ISSUES IN SCIENCE POLICY

BIOTECHNOLOGICAL RESEARCH IN AN AGE OF TERRORISM

A report approved by the Council of the
Israel Academy of Sciences and Humanities
and the Israel National Security Council, 2008

Jerusalem 2008

The Steering Committee on Issues in
Biotechnological Research in an Age of Terrorism

The Israel Academy of Sciences and Humanities
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Executive Summary

Introduction

The terrorist attacks of September 11, 2001 and the wave of anthrax envelopes sent through the U.S. mails later that same year were a watershed for public perceptions of the threat of unconventional terror in general and of biological terror in particular. They changed the way Western countries, and the United States in particular, perceived this threat and brought home the vital need to confront it. Both decisionmakers and the public at large realized that accelerating international terror activity and the use of biological weapons (bioweapons) created a new and potent danger. Forecasts predict that biotechnology will advance dramatically in the 21st century and that terrorists will exploit the burgeoning availability of related information to obtain destructive offensive bioweapons capabilities.

The current campaign against biological terrorism is conducted simultaneously on three levels: prevention, defense and response. This report, in keeping with the Committee's mandate, addresses only one aspect of prevention — that is, preventing a hostile state or terrorist organization from obtaining materials or information from Israeli laboratories which might enable it to carry out a biological attack.

In practice, prevention consists primarily of appropriate legislation, the introduction of surveillance and supply regimes, and international treaties. The United States took the lead in this area when Congress passed, in an expedited process, two important laws in the wake of the 2001 attacks. Their purpose was to enhance the ability of the U.S. to prevent the spread of bioweapons and to develop a response to biological terror and other emergency

health situations. Responsibility for implementation with regard to human-risk agents was assigned to the Department of Health and Human Services (DHHS). Implementation regarding animal-risk agents was assigned to the Department of Agriculture.

Both laws mandate oversight of work with dangerous microorganisms and the law includes a specific list of these "select agents." In addition, the U.S. National Research Council (NRC) appointed an expert committee headed by Professor Gerald Fink (the Fink Committee) to examine the issue of biotechnological research in the age of terror. In 2004 the committee issued a report containing a list of recommendations for preventing or restricting the use of biotechnological information by terrorist organizations for the development and production of bioweaponry.

The Situation in Israel

Israeli scientists perform forefront research in the life sciences, biotechnology and biomedicine. They engage in a wide range of projects, using a wide variety of microorganisms, some of them virulent. Based on a heterogeneous research infrastructure, they use all internationally available scientific methods. This research, and related routine work, is conducted in three major sectors: academia (universities and research institutes), hospitals and biotech industry.

Researchers who use virulent microorganisms are obliged, under Israeli law, to follow specific protocols and safety standards, generally those required by such internationally respected groups as the World Health Organization (WHO) and the U.S. Center for Disease Control and Prevention (CDC).

Israel has a comprehensive legislative infrastructure that mandates biological safety (biosafety) procedures. Some of this legislation is implemented by the Ministry of Industry, Trade and Labor, which deals with workplace safety regulations. Other

ministries such as the Ministry of Health and the Ministry of Environmental Protection have also issued and implemented regulations in this area. Ministerial awareness of the importance of this issue is on the rise, and enforcement is also tightening. In other words, biosafety is being addressed properly in terms of both awareness and practice.

In contrast, Israel lacks a proper legal infrastructure for *biosecurity* (as distinct from biosafety), largely because no one has ever demanded one. Furthermore, since the awareness of its importance is relatively new, it remains minimal.

In practical terms, there is a certain amount of overlap between the demands of biosafety and of biosecurity. The existing biosafety procedures do contribute somewhat to biosecurity, but this contribution is far from comprehensive and certainly imperfect. In particular, biosafety rules do not directly address the seepage of dangerous microorganisms and information to hostile elements.

The Committee

The present Committee was established to address the problem of biosecurity threat. Its members were appointed jointly by the President of the Israel Academy of Sciences and the Head of the Israel National Security Council. To achieve its goals, the Committee has been examining and formulating recommendations on the following subjects:

- Changes required in Israel's existing legislative infrastructure. Such changes could update existing legislation on biosafety or supplement them with new laws and/or standards (e.g., physical defense and information security). They must address both academic research institutions, life sciences research facilities, the biotech industry, and hospital and government laboratories.

- Compilation of a list of biological agents and fields of research that should be subject to inspection and supervision.
- Establishment of a regime for tracking, supervision, oversight and legal/regulatory enforcement. It must address all areas of biosecurity, physical containment, the transfer and transport of micro-organisms and of information on sensitive subjects. The Committee must also formulate the types of supervision and the mechanisms required for implementation.
- Examination of the need for a national inter-ministerial body and or a national professional commission to guide, follow and maintain biosecurity.

To accomplish these tasks, the Committee conducted plenary meetings and met with representatives of relevant government and research institutions. The Committee also received data, surveys and conducted discussions of the following issues: possible scenarios of bioterror, dual-use biological research, legal issues, characteristics of the Israeli R&D system in the life and medical sciences, and issues of safety and security. It also perused the relevant international literature and the reports of foreign bioterror committees, especially the U.S. Fink Committee report.

Recommendations

The Committee's efforts have resulted in the following ten recommendations:

Recommendation 1: Awareness, Consciousness and Education

The Committee recommends an ongoing effort to raise awareness and understanding of the risks associated with the biological threat in general, and with dual-use biological research in particular, among the Israeli life and medical sciences R&D community.

Recommendation 2: Legislation

Legislation must be addressed on two levels:

- Since the creation of totally new legislation, under Israeli conditions, can be a long, slow and uncertain process, the Committee recommends that existing Israeli secondary legislation on biosafety should immediately be used as a model for ministerial executive orders and institutional (e.g., university) procedures designed to prevent the seepage of organisms, materials and information to potential terrorist elements. This will also empower the National Biosecurity Council (NBC), (see Recommendation 8) to carry out a survey intended to assure that the different laboratories have indeed adopted the operational procedures necessary to enforce biosecurity as suggested by the committee.
- In parallel, specific longer-term legislation should be formulated. This legislation must be comprehensive and cover all issues involved with the bioterror threat, including all aspects of biosecurity, subject to the needs and principles of the State of Israel.

Recommendation 3: Oversight and Supervision Mechanisms

Similarly, the Committee believes that the fastest and most efficient way to enforce a regime ensuring biosecurity at relevant institutions is to upgrade and adapt existing biosafety oversight procedures to also assure biosecurity. This is the optimal and most practical solution for both R&D and service laboratories in the life and medical sciences. Local responsibility for the enforcement of biosecurity should be delegated to existing institutional biosafety committees (renamed "biosafety and biosecurity committees") for the academic sector and special Central Safety and Security Committees for biomedical laboratories affiliated with the MOH, MOA and MOS. National biosecurity policy,

procedures and enforcement should be overseen by a National Biosecurity Council (NBC) to be appointed by the Ministry of Health.

Recommendation 4: List of Dangerous Agents

The Committee believes that there should be an itemized core list of dangerous agents. Not all biological agents should be placed in this category. The Committee has reviewed the list of agents issued by the U.S. Department of Health and Human Services and adopted it as its initial core-list. This list is a minimal list of well-known pathogenic or toxic agents, and additional agents could emerge continuously at any time, or be produced artificially in the research labs. The list should be reviewed and updated annually, as required, by the NBC.

Recommendation 5: Oversight and Approval of the Publication of Information Generated by Dual-Use Research

This sensitive subject must be an essential part of Israel's biosecurity policy. Given the risks involved, the Committee recommends the establishment of a system to oversee and approve dual-use research projects, by an internal mechanism based on the judgment by the academic community itself (see comments on Recommendation 5).

Recommendation 6: Consideration of Biosecurity Issues by Funding Agencies

The Committee recommends that the Israel Science Foundation (ISF) and government research foundations (national and binational research funds under the auspices of various government ministries) require, as part of their approval process, biosecurity approval from the institution in which the research will be con-

ducted. This would ensure that these issues are considered by applicant institutions and that proper safety and security measures are enforced. In the case of non-academic laboratory research, similar certification should come from the chairman of the Central Safety and Security Committee in the relevant ministry (e.g., Health, Agriculture or Science).

Recommendation 7: Oversight of Importation and Sale of Dual-Use Biological Equipment and Agents

In addition to existing export regulations, the Committee believes that it is necessary to establish a system to oversee the Israeli import of dual-use biological laboratory equipment and biological agents, as defined by the (export) risk list maintained by the MITL Export Authority, as well as the sale of these items in the local market (in particular, the sale of used equipment).

Recommendation 8: National Responsibility for Biosecurity

The establishment of a biosecurity regime and its enforcement should be assigned to the Ministry of Health (MOH), which has both primary responsibility for public health and the requisite scientific knowledge and professional experience. It is especially important the MOH should establish, as soon as possible, a National Biosecurity Council (NBC). The Chairman and members of the Council should be appointed by the Minister of Health in consultation with the Head of the National Security Council and the President of the Israel Academy of Sciences.

Recommendation 9: Budget

The Committee recommends that the government allocate a budget for the operation of this biological security system on the national and institutional level. The recommendations of this

committee can be realized only if an appropriate budget is approved.

Recommendation 10: Implementation of the Committee's Recommendations

The Committee recommends, following the approval of the head of the National Security Council and the president of the Israel Academy of Sciences and Humanities (once these recommendations are accepted by both bodies), that this report be submitted to the Interministerial Committee for Science and Technology (ICST), which will be asked to:

- Approve the recommendations
- Assign implementation to the Ministry of Health, who shall be responsible for civilian biosecurity
- Decide in principle to allot the required budget
- Instruct the Ministry of Health to appoint, as soon as possible, a National Biosecurity Council, which will be responsible for realizing the recommendations of this report. (Decisions of the ICST are rarely challenged and, de facto, have the status of a cabinet decision.)
- Instruct that 2–3 years from the initiation of the program, a general evaluation of the committee's recommendations should be done by independent ad hoc committees.

Given the extreme importance of this subject, and its serious implications for both national security and for scientific research, the Committee hopes that this report and its recommendations will be approved and implemented in full.

Introduction to Biosecurity

1. Political-Strategic Background

The terror attacks of September 11, 2001 and anthrax envelopes sent through the U.S. mail later that year mark a watershed in public perceptions of the threat of non-conventional terror in general, and of biological terror in particular. Bioweaponry is now recognized as a new and dangerous threat. Several recent U.S. reports have documented and analyzed this emerging threat and its implications. They predict that the availability and wide distribution of scientific information on new advances will eventually enable terrorists to obtain and prepare bioweapons capable of inflicting huge damage.

At the same time, international political-strategic developments have somewhat neutralized the bioweapon threat of nation states. Among these the dissolution of the Soviet Union was of particular importance. Many new states of the former Soviet Union have entered into disarmament treaties and other agreements with the United States, under which they had to dismantle and destroy their stockpiles of non-conventional weapons.

The United States, declaring "war against terror," has sought all means to prevent terror organizations from taking advantage of material, facilities or information originating in U.S. laboratories. It also has sought to reduce the damage such an attack could cause. The U.S. response was built on four foundations: deterrence, prevention, defense and response to terror attacks. The United States is investing considerable effort and resources simultaneously in all four areas. Existing laws have been reinforced and new legislation passed to facilitate efforts, particularly those against non-conventional terror. European countries have

also joined this U.S.-led crusade, although, with the exception of U.K., they are acting with less decisiveness and determination.

2. U.S. Initiatives in Bioweapon Nonproliferation

The international treaty governing the inspection and (control of) proliferation of biological weapons is the Biological Weapons Convention (BWC) of 1975. The BWC forbids the development, manufacture and stockpiling of bacteriological (biological) and toxin weapons and requires the destruction of existing stockpiles. The Convention's major Achilles heel is the lack of agreement on an inspections regime to enforce and ensure the compliance of the signatories, which limits its effectiveness. Furthermore, by its nature, it is an agreement between nation states and thus provides no protection against independent terror organizations.

The United States thus regards the enforcement of national legislation against bioterror as a more effective tool than international treaties for coping with the problem. It also supports oversight and supply regimes as additional tools for preventing proliferation and for encouraging other states to do the same.

