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Biological Weapons: A Primer

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Biological Weapons: A Primer

Summary

In the past decade, public and congressional concerns over biological weapons (BW), and bioterrorism in particular, have sharply increased. Though the use of living organisms (e.g. bacteria, viruses, fungi) to harm or kill humans, livestock, or plants has never occurred on a large scale, many government officials are viewing a BW attack as a “when, not if” scenario. Some experts, however, question this assertion, noting that BW production and employment is significantly more difficult than often portrayed, and that there are significant political down sides for any nation or group who would employ them. There have been a number of calls from Congress, the GAO, and congressionally-mandated commissions for a comprehensive integrated national threat assessment to be performed, so that perceived vulnerabilities alone do not drive government’s response.

The United States has both statutes and regulations that govern possession and use of dangerous biological agents, though some have deemed these too loose to maintain effective control of these agents. Though no legislation has been introduced to date in the 107th Congress, legislation considered in the 106th Congress may be reintroduced later in the session.

Federal programs intended to deter, respond to, and/or mitigate a BW attack exist in a broad range of government departments and agencies, and have been subject to criticism for lack of coordination. Vice-president Cheney is overseeing a review of all programs related to chemical/biological/radiological/nuclear threat response, and in October 2001 is expected to provide recommendations, which would be implemented under the direction of the Federal Emergency Management Agency.

As a state party to the Biological Weapons Convention, the United States has participated in a decade-long effort to negotiate a protocol to the Convention that would improve assurance of compliance. It had been hoped that a draft protocol would be ready for consideration by the BWC Review Conference in November 2001, however significant remaining disagreements (both between the United States and its Western Group allies and with developing countries) over the effectiveness of verification measures, technology assistance, and protection of commercial proprietary information appear to have stalled this effort.

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Biological Weapons: Issues for Congress

Background

Origins of Current Interest

A number of factors have contributed to the greatly heightened interest in biological weapons (BW) over the last several years. The Persian Gulf War brought to light Iraq's BW capabilities, and years of post-war confrontations with United Nations inspectors served to keep public awareness high. Investigations of the Aum Shinrikyo, the Japanese terrorist group that released a chemical nerve agent in the Tokyo subway, revealed it had acquired and sought to weaponize biological agents as well. The bombings of the World Trade Center and the Oklahoma City Federal Building, though using only conventional explosives, brought the reality of very large scale terrorist attacks to U.S. shores. The Defense Department, the Central Intelligence Agency, and several independent studies have all spotlighted biological weapons as a growing concern both for the U.S. military and the general population. On the other hand, a significant number of experts have begun to question whether the concern over biological weapons is out of proportion to the actual threat.¹ Nevertheless, the potential vulnerability of the general public and the military and the relatively limited BW defense capabilities currently available, though long-standing, have been highlighted as never before. These events, accompanied by BW-related novels and movies which attract public interest and a strong press interest in biological weapons, will continue to make them a focal point for federal, state, and local governments.

What Are Biological Weapons?

A biological weapon is a biological agent that is intentionally used to harm or kill humans, animals, or plants. Biological agents, unlike chemical weapon agents, are living organisms. Types of agents typically considered for use as biological weapons are bacteria, viruses, rickettsiae, or fungi. A unique agent category, bridging the

¹ *Countering the Changing Threat of International Terrorism*. National Commission on Terrorism, June 2000; *Global Trends 2015*. National Foreign Intelligence Board, December 2000; *Weapons of Mass Destruction: Threat and Response 2001*. Department of Defense, January 2001; *Toward a National Strategy for Combating Terrorism*. Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction, Second Annual Report, December 2000; *Combating Chemical, Biological, Radiological, and Nuclear Terrorism: A Comprehensive Strategy*. Center for Strategic and International Studies, December 2000. *Hype or Reality: The "New Terrorism" and Mass Casualty Attacks*. Brad Roberts, ed., Chemical and Biological Arms Control Institute.

chemical and biological distinction, is toxins. These are biologically produced chemicals such as shellfish toxin, snake venom, botulinum toxin, or ricin.²

For arms control and legal purposes, the definition of biological weapons has proven a challenge. The agents themselves are in wide-spread use for legitimate medical research, and are often stored in significant quantity. Consequently, their production and possession cannot be completely prohibited without severe effect on legitimate and desirable activities. Hence, statutory and treaty language has focused on the **use** or **the intention to use** biological agents to harm, and their possession in quantities **incompatible** with legitimate purposes, rather than on the agents themselves. (See **U.S. Laws and Regulations**)

The number of biological agents that have been seriously considered for use as weapons is relatively small because most agents do not meet the necessary criteria. (For discussion of the criteria, see **The Nature of Biological Weapons**.) Two organizations, however, maintain rather extensive lists of agents that could possibly be used as biological weapons. The U.S. Centers for Disease Control and Prevention have established a list of agents whose transfer and possession are under regulatory control in the United States. The Australia Group, an informal association of nations seeking to stem CBW proliferations, maintains a list of agents over which member countries, including the United States, have pledged to maintain export controls. (See **Appendix**)

Nature of Biological Weapons

Biological weapons are unique, presenting a complex array of differing characteristics. They have never been used on a large-scale, and incidents of small-scale use are isolated and rare. Though some nations, including the United States, have produced BW stockpiles in the 20th Century, military leaders have generally viewed biological weapons with ambivalence.³ They can be unpredictable in the lethality, geographical extent, and onset of their effects, and conceivably present as great a threat to one's own forces as those of the enemy. While these considerations may cause reservations among military planners, they may not with those terrorists who are unconcerned about indiscriminate harm.

Though there are literally thousands of biological pathogens, relatively few have met the criteria for an effective biological weapon. The traditional requirements for a "battlefield" biological weapon are summarized below. Some of these requirements, however, may be irrelevant to a terrorist group unconcerned about the extent of harm caused, or to a nation state using BW as a strategic weapon. For instance, military planners have avoided highly contagious diseases (e.g. smallpox) for fear of epidemic spreading to their own forces. An uncontrolled epidemic, however, may be the

²Botulinum toxin is produced by the bacteria *clostridium botulinum*; Ricin is a toxin obtainable from castor beans.

