported that Iraq miniaturized biological weapon production to such an extent that a small laboratory could be contained within a cargo truck. See Paul Richter and Greg Miller, "Inspectors to Scour Iraq for Mobile Weapons Labs; Western Analysts Believe a Nondescript Fleet of Trucks Could Be Evasive – and Lethal If Bombed," *Los Angeles Times*, November 17, 2002.

[4] See Amy E. Smithson and Leslie-Anne Levy, *Ataxia: The Chemical and Biological Terrorism Threat and the U.S. Response*, (Washington DC: The Henry L. Stimson Center) October, 2000.

[5] Other theories have also been put forth regarding the 2001 anthrax mailings. For the current status of the FBI Amerithrax investigation, see [http://www.fbi.gov/anthrax/amerithraxlinks.htm].

[6] Matt Crenson, "Experts Offer Competing Theories for Source of Anthrax: Was It New Jersey Basement or Iraq?" *The Associated Press*, November 9, 2001.

multiple pieces of dual-use biological equipment. Additionally, dual-use biological equipment exists on many different production scales. Using fermenters as an example, large, temperature and atmosphere controlled fermenters are used in industrial settings. Home brewers use fermenters of varying size and complexity, from stainless steel, temperature controlled brew pots to 5-gallon closed plastic buckets. Diagnostic and research facilities use plastic petri dishes to culture and grow bacteria.

Dual-use biological equipment may be used for different purposes in each field. Fermenters, again as an example, may be used in developing biological pesticides (the bacterium used as "Bt" pesticide, *Bacillus thuringiensis*, is commonly grown through a fermentation process), production of medicines (insulin is commercially extracted from genetically modified microbes), vaccine development (anthrax vaccine is generated using fermenters), and industrial enzymatic processes (such as those generating ethanol from biomass). Biodefense research uses dual-use biological equipment to develop new detectors, vaccines, and treatments against pathogens.

What Control Mechanisms Currently Are in Place?

While export controls do not apply to purchase of dual-use biological equipment when the equipment is bought domestically from a domestic supplier, they may be considered as a framework for domestic regulation of such equipment. Treaties and multinational agreements are used to control dual-use biological equipment at the international level. The goal of multinational programs is to inhibit proliferation by increasing the technical barrier to weapon production. Examples of such multilateral controls include the Wassenaar Arrangement and the Australia Group.[7] Dual-use biological technologies are included within U.S. export regulations, which block export of some equipment without a license. These export control programs have thresholds below which such controls do not apply. Equipment with capacity below these thresholds may be sufficient to develop a limited biological weapons capability and would not trigger such regulations. Export controls include Export Administration Regulations and International Traffic in Arms Regulations.[8]

Other mechanisms, including voluntary governmental programs, increased contacts between suppliers and purchasers, and industrial best practices, are used to monitor the use of domestic dual-use biological equipment. The Department of Homeland Security has continued a program named "Project Shield America," which has agents visit U.S. firms which manufacture or distribute technologies which may interest terrorist groups. These agents provide firms with information about U.S. export controls and request that vendors notify the federal government if they are approached by customers looking to

---

[7] Information on the Australia Group is found online at [http://www.australiagroup.net]. For more information about the Wassenaar Arrangement, see CRS Report RS20517, *Military Technology and Conventional Weapons Export Controls: The Wassenaar Arrangement*, by Richard F. Grimmett.

[8] Export Administration Regulations can be found at 15 CFR Parts 730-774. International Traffic in Arms Regulations can be found at 22 CFR Parts 120-130.

acquire and export their products illegally.[9] Some industries, such as parts of the chemical and pharmaceutical industries, are developing best practices programs to limit potential misuse of dual-use equipment. These practices include higher physical security of laboratory and production facilities.[10]

Congressional Action

107th Congress. No legislation was passed in the 107th Congress controlling domestic sale or use of dual-use biological equipment. However, on November 6, 2001, the Senate Committee on the Judiciary, Subcommittee on Equipment, Terrorism, and Government Information held a hearing addressing bioterrorism. During this hearing, the prospect of employing licensing or regulation of dual-use biological equipment was considered. Dr. Ronald Atlas, President of the American Society for Microbiology, expressed his opinion that licensing and regulation would not be a successful mechanism for controlling domestic development of biological weapons.