In response to the anthrax envelopes attack, which was generally assumed to originate from a U.S. source, the U.S. Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 "to improve the ability of the United States to prevent, prepare for and respond to bioterrorism and other public health emergencies." The law mandates specific activities to confront biological terror and assigns the responsibility for action to the Department of Health and Human Services, including the CDC, for human targets and to the Department of Agriculture (USDA) for animal targets. This law also contains extremely stringent steps to prevent and minimize, to the greatest extent possible, the seepage of dangerous biological agents and toxins, as well as relevant technology and information, from

laboratories and research institutes in the U.S., including academic institutions, into hostile hands.

The law includes a list of specific biological agents that present a clear danger of being turned into bioweapons. Regarding these, the law establishes severe security measures. These include reporting and registration of all institutions, organizations and individuals who have the listed agents in their possession. Likewise, there is a requirement to register, inspect, physically oversee, guard and track all stockpiles of these agents. The law establishes safety procedures for the transport of these agents and requires the registration and reporting of all workers authorized to work with and deal with them. Government representatives have the authority to refuse certification to workers in accordance with specific criteria. The most important is any known or suspected connection with a terror organization.

Despite being a symbol of individual freedom, in this case the United States has adopted a strict security approach, giving national security priority over scientific and academic freedom. The United States has also taken energetic, large-scale measures to enforce its supply and export inspection regimes, a responsibility of the Department of Commerce. The U.S. has enacted stringent laws and regulations to prevent import and export of weapons of mass destruction and their components including dual-use materials and equipment.

As part of its international control activity, the United States participates in the "Australia Group" (AG). Founded in 1984, the 38-country AG has become an active and key player in recommending and coordinating import and export control measures for chemical and biological materials. It regularly and systematically updates its standards in keeping with global strategic and scientific-technological developments. For example, the AG recently addressed what changes are required in its standards in the face of the non-conventional terror threat, publishing, in 2004, its "Guidelines for Transfers of Sensitive Chemical or Biologi-

cal Items" (available at: www.australiagroup.net/en/guidelines.html). It has also added new biological agents to its list of forbidden materials. Recently, its list of equipment requiring oversight has been expanded considerably to include, for example, aerial sprayers. AG activity has almost certainly reduced traffic in dual-use materials and equipment, as well as their dissemination to countries that support terror and terror organizations.

In 2003, President George W. Bush initiated a new international framework called the Proliferation Security Initiative (PSI). This is a global attempt to prevent the shipment of weapons of mass destruction, the means for launching such weapons, and other components. It seeks to create a dynamic, proactive approach to preventing the spread of such items to and from terror organizations and their state supporters. Its principles were published in September 2003 by eleven countries and, since then, many other countries have also adopted them. Participation is voluntary, but the founding states encourage its spread, since success depends on international cooperation. The PSI is part of a comprehensive non-proliferation effort, comprising intelligence, diplomatic, law enforcement and other means to this goal. New federal laws deriving from the PSI and affecting 3,000 ports and terminals came into force in the United States on July 1, 2004, to prevent the smuggling of biological materials in containers. Every container and every vessel must receive cargo certification from its country of origin. The United States' resolute anti-proliferation policy, and its pressure on other international actors, have stimulated related action in additional organizations, such as the United Nations, the G8 Forum and the European Union.

3. Biosafety, Biosecurity and Biodefense

The term "biosafety" has been familiar for many years, and has no direct connection to biological weaponry. It signifies the en-

tire set of physical and administrative means that help prevent accidents while using dangerous biological agents for research, development, production and other purposes. Such accidents can harm workers and biosafety laws and regulations have advanced considerably in recent years, their requirements have been successfully imposed and effective inspection regimes have been organized.

In contrast, "biosecurity" is a relatively new term, tightly linked to the concept of bioweaponry. Its most appropriate definition in the context of this report is: the sum total of measures meant to prevent deliberate attempts by terrorists and terrorist organizations to obtain dangerous biological agents, technologies or information that will allow them to make biological weapons. However, the requirements of biosafety and biosecurity (and the means used to achieve them) overlap to a considerable extent. Biosecurity measures can be divided into six categories:

- Physical containment of dangerous organisms
- Preventing leakage of relevant information and materials
- Reporting and inspecting work with dangerous organisms
- Transport and transfer security
- Worker reliability
- Information security
- Integrated overview of scientific research programs.

A third term, "biodefense," constitutes all means meant to minimize or counteract the consequences of a biological attack after it has occurred. The current report does not address this subject which is not part of the Committee's mandate.

4. The Fink Committee Report (2004)

In 2004, the NRC's Fink Committee issued its report, *Biotechnological Research in an Age of Terrorism — Confronting the Dual-Use Dilemma*, which examined the state of biosecurity in civilian

research in the U.S. Such research is performed in government laboratories, universities, and biotech industries (their report did not examine classified research at defense research facilities). Their findings were used to draft recommendations regarding inspection and oversight mechanisms for biosecurity, focusing on dual-use research.

The Fink Committee found that existing U.S. legislation adequately provided for the physical aspects of biosecurity, especially with regard to safeguarding the biological agents themselves. In contrast, existing legislation was inadequate to curb the transfer of bioweapons-relevant technology, including information about research methods and results, into hostile hands. Nor did any other existing mechanisms address this concern. The dual-use nature of much biological research made this issue all the more serious (the dual-use research problem is further explored in Chapter 1, Section 4).

5. The Biosecurity Situation in Israel

Israel and the United Sates share common views concerning the threat of bioweapons, bioterror and the proliferation of weapons of mass destruction (WMD) among rogue states and terror organizations. Israel has repeatedly stated that its national policy is to prevent such proliferation, and it has taken concrete steps in this direction, some in the framework of internal legislation and some as part of international initiatives, including those of the United Nations.

Although Israel has not formally joined the BWC (regarding it as an inseparable part of a more general regional disarmament) it wholeheartedly adheres to the U.S., E.U. and U.N. initiatives combatting bioterror and WMD proliferation. It adheres to (and coordinates its activities with) the AG regime and fully supports

U.N. Resolution 1540. Israel also has consistently supported the policy of the United States in its war against international terror of all kinds.

Although the Israeli Ministry of Defense and the Israel Defense Forces have a longstanding tradition of *biodefense*, Israel has been largely inactive, beyond the declarative level, in the area of prevention (particularly *biosecurity*). Unlike the U.S., Western Europe and other countries, Israel has yet to adopt legislation directly aimed at preventing or minimizing the spread from its own laboratories, of non-conventional weaponry and its components (including dangerous biological agents).

Israel does have a well-developed system of civilian biosafety (as distinct from biosecurity) laws and regulations; but these can make only a limited and indirect contribution to oversight and inspection aimed at preventing the seepage of dangerous agents or information into hostile hands. There is also an executive order issued by the Ministry of Industry, Trade, and Labor (MITL) in 2004 which mandates the oversight of chemical, biological and nuclear exports "to help prevent the spread of non-conventional weaponry… [by] forbidding the export from Israel of products, technologies and services that can be used to develop and manufacture chemical, biological or nuclear weapons." It is important to note that — to minimize any harm to basic and clinical biomedical research — this MITL order specifically *exempts* the export of chemical and biological agents used for medical and veterinary diagnosis, treatment or research, and information related to such agents.

Despite such gaps, the prevention of biological terror remains of supreme importance at the national level. Preliminary staff work at the National Security Council produced the following findings:

- There is virtually no awareness of the need for biosecurity within Israel's civilian life sciences research community.
- Israel has no legal and/or regulatory infrastructure directed

specifically towards biosecurity. Existing biosafety laws and regulations provide only indirect and partial means for dealing with biosecurity.

- Institutions where biomedical R&D and other work (diagnosis, production, etc.) is performed are not subject to inspection or supervision by any single Israeli authority or ministry. Instead this responsibility is divided between a number of different ministries where division of responsibility is often not clear.
- As a result, neither on the national nor on the ministerial level is there a system of control or supervision of biomedical research laboratories, nor is there sufficient information about any dangerous biological agents used, the types of research performed, or the technologies employed.

6. Goals of the Committee

Clearly, the status of Israel's biosecurity is far from satisfactory. Given the risk posed by biological terrorism, biosecurity must be adequately addressed on the national level. Therefore, this Committee on Biotechnology Research in an Age of Terrorism was formed and assigned to study the issue and to draft recommendations for a national biosecurity policy, to be submitted to the President of the Israel Academy of Sciences and Humanities and Head of the National Security Council, who jointly appointed the members of the Committee. It included senior scientists with expertise in different areas of the life sciences and medicine, as well as jurists with relevant expertise. The appointments were personal rather than institutional. The Committee worked from November 2005 to January 2007.

The Committee's mandate was:

- To review the biosafety and biosecurity legislative and regulatory infrastructure governing Israel's academic research in-

stitutions, biotechnology industry, hospital laboratories and government agencies.

- To determine the need for updating existing legislation and for supplementing it with new laws and/or regulations in areas not currently covered (such as the containment of dangerous materials, the control of sensitive information, and the prevention of seepage to hostile organizations).
- To decide on the biological agents (Appendix B) and areas of biomedical and life sciences research (Appendix C) to be protected.
- To suggest models of oversight for enforcing those biosecurity provisions, and to recommend whether such supervision should be centralized or decentralized.
- To explore the need for an ongoing interministerial body to advise, guide, monitor and maintain national biosecurity.

The committee received surveys and testimony from many organizations, including the National Security Council; the Ministry of Health; the Ministry of Industry, Trade and Labor; the Ministry of Science, Culture and Sport; the Ministry of Agriculture; the Israel Science Foundation; the National Council for Animal Experimentation; the Israel Academy of Sciences and Humanities; institutional safety committees; universities; and other research institutions. It also discussed position and staff papers obtained by the Committee's coordinator and chairman.

The Committee believes that its report will increase public awareness of the importance of biosecurity among the public at large and in all parts of Israel's life sciences research community. The Committee also hopes that its recommendations will be adopted and implemented. The Committee is convinced that the State of Israel must establish laws and procedures to prevent bioterrorism and that adoption of its recommendations is essential to prevent or minimize the possibility of terrorist development of biological weapons originating from materials, technologies or information from Israel's own laboratories. The Committee

also believes that its work will contribute to Israeli academic research, by ensuring that it conforms to the spreading worldwide culture of biosecurity. Such conformance is increasingly a criterion for international cooperation.

Chapter 1
The Biological Threat in the 21st Century

1. Historical Background

Biological weapons have a long history. In the medieval period and in the 18th century in Europe and the Americas, virulent disease-causing bacterial agents were used for military purposes. In 20th century Japan (1930–1940) and later (1950s) in the United States, the Soviet Union, the U.K. and other countries, bioweapons were viewed as an important component of non-conventional arsenals, alongside chemical and nuclear weapons. Not just a strategic deterrent, such weapons were designated for battlefield use under a variety of conditions. In general, these countries used natural pathogenic microorganisms, such as anthrax, plague, yellow fever, smallpox and botulinum and their toxic products. The weaponization process included culturing these agents on a large scale, converting them into liquid or powder form, and using them to arm air bombs, rockets or warheads of various kinds. In the early 1980s this trend was reversed, as a result of the Biological Weapons Conventions (BWC) and for other political and strategic reasons. Subsequently, U.S. President Richard Nixon declared a moratorium on the development, manufacture and use of biological weapons and destroyed the existing U.S. arsenal. European countries, including the U.K. and France, followed suit. Despite its public accession to the BWC, the Soviet Union secretly continued to develop, manufacture and stockpile huge quantities of very advanced biological weaponry.

During the 1960–70s Third World countries in the Middle East and Asia began developing and manufacturing their own biological and chemical weaponry. These poor and undeveloped

countries viewed such weapons as their answer to the nuclear weapons possessed by other countries, including Israel. The result was a concrete threat to Israel by hostile states both on its inner perimeter (Egypt, Syria) and on its outer perimeter (Iraq, Iran and, for a while, Libya). The first layer of threat was thus from the countries of the so-called "Axis of Evil." These bioweapons, mounted on long-range missiles, gave them a perceived strategic balance against the nuclear weapons they believed Israel to possess. The same countries support Islamic terrorism and might well help terror movements develop and/or obtain biological weaponry.