³In 1969, after review under the Nixon Administration, the United States unilaterally foreswore biological weapons, and destroyed its BW stockpile. Major factors in this decision were the unpredictability of biological weapons, and faith in the U.S. nuclear arsenal for purposes of deterrence and retaliation.

desired result for a millenarian terrorist group or a nation-state seeking to destabilize an adversary who is at distance. These traditional requirements

- ! Relatively small dose to infect
- ! High virulence
- ! Capable of being widely dispersed
- ! Survivable in storage and through dispersal
- ! Insusceptible to common medical treatment
- ! Short period between infection and symptom onset
- ! Minimal contagiousness to avoid infecting one's own forces
- ! Availability of protective measures for one's own forces, if infected

Another characteristic of concern for those who would attempt *clandestine* BW use is natural occurrence in the target area. If natural outbreaks of a disease (e.g. cholera or typhoid) are relatively common, it could be used as a biological weapon with increased probability of plausible denial. Biological weapons could also lend themselves to "false flag" attacks, in which the perpetrator plants evidence incriminating another group or nation. These characteristics could enhance BW's attractiveness for some terrorists

It is often maintained that biological weapons are relatively easy to produce and use. This statement, however, is valid only in comparison to chemical and nuclear weapons production and use. Biological weapons do pose some significant challenges for potential users. Some nations have been attempting for years to develop a BW capability with apparently limited success. The terrorist group Aum Shinrikyo in Japan – although it had substantial financial resources, laboratories, and trained scientists – was unable to develop an effective biological weapon over several years.⁴ Giving a sense of the challenges involved, the following is a summary of a flowchart developed by the U.S. Office of Technology Assessment showing the steps involved in developing and using a biological weapon.⁵

- ! Obtain microbial seed stock
- ! Test suitability for weapon purposes
- ! Develop and test production process
- ! Mass produce and harvest agent
- ! Induce spore formulation or freeze-dry
- ! Micro-encapsulate (optional)
- ! Acquire/build/test delivery system
- ! Fill munitions or delivery system
- ! Transport and disseminate on target area

These steps present differing levels of challenge. Obtaining seed stocks has been relatively easy in the past, though heightened awareness and new regulatory steps have raised this threshold; certainly in the United States and, to a lesser extent world-

⁴Kaplan, David E., "Aum Shinrikyo", in *Toxic Terror: Assessing Terrorist Use of Chemical and Biological Weapons*. Jonathan Tucker, ed. MIT Press, 2000. p.207.

⁵Office of Technology Assessment, U.S. Congress. *Technologies Underlying Weapons of Mass Destruction*. 1993. p. 83.

wide. Producing significant amounts of a pathogen could take as little time as several days, and requires only equipment that is commercially available. The former director of Great Britain's CBW defense research program has estimated that a small BW production facility could be operated by ten trained personnel, though brief production of BW agents in small quantities could be produced by fewer personnel.⁶

The more difficult challenges arise in weaponizing and delivering the pathogen. Ideally, the pathogen particles must be of an appropriate size for inhalation, and achieving this has been described as "one of the more technically demanding aspects of weaponization."⁷ The pathogen must also be stabilized during storage and delivery. Though "simple aerosolizers" can be used to deliver BW agents, the Aum Shinrikyo's repeated failures in BW aerosol dispersal in Japan gives some indication of the difficulties in developing an effective delivery system.⁸ Throughout all the steps of BW production and delivery, those involved must also take extraordinary care to ensure they themselves are not infected inadvertently, unless they are dealing with plant or livestock pathogens that do not infect humans.

These challenges notwithstanding, most observers agree that the increasing availability of technology and numbers of trained biotech personnel will continue to erode the technical obstacles to BW production and use.⁹

Threat Assessments

In congressional testimony, CIA Director George Tenet noted that "chemical and biological weapons pose, arguably, the most daunting challenge for intelligence collectors and analysts."¹⁰ Large-scale weapons systems are more easily detectable by national technical intelligence means. BW facilities and weapons are notably easier to hide, and often require human intelligence sources to identify and evaluate. Consequently, little detailed information is available in unclassified form.

Until recent years, the BW threat was viewed as limited to U.S. armed forces who might engage an adversary with biological weapons capability. Hence, the emphasis was on national programs, and assessments focused on national biotechnological capabilities, as the two U.S. government reports summarized below indicate. As the potential for BW terrorism began to receive greater attention, many public officials have assumed the position that a BW attack upon the U.S. civilian population is "not a question of if, but when." As some observers have pointed out,

⁶Pearson, Graham. "The Threat of Deliberate Disease in the 21st Century", *Biological Weapons Proliferation: Reasons for Concern, Courses of Action*. Henry L. Stimson Center Report No. 24, January 1998. p. 7. Also available at [<http://www.brad.ac.uk/acad/sbtwc/other/disease.htm>]

⁷Ibid. p. 7.

⁸Kaplan, p. 216.

⁹Office of Technology Assessment, pp. 84-85.

¹⁰Testimony before the Senate Foreign Relations Committee, March 21, 2000.

this viewpoint is driven more by the extent of domestic population's *vulnerability* to a BW attack than by a "validated threat assessment" estimating the likelihood of such an attack occurring.¹¹ For some, CIA reports of the followers of terrorist leader Osama bin Laden trying to acquire BW-related materials is sufficient basis to assume he will eventually undertake a BW attack against U.S. citizens.¹² Others suggest that there are a variety of factors, both technical and political, that should be considered in assessing the likelihood of this occurring. It can also be noted that if a terrorist's goals are to gain publicity, engender fear, and cause his enemies to adopt significant defensive measures, simply implying the possibility of BW possession may be sufficient. The considerable funds expended and extensive measures undertaken in the last several years by U.S. federal, state, and local governments to prepare for a possible BW attack are indicative.

Threat assessments by their nature will always be imprecise. They are based upon available information and intelligence, which is often sketchy and unconfirmed. Consequently, regardless of the methodology used to analyze the data, a significant degree of uncertainty generally remains. As was demonstrated with the unanticipated Indian and Pakistani nuclear weapons tests in 1998, even large national nuclear weapons programs can evade accurate assessment. It is even more difficult when attempting to monitor or predict the activities of loosely organized terrorist groups and a type of weapon that requires considerably less infrastructure. It is this uncertainty, when juxtaposed with the theoretical potential for casualties, that encourages decision-makers to err on the side of greater caution when considering the BW threat.