> As worrisome as it may be, small flasks, canisters, home brewing bottles, and other similarly mundane equipment provide all that is needed to grow the bacteria that cause anthrax, plague, and other select agents. ... To cover the size relevant for bioterrorism one would have to capture everything of 5 liters and above and that would still not eliminate the possibility of growing the organisms in simpler vessels.[11]

108th Congress. Export control legislation was introduced by Rep. Dreier (H.R. 55) and referred to the House Committee on International Relations. No further action was taken. For more information on the export control debate, see CRS Report RL31832, *The Export Administration Act: Evolution, Provisions, and Debate*, by Ian F. Fergusson.

The House Committee on Government Reform, Subcommittee on National Security, Emerging Threats, and International Relations held a hearing on October 7, 2003 investigating Department of Defense control of surplus chemical and biological equipment. The General Accounting Office (GAO) testified that surplus dual-use biological equipment was purchasable from the Department of Defense at discounted cost.[12] Equipment purchased by GAO included both manufacturing and safety related equipment.

---

[9] For more information on the Department of Homeland Security's Project Shield America, see [http://www.cbp.gov/xp/cgov/enforcement/ice/investigative_priorities/ecee/].

[10] Members of the American Chemistry Council have adopted a Responsible Care Security Code to limit the effects of terrorist attacks or infiltration at their facilities. See *Protecting a Nation: Homeland Defense and the Business of Chemistry*, American Chemistry Council, 2002. Other industry groups have developed similar plans.

[11] Dr. Ronald Atlas, President, American Society for Microbiology, Testimony before the Senate Committee on the Judiciary, Subcommittee on Equipment, Terrorism, and Government Information, November 6, 2001.

[12] Testimony by Gregory D. Kutz, General Accounting Office, before the House Committee on Government Reform, Subcommittee on National Security, Emerging Threats, and International Relations, October 7, 2003.

Policy Options

Maintaining the Status Quo. The export controls currently employed to limit proliferation of dual-use biological equipment were developed with the perceived threat being from nations, rather than terrorist groups. Some have claimed that export control mechanisms are not well-suited to blocking terrorist acquisition of biological weapons. Since nations generally are interested in producing bulk amounts of weapons, purchases generally are on a large scale, and failure to interdict a single purchase may not be greatly detrimental to a nonproliferation program. In the case of a lone terrorist, purchase of equipment with small, limited capacity may allow biological weapon development sufficient for use in terrorist acts. For example, the sale of fermenters with more than 100-liter capacity is controlled under export regulation.[13] Consequently, a 10- or 50-liter fermenter, which has been suggested as sufficing for limited development of biological weapons,[14] could be purchased without triggering licensing requirements. It has been reported, though not confirmed by the government, that a research project called Project BACUS, funded by the Defense Threat Reduction Agency, demonstrated the feasibility of assembling the equipment needed to establish a biological weapons laboratory through purchase of dual-use biological equipment.[15]

Some contend that export controls economically injure domestic manufacturers of such equipment and that the United States is not a sole supplier of many export-controlled technologies. They suggest that export control does not significantly increase barriers to proliferation of widely manufactured technologies, and that controls should be lowered on these items. Advocates of maintaining strict export control regulations maintain that the barriers created by export control are valuable and should be continued or expanded. See CRS Report RL31832, *The Export Administration Act: Evolution, Provisions, and Debate*, by Ian F. Fergusson for a discussion of these positions.