The Twin-Towers and anthrax-letter attacks of 2001 increased awareness of worldwide Islamic terror and the ability of such groups to obtain nonconventional weaponry, especially bioweapons. The principal biological threat today comes from such terrorist organizations, since a biological attack requires only small amounts of material that can be concealed easily and dispersed secretly. In addition to creating huge casualties and a potent psychological effect, biological weapons also could create extensive peripheral and indirect economic, social and political disruption, a major goal of terrorism.

Recent years have seen a revolution in the biological sciences. New molecular biological approaches and related technologies promise great benefit, but could also create more virulent microorganisms that are resistant to antibiotics and vaccines, or that have other characteristics of effective biological weapons. Such new technologies may initially be available only to a select few; but the rapid dissemination of information through modern communications make it possible for hostile forces to access them. Such forces can use them to develop and produce sophisticated, dangerous biological weaponry that would be very difficult to counter. It is thus imperative to prevent knowledge, organisms and materials relevant to the production of bioweapons from reaching hostile hands.

2. New Biological Technologies that Could Be Used to Develop Bioweapons

Biology — and such complementary fields as mathematics, computer science, and physics — began to develop at an unprecedented pace towards the end of the last century. Forecasts indicate that the pace will increase exponentially, even if its precise directions are unknown. Although such biological research and development can benefit humanity, hostile forces could also take advantage of biotechnological advances to harm humans and other species on a catastrophic scale. To counter this possibility, we must first understand the areas that modern biotechnology addresses and their likely directions of future development. This is not to underrate the bioweapons potential inherent even in the technologies of classic biology. These include methods for producing massive quantities of pathogenic bacteria and viruses, and sophisticated ways to store and disperse large quantities of such agents.

By the 1980s, researchers were already expressing concern that recombinant DNA technology (genetic engineering) might be put to unacceptable use. While most discussion concerned ethical issues, the possibility of such technology providing dangerous capabilities to terrorists was also considered.

Today, astonishing as it may seem, that technology has been largely superceded! Subsequent advances in DNA manufacture and cloning will soon make it possible to produce any desired gene rapidly on an industrial scale at ever less cost. All that is needed are the necessary enzymes and a single copy of the gene to be reproduced. Soon, even the original gene will not be required, since just its nucleotide sequence will suffice for chemical synthesis.

Other important advances go hand-in-hand with this gene production capability. The genomes (the entire genetic codes) of a number of organisms have already been mapped, and this

number is growing at the rate of about 10 eukaryote and 100 prokaryote genomes a year. This huge amount of information is freely available, and the list of organisms whose genome has been sequenced is hardly selective in terms of biological risk. For example, the genome of the Spanish flu virus has been published, and so has an article that describes how to make a virus out of a genome map (see below). Eventually, it will be possible to manufacture entire genomes, e.g., of a pathogenic virus at low cost and with huge speed. For example, by 2010, a single laboratory technician should be able to produce or transcribe a DNA chain of 1010 base pairs (the individual components of DNA) in a single day, which is three times the length of the entire human genome! In other words, the same technician will be able to produce both genes that encode pathogens or resistance to antibiotics and genes to be used in genetic medicine (see below).

Even virulent and dangerous proteins may have bioweapons potential (although current prion proteins, e.g., the infectious agent in Mad Cow Disease, are slow acting). It would hardly be difficult for hostile forces to manufacture large quantities of faster-acting prions (if such exist) for use as bioweapons.

These examples are only a sampling of the many of recent breakthroughs that are liable to be exploited by hostile forces. Others include research on transgenic organisms (e.g., insects and plants), on weak links in the immune system (e.g., development of a virulent mousepox virus), and impressive developments in producing drug targeting and delivery mechanisms. In light of the almost unlimited technological possibilities and the explosion in knowledge, questions such as whether it is possible to engineer more dangerous pathogens assume a meaning quite different from that of the previous century.

Such biological developments are generally not linear in time but often appear suddenly, unexpectedly and sometimes by chance. (For example, RNAi, the topic of a 2006 Nobel Prize, was discovered by chance during research on producing multicolored

petunias!) Specific predictions are thus difficult to make. Hence, biosecurity policymakers must be up-to-date on research developments if they are to prevent hostile uses of biological technology.

3. Supplementary Technologies that Could Serve Developers of Bioweapons

Modern biological research is often supported by experimental and theoretical methods borrowed from the exact sciences, engineering sciences, materials sciences and other fields. This interdisciplinary approach has become an inseparable part of modern biology, so one must also consider relevant developments in these fields. This is not the place for a comprehensive survey, but a few brief examples may be useful.

Nanotechnology involves the miniaturization of technological components to the molecular or near-molecular (10-7–10-9m) level. Nanoparticles are already used in many commercial products, such as paints and cosmetic creams; and nanocrystals can help dissolve materials, including medicines, that are insoluble in water. Nanobiotechnology is quickly becoming important to biology and medicine.

Mathematics and computer science are increasingly important for the purpose of precise and rapid analysis of the huge amounts of information needed to construct biological models. These and other applications are called systems biology. While these and other technologies have made a huge contribution to science and to humanity, they also have considerable dual use potential.

4. Dual-Use Biological Research

The term "dual-use" was originally coined to denote technologies that can be used for both civilian and military purposes. The

latter term was broadened to include terror, when that became relevant. The fear of the hostile use of dual-use biological and biotechnological research exists on several levels, beginning with ostensibly civilian enterprises that secretly pursue exceptional applications. These can range from the conversion and exploitation of dual-use equipment and/or risk agents for terrorist purposes, to the use of biological information for developing biological weapons.

a. The Dual-Use Dilemma

Can't all scientific research be classified as dual-use? Past proposals to block dual-use scientific research would have dealt a serious blow to nearly all biological research. Others argue that every biological research program can be evaluated in terms of its benefits (e.g., potential to cure serious illnesses) and risks (e.g., potential for catastrophic adverse use). The problem with this approach is the essential difference between benefits and costs. While every rational person understands the implications of a deadly terror attack, only a select few can foresee the results of a revolutionary scientific discovery. Usually, in fact, it is impossible to know whether (or how) any given research project will produce findings of practical value. Therefore, any attempt to prevent future biological research might be influenced more by populist considerations than by professional, scientific ones.

Nevertheless, one cannot ignore the risk of dual-use research, nor forget that some researchers might deliberately seek to develop harmful applications for ideological, practical or financial reasons. There are surely financial backers and states who might support such research.

To address the issue intelligently, dual-use research must be categorized. The first category includes research deliberately aimed at producing bioweaponry, even if it also produces useful civilian applications as a side benefit. This is of obvious concern.

The second group comprises civilian research projects whose dual-use potential is known in advance. The third group encompasses research projects that are thought to have dual-use potential, but such potential can be evaluated only once the research is completed. The fourth group includes research projects that were initially considered to be free of dual-use potential, but which unexpectedly produced findings with potential for hostile use.

b. Examples

Although almost all biological research has some dual-use potential, that is not a reason for total inaction. The following two examples demonstrate the importance of addressing this issue.

The first example comes from Australia, where scientists sought to control the mouse population by developing a contraceptive vaccine. They created an attenuated, non-infective mousepox virus and then inserted into it the gene that codes for interleukin-4 (IL-4), in the hope that it would boost antibody production in infected mice. When the engineered virus was injected into mice, it unexpectedly turned off the mice's entire immune system, killing all the animals, even those vaccinated against mousepox.

The experiment showed how easily a harmless virus could be changed into a lethal one. Mousepox, by the way, is very similar to the human smallpox virus, so terrorists could theoretically produce a lethal smallpox virus from vaccinia (the cowpox virus), which is regularly used for vaccinations against smallpox.

The second example comes from a study whose dual-use potential was evident from the start. In 2006, an American team published the complete genomic sequence of the Spanish flu virus, the cause of the flu pandemic that killed millions of people in 1918–1919. In a subsequent project, researchers manufactured an entire virus in the laboratory and showed, by injecting it into mice, that the artificial virus was indeed virulent and lethal. Both these studies were publicly published in full and their details are

available to anyone interested in them for any purpose, although these scientific papers could potentially aid the production of one of the most deadly biological weapons ever known. In fact, the Spanish flu virus research was performed and published in the face of the considerable criticism that was leveled at a previous project, which described the chemical synthesis of a complete polio virus.

5. Biological Terror: Possible Scenarios

a. Types of Biological Attack

Biological terror (bioterror) is the deliberate use of biological weapons to directly harm human beings. The extent of injury depends on the agent used, its biological characteristics, and its means of dissemination. Such harm can also be indirect, aimed at creating panic, demoralization, damage to national image, and political and economic damage. Biological attacks can be:

- Overt attacks, which can be detected by an explosion, smoke or other obvious signs
- Covert attacks, which involve quiet or camouflaged dissemination by unseen aerosols, individual infections, or the poisoning of food or water sources.

The type of attack has immediate implications for its effects and the possibility of taking appropriate defensive action. An overt attack triggers immediate suspicion and subsequent identification of the biological agent. Pre-planned preventive actions can then be taken. In contrast, a covert attack, in the absence of concrete intelligence information, may be discovered only after the first wave of casualties appears. This could be several hours or days after the attack itself, depending on the agent. The preferred targets for biological attack are generally crowded places such as shopping malls, train stations (especially underground stations), airport terminals, sports stadiums, halls and large dining areas.

b. Possible Sources for Bioweapons Components

To prevent biological weapons and/or their components from reaching terrorist organizations, we must first identify their sources and the channels through which the terrorists might obtain them. In the current circumstances, several such channels can be posited:

- A terror-supporting state could actively and directly supply biological armaments or components from its own arsenal to an organization it supports. For example, Iran, in the framework of its current general strategy, could supply bioweaponry to Islamic terrorist organizations such as al-Qaeda and Hizbullah.
- Terror organizations could steal biological weapons, components or information from countries with biological arsenals or weapons programs. For example, countries of the former Soviet Union were participants in the huge biological weapons program pursued by the Soviets; and a good deal of this biological arsenal is in their possession. The level of security in these stockpiles is not known, and there have been reports of such weapons being sold for financial gain. This channel is certainly liable to enable terrorist groups to obtain bioweapons.
- Terrorist groups could produce bioweapons on their own. In a few cases, proof has been found of intentions, programs and actual attempts to do so, including the construction of a laboratory infrastructure appropriate for bioweapons production. In fact, the Japanese terror group Aum Shinrikyo succeeded in producing its own non-virulent anthrax and released it in Tokyo. An ideologically-motivated terror group with large financial resources could acquire the knowledge, experts and infrastructure to develop and manufacture its own bioweapons. These may be primitive at first, but in time such a group might be able to produce dangerous, sophisticated weapons.

c. Channels for Acquiring Bioterror Agents and Technologies

How can biological agents, methods and research results of interest to terrorist groups reach them from civilian research laboratories in academia, medical centers and industry? Two main paths can be surmised.

Intentional. For example, workers in a research or industrial laboratory, due to financial or ideological inducements, might steal appropriate microorganisms and pass them on to terrorists. Alternatively, they might use them themselves to produce bioweapons in the laboratory where they work, or outside it, or even through the use of an industrial production plant. Such workers could also use or transfer specialized knowledge and biotechnological methods to the terrorist group they serve.

Unintentional. In the framework of scientific work and cooperation, strains of microorganisms are sent from one research institution to another, both within Israel and abroad. Scientists do not always observe appropriate security procedures, and a shipment of a dangerous agent could in error reach unauthorized individuals liable to use them for harmful purposes. The uncontrolled import and purchase of certain basic materials, biological agents, and laboratory and industrial equipment could also increase the chances that terror groups could construct a laboratory and research infrastructure for the secret production of biological weapons. The dissemination of sensitive research results via publications, conferences and the internet could also have unintended consequences.

Chapter 2
Legal Aspects: A Selective Survey of Relevant Legislation

1. The U.S., U.K. and E.U.

In the post-September 11 age, the international community faced an urgent need to establish stringent legal frameworks to prevent the use of biological agents as weapons of mass destruction by terrorists, either by malicious transfer, intentional release, or unintentional seepage. The United States, the European Union, and the United Kingdom responded quickly to increase their oversight and inspection of laboratory work involving dangerous biological agents.