U.S. Government Assessments

While the Central Intelligence Agency has issued, in classified form, the National Intelligence Estimate regarding foreign-based terrorism, there is still no single integrated assessment covering both foreign and domestic threats. And, as the General Accounting Office has repeatedly noted, there has been no national risk assessment undertaken.¹³

Foreign Countries. Two U.S. government reports provide information on national BW programs. Both of these reports focus on capabilities and do not address the intentions of the nations involved. *Adherence To and Compliance With Arms Control Agreements: Report to Congress*, published by the former Arms Control and Disarmament Agency (ACDA), has provided some information on countries that are parties to the Biological Weapons Convention, yet who are suspected or known to

¹¹ *Combating Terrorism: Need for Comprehensive Threat and Risk Assessment of Chemical and Biological Attack*. General Accounting Office. GAO/NSIAD-99-163. September 1999.

¹² Testimony of the Director of Central Intelligence before the Senate Foreign Relations Committee. March 21, 2000.
[http://www.cia.gov/cia/public_affairs/speeches/dci_speech_032100.html]

¹³ General Accounting Office, *Combating Terrorism: Need for Comprehensive Threat and Risk Assessments of Chemical and Biological Attacks*. GAO/NSIAD-99-163. September 1999.

possess a bioweapons capability. The Department of Defense offers some unclassified information on nations who are not parties to the BWC (and consequently not included in the ACDA report) in its latest annual report on proliferation.¹⁴ The ACDA and DOD national assessments are summarized below, in alphabetical order by nation:

- ! China – Possessed a BW program prior to joining the BWC, and it is “likely” that China continues to maintain that program covertly.
- ! Egypt – Possessed a BW program prior to signing the BWC. Egypt has not ratified the BWC, and it is “likely” that it still has a biological weapons capability.
- ! Iran – Has produced BW agents and “apparently” weaponized a small quantity. Iran has used civilian medical, educational, and scientific organizations, in addition to its biotechnology and pharmaceutical industries, to provide cover for its biological warfare program.
- ! Iraq – Since 1972 has developed, produced, and stockpiled BW agents and weapons. Though Iraq has made substantial disclosures to the United Nations about its BW program, they are incomplete and have led to the assessment that Iraq still possesses a BW program, and may have BW agents still stockpiled.
- ! Libya – Has been seeking a BW capability for years, but has been hampered by lack of expertise. Libya’s program remains in the R&D stage though it may be able produce small amounts of biological agents. Without foreign assistance, it is unlikely to make significant progress in agent weaponization.
- ! North Korea – Has conducted BW research for over thirty years, and is believed capable of limited BW production and weaponization. Non-governmental sources have suggested that the majority of North Korea’s investment has been focused on defensive BW measures, though acknowledging a limited offensive capability.¹⁵
- ! Russia – Acknowledged in 1992 that it had conducted a covert offensive BW program, and claimed to have ended it. Its declarations under the BWC since 1992 have been incomplete and misleading, leading to the suspicion that an offensive program still exists. The continued presence of “old hands” at certain facilities, denial of visitations to some former BW research/production sites, and information from defectors regarding “ongoing offensive biological warfare activities” contribute to these suspicions. The Russian BW effort was very extensive, exploring the full range of human, animal, and plant pathogens, and experimenting with genetic engineering to enhance agent effectiveness.
- ! Syria – has sought a BW arsenal for some time, and it is assessed as “highly probable” that it is developing an offensive BW capability. However, it is

¹⁴*Proliferation: Threat and Response*. Department of Defense. January 2001.

¹⁵*Jane’s U.S. Chemical-Biological Defense Guidebook*, Jane’s Information Group, 1997. p. 237.

believed Syria has not yet weaponized biological agents and would require foreign assistance to manufacture significant amounts of biological weapons.

The Secretary of State has designated six of the countries listed above as state-sponsors of terrorism – Iran, Iraq, Libya, North Korea, and Syria.¹⁶ Cuba, another designated state-sponsor of terrorism, has a well-developed biotechnology sector, and has been on a “watch list” for BW proliferation, but has not been listed by ACDA or DOD in their threat assessments. Most observers believe that there is a low probability of state-sponsors providing biological weapons to terrorist groups to use at their discretion.¹⁷ This opinion generally hinges on the assumption that these nations hold biological weapons to be too valuable or too dangerous to be trusted outside of government control. However, should a state decide to use BW, its client terrorist groups could be enlisted in the effort, and would provide at least a minimal level of plausible denial.

In addition to the countries noted above, there are several countries about which there is occasional press speculation, but no confirmed information, regarding BW programs. These include India, Israel, Pakistan, and Taiwan. South Africa has acknowledged that under the Apartheid-era governments an offensive BW program did exist, but has since been dismantled.¹⁸

Terrorist Groups. The Japanese Aum Shinrikyo sect is the only terrorist group known to have produced and attempted to weaponize biological agents.¹⁹ The Muslim extremist Usama Bin Ladin, who is believed to have organized the bombing of the U.S. embassies in Kenya and Tanzania, is apparently seeking to obtain biological toxin weapons.²⁰ Aside from these cases, unclassified sources provide almost no information on which to judge the extent of the BW threat from terrorist groups or individuals.

Those who believe that biological weapons are becoming more attractive to terrorist groups attribute this to several factors:

¹⁶*Patterns of Global Terrorism – 2000*, Department of State, April 2001, p. 31.

¹⁷*Proliferation: Threat and Response*, Section I, Transnational Threat, Department of Defense, November 1997. p. 1.

¹⁸ *Nuclear, Biological, and Chemical Weapons and Missiles: The Current Situation and Trends*. CRS Report RL30699. January 2, 2001;

¹⁹ In 1984, the Rajneeshee religious sect poisoned local restaurant salad bars in rural Oregon with *Salmonella* bacteria in hopes of reducing voter turnout in a local election, thereby allowing Rajneeshee candidates a victory. Over 700 people were sickened, and for quite some time public health officials considered the outbreak to be a natural occurrence. This incident is often cited in literature on terrorism, though it lacks the coercive element of traditional terrorism, and is perhaps more appropriately categorized as a simple criminal use of a biological agent.

²⁰Testimony of the Director of Central Intelligence before the Senate Foreign Relations Committee. March 21, 2000.

[http://www.cia.gov/cia/public_affairs/speeches/dci_speech_032100.html]

- ! Continuing publicity over the vulnerability of civilian populations to biological weapons.
- ! An increase in terrorist groups whose ideology embraces or does not shy from large numbers of indiscriminate casualties.
- ! Increased awareness of the strong psychological, as well as physical, effects of biological weapons.
- ! Increasing diffusion of bio-technological expertise.