Current domestic oversight of dual-use biological equipment through Project Shield America has also been questioned. Three concerns have been raised: the degree to which industry members may take on the job of federal officers; the mechanism of identifying manufacturers and technologies; and the manner by which manufacturers are to determine suspicious behavior.[16] Also, while best manufacturing practices may limit access to dual-use equipment in industrial settings, such efforts do not address purchase and illicit use of dual-use equipment outside of those settings.

Licensing or Registering Domestic Sales. Another option might be to license companies and individuals for purchase of dual-use biological equipment or registering the sale of such equipment. This approach might mirror that now used for purchase of pathogens. Mechanisms involved in registering sale and possession of equipment exist

---

[13] U.S. Department of Commerce, Commerce Control List, Part 774, Category 2, found online at [http://w3.access.gpo.gov/bis/ear/ear_data.html].

[14] Kathleen C. Bailey, *Why the United States Rejected the Protocol to the Biological and Toxin Weapons Convention*, National Institute for Public Policy, October 2002.

[15] Judith Miller, Stephan Engelberg, and William Broad, *Germs: Biological Weapons and America's Secret War*, (New York: Simon and Schuster) 2001.

[16] Brock N. Meeks, "Terrorism 'Shopping List' Targeted," *MSNBC*, December 10, 2001.

(e.g., automobile purchase is registered), and could be implemented. Also, a mechanism for the retirement and removal of equipment no longer in service may be required if a registry format is used for dual-use biological equipment.

Some difficulties inherent in such a plan have been identified. A significant concern is the scale on which such licensing and registration would be effective. Registration of the purchase of common items, such as disposable, plastic petri dishes, might impose an unacceptable burden with respect to tracking, paperwork, and verification. Alternately, a registration program that was too limited might prove to provide no barrier to acquisition. Another concern lies in determining what criteria would be used to develop a licensing protocol, as a wide range of individuals, ranging from home brewers to research scientists, utilize this equipment. A final concern surrounds the effectiveness of such a program in prohibiting secondary sales, transfer, or use by unlicenced individuals. Others have advocated as solutions to secondary transfers, installing electronic tracking devices or indelible registration methods as alternatives or additions to a formal registry tracking.[17]

Encouraging Information Tracking of Dual-use Equipment. As a method to police the application of dual-use equipment, some have advocated increasing collection and coordination of information on dual-use equipment. Integration of vendor and other information might increase the ability of the U.S. government to detect small-scale, domestic, clandestine weapons programs. Others are concerned that such a program might raise civil liberty issues.[18]

Another approach that has been suggested is to request that entities selling such dual-use equipment show greater diligence in determining the end use for their products. Federal agencies selling surplus equipment might be required to verify or validate the end receiver or use of dual-use equipment. Companies that sell dual-use equipment might be advised to scrutinize sales to ensure that their products are not diverted to production of weapons. Some have suggested the development of civil liability for companies who fail to perform due diligence before selling equipment that is later misused.[19] Critics of this proposal doubt the practicability and political viability of such a position both in terms of industry incentive[20] and in the ability of vendors to control equipment end-use.[21]

---

[17] Robert Wright, "A Real War on Terrorism: Policing Weapons of Mass Destruction," *Salon*, September 12, 2002.

[18] Michael Powell, "Domestic Spying Pressed. Big-City Police Seek to Ease Limits Imposed After Abuses Decades Ago," *Washington Post*, November 29, 2002; Page A01

[19] Richard A. Falkenrath, *op. cit.* and Jonathan B. Tucker, "Chemical/Biological Terrorism: Coping with a New Threat," *Politics and the Life Sciences*, Vol. 15, September 1996, pp. 167-83.

[20] Graham S. Pearson, "Chemical/Biological Terrorism: How Serious a Risk?" *Politics and the Life Sciences*, Vol. 15, September 1996, pp. 210-12.

[21] Kathleen C. Bailey, "Policy Options for Combatting Chemical/Biological Terrorism," *Politics and the Life Sciences*, Vol. 15, September 1996, pp. 185-7.