For example, the United States toughened the sanctions in its Biological Weapons Anti-Terrorism Act of 1989, which forbids "any person from knowingly engaging in the following actions: manufacture, possession, use, stockpiling, storage, transfer, and associated actions regarding dangerous biological agents as defined in the act, for any purpose not permitted by law." Such actions are criminal violations punishable by from ten years to life imprisonment (sections 175–178 of the act).

Shocked by the World Trade Center attack, Congress passed the USA Patriot Act of 2001, whose purpose is apparent from its official title: The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001. The act prohibits funding terrorist acts and mandates more stringent interrogative and enforcement mechanisms. Two subsequent laws, the Public Health Security and Bioterrorism Preparedness and Response Act (2002) and the Project

Bioshield Act (2003), also sought to protect public health from biological terror. They include a long list of urgent actions to prevent such threats or to restrict their impact. These laws provide a series of prohibitions and procedures to tighten the oversight and inspection of the dangerous biological agents used in laboratories. Especially important is the section "Enhanced Control of Dangerous Biological Agents and Toxins." Other prohibitions and procedures relate to biomedical research.

The United Kingdom (U.K.) also forbade "the development, manufacture, transfer, stockpiling, possession, or any other use of specific biological agents for uses that are not prophylactic and not for the purposes of defense or other peaceful purposes." They also updated their Biological Weapons Act (1974), which defined such acts as criminal and subject to life imprisonment. The range of forbidden acts was widened to include "attempt, preparation, conspiracy, assistance, promotion, persuasion, and other acts." The law was also given extraterritorial force and applied to British subjects abroad. A separate Anti-Terrorism, Crime and Security Act was legislated in 2001.

The European Union (E.U.) prepared a series of strategies and a "road map" for making appropriate arrangements for the life sciences. These documents stress the importance of scientific research and the commitment of the E.U. to encouraging and advancing it. Yet it also declares the obligation of the E.U. to take measures to prevent exploitation of the positive results of this research for malicious purposes.

2. Israel

Israel also needs, but does not yet have, a comprehensive explicit legal framework governing defense against biological terror and its consequences. The Committee has sought to clarify to what extent Israeli law contains normative instructions to deal

with bioterror threats that could result from scientific research conducted in Israel's biological and medical laboratories. The Committee found that Israel lacks legislation that specifically addresses this goal, although many existing statutes are relevant to the problem. In particular, there is a clear link between the need to protect the safety and health of laboratory workers handling dangerous biological agents and the need to protect the security and health of the public at large. The Committee thus carefully examined existing biosafety laws, which address inspection, work safety, hygiene and public health as they relate to biological laboratories.

The Committee has concluded that, although Israel has an effective legal framework for biosafety, it urgently needs a similar normative framework for biosecurity. A statutory list of dangerous biological agents and their forbidden uses must be drawn up and updated frequently. Relevant laboratories must be identified and certification procedures for using dangerous organisms must be legislated. Legislation must also provide for the adequate supervision of anti-theft, transfer and storage procedures. Clearly, existing biosafety provisions intended to protect people working with dangerous biological agents from laboratory accidents are also relevant for biosecurity.

Because totally new biosecurity legislation would take an unacceptably long time, more efficient means of initiating a biosafety regime must be considered. In particular, the expansion of Israel's existing biosafety laws to cover biosecurity would seem an optimal way to proceed in the short-term and mid-term future. Other efforts must include raising the awareness of laboratory directors, scientists and students regarding: existing legal requirements, the current bioterror threat, and the vital need for biosecurity and biosafety procedures. An active concern for biosecurity plays an important role in establishing normative frameworks for working with dangerous biological agents. International initiatives followed by national legislation in many

states focus on laboratories holding stores of dangerous biological agents, because these are a prime target for hostile forces.

"Preventive caution" requires rules that specify how to prevent hostile forces from acquiring bioweapons. The Committee believes that any normative framework must provide for both the continued performance, publication and implementation of scientific research, and for the defense, oversight and inspection mechanisms needed to prevent or minimize any hostile use of ostensibly positive research results. (For the relevant Israeli legislation and a list of relevant U.S. and U.K. laws, see Appendixes A-1 and A-2).

Chapter 3
Overview of Israel's Biological Research and Development System

1. Introduction

Israel conducts world-class biomedical research. This research is conducted in a number of sectors — at universities, research institutes, hospitals and in government laboratories. A 2003 National Security Council survey, performed by the Center for Technological Analysis and Forecasting (ICTAF, Tel Aviv University) identified and mapped close to 500 Israeli focal points of biological research, development and manufacture of potential relevance to bioterror. The map includes academic, non-academic research institutions, government institutions (e.g., the ministries of health, agriculture, and science), and industry.

Work on microorganisms, often virulent ones, takes place in many of these institutions. Most use advanced biological methods and technologies, and possess considerable manufacturing expertise, knowledge potentially relevant to developing bioweapons.

Organizationally and functionally, the system is extremely decentralized, with no single national authority having comprehensive responsibility for these laboratories and focal points. Instead, responsibility is divided between a number of ministries, authorities and academic institutions. Nor does any single centralized authority deal formally with professional issues relevant to the proper performance of this system. Nor does any national organization possess complete information about the system's

scientific personnel, their research interests and their laboratory's research.

On the other hand, awareness of biosafety problems and measures to assure biosafety are well-entrenched in such institutions. Israel's extensive legal and regulatory framework for the enforcing biosafety is generally well-followed. In contrast, Israel's biosecurity problem has yet to be seriously addressed by either national bodies or Israel's R&D system itself.

2. Ministry of Industry, Trade and Labor (MITL)

De jure, the primary legislated responsibility for worker and workplace safety, and hence laboratory biosafety, rests with the MITL. *De facto*, oversight and supervision of Israel's biomedical laboratories is considerably more complicated. The MITL tends not to focus its attention, expertise and inspections in that sector. In contrast, the Ministry of Health has major, expanding interest, expertise and — increasingly — activity in that area, which falls under the rubric of its general mandate to promote national health (see section 3).

The MITL's Laboratory Accreditation Authority (LAA) was established by law to accredit and inspect laboratories, and ensure their compliance with international quality and safety standards. Compliance with each standard is judged separately; there is no evaluation of the laboratory as a whole. Israeli law requires LAA accreditation only in specific sectors, for example, cement standards. In all nonspecified areas it is voluntary. This can lead to some unevenness. For example, the MOH's water and food laboratories must be accredited, but the same ministry's medical laboratories are exempt. A few Israeli medical laboratories do voluntarily seek accreditation for commercial reasons; but the lack of a comprehensive accreditation requirement for all biomedical laboratories prevents their effective central regulation.

3. Ministry of Health (MOH)

The Ministry of Health's responsibilities are different for Israeli biomedical laboratories in different sectors. Most conduct research and undertake routine diagnoses, are situated in hospitals, and many work with virulent bacteria or viruses. Laboratories in state-owned hospitals are under full MOH supervision. Other hospitals and laboratories belong to one of Israel's Kupot Holim (private health plans, HMOs): these are not under direct (or even full indirector) MOH supervision. The country's medical schools enjoy absolute independence and are not supervised by the MOH, rather each medical school/university has its own safety committees.

The MOH's own Department of Laboratories, part of the ministry's Public Health Service, is directly and fully responsible for the operation of the ministry's six internal public health laboratories. It also provides (varying amounts of) *administrative* oversight for hospitals, public and private sector medical laboratories and for LAA-accredited environmental health laboratories.

The MOH must approve medical laboratories in hospitals and HMOs and their professional staff. However, the ministry's Department of Laboratories does not possess information about, much less oversee, the research actually carried out in such laboratories. A dwindling number of private medical laboratories (only 13 are still operating today) are, in principle, supervised by the MOH.

Recently the MOH has begun to expand its oversight of medical laboratories in hospitals and health service organizations, including the tracking of biological agents, the registration of workers, and, for the last few years, a regime of regular inspections. The Ministry's six public health laboratories follow orderly safely procedures, including registration and documentation. However, the MITL biosafety regulations provide for MITL biosafety oversight and MITL supervision of all other medical

laboratory work. The MITL regulations assign broader responsibility for these issues to the laboratory director, who must also appoint a laboratory safety supervisor.

Other (often industrial) private laboratories are not classified as "medical," but rather as "biological laboratories," although they do work with dangerous biological agents. The MOH does not oversee these laboratories in any way. Such laboratories need only a MITL business license and are subject only to the usual MITL biological safety oversight. This potentially serious problem should be dealt with (within some appropriate framework).

4. Ministry of Agriculture (MOA)

The Ministry of Agriculture and Rural Development (MOA) operates three major laboratories that engage in biological and biotechnological research: the Volcani Center, the Veterinary Institute and the Institute of Plant Protection. The Veterinary Institute, the laboratory most relevant to the Committee's work, conducts studies on a large variety of microorganisms, including strains virulent in both animals and man. Some appear on lists of potential terror agents. It also supervises the industrial manufacture of veterinary vaccines. All cases of animal disease and all isolations of animal pathogens must be reported to the Institute. The Institute internally observes, and effectively enforces both biosafety and biosecurity procedures, with special safeguards being applied to such virulent strains as anthrax and botulinum. Work in the institute's laboratories is at biosafety level 3 (BL-3), as demanded by international standards.

There are well-defined entry and security procedures for access to sensitive storage facilities; and inspection and tracking procedures are regulated and enforced. Research projects are overseen and inspected by the researchers themselves with interinstitutional cooperation. Finally, the initiation of research

projects and their publication must be approved by the Institute's director. It is thus a good example of how good science and good biosecurity can work together in harmony.

5. Ministry of Science (MOS)

Although Israel's Ministry of Science, Culture and Sport (MOS) does not manage any research laboratories of its own, it does maintain contacts with the ten independent, non-profit regional R&D centers it had previously established (and still provides matching funds). Each laboratory is linked to a recognized academic institution and each has its own steering committee. The ministry receives regular reports, conducts site visits, and is kept informed of ongoing or planned research programs**.** It also oversees their budgets and equipment, although the oversight and supervision are fairly loose. The MOS has no responsibility for their biosafety or biosecurity.

The MOS is mostly a research funding agency, which manages funds for national scientific infrastructure and awards grants to laboratories at a variety of institutions. The ministry's influence is a function of the contracts it concludes with them. It has no authority over the biosafety or biosecurity of its grantees and their laboratories. However, contracts between the ministry and grantee laboratories do require a number of certifications — for example, approval from Israel's Helsinki Committee for experiments involving human subjects and from the National Council for Animal Experiments for animal subjects.

6. Institutions of Higher Education

The lion's share of Israeli life sciences and medical R&D is conducted at the country's universities and academic research

institutions: the Hebrew University, Tel Aviv University, Ben-Gurion University, Bar-Ilan University, the University of Haifa, the Technion, and the Weizmann Institute of Science.

Israel's universities are not formally subordinate to any government or public body, although they retain strong links to the Israel's Council for Higher Education and its Planning and Budget Committee which divides the government's total budget for higher education among them. All Israeli institutions of higher education share a similar organizational structure. Each is headed by a president, who usually appoints a vice-president for research and development.

Individual university scientists usually enjoy considerable scientific freedom with no institutional reporting, oversight or supervision of their work. Their work is only reviewed once every few years in the framework of institutional promotion committees. Only a few special activities are regulated by national or institutional procedures. For example, an Animal Experimentation Law establishes standards for the use of research animals; and Helsinki Committees oversee experiments on humans. Work with dangerous biological agents and poisons are regulated under Israel's extensive biosafety legal infrastructure, and academic institutions have appropriate procedures and organizations to ensure compliance.

This Committee solicited comprehensive assessments from the senior safety officials at two large academic research institutions, the Hebrew University of Jerusalem and the Weizmann Institute of Science. The Committee's impression is that awareness of biosafety and its legal requirements are increasing. This existing framework may also help provide an effective oversight mechanism for enforcing biosecurity regulations in Israeli academia. Since international research funding bodies (e.g., the U.S. National Institutes of Health and the United States military) are increasingly demanding effective biosafety supervision and oversight in the foreign laboratories it supports), Israel's academic

biosafety procedures are continuously improving. These international concerns might well include biosecurity in the near future.All academic research institutions have safety units, a full-time safety director, and safety committees. Each safety system complies with the relevant laws and the directives of the MITL Workplace Inspection Division (see Chapter 2). Relevant laws include the Workplace Safety Order (1970), the Workplace Inspection Organization Law (1945), and the Safety Oversight Order for Medical, Biological and Chemical Laboratories (2001).