Among government sources, the State Department's most recent edition of *Patterns of Global Terrorism 2000* remained unchanged from previous years in its assessment that:

“Most terrorists continued to rely on conventional tactics,...but some terrorists—such as Usama bin Laden and his associates—continued to seek chemical, biological, radiological, and nuclear capabilities.”²¹

Before the Senate Foreign Relations Committee, CIA Director George Tenet has testified:

“Beyond state actors, there are a number of terrorist groups seeking to develop or acquire biological and chemical weapons capabilities. Some such groups—like Usama bin Ladin's—have international networks, adding to uncertainty and the danger of a surprise attack. There are fewer constraints on non-state actors than on state actors. Adding to the unpredictability are the “lone militants,” or the ad hoc groups here at home and abroad who may try to conduct a biological and chemical weapons attack.”²²

Both the State Department and the Central Intelligence Agency focus on foreign terrorist groups. However, the possibility of domestic-based BW terrorism came to the fore with the 1995 arrest of an individual with white supremacist associations in possession of freeze-dried bubonic plague bacteria.²³ Since then the number of BW-related threats and hoaxes has continued to rise. There have been a number of calls for a comprehensive domestic terrorist threat assessment, but none has been undertaken. Though it might seem that the Federal Bureau of Investigation would be the logical agency to do this, the FBI is a law enforcement, not an intelligence collection, agency. Consequently, its investigative activities must be tied to evidence of suspected or actual crimes and their prosecution, rather than the kind of sweeping intelligence collection needed to prepare an overall domestic BW threat assessment.

²¹*Patterns of Global Terrorism 2000*, Department of State, April 2001. p. 35.

²²DCI Testimony, SFRC, March 21, 2000.

²³ Testimony of Robert Burnham, Chief, Domestic Terrorism Section, Federal Bureau of Investigation before the Transportation and Infrastructure Subcommittee on Oversight and Investigations. May 19, 1999.

Indeed, no government agency possesses a domestic mandate to collect intelligence equivalent to that of the U.S. intelligence community collecting overseas, and seeking such a mandate could raise significant constitutional issues.

National Commission and Panel Reports

Two recent executive branch and congressional commissions have published reports that address the threat of biological weapons. The U.S. Commission on National Security/21st Century, widely known as the Hart-Rudman Commission, comprised former senior government officials and military commanders, private sector executives, and journalists.²⁴ In its sweeping 3-volume examination of national security challenges, the Commission asserts that the “United States should assume that it will be a target of terrorist attacks against its homeland using weapons of mass destruction.”²⁵ The Commission also concludes that:

“biological weapons are the most likely choice of means for disaffected states and groups of the 21st century. They are nearly as easy to develop as chemical weapons, they are far more lethal, and they are likely to become easier to deliver.”²⁶

Perhaps more significantly, the Hart-Rudman Commission also predicts that:

“The design and deployment of genetically engineered pathogens could thwart most antibiotics and vaccines, and readily outcycle our detection, antidote development, and distribution timelines.”²⁷

The Congressionally-mandated Advisory Panel to Assess Domestic Response Capabilities For Terrorism Involving Weapons of Mass Destruction, popularly known as the “Gilmore Panel” has published two annual reports.²⁸ The Panel adopts a more

²⁴ The United States Commission on National Security/21st Century was originally chartered in 1998 by the Secretary of Defense, as the National Security Study’s Senior Advisory Board. It continues to operate as a Federal advisory committee in accordance with the Federal Advisory Committee Act (Public Law 92-463). [<http://www.nssg.gov>]

²⁵ *New World Coming: American Security in the 21st Century*. Appendix 1: *Supporting Research and Analysis*. p. 49. [http://www.nssg.gov/NWR_A.pdf]

²⁶ *Ibid.* p. 50

²⁷ *Ibid.* p. 51

²⁸ *First Annual Report to the President and the Congress: Assessing the Threat*. Advisory Panel to Assess Domestic Response Capabilities For Terrorism Involving Weapons of Mass Destruction. December 1999.

Second Annual Report to the President and the Congress: Toward a National Strategy for Combating Terrorism. Advisory Panel to Assess Domestic Response Capabilities For Terrorism Involving Weapons of Mass Destruction. December 2000.

The Secretary of Defense, in consultation with the Attorney General, the Secretary of Energy, the Secretary of Health and Human Services, and the Director of the Federal Emergency
(continued...)

conservative position regarding the likelihood of domestic bioterrorism resulting in mass casualties. Citing the technical difficulties and the relative unlikelihood of a terrorist group combining the scientific expertise and the willingness to commit mass murder, the Panel's report advises against focusing exclusively on worst case scenarios and suggests that recent spending levels are less threat-based than an "overcompensation for years of neglect".²⁹ The Commission also suggests particular attention to the possibility of terrorist attacks against U.S. agriculture, deeming this the easiest application of BW, and virtually "risk-free" for the perpetrators.³⁰ The Commission echoes the call for an integrated national threat assessment, which includes potential U.S.-based threats, to permit more rational allocation of resources.

U.S. Laws and Regulations

Biological Weapons Anti-Terrorism Act of 1989 (P.L. 101-298)

This act implements the Biological Weapons Convention of 1975, criminalizing the production, stockpiling, transfer, acquisition, and possession of any biological agent, toxin, or delivery system for use as a weapon. The act specifically exempts agents intended for protective or peaceful purposes. The 1996 Antiterrorism and Effective Death Penalty Act amended this law to extend its coverage to threats or attempts to use biological agents as weapons, and to include bio-engineered agents. Violators can be imprisoned for any term of years, including life imprisonment.

This act also provides the Attorney-General with the authority to request a seizure warrant for any covered agent that is of a type or quantity that has "no apparent justification for prophylactic, protective, or other peaceful purposes." The Attorney-General is also authorized to obtain a civil injunction against conduct prohibited under this act.

The primary issue of concern regarding this act is the challenge it provides for criminal prosecution. Intent to use an agent as a weapon must be proven, and it is an affirmative defense that possession or other activity with the agent is intended for peaceful purposes. Some have argued this makes it far too easy for a group or individual to have legal possession of potentially very dangerous pathogens, and places too high a burden of proof upon the prosecution. These concerns were, in part, the reason for certain provisions of the Antiterrorism and Effective Death Penalty Act of 1996 discussed below.

²⁸(...continued)

Management Agency, entered into a contract with the National Defense Research Institute (NDRI), a federally funded research and development center (FFRDC) at RAND, to establish the Advisory Panel in accordance with Section 1405 of the National Defense Authorization Act for Fiscal Year 1999, P.L.105-261.