An institution's safety officials oversee work with dangerous biological agents, with human blood and tissue samples, with DNA manipulation, with toxic materials, and with pathogenic organisms. Workplace regulations and guidelines are constantly updated, and laboratories are inspected regularly to ensure compliance. Record-keeping and periodic reporting regarding high-risk materials are required, and automated systems are being created to track the purchase of dangerous strains and special biological materials.

In summary, biosafety oversight takes place at two loci: first, when research proposals are submitted, and second during its progress. In addition, safety authorities conduct instructional workshops for scientists, laboratory workers and students in safety procedures. In some institutions, when a research project requires safety certification, it is given only after the safety division has confirmed that the laboratory's work conditions meet legal requirements.

7. Israel Science Foundation

Israel Science Foundation (ISF) grant applicants must be endorsed by the recipient institution and by its Helsinki Committee (for experiments involving human subjects) or by its Institutional Committee on Experiments with Animals (for animal

experiments) or, in some cases, by Israel's National Parks Authority. Work with genetically engineered plants must be approved by the National Committee for Transgenic Plants (NCTP). The ISF does not require institutional certification of biosafety. The ISF told the Committee that it could and would, in principle, request biosecurity and biosafety certification from the applicant's institution if requested.

8. Industry

The Committee did not receive a comprehensive survey of Israeli companies that conduct biomedical and biotechnological R&D, with the exception of those in a survey of centers of Israeli biotechnological research, development and manufacture conducted by the Center for Technological Analysis and Forecasting (ICTAF) of Tel Aviv University. The Chief Scientist of the MITL, when asked, refused to provide the Committee a list of private-sector companies involved in relevant fields, on the grounds that this constituted confidential commercial information. We were, therefore, unable to formulate comprehensive recommendations for this sector.

However, the ICTAF survey and partial data from Committee members made it clear that several laboratories in the commercial sector do indeed work with dangerous biological agents. Most of these are classified as biological, rather than medical, laboratories and are thus not overseen by the Ministry of Health. Although they are generally subject to biosafety regulation by the MITL's Inspector of Labor, the Committee did not receive information from the MITL on the manner and extent of MITL enforcement of biosafety regulations in industry. This important issue must eventually be more comprehensively addressed.

Chapter 4
Presentation and Discussion of the Committee's Recommendations

After due investigation and deliberation, the Committee has concluded that the bioterror threat (described in Chapter 1) is real and that Israel (can and should) do more to meet it. The Committee also believes that the best long-range solution for ensuring biosecurity in Israeli laboratories should be based on a solid legal and regulatory foundation. However, since the passage of new legislation by Israel's parliament is a complex, time-consuming and uncertain process, and since the current bioterror threat is urgent, the Committee recommends, as an immediate interim step, that Israel's existing biosafety laws and procedures be used as a basis for appropriate ministerial executive orders and institutional initiatives to improve biosecurity at both the national and local level. Within this overall strategy and framework, the committee presents the following ten (10) specific recommendations

Recommendation 1: Awareness, Consciousness and Education

The Committee recommends an ongoing effort to raise awareness and understanding of the risks associated with the biological threat in general, and with dual-use biological research in particular, among Israel's life and medical sciences research and development (R&D) community.

Comments

The Committee believes that the fundamental problem preventing the introduction of a biosecurity regime in Israel is a widespread lack of awareness that bioweapons exist in many countries, that "dual-use technologies" can help produce them, and that technologies and infective agents already found in Israeli laboratories could be effectively exploited by terrorists. This lack of awareness characteristics not only the Israeli general public, but also — and more worryingly — the Israeli scientific community, including laboratory directors, researchers and students.

Raising their level of awareness is essential to improving the norms of scientific behavior and forming a "biosecurity culture" to help prevent the seepage of critical information and materials into hostile hands.

The Committee therefore recommends:

- Preparation of a biosecurity curriculum[1] to be integrated into university courses in the medical and life sciences. This unit could be integrated with the teaching of biosafety, given the common ground between the two subjects.
- Preparation of biosecurity refresher courses and workshops for researchers working in all biological and medical laboratories in Israeli academic institutions, research institutions, hospitals and industry.
- Preparation of workshops and refresher courses for supervisory personnel, safety committees and safety/security officers.
- Organization of biosecurity lectures and workshops in the framework of conferences and seminars of professional organizations, such as the Israel Society for Microbiology.
- Preparation and presentation of these materials should be

1 Professional assistance and guidance for this could be provided by the proposed National Biosecurity Council (see Recommendation 8).

the responsibility of the relevant ministries and their associated institutions, namely: the Ministry of Health (for internal and external medical laboratories), and the Ministries of Agriculture and Science (for regional research and development laboratories), in conjunction with the administration of Israel's academic research institutions. The National Biosecurity Council should oversee this process.

Recommendation 2: Legislation

Legislation must be addressed on two levels:

- Since the creation of totally new legislation, under Israeli conditions, can be a long, slow and uncertain process, the Committee recommends that existing Israeli secondary legislation on biosafety should be used as a model for ministerial executive orders or temporary orders and institutional (e.g., university) procedures designed to prevent the seepage of organisms, material and information to potential terrorist elements. This will also empower the National Biosecurity Council (NBC), (See Recommendation 8) to carry out a survey intended to assure that the different laboratories have indeed adopted the operational procedures necessary to enforce biosecurity as suggested by the committee.
- In parallel, specific longer-term biosecurity legislation should be formulated. This legislation must be comprehensive and cover all issues involved with the bioterror threat, including all aspects of biosecurity, subject to the needs and principles of the State of Israel.

Comments

Since September 11, 2001 the U.S., U.K. and E.U. have established strict legal frameworks to prevent chemical and biological terror

by tightening the supervision of laboratory work with dangerous biological agents. Although Israel lacks such a normative framework, it does have fairly broad legislation addressing workplace safety applicable to work with dangerous biological agents. In the Committee's view, many of these biosafety procedures can be expanded to promote biosecurity as well. The Committee, therefore, urges the immediate adoption of this recommendation, since the introduction of new Israeli legislation is a prolonged process that could take several years. Such a delay would not be in the State's best interest.

The Committee believes that the potential severity of the bioterror threat requires the immediate meticulous professional examination of existing secondary legislation that can be adapted for use as a model for ministerial action designed to promote biosecurity. Implementation of these measures might best be accomplished via consultation between the professional departments of the relevant government ministries, in cooperation with the National Biosecurity Council (see Recommendation 8).

Recommendation 3: Oversight and Supervision Mechanisms

Similarly, the Committee believes that the fastest and most efficient way to enforce a regime ensuring biosecurity at relevant institutions is to upgrade and adapt existing biosafety oversight procedures to also assure biosecurity. This is the optimal and most practical solution for both R&D and service laboratories in the life and medical sciences. Local responsibility for the enforcement of biosecurity should be delegated to existing institutional biosafety committees (renamed "biosafety and biosecurity committees") for the academic sector (see subsection c) and special Central Safety and Security Committees for biomedical laboratories affiliated with the MOH, MOA and MOS (see subsection d).

National biosecurity policy, procedures and enforcement should be overseen by a National Biosecurity Council (NBC) to be appointed by the Ministry of Health (Recommendation 8).

Comments

The Committee has examined several possible biosecurity supervision and oversight mechanisms — based on existing biosafety committees — and it recommends a two-level approach. National civilian biosecurity should be the responsibility of the Ministry of Health (MOH), via the NBC (see Recommendation 8). Local biosecurity should be the responsibility of the upgraded institutional biosafety and biosecurity committees (supervised by the NBC). The detailed mechanisms to be used would contain the following elements.

a. Licensing

As a rule, work with dangerous pathogenic biological agents (defined by a list promulgated by the NBC) would be permitted only in licensed laboratories.

- Licenses for academic research laboratories would be granted by the chairman of the institution's biosafety and biosecurity committee.
- Licenses for Ministry of Health laboratories, medical laboratories in government hospitals, health service provider laboratories, and private laboratories will be granted by the director-general of the Ministry of Health at the recommendation of a Central Biosafety and Biosecurity Committee to be established within the ministry (see subsection d).
- The same principle should also apply to projects and laboratories under the purview of the Ministry of Agriculture and Ministry of Science.

Licenses will require the existence of biosafety standards and procedures as defined by the MITL and biosecurity requirements

as established by the Central Biosafety and Biosecurity Committee (in accordance with the principles in subsection b), until the establishment of a national legal and regulatory biosecurity infrastructure.

b. Control and Supervision

Responsibility for biosecurity (and biosafety) control and supervision should be assigned to the laboratory director, a position defined by law in "Inspector of Labor: Work Safety Regulations (Occupational Safety and Hygiene in Work with Dangerous Substances in Medical, Chemical and Biological Laboratories, 2001)" or, in the case of academic biomedical laboratories, the chairman of the institutional biosafety and biosecurity committee (see subsection d).

In particular, all materials appearing on the list of dangerous biological agents should be locked up and guarded. The laboratory director and the safety and security supervisor (or, where appropriate, the chairman of the Central Biosafety and Biosecurity Committee) should maintain lists of the dangerous agents in storage, to be updated each time an agent is removed or a new one added. They should also maintain a list of personnel authorized to work with these agents and certify and record all experiments involving the large-scale culture and manipulation of such dangerous microorganisms. They should approve and record the conveyance of such dangerous agents outside the laboratory. The procedures and means of transport should be approved by the safety and security supervisor.

Every mishap, accident, shortfall, theft or other exceptional event should be reported by the laboratory director to the safety and security supervisor. The institutional biosafety and biosecurity committee must approve and monitor the purchase of dual-use equipment and materials and materials appearing on the list of dangerous agents (Appendix B).

c. Sector-specific Comments: Academic Laboratories

Biological and medical research in academia maintain a relatively organized and effective biosafety regime. As a rule, there are safety units, safety committees and safety supervisors. The Committee recommends that the chairman of the safety committee or the safety supervisor currently responsible for biosafety should also assume responsibility for biosecurity in cooperation with the institution's security officer. The nature of this cooperation will be determined by the local safety supervisor at his own discretion, and will be codified in the institution's regulations. For example, the security officer might be a member of the institution's new biosafety and biosecurity committee (or of a relevant subcommittee); similarly, scientists may join the institutional biosafety and biosecurity committee as needed.

The institution's laboratory director will be responsible for implementing the safety and security supervisor's instruction and guidelines in his laboratory, and will report to him in accordance with specified procedures.

d. Sector-specific Comments: Hospital and Government Laboratories

Regarding medical laboratories in hospitals, in the Ministry of Health, in the Ministry of Agriculture and in (Ministry of Science-related) Regional Research and Development Centers, the Committee recommends that the model described in subsections a–c above be applied to these laboratories as well, on the assumption that they currently implement existing biosafety laws and have both a laboratory director and/or a safety supervisor or safety committee.

Nevertheless, because of the decentralization and large number of these laboratories and the extent to which they deal with dangerous agents and potentially sensitive subjects — especially in the Ministry of Health — the Committee recommends

establishing, within the framework of that ministry, a Central Safety and Security Committee to supervise and oversee the entire system, working with local institutional committees.

e. Sector-specific Comments: Industry Laboratories

The Committee did not discuss this sector in depth. In general, the Committee recommends that its recommendations in subsection c above be adopted and adopted in this sector as well. Details of implementation should be determined by the NBC (established under Recommendation 8).

Recommendation 4: List of Dangerous Agents

The Committee believes that there should be an itemized core list of dangerous agents. Not all biological agents should be placed in this category. The Committee has reviewed the list of agents issued by the U.S. Department of Health and Human Services and has adopted it as its initial core list.

This list is a minimal list of well-known pathogenic or toxic agents, and additional agents could emerge continuously at any time or be produced artificially in the research labs. The list should be reviewed and updated annually, as required, by the NBC.

Recommendation 5: Oversight and Approval of the Publication of Information Generated by Dual-Use Research

This sensitive subject must be an essential part of Israel's biosecurity policy. Given the risks involved, the Committee recommends the establishment of a system to oversee and approve dual-use research projects by an internal mechanism based on the judgment of the academic community itself.

Comments

The issue of performing and publishing the results of dual-use biological research is discussed at length in the body of this report (Chap. 1, section 4). The Committee is aware that this is a sensitive and complicated issue, given a potential conflict with the principle of academic freedom. However, this is hardly the only area in which scientific experiments are governed by external regulations, such as those governing human and animal experimentation.

Dual-use research issue can be addressed at two junctures: during the initial evaluation for funding (the submitting institute already checks grant proposals for adherence to safety regulations, etc.) and upon completion before its results are published (or disseminated via conferences, the internet, etc.). As a general rule, the Committee recommends focusing on the initial evaluation stage. In principle, subsequent control should be exercised by the scientists themselves, who should be conscious of possible risks and their public responsibility — to the point of abandoning work that constitutes a clear danger, or whose potential damage outweighs its potential benefit. At the final stage, institutional and editorial judgment can also influence the way results are disseminated.

On the practical level, the Committee recommends that the existing criteria for approving research proposals, which already includes adherence to regulations governing human or animal subjects,[2] should also include an assessment of its potential contribution to bioterror. Scientists submitting research proposals to their institutions' authorized grant-submitting body (e.g., Research and Development Authority) would state whether their

2 Institutional and national committees oversee such research, and their prior consent is required by most foundations before acceptance.

proposed project falls into a bioterror risk category (one of seven areas of concern listed in the Fink Committee report[3]). If there is such a risk, the proposal must explain why the research should nevertheless be pursued. The scientist will request the approval of the chairman of his institution's safety and security committee (or, in government laboratories, the chairman of the Central Safety and Security Committee). When a lack of clarity or difference of opinion appears at the institutional level, the NBC (Recommendation 8) would be consulted.

Such an internal mechanism, would both control, adjust, or (when necessary) even prohibit research with a significant potential for harm, and also contribute to increasing awareness of and sensitivity to this issue among the scientific community. The Committee stresses that this system of institutional and individual self-supervision — in which the scientific community oversees its own professional behavior — gives due weight to both freedom of academic inquiry and mitigation of risks. It is far better than the undesirable alternative of external oversight, which is liable to violate this freedom.

Recommendation 6: Consideration of Biosecurity Issues by Funding Agencies

The Committee recommends that the Israel Science Foundation (ISF) and government research foundations (national and binational research funds under the auspices of various government ministries) require, as part of their approval process, biosecurity approval from the institution in which the research will be conducted. This would ensure that these issues are considered by ap-

3 *Biotechnological Research in an Age of Terrorism: Confronting the Dual Use Dilemma* (U.S. NRC Report, 2004; www.nyas.org/ebriefreps/ebrief/000243/rr/RRdr008.pdf).

plicant institutions and that proper safety and security measures are enforced. In the case of non-academic laboratory research, similar certification should come from the chairman of the Central Safety and Security Committee in the relevant ministry (e.g., Health, Agriculture or Science).

Recommendation 7: Oversight of Importation and Sale of Dual-Use Biological Equipment and Agents

In addition to existing export regulations, the Committee believes that it is necessary to establish a system to oversee the Israeli import of dual-use biological laboratory equipment and biological agents, as defined by the (export) risk list maintained by the MITL Export Authority, as well as the sale of these items in the local market (in particular, the sale of used equipment).

Comments

Other channels for the seepage of sensitive biological development and manufacturing equipment into hostile hands is the importation of such equipment and/or the sale of such used equipment on the local market, as well as the importation of biological agents that appear on the NBC's risk list. MITL Import and Export Order: Control of Chemical, Biological and Nuclear Exports (5764, 2004) already controls the *export* of chemical, biological and nuclear materials and equipment. However, there is no similar mechanism regarding *imports*.

The MITL, in cooperation with the other relevant ministries, must propose such a mechanism. The list of equipment to be import-regulated should be based on the list of dual-use biological equipment that already appears in the above export-regulation order. In contrast, the sale of used dual-use equipment to terrorist organizations on the local market is far more difficult to prevent.

A partial solution is a "final-user" declaration[4] by the first purchaser, and subsequent tracking by Israel's General Security Service.

Recommendation 8: National Responsibility for Biosecurity

The establishment of a biosecurity regime and its enforcement should be assigned to the Ministry of Health (MOH), which has both primary responsibility for requisite scientific knowledge and professional experience. It is especially important that the MOH should establish, as soon as possible, a National Biosecurity Council (NBC). The chairman and members of the Council should be appointed by the Minister of Health in consultation with the head of the National Security Council and the President of the Israel Academy of Sciences and Humanities.

Comments

The NBC will be responsible for implementing the recommendations of this report and for advising the Minister of Health on all aspects of biosecurity on the national level, in all biological research areas and venues (e.g., academic institutions, government ministries and industry). The NBC will keep in contact with the academic community, especially the "safety and biosecurity committees," and the governmental community, especially the biosecurity sector. In particular:

- As a guiding and advisory body, the NBC will set policy, formulate criteria, and provide instruction, evaluation and oversight in biosecurity to academic institutions, government ministries and industry.
- In the initial phase, the NBC will also oversee and supervise

4 In a "final-user declaration," the purchaser undertakes not to transfer the equipment to a third party.

the implementation of the Committee's recommendations in all the above sectors.

- To address the current absence of biosecurity legislation and standards in Israel (see Chapter 2), the NBC will initiate and advise ministries and other relevant institutions on the establishment of an appropriate legal infrastructure for biosecurity at all levels, both by updating existing laws and/or by the legislation of new laws.
- The NBC will serve as an advisory and guiding body for research institutions regarding the evaluation and supervision of dual-use research.
- The NBC will review its list of dangerous agents (Recommendation 4) once a year and update it as needed.
- The Chairman of the NBC should initiate seminars on subjects of interest and send his representatives to national seminars in the field.
- The NBC will maintain a working relationship and exchange of information with similar bodies abroad.
- The NBC will submit an annual report to the Minister of Health.
- 2–3 years from the initiation of the program, the NBC should instruct a general evaluation of the committee's recommendations by independent ad hoc committees.
- The Committee recommends that the NBC consist of 15 members, most of them biomedical and legal professionals, as well as a public representative and professionals from the relevant ministries, academic research institutions and relevant government authorities, especially the security sector.

Recommendation 9: Budget

The Committee recommends that the government allocate a budget for the operation of this biological security system on the

national and institutional level. The recommendations of this committee can be realized only if an appropriate budget is approved for establishing the National Biosafety Council and the necessary biosecurity arrangements in academia.

Comments

Special supervision and oversight systems require a special budget for their operation. In the pertinent example of animal-experiment supervision, a central budget is allocated for operating the National Council for Animal Experimentation and for the regular operation of the system within research institutions. In the case of biosecurity, funds are required for operating the NBC and the biosecurity system of pertinent research institutions. In particular, existing institutional biosafety systems must be provided appropriate personnel for addressing biosecurity issues. The Ministry of Health (see Recommendation 8) will require additional funding and at least two additional full-time positions to operate the NBC. Furthermore, relevant Israeli academic institutions (perhaps via the Planning and Budget Committee of the Israel Council for Higher Education, VATAT) and government ministries (MOH, MOA, MITL) must assign a portion of their budgets for internal biosecurity activities in their laboratories.

Recommendation 10: Implementation of the Committee's Recommendations

The Committee recommends, following the approval of the head of the National Security Council and the president of the Israel Academy of Sciences (once these recommendations are accepted by both bodies), that this report be submitted to Israel's Interministerial Committee for Science and Technology (ICST), which will be asked to:

- Approve the recommendations
- Assign implementation to the Ministry of Health, who shall be responsible for civilian biosecurity.
- Decide in principle to allot the required budget (see Recommendation 9).
- Instruct the Ministry of Health to appoint, as soon as possible, a National Biosecurity Council, which will be responsible for realizing the recommendations of this report.
- Instruct that 2–3 years from the initiation of the program, a general evaluation of the committee's recommendations should be done by independent ad hoc committees.

(Decisions of the ICST are rarely challenged and, de facto, have the status of a cabinet decision.)

Table of Recommendations[5]

Recommendation	Responsibility for Implementation	Schedule
1. Awareness, Consciousness, Education	Academic institutions — vice-president, rectors, deans, heads of biomedical professional associations, Ministries of Health, Science, Agriculture	Immediate
2. Legislation and Standards	National Biosecurity Council (NBC), Directors-General of the Ministries of Health, Science, Agriculture, Justice, Defense	Six months
3. Institutional and Ministerial Oversight and Supervision Mechanisms	Vice-presidents of academic institutions; Directors-General of Ministries of Health, Science, Agriculture, Industry	Year
4. List of Dangerous Agents	All agents	Immediate
5. Evaluation of Sensitive Research Projects	Academic institutions: vice-presidents for R&D Ministries: Health, Science, Agriculture	Year
6. Approval of Research Proposals	All competitive national, binational, and ministerial research funds	Year

5 Subsequent to the approval of this report and before it went to press, the Knesset approved the first reading of the bill "Supervision of Research on Pathogenic Agents," based on the committee's recommendations.

Recommendation	Responsibility for Implementation	Schedule
7. Oversight of Importation and Sale of Dual-Use Biological Equipment	Ministry of Industry, Trade and Labor, General Security Service	Year
8. Establishment of National Biosecurity Council (NBC)	Ministry of Health (in consultation with the National Security Council and the Israel Academy of Sciences and Humanities)	Immediate
9. Budget	Treasury, Ministry of Health	Immediate
10. Implementation Decision	Interministerial Committee for Science and Technology; Ministry of Health	Immediate

Appendix A1

Israeli Statutory Provisions on Occupational Safety and Hygiene in the Handling of "Dangerous Agents at Biological, Chemical and Medical Laboratories" as Relevant to the Issues Discussed by the Committee

The existing provisions of the law deal mainly with the supervision of labor, occupational hygiene and safety of personnel in the various fields of work, including the handling of "dangerous agents" in medical, chemical and biological laboratories. Particular attention is devoted to the protection of personnel from "emergencies" (i.e. leakage, spill, spread etc.). Paramount importance is attributed to the existence of "environmental monitoring" and "biologic monitoring" of personnel handling harmful, dangerous agents.

The supplement to the regulation on biologic monitoring contains details on "harmful agents" subject to "annual environmental-occupational examination." It must be determined whether these definitions cover the whole array of potentially or actually dangerous biologic factors, with particular attention on ascertaining that the lists include protection against biologic threats, filling any encountered gaps.

The following is an itemization of legal and statutory provisions enacted or issued for protecting the health and safety of employees. It appears that these can be applied with slight modifications to protection from biologic threats, by way of adjustments under meticulous interdisciplinary scrutiny.

I. Work Safety Regulations (Occupational Safety and Hygiene in the Handling of Dangerous Agents in Medical, Chemical and Biological Laboratories), 2001

These regulations are intended mainly to safeguard the health of employees and protect them from exposure to dangerous agents present in the air in their breathing space and work environment. They deal with terms such as "maximum allowed short term exposure" and "maximum allowed weighted exposure."

The regulations classify workers exposed to contagious biologic agents into risk groups as follows:

Risk Group 1. Here the exposure to the contagious biologic agent involves little or no risk of infection with the contagious biologic agent;

Risk Group 2. The exposure to the biologic agent carries a considerable risk of contracting a contagious biologic agent;

Risk Group 3. Exposure to the contagious biologic agent may cause a grave disease, disability, and death;

Risk Group 4. Exposure to the biologic agent may cause a grave disease, disability, death, and the outbreak of epidemics.

Dangerous Agents as defined in the Regulations are factors of a chemical, physical, and biological nature as causal agents of direct or indirect health damage which may be acute or chronic among laboratory workers.[6]

Laboratory is defined in the Regulations as "a place for the performance of samples, tests, analyses, syntheses, trials, research and development, training, study and teaching involving the use

6 Expanding the definition of "harmful agents" so as to cover dangerous agents that may cause "grave or lasting bodily damage" to any person located in the laboratory as well as to passers by in the vicinity (i.e. to any person, not just those working in the laboratory), it will be possible to adjust these regulations so as to include the public security against emergencies in such laboratories. If so expanded, such definition may provide a protective umbrella against damage caused to large populations.

of dangerous agents, with the exception of laboratories in educational institutions, vocational schools." The Regulations define three types of laboratories: biological, chemical, and medical.