²⁹Gilmore, Vol. I, p. 36.

³⁰Ibid, p. 12

Antiterrorism and Effective Death Penalty Act of 1996 (P.L. 104-132)

Subtitle B (Sec. 511) of this legislation directs the Secretary of Health and Human Services to 1) maintain a list of biological agents that have the “potential to pose a severe threat to public health” and 2) to promulgate rules for the transfer of listed agents to ensure proper training of personnel and laboratory facilities, and proper safeguards to prevent access to these agents for criminal or terrorist purposes. Fulfilling this statutory requirement, the Centers for Disease Control and Prevention (CDC) promulgated federal regulation 42 CFR Part 72.

The regulation requires any person or institution either transferring or receiving listed agents to 1) register with CDC; 2) to report shipments or transfers, noting end-users and purposes; 3) comply with appropriate federal biosafety requirements, and 4) submit to random or “for cause” inspections to assure compliance. One criticism of this legislation and the implementing regulation is that they focus solely on agent transfers, and consequently do not capture those institutions or individuals who currently possess listed agents, but have no cause to transfer them. Therefore, it still remains legal to possess these agents without registration, as long as no transfers take place. This continues to concern some lawmakers and members of the law enforcement community. In May 1999, the House Committee on Commerce Subcommittee on Oversight and Investigations held a hearing to address this issue.³¹ Department of Justice officials testified that the department had been working with Health and Human Services to draft new legislation addressing this issue, and it would be presented by the Administration “in the near future,” however, no Administration-sponsored legislation has as yet been introduced.

Recent Congressional Actions

Near the end of the 106th Congress, Senators Kyl and Feinstein introduced S. 3205, the Counterterrorism Act of 2000, which mandated reports from the Attorney General and the Secretary of Health and Human Services on ways to improve controls over biological pathogens and BW-related equipment, and ways to improve physical security in facilities that handle these pathogens. This legislation passed the Senate by unanimous consent on November 14, 2000, but the House did not act upon it before adjournment *sine die*.

Also in the 106th Congress, Sen. Biden introduced S. 3202, The Dangerous Biological Agent and Toxin Control Act of 2000. This legislation sought to tighten restrictions on the possession and transfer of biological pathogens. It did not receive Senate consideration before the 106th Congress adjourned.

These bills have not been re-introduced in the 107th Congress. Indeed, no legislation directly related to biological weapons has been introduced in the 107th.

³¹U.S. Congress. House of Representatives. Committee on Commerce, Subcommittee on Oversight and Investigations. *The Threat of Bioterrorism in America: Assessing the Adequacy of the Federal Law Relating to Dangerous Biological Agents*. Hearing, May 20, 1999. Serial No. 106-19.

The focus during this Congress has been on the larger issue of “homeland security”, which, among a broad range of issues, encompasses U.S. capabilities to respond to the use of biological weapons. Three bills on “homeland security” have been introduced in the 107th Congress: H.R. 525, H.R. 1198, and H.R. 1292. (For further information see the CRS Terrorism Electronic Briefing Book [<http://www.congress.gov/brbk/html/ebter1.html>])

Current Federal Programs

The federal programs related to biological weapons are all defensive in nature, and with the exception of the Department of Defense programs are in response to increased concerns about possible bioterrorism. They focus on improving pathogen detection, developing new treatments and vaccines, and upgrading incident response capabilities. Almost every cabinet-level department is currently playing some role in these efforts. A brief summary of the major federal BW-related programs follows. More detailed information can be found in individual agency budget documentation and in the Office of Management and Budget’s Annual Report to Congress on Combating Terrorism

Department of Agriculture

The Department of Agriculture (USDA) is seeking to improve detection techniques for the more highly infectious plant and animal pathogens, making it possible to locate their precise geographical origins. The Animal and Plant Health Inspection Service is undertaking to establish a “genetic fingerprint” library of animal pathogens, and is intensifying its emergency management training and education to cope with animal and disease outbreaks. The Plum Island Animal Disease Center (NY) [<http://www.ars.usda.gov/plum/bsl4.htm>] may be upgraded to a Biosafety Level 4 facility, and new Level 2 and Level 3 research laboratories are to be built at the National Animal Disease Center (IA) [<http://www.nadc.ars.usda.gov/>].

Department of Commerce

The primary BW-related efforts of the Commerce Department are centered in the Office of Chemical and Biological Controls and Treaty Compliance located in the Bureau of Export Administration (BXA) [<http://www.bxa.doc.gov/>]. This office oversees the enforcement of export controls on biological pathogens and BW-related equipment and technology that have been established in cooperation with the Australia Group.

Department of Defense (DOD)

The Department of Defense’s primary focus regarding biological weapons is the protection of U.S. armed forces, though it is prepared to offer assistance to civilian authorities as required in the event of a BW terrorist attack. The DOD Chemical and Biological Defense Program [<http://www.acq.osd.mil/cp/index.html>] divides its BW defensive programs into four areas: contamination avoidance, NBC battle management, protection, and decontamination. Much of DOD’s vanguard research

is being conducted by the Defense Advanced Research Agency (DARPA) [<http://www.darpa.mil/>] by its Defense Science Office, Microsystems Technology Office, and Special Projects Office. Among the subjects currently under study are:

- ! Advanced Consequence Management
- ! Advanced Diagnostics
- ! Pathogen Genomic Sequencing
- ! Unconventional Pathogen Countermeasures
- ! Air and Water Purification
- ! Component Technologies for Bio Agents Sensors
- ! Sensor Integration and Modeling for Biological Agent Detection (SIMBAD)

Department of Energy

Though the Department of Energy has traditionally focused on nuclear weapons, since the end of the Cold War and the emergence of concern over biological weapons, the department has initiated several BW-related defensive research and development programs under the Chemical and Biological Nonproliferation Program [<http://www.nn.doe.gov/cbnp/index.shtml>]. Technology research is divided into four areas: detection equipment, DNA characterization of pathogens, modeling pathogen dispersion patterns, and large-scale decontamination. Two “demonstration and application” programs are the Biological Aerosol Sentry and Information System (BASIS) and the Program for Response Operations and Technology Enhancements for Chemical/Biological Terrorism (PROTECT). BASIS would provide an area detection system for use at large-scale civilian events, providing agent identification, along with location, duration, and level of exposure. PROTECT is a system intended for large civilian facilities that may be at risk for a BW attack (e.g., airports, subways). The system will integrate detection, dispersion modeling, and decontamination technologies customized to a given facility, and capable of providing alarms and response options to emergency personnel. DOE also participates in U.S. efforts to redirect former Soviet biological weapons scientists to peaceful research activities by funding collaborative research programs through the DOE Initiatives for Proliferation Prevention Program.³²