A Biological Laboratory is a laboratory handling a "transmissible biological agent possessing biological properties of reproduction so that exposure to it may impair the health of humans or their progeny or both."

A Chemical Laboratory is a laboratory involving the use of toxins as defined in the Dangerous Substances Regulations (Classification and Exemption), 1966.

A Medical Laboratory as defined in the Public Health Regulations (Medical Laboratories), 1977, is "a place where examinations of samples originating from humans are made" (except a family health station and certain laboratories of licensed physicians).[7]

It follows from the context with the Public Health Regulations that a medical laboratory as defined above includes no "research laboratory", "teaching laboratory", or "quality control laboratory."

A Research Laboratory is "a place intended for the performance of tests for research and development purposes only, without any transfer of contaminated test results to other persons including the person from whom the sample for testing was taken."

A Teaching Laboratory is "a place where tests are performed for study and teaching purposes only, without any transfer of contaminated test results to another person, including the person from whom the sample for testing was taken."

A Quality Control Laboratory is "a place where tests are carried out for quality control of the production of diagnostic kits

7 It must be ascertained whether all research laboratories fall outside the scope of a medical laboratory according to the definitions in these Regulations, and whether the definitions cover the whole diversity of "places" where the biologic threat can be tangible.

only, without any transfer of contaminated test results to other persons including the person from whom the sample for testing was taken."

A. Laboratory Officers and Workers

1. Laboratory Holder

The Regulations apply to all laboratories. They stipulate that the "laboratory holder" must ensure, among other things, "that the dangerous agents not in immediate use in the laboratory are stored in a closed and locked cabinet with suitable ventilation and so as to avoid any chemical reactions between the various dangerous agents"; he must make sure that no dangerous agents that are not in immediate use are left or stored in a hood; he must also make sure that all shelves "intended for handling, carrying and placement of bottles and containers are provided with "stop rims."

The laboratory holder must ensure a regular removal of waste containing dangerous agents so as to avoid nuisances or damage to the health of the workers and the public.[8]

In addition, the laboratory holder must apply safety measures; among other things, he must ensure a protection of the laboratory against fire, establish special arrangements for emergencies, install special safety facilities for protecting the workers, and provide semiannual training and drills of the personnel for dealing with emergencies.

The laboratory holder must conduct "periodic environmental-occupational tests for dangerous agents" located in the workers' breathing space. Immediately after every such test he must send

8 It appears that the generality of these provisions can fit our case. A reference to public health is indeed made here. See: Business Licensing Regulations (Removal of Dangerous Waste), 1990; Public Health Regulations (Handling of Waste in Medical Institutions), 1997; section 4 (6–7) of the Work Safety Regulations.

a copy of the results to the district work inspector and to the Occupational Hygiene Laboratory of the Ministry of Labor and Welfare.[9]

A "laboratory holder" is any one of the following: (1) the employer; (2) the enterprise occupant or owner; (3) the workplace owner; (4) the actual manager of the workplace; (5) the actual manager of the corporation, if the enterprise is under corporate ownership.

Handling: Including storage, arrangement, assembly, coating, dismantling, renewal, or cleaning.

Carrying: Including transport, displacement, transfer from one place to another, filling, emptying, loading and unloading.

Emergency: Leak, spill, spread, contamination, exposure or ignition of a dangerous agent outside the normal course of work in the laboratory, or other combustion within the premises of the laboratory.

Biological (Type 1–3) or Chemical Hood: A closed work compartment that rules out the escape of dangerous agents from it to the work environment and the outer air — everything in accordance with IS 1839 — Safety in Laboratories (Hoods). The Regulations contain a list of hoods designed to prevent the escape of dangerous agents.

With regard to the definition of "emergency" and the protection against it, the protection of the "escape area" must be expanded beyond the narrow confines of the laboratory and its immediate surroundings in order to guarantee the security and health of the public at large.

2. Laboratory Manager

The laboratory holder must appoint a "laboratory manager" to

9 See the provisions of the Work Safety Regulations concerning "a dangerous agent" in use in a laboratory; also the Organization of Work Supervision (Environmental Monitoring and Biological Monitoring of Personnel Working with Dangerous Agents), 1990.

be in charge of the operations of the laboratory. The laboratory manager bears statutory duties. He must prepare an annual plan of work comprising, among other things, a list of dangerous agents in use in the laboratory; a description of the safety methods and procedures applied in the laboratory with regard to the handling of dangerous agents. The laboratory holder must make sure that the workers comply with all the provisions of the work plan. The work plan must be sent by registered mail to the District Work Inspector, who may require the preparation of an additional plan during the year. "The laboratory manager must report in writing to the district work inspector for every instance of accident involving sprays, spills and general contamination involving exposure to a contagious biologic agent."

The laboratory manager has numerous other tasks regarding the security of the workers. Among other things, the laboratory manager must install and maintain good, effective biological and chemical hoods suitable for work with the dangerous agents used in the laboratory; he must cause the hoods to be inspected at least once a year by a technician trained in the testing of hoods; he must install and maintain facilities for preventing the contamination of external air, including proper filters and scrubbers."

3. The Worker

A worker for the purpose of these Regulations means a person exposed to dangerous agents in a laboratory, including a student, researcher or volunteer engaged for at least four hours daily, three days a week over a period of two months per year, unless rules otherwise by the District Work Supervisor.

Work includes sampling, testing, analysis, synthesis, trials, use, processing, handling, carrying or maintenance, research and development, training, study and teaching involving the use of dangerous agents.

B. Occupational Means of Safety and Hygiene in Laboratories

1. Occupational Means of Safety and Hygiene in Biological Laboratories

Apart from the foregoing, the holder of a biological laboratory must apply the precautions referred to below. These means, expanded in scope for protecting the public health generally and subject to a meticulous verification of their suitability, may provide protection against a biological threat.

The holder of a biological laboratory must "ensure that the work with dangerous biological agents of risk group 1 is carried out under the supervision of a person possessing general knowledge in microbiology or related fields of science"; also, that "work with dangerous biological agents of risk group 2 is carried out by a team of workers skilled in work with pathogenic biological agents under the supervision of a person skilled and experienced in microbiology or related fields of science." He must "make sure that work with dangerous biological agents of risk groups 3 or 4 is carried out by a team of skilled workers experienced in the handling of such agents, under the supervision of a person skilled in work with the said agents." He must make sure that the work is done in biologic hoods of the types indicated in the Regulations and "in rooms providing environmental protection from spread of the biologic agent (safety level 3)… or with overpressure suits and in rooms provided with environmental protection from spread of the biological agent, applying safety levels 1–4 depending on circumstances. Further, he must make sure that the workers dealing with dangerous biological agents wear appropriate, efficient and reliable disposable gloves." The laboratory manager must "make sure that in the course of work with a biologic agent of risk groups 2–4 is carried out with the laboratory doors closed and bearing warning signs: WARNING! BIOLOGIC RISK — AUTHORIZED ENTRY ONLY. He must make sure that the working surfaces are properly disinfected at

the end of every working day; that pipetting is done by mechanical or electrical means only, and that the centrifuges are properly sealed to prevent environmental contamination", etc.[10]

2. Occupational Safety and Hygiene Measures in a Medical Laboratory

Apart from the provisions of Regulation 4 above, the medical laboratory holder must apply safety and hygiene measures as stipulated in the Public Health Regulations (Medical Laboratories).[11]

3. Obligatory Training of the Worker

Acting in conjunction with the safety officer, the workers representation and the local safety committee (if these organs exist), the laboratory holder will organize a proper training for all workers on their acceptance to the job and then at least once a year on matters related to safety, hygiene and health risks arising from work with dangerous agents as related to the various methods for the prevention of such risks.

The employer will make sure that the worker has understood the taught material; the employer and the safety committee will ascertain that the worker is acting in accordance with all the provisions and procedures established with regard to the handling of dangerous agents.

The laboratory holder will hold in his possession, with regard to every chemical dangerous agent, a Safety Sheet (SDS) as defined in the Work Safety Regulations (Safety, Classification, Packaging, Labeling and Marking of Packagings), 1998.

"Nothing in the provisions of this regulation will detract from any obligation pursuant to the Organization of Supervision of

10 See Reg. 4, 1–12.

11 See the important amendments made to these Regulations, effective from the beginning of 2006.

Work (Delivery of Information and Training of Workers) Regulations, 1999."[12]

4. Obligatory Notification of Work with Dangerous Agents
"The holder of a laboratory where it is intended to start work with dangerous agents ('new laboratory') must report this to the district work supervisor at least three months in advance; and no work with dangerous agents in a new laboratory may be started until after the said notification."[13]

II. Mechanisms of Supervision, Control and Enforcement for Implementation of the Statutory Provisions

A statutory umbrella concerning the supervision and safety of work, including work in laboratories, pursuant to the Work Organization and Supervision Law, 1954, and the Work Safety Ordinance (New Version), 1970.

1. Work Supervision Service

The work safety, professional hygiene and training of both workers and employers "in places where persons work for a business or occupation" (including laboratories) are entrusted to the Work Supervision Service, which disposes of a statutory supervision mechanism as stipulated in the Work Organization and Supervision Law, 1954. The work supervision mechanism as dictated by the existing laws may provide the necessary supervision also for

12 See Reg. 11, a–c.
13 See Reg. 12.

the purpose of protection against biologic threats if "the professional authority" is added to these matters.[14]

2. Statutory Supervision Mechanism

"The Safety and Hygiene Institution; work supervisors — district and chief level; safety committees; safety trustees, and the safety commissioner — all of these as defined in the Work Organization and Supervision Law, 1954;

Work Supervisors (down from Chief Work Supervisor, his deputy and district work supervisors) are appointed by the Minister in charge of the law. Supervision of work and safety by means of external supervisors and members of the Institute of Safety and Hygiene is accompanied by self supervision, within the institution, in workplaces controlled by the appointment of 'safety committees', 'safety trustees', and 'safety officer', manned by representatives of the workers and the employers who work anyway in the plants. All of the above officers act on powers granted by the law.

Pursuant to the Work Organization and Supervision Law and the Work Safety Ordinance (New Version), 1970, the legislator has established a broad statutory mechanism that establishes a proper control, supervision and safety with regard to work at various places, including biological, chemical and medical laboratories.

3. Functions and Powers of the Statutory Mechanism

Work supervisors have the right "of entry" at any time to any workplace for inspecting the work arrangements, the safety

14 If persons possessing the proper qualifications for handling the protection from biologic terrorism are included in the existing statutory mechanism or are appointed from it after training and guidance, perhaps no special new mechanism will be necessary.

provisions, the work processes, and also for investigating and examining various certificates and documents kept there as required by law. The work supervisor is entitled, among other things, "to take a sample of a product, intermediate product or raw material after notifying the workplace holder to this effect, and also to photograph any material, facility, machine, structure or work process; and if he has grounds for suspecting an interference with the discharge of his duties, he is entitled to avail himself of police protection.[15] If the work supervisor is of the opinion that the health or welfare of persons working on the site is in danger because of the work or its process… or for any other reason, he may bring in an expert to the place for performing the tests he is entitled to carry out.[16]

It is noteworthy concerning the extensive powers granted to inspectors with regard to dangerous (listed) agents, allowing them or persons on their behalf free access to the 'dangerous agents', data collection, taking of samples, etc., that a meticulous revision is necessary about the special activity taking place in the said laboratories, and it appears that these powers are subject to considerable restriction or control of their exercise.

4. Safety Orders

If the work supervisor is of the opinion that a process, act or default at the workplace "endangers the human welfare or health, he may among other things, **by means of an order,** "ban the use of a facility, equipment of material or of any part of the foregoing pending the elimination of the underlying risk", or "order the workplace holder to apply necessary measures for eliminating the risk", all this according to the procedure laid down in para. 6 (a)–(d).

15 See para. 3, 4–8.
16 See section 5 of the Law.

This provision should likewise be reviewed.