Department of Health and Human Services (HHS)

The Department of Health and Human Services, through its Centers for Disease Control and Prevention (CDC) [<http://www.bt.cdc.gov/index.asp>], is seeking to improve the laboratory and epidemiology capabilities of public health surveillance systems at the state, local, and federal level. The HHS Office of Emergency Preparedness [<http://ndms.dhhs.gov/>] is developing Metropolitan Medical Response Systems [<http://www.mmrs.hhs.gov/>] in major urban areas to coordinate the response

³²The General Accounting Office has published a brief assessment of this effort: *Biological Weapons: Effort to Reduce Former Soviet Threat Offers Benefits, Poses New Risks* (Letter Report, 04/28/2000, GAO/NSIAD-00-138).

of a region's medical and emergency personnel in the event of a biological incident.³³ HHS is also overseeing the creation of a National Pharmaceutical Stockpile that can be tapped in the event of a mass-casualty incident. HHS research and development efforts are centered on vaccines, new therapeutic drugs, diagnostic techniques, and genomics. The Food and Drug Administration has also received funds to expedite pharmaceutical review and approval for drugs intended to combat BW agents.

Department of Justice (DOJ)

In addition to its law enforcement responsibilities, the Department of Justice, until recently, assumed responsibility for providing equipment grants to state and local first responders through the Office of Justice Programs. Within the Federal Bureau of Investigation, the National Domestic Preparedness Office [<http://www.ndpo.gov/>] was given coordination responsibility for domestic preparedness programs throughout the Federal Government, and sought to be the "clearinghouse" for assistance to state and local authorities. The Bush Administration is now transferring these responsibilities from DOJ to the Federal Emergency Management Agency.

Department of Veteran's Affairs (VA)

The Department of Veteran's Affairs has entered into an inter-agency agreement with HHS's U.S. Public Health Service to warehouse a portion of the National Pharmaceutical Stockpile. The VA is also setting up a training program for civilian hospital personnel to prepare them to treat patients exposed to both biological and chemical weapons.

Environmental Protection Agency (EPA)

The Environmental Protection Agency focuses primarily on hazardous materials spills, however its HAZMAT On-Scene Coordinators and Environmental Response Team are participating in bioterrorism exercises with other agencies. The EPA is also undertaking an assessment of the vulnerability of the national drinking water supply to terrorist action and ways to reduce that vulnerability.

Federal Emergency Management (FEMA)

On May 8th, 2001, President Bush directed the Federal Emergency Management Agency to create the Office of National Preparedness, and it was officially established on June 18th. This office will coordinate all federal programs dealing with weapons of mass destruction consequence management within the Departments of Defense, Health and Human Services, Justice, Energy, the Environmental Protection Agency, and other federal agencies. It will be responsible for implementing the recommendations of Vice-President Cheney's review of the Federal Government's counter-terrorism efforts. This review is expected to be completed by October 2001.

³³ According to HHS, ninety-seven Metropolitan Medical Response Systems will be in place by the end of FY2001.

The Biological Weapons Convention and the Australia Group

Biological Weapons Convention of 1975 (BWC)

The United States ratified the BWC in 1975. Parties to the BWC have agreed not to develop, produce, stockpile, or otherwise acquire or retain: 1) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective, or other peaceful purposes; and 2) weapons, equipment, or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

They also have agreed not to transfer directly or indirectly, or to assist any State, group of States or international organizations to manufacture or otherwise acquire any of the BW agents, toxins, weapons, equipment, or means of delivery. The BWC also requires all parties to destroy their BW stockpiles within nine months of ratification. The United States ratified the BWC in 1975 and enacted implementing legislation in 1989 (P.L. 101-298). The BWC codified what the United States had already unilaterally undertaken in 1969 when President Nixon ended the U.S. biological weapons program and ordered the stockpile destroyed.

The BWC was negotiated in a relatively short period of time (1969-1972) primarily because it contains no provisions for enforcement or verification of compliance, which are often the most difficult elements of an arms control treaty to conclude. Efforts to remedy this lack began in 1986 when the States Parties agreed to certain confidence-building measures. Compliance with even these unverified information exchanges was limited.³⁴ Since 1991 a so-called Ad Hoc Group of Government Experts has sought first to identify possible verification measures, and then to negotiate a verification protocol which could have a reasonable chance of acceptance by the BWC Review Conference in 2001.

A number of factors have informed the U.S. position in the BWC Protocol negotiations. Perhaps the single most important is the assertion that the BWC is inherently unverifiable, and that the best that can be hoped for is a “bolstering of confidence” regarding compliance. The reasons the United States has long held that the BWC is not verifiable are many, but almost all stem from the uniqueness of biological weapons. All other subjects of arms control agreements are: countable (aircraft, missiles), measurable (nuclear detonations), or not naturally occurring (nerve agents).³⁵ None of these conditions is true for biological weapons. Biological

³⁴These measures comprised sharing information on biocontainment facilities, biodefense programs; previous bioweapons programs, and current vaccine facilities. Fewer than 50% of the Parties ever filed declarations, and most have been incomplete or suspected of inaccuracies. See Pearson, Graham, “The Protocol to the Biological Weapons Convention Is Within Reach”, *Arms Control Today*, June 2000. [<http://www.armscontrol.org/ACT/june00/bwcjun.htm>]

³⁵Testimony of Al Zelicoff, Sandia National Laboratories, before House Government Reform (continued...)

pathogens are naturally ubiquitous, most often identified only with difficulty, and their possession (or the possession of equipment to produce them) is necessary for a wide range of perfectly legitimate and beneficial purposes, e.g. pharmaceutical and medical research.³⁶ The facilities required to produce biological weapons may be quite small, have no visible “signature”, and could otherwise carry out legitimate activities. Hence, the universe of potential BW facilities that would have to be monitored to achieve total verification is virtually limitless.

Once non-verifiability is assumed, it raises the threshold for the costs or risks that are deemed acceptable in obtaining an agreement. In the calculation of benefit and risk, the United States has accepted as fundamental principles the protection of the U.S. biotechnology industries’ confidential business information and the security of U.S. biodefense programs. Simply put, the U.S. believes that the low level of compliance assurance expected from the BWC Protocol does not justify placing these commercial and defense interests at any significant risk through broadly defined declarations or inspection procedures. This position has put the United States at odds with most of its European allies, who favor a more stringent and intrusive regime.

Another fundamental principle for the United States is the maintenance of existing non-proliferation export controls, independent of the BWC. The Non-Aligned Movement (NAM) of developing nations has quite energetically sought to prohibit such controls and to require/encourage technology transfer within the framework of the Protocol, making such measures a fundamental condition for their acceptance of any protocol. The United States and its European allies continue to resist these efforts, emphasizing that the BWC Protocol is to address security issues and is not a “trade treaty.” This issue is still seen by many as a “show-stopper”, unless the NAM nations modify their stance, which is deemed unlikely.

U.S. negotiators have also emphasized that any protocol would apply only to BWC state parties. Several nations hostile to the United States are suspected or known to have BW programs, and are not BWC state parties (e.g. Iraq, North Korea). Consequently, a protocol would have no effect on their conduct. This unmitigated threat is then perceived to place even greater importance on preventing the inadvertent release of technologically valuable information through declarations or visit/inspections.

Finally, U.S. negotiators have kept in mind the need for Senate advice and consent to any protocol, and the difficulties experienced in this process with the somewhat less controversial Chemical Weapons Convention. Some consideration, therefore, must be given to possible Senate reaction to protocol provisions to avoid a contentious, and possibly unsuccessful, ratification effort.

In the BWC Protocol negotiations, these principles have led the United States to favor narrower declaration thresholds and reporting requirements for facilities, to

³⁵(...continued)

National Security Subcommittee, June 5, 2001.

³⁶Indeed, the legal definition of biological weapon is dependent upon the intent of the pathogen possessor to harm.

oppose random visits to declared facilities, to seek restrictions on the number of mandatory on-site visits, and to support managed-access under the final control of the visited/inspected facility. These positions, held to protect U.S. commercial and biodefense information, have led some to characterize the U.S. position as somewhat paradoxical, i.e. expressing concerns over the lack of verifiability inherent in the Protocol draft, yet opposing tighter verification measures.

In press reports and in testimony before the House Committee on Government Reform National Security Subcommittee, there has been criticism that the United States has failed to assume a leadership role in the Protocol negotiations or has been “paralyzed” owing to bureaucratic conflict within the government³⁷. The relative silence of the U.S. delegation in Geneva, has resulted in our European allies taking the initiative and pressing for a more elaborate and intrusive regime (based largely upon the Chemical Weapons Convention) than the United States will support. This has led some to believe that the U.S. commitment to completing negotiations is not whole-hearted, and that perhaps the United States would prefer the negotiations to drift indefinitely.³⁸ These speculations have increased with reports that a Bush Administration review panel has concluded that the so-called Chairman’s Draft of the Protocol under consideration should not be accepted. There has also been speculation that the Administration will not, however, announce an outright rejection of the protocol draft, owing to concerns over the internationally sensitive issue of U.S. unilateralism, but rather will simply continue negotiations. To those who emphasize a need to complete negotiations so that the Protocol can be considered for approval by the November 2001 BWC Review Conference, the United States has maintained that it will not “negotiate against a deadline.”

The Australia Group and Export Controls

The United States, in coordination with the 30-member Australia Group maintains export controls over selected microorganisms, toxins, and biotechnology. The Australia Group is an informal consortium of nations formed in 1984 to combat the proliferation of chemical and biological weapons.³⁹ The AG has developed lists of agents and equipment over which each member has agreed to maintain export controls. It has also developed more extensive “warning lists” of dual-use materials which are circulated to commercial industry with a request to voluntarily report potentially suspicious transactions to their national government. The AG also serves as an information-sharing forum among its members.

³⁷Zelicoff.

³⁸Leonard, Jame F. “An Essential First Step”, *Arms Control Today* .May 200.

³⁹The Australia Group’s members are: Argentina, Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Slovak Republic, South Korea, Spain, Sweden, Switzerland, United Kingdom, United States, and the European Community Commission as an observer.

The biological agents and equipment under U.S. export control are listed on the Commerce Control List.⁴⁰ Export licenses are required for these items for all destinations, except Canada, and re-export or transfer is also prohibited without licensing. The Bureau of Export Administration considers license applications on a case-by-case basis, and will deny a license if it determines there is an unacceptable risk the materials could be used in a biological weapons project.

⁴⁰The Commerce Control List can found in .pdf format on the Department of Commerce Web site: [http://w3.access.gpo.gov/bxa/ear/ear_data.html]. For more detailed information on BW export controls, see the Bureau of Export Administration's *Foreign Policy report 2000*, Chapter 7. [<http://www.bxa.doc.gov/press/2000/Reports/ForPolTOC.html>]

**Appendix:
Centers for Disease Control and
Australia Group
Biological Agent/Equipment Control Lists**

Centers for Disease Control and Prevention List of Select Biological
Agents Subject to Regulation

Viruses

Crimean-Congo haemorrhagic fever virus
Eastern Equine Encephalitis virus
Ebola viruses
Equine Morbillivirus
Lassa fever virus
Marburg virus
Rift Valley fever virus
South American Haemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal,
Guanarito)
Tick-borne encephalitis complex viruses
Variola major virus (Smallpox virus)
Venezuelan Equine Encephalitis virus
Viruses causing hantavirus pulmonary syndrome
Yellow fever virus

Bacteria

Bacillus anthracis
Brucella abortus, B. melitensis, B. suis
Burkholderia (Pseudomonas) mallei
Burkholderia (Pseudomonas) pseudomallei
Clostridium botulinum
Francisella tularensis
Yersinia pestis

Exemptions: vaccine strains as described in Title 9 CFR, Part 78.1 are exempt.

Rickettsiae

Coxiella burnetii
Rickettsia prowazekii
Rickettsia rickettsii

Fungi

Coccidioides immitis

Toxins

Abrin
Aflatoxins

Botulinum toxins
Clostridium perfringens epsilon toxin
Conotoxins
Diacetoxyscirpenol
Ricin
Saxitoxin
Shigatoxin
Staphylococcal enterotoxins
Tetrodotoxin
T-2 toxin

Exemptions: Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD50 for vertebrates of more than 100 nanograms per kilogram body weight are exempt. National standard toxins required for biologic potency testing as described in 9 CFR Part 113 are exempt.