In the event of issue of a safety order the work supervisor may, with the assistance of the police, use force as necessary for carrying out the order, and if the order is not complied with "the workplace holder" is subject to penalty as stipulated in the Work Supervision Organization Law, 1954 (section 8, 8a). The supervisor may also issue orders for improvement of the situation.

5. Safety Plan

The holder of a workplace of the type established in the Regulations must prepare a safety plan for the workplace. The said work plan must include, among other things, procedures for occupational safety and health (in consultation with the Minister of Health); emergency procedures for special risk situations and for work accident cases, and is to be submitted to the district work supervisor. He may require the introduction of corrections on finding faults therein. Breach of any of these requirement is to be construed as breach of the order.

6. Safety Information and Training

The minister in charge of the law may obligate the "workplace holder" to provide the workers with information and training as necessary for the prevention of work accident or occupational diseases.

This is to be established by way of regulations, which may be of a general nature or specific for a particular type of workplace, branch of occupation, profession, or region.[17]

The above safety provisions are of particular importance. They contribute to the biologic security, but these too are in need of

17 See section 8e.

revision in view of the specific nature of work with dangerous agents.

7. Reinforcement of the Supervision of Workplace Safety by Safety Committees, Safety Trustees and Safety Officers

Apart from the external supervision of workplaces by work supervisors and the Institute of Safety, it is necessary to appoint safety committees, safety trustees and safety officers at the workplaces. The duties, powers and obligations of these are indicated in sections 9–25 of the law.

An enterprise employing at least 25 workers "must have a safety committee composed of representatives of the workers and the employer on a parity basis…". subject to the provisions of the law, the Minister of Labor and Welfare may establish the need for a safety committee even for an anterprise with less than 25 workers. For the present purpose, the employer is the holder of the enterprise.[18]

Safety Committees: "The workers' representatives on the safety committee will be from among the workers elected or appointed by the employer, and inasmuch as possible they will include foremen and persons on charge of safety matters on behalf of the employer. The duration of service and required qualifications of the members of the safety committee will be established in the Regulations.[19]

The powers and obligations of the safety committee are indicated in the law.[20] Among other things, they include the obligation and power to examine the causes and circumstances of work accidents occurring on the site and to recommend preventive measures; to examine the safety conditions of the workplace, to

18 See sections 9–10.
19 See section 11 a, b, c.
20 See section 14.

advise on the establishment or improvement of these. The legislator enhances the powers of the safety committees and orders the employers to comply with their recommendations. The safety committee may recommend that the employer introduce disciplinary measures against those who breach the safety rules.

In an enterprise with a safety committee, the workers' representatives on the committee and other workers appointed by the committee will serve as trustees for safety and hygiene in the enterprise.

The duties and powers of a safety trustee are indicated in section 21 of the law; among other things, he must monitor the safety and hygiene conditions and act for their improvement; train the workers and advise them on improving the safety and hygiene.[21]

Safety Officer. The Minister may instruct the employer to appoint a properly trained person to serve as safety officer of the enterprise so that his function is to consist mainly in that. "The Labor Minister will not issue such order unless satisfied that that the extent of the enterprise and the nature of work in it justify this, and after consultation with the council of the Safety and Hygiene Institute.[22]

The Minister of Labor may establish, by way of regulations, provisions regarding the appointment and dismissal of a safety officer, his duties toward the work supervisor and the safety committee, and the penalty for him in case of noncompliance with his duties.

The institutional safety committee with the participation of representatives of the laboratory may provide the forum for electing the safety officer as the person with special qualifications on security with regard to the biologic threat.

21 See sections 14–21.
22 See section 25.

8. The Institute of Safety and Hygiene

The Institute of Safety and Hygiene operates under the Work Supervision Organization Law. It advises the relevant minister on general matters of safety and hygiene; it assists the Work Supervision Service; it conducts information campaigns; it performs research works and publishes them; it assists in the formation of safety committees and the selection of safety trustees; it trains them and supports them in their tasks.

This track might similarly be made more effective by the inclusion of experts.

III. Confidentiality

The workers will not disclose any information reaching them in the course of their duties except as provided by law. Breach of this provision is punished with the penalties provided by law.

IV. Environmental Monitoring with Regard to Dangerous Agents

Work Supervision Organization Regulations (Environmntal Monitoring and Biological Monitoring of Persons Handling Dangerous Agents), 1990

These regulations impose environmental monitoring at an enterprise or workplace engaged in work with certain harmful agents as indicated in the Appendix to these Regulations.

Harmful Agents means "harmful chemical and physical agents located in the workplace to which the workers are exposed in the course of work."

The employer in such place must perform annual environmental-occupational tests, unless the district work supervisor has order a different frequency.

Worker with Certain Harmful Agents: "A worker exposed to one or more of the harmful agents listed in the First Appendix, at a concentration in excess of the environmental-occupational action level for production work, in medical laboratories and centers, in part time or full time work, for a period of at least 30 days per year, or such different period as established by the district work supervisor."

Environmental-Occupational Tests: Environmental monitoring of harmful agents by a qualified laboratory tester for determining the weighted exposure level, the short term exposure level and the workplace exposure ceiling (as defined in the Regulations).[23] Regulation 3 stipulates:

(a) The tests are to be performed strictly by a qualified laboratory tester and a qualified laboratory, using calibrated equipment, by generally accepted methods including a quality control plan approved by the Chief Work Supervisor;
(b) The qualified laboratory will record the calibration data, the results of the quality control, and the results of the tests; these are to be saved for at least 20 years;
(c) The quality control results and the test results are to be submitted to the Chief Work Supervisor or District Work Supervisor, as well as to the Occupational Hygiene Laboratory at the Ministry of Work and Welfare;
(d) The employer will publish the respective results at the workplace so as to inform the workers of them.

Qualified Laboratory. The Occupational Hygiene Laboratory at the Ministry of Labor and Welfare, and any other laboratory authorized by the Chief Work Supervisor in a general manner to carry out environmental occupationsl tests at workplaces.

23 See Regulation 2 and Definitions.

Qualified Laboratory Tester. As defined, a worker of a qualified laboratory authorized by the Chief Work Supervisor to perform environmental occupational tests at workplaces.

Regulation 4 defines the performance of toxicologic biologic tests and the delivery of the results (incl. amendments).

Regulation 5 determines allowed values (incl. amendments)

Regulation 6 stipulates, among other things: "The allowed weighted exposure, the maximum allowed short-term exposure, the allowed exposure ceiling, and the biologic markers of occupational exposure must be as published in the United States in the latest edition of the book."

VI. Public Health Regulations (Medical Laboratories), 1977

These regulations define the work and testing procedures in medical laboratories. They were formulated on the basis of the Public Health Ordinance, 1940; the Business Licensing Law, 1968; the Supervision of Commodities and Services Law, 1957 (including the amendment of 2005, which entered in effect on February 1, 2006).

VI. Summary

Covering the whole variety of legislation on the issues discussed here would extend far beyond the scope of this document. The random outline made here shows the existence in Israel of numerous important laws that could be applied with minor adjustments to cover the biologic threat, albeit in part, yet without delay. On the other hand it is clear that many issues arising from the gravity of the biologic threat have not been treated at all, so that the legislator — both principal and subsidiary — would be

well advised to provide a fit answer to the grave problems waiting round the corner.

Of course, it will be necessary to find out if there exist any other administrative and/or institutional guidelines or procedures in addition to the provisions of the law, and also to gauge the awareness of scientific and other workers of the existing provisions of the relevant laws and regulations. The actual implementation of these will have to be determined.

Appendix A2
List of Relevant U.S. and U.K. Laws

U.S.

Biological Weapons Anti-Terrorism Act of 1989
USA Patriot Act of 2001 (The Uniting and Strengthening of America by Providing Appropriate
Tools Required to Intercept and Obstruct Terrorism Act of 2001)
Public Health, Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107–188, 107th Congress)
Project Bioshield Act of 2003

U.K.

Biological Weapons Act 1974, ch. 6, s.1 (Eng.)
Terrorism Act 2000, ch.11, s. 55 (Eng.)
Anti-terrorism, Crime and Security Act 2001, ch. 24, s. 50 (Eng.)
Health and Safety at Work (ETC) Act 1974, ch. 37, s. 3 (Eng.)

Appendix B
Lists of Selected Agents and Toxins

1. U.S. Department of Health and Human Services (HHS)

Abrin
Ceropithecine herpesvirus 1 (Herpes B virus)
Coccidoides psadiasii
Conotoxins
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Ebola virus
Lassa fever virus
Marburg virus
Monkeypox virus
Competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 influenza virus)
Ricin
Rickettsia prowazekii
Rickettsia rickettsii
Saxitoxin
Shiga-like ribosome inactivating proteins
South American haemorrhagic fever viruses
- Flexal
- Guanarito
- Junin
- Machupo
- Sabia

Tetrodotoxin

Tick-borne Encephalitis complex (flavi) viruses
- Central European tick-borne encephalitis
- Far-eastern tick-borne encephalitis
- Kyasanur forest disease
- Omsk haemorrhagic fever
- Russian spring and summer encephalitis

Variola major virus (smallpox virus)
Variola minor virus (Alastrim)
Yersina pestis

2. Overlap (HHS/USDA)

Bacillus anthacis
Botulinum neurotoxins
Botulinum neurotoxin producing species of clostridium
Brucella abortus
Brucellamelitenis
Brucella suis
Burkholderia mallei (formerly Pseudomonas pseudomallei)
Clostridium perfingens epsilon toxin
Coccidoides immitis
Coxiella burnetii
Eastern equine encephalitis virus
Fransisella tularensis
Hendra virus
Nipah virus
Rift Valley fever virus
Shigatozxin
Staphylococcal enterotoxins
T-2 toxin
Venezuelan Equine Encephalitis virus

3. U.S. Department of Agriculture (USDA)

African horse sickness virus
African swine fever virus
Akabane virus
Avian influenza virus (highly pathogenic)
Bluetongue virus (exotic)
Bovine spongiform encephalopathy agent
Camel pox virus
Classical swine fever virus
Cowdria ruminatium (heartwater)
Foot-and-mouth disease virus
Goat pox virus
Japanese encephalitis virus
Lumpy skin disease virus
Malignant catarrhal fever virus
(Alcelaphine herpesvirus type 1)
Menangele virus
Mycoplasma capricolumi/ M.F38/M.mycoides Capri
(contagious caprine pleuropneumonia)
Mycoplasma mycoides
(contagious bovine pleuropeneumonia)
Newcastle disease virus (velogenic)
Peste des petits ruminants virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus
Vesicular stomatitis virus (exotic)

From: *Biotechnological Research in an Age of Terrorism: Confronting the Dual Use Dilemma* (U.S. NRC Report, 2004).

Appendix C
Fields of Research Considered Sensitive

The fields of research considered sensitive from a biosecurity perspective include those that:

1. **Would demonstrate how to render a vaccine ineffective**. This would apply to both human and animal vaccines. Creation of vaccine-resistant smallpox virus would fall into this class of experiments.

2. **Would confer resistance to therapeutically useful antibiotics or antiviral agents**. This would apply to therapeutic agents that are used to control disease agents in human, animals or crops. Introduction of ciprofloxacin resistance in *Bacillus anthracis* would fall into this class.

3. **Would enhance the virulence of a pathogen or render a nonpathogen virulent.** This would apply to plant, animal, and human pathogens. Introduction to cereolysin toxic gene into *Bacillus anthracis* would fall into this class.

4. **Would increase transmissibility of a pathogen.** This would include enhancing transmission within or between species. Altering vector competence to enhance disease transmission would also fall into this class.

5. **Would alter the host range of a pathogen.** This would include making nonzoonotics into zoonotic agents. Altering the tropism of viruses would fit into this class.

6. **Would enable the evasion of diagnostic/detection modalities.** This could include microencapsulation to avoid antibody-based detection and/or the alteration of gene sequences to avoid detection by established molecular methods.

7. **Would enable the weaponization of a biological agent or toxin.** This would include the environmental stabilization of pathogens. Synthesis of smallpox virus would fall into this class of experiments.

From: *Biotechnological Research in an Age of Terrorism: Confronting the Dual Use Dilemma* (U.S. NRC Report, 2004).

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בשנת תשס״ח/2008

ירושלים תשס״ט

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