Australia Group
List of Biological Agents for Export Control

Viruses

Chikungunya virus
Congo-Crimean haemorrhagic fever virus
Dengue fever virus
Eastern equine encephalitis virus
Ebola virus
Hantaan virus
Junin virus
Lassa fever virus
Lymphocytic choriomeningitis virus
Machupo virus
Marburg virus
Monkey pox virus
Rift Valley fever virus
Tick-borne encephalitis virus (Russian Spring-Summer encephalitis virus)
Variola virus
Venezuelan equine encephalitis virus
Western equine encephalitis virus
White pox
Yellow fever virus
Japanese encephalitis virus

Rickettsiae

Coxiella burnetii
Rickettsia quintana (now known as Rochalimea quintana)
Rickettsia prowasecki
Japanese encephalitis virus

Bacteria

Bacillus anthracis
Brucella abortus
Brucella melitensis
Brucella suds
Chlamydia psittaci
Clostridium botulinum
Francisella tularensis
Pseudomonas mallet
Pseudomonas pseudomallei
Salmonella typhi
Shigella dysenteriae
Vibrio cholerae
Yersinia pestis

Genetically Modified Micro-organisms

Genetically modified micro-organisms or genetic elements that contain nucleic acid sequences associated with pathogenicity and are derived from organisms in the core list. Genetically modified micro-organisms or genetic elements that contain nucleic acid sequences coding for any of the toxins in the core list.

Toxins

Botulinum toxins
Clostridium perfringens toxins
Conotoxin
Ricin
Saxitoxin
Shiga toxin
Staphylococcus aureus toxins
Tetrodotoxin
Verotoxin
Microcystin (Cyanginosin)

Warning List

Viruses

Kyasanur Forest virus
Louping ill virus
Murray Valley encephalitis virus
Omsk haemorrhagic fever virus
Oropouche virus
Powassan virus
Rocio virus
St Louis encephalitis virus

Bacteria

Clostridium perfringens*
Clostridium tetani*
Enterohaemorrhagic Escheichia coli
Legionella pneumophila
Yersinia pseudotuberculosis

* The Australia Group recognizes that these organisms are ubiquitous, but, as they have been acquired in the past as part of biological weapons programs, they are worthy of special caution.

Genetically Modified Micro-organisms

Genetically modified mico-organisms or genetic elements that contain nucleic acid sequences associated with pathogenicity and are derived from organisms in the warning list. Genetically modified mico-organisms or genetic elements that contain nucleic acid sequences coding for any of the toxins in the warning list.

Toxins

Abrin
Cholera toxin
Tetanus toxin
Trichothecene mycotoxins

Australia Group Updated List of Animal Pathogens for Export Control

Viruses

African swine fever virus
Avian influenza virus*
Bluetongue virus
Foot and mouth disease virus
Goat pox virus
Herpes virus (Aujeszky's disease)
Hog cholera virus (*synonym*. swine fever virus)
Lyssa virus
Newcastle disease virus
Peste des petite ruminants virus
Porcine enterovirus type 9 (*synonym*: swine vesicular disease virus)
Rinderpest virus
Sheep pox virus
Teschen disease virus
Vesicular stomatitis virus

Bacteria

Mycoplasma mycoides

Genetically modified Micro-organisms

Genetically modified micro-organisms or genetic elements that contain nucleic acid sequences associated with pathogenicity and are derived from organisms in the list.

Australia Group List of Plant Pathogens for Export Control

Bacteria

Xanthomonas albilineans
Xanthomonas campestris pv. citri

Fungi

Colletotrichum coffeanum var. virulans
Cochliobolus miyabeanus (Helminthosporium oryzae)
Microcyclus ulei (syn. Dothidella ulei)
Puccinia graminis (syn. Puccinia graminis f. sp. tritici)
Puccinia striiformis (syn. Puccinia glumarum)
Pyricularia grisea / Pyricularia oryzae

Genetically-modified Micro-organisms

Genetically-modified micro-organisms or genetic elements that contain nucleic acid sequences associated with pathogenicity derived from the plant pathogens identified on the export control list.

Australia Group List of Dual-use Biological Equipment for Export Control

1. Complete containment facilities at P3, P4 containment level

Complete containment facilities that meet the criteria for P3 or P4 (BL3, BL4, L3, L4) containment as specified in the WHO Laboratory Biosafety manual (Geneva, 1983) should be subject to export control.

2. Fermenters*

Fermenters capable of cultivation of pathogenic micro-organisms, viruses or for toxin production, without the propagation of aerosols, and having all the following characteristics:

- (a) capacity equal to or greater than 300 litres;
- (b) double or multiple sealing joints within the steam containment area;
- (c) capable of in-situ sterilisation in a closed state.

* Sub-groups of fermenters include bioreactors, chemostats and continuous-flow systems.

3. Centrifugal Separators

Centrifugal separators capable of the continuous separation of pathogenic micro-organisms, without the propagation of aerosols, and having all the following characteristics:

- (a) flow rate greater than 100 litres per hour;
- (b) components of polished stainless steel or titanium;
- (c) double or multiple sealing joints within the steam containment area;
- (d) capable of in-situ steam sterilisation in a closed state.

4. Cross-flow Filtration Equipment

Cross-flow filtration equipment designed for continuous separation of pathogenic microorganisms, viruses, toxins and cell cultures without the propagation of aerosols, having all the following characteristics:

- (a) equal to or greater than 5 square metres;
- (b) capable of in-situ sterilisation.

5. Freeze-drying Equipment

Steam sterilisable freeze-drying equipment with a condenser capacity greater than 50 kgs of ice in 24 hours and less than 1000 kgs of ice in 24 hours.

6. Equipment that incorporates or is contained in P3 or P4 (BL3, BL4, L3, L4) containment housing, as follows:

- (a) Independently ventilated protective full or half suits;
- (b) Class III biological safety cabinets or isolators with similar performance standards.

7. Aerosol inhalation chambers

Chambers designed for aerosol challenge testing with pathogenic microorganisms, viruses or toxins and having a capacity of 1 cubic metre or greater.

The experts propose that the following item be included in awareness raising guidelines to industry:

1. Equipment for the micro-encapsulation of live micro-organisms and toxins in the range of 1-10 nanometer particle size, specifically:
 - (a) Interfacial polycondensators;
 - (b) Phase separators.
2. Fermenters of less than 300 litre capacity with special emphasis on aggregate orders or designs for use in combined systems.
3. Conventional or turbulent air-flow clean-air rooms and self-contained fan-HEPA filter units that may be used for P3 or P4 (BL3, BL4, L3, L4) containment facilities.

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