



Report of the State Comptroller of Israel |  
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## Systemic Issues

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# **Aspects of Preventing the Leakage of Biological Pathogens and Knowledge for the Development of Biological Weapons**





# Aspects of Preventing the Leakage of Biological Pathogens and Knowledge for the Development of Biological Weapons

## Background

In Israel, research groups in the medical, biological, and microbiological fields make use of biological pathogens (pathogens or disease-causing agents<sup>1</sup>) for research and commercial purposes. Entities in Israel that hold pathogens operate in three main sectors: government institutions (the Ministry of Health and the Ministry of Agriculture and Food Security); universities and research institutes; and the biotechnology industry<sup>2</sup>.

A biological terrorism incident could occur, among other scenarios, if a perpetrator were to obtain a disease-causing biological agent and possess basic knowledge of its properties, its methods of cultivation or preservation, and the means by which it could be employed to achieve the objective of effectively infecting human beings with disease.

Biological security is "the set of measures intended to prevent deliberate attempts to obtain dangerous pathogens, or technologies and information that could enable the development of biological weapons. Measures of biological security include: physical protection; reporting and oversight; security in transport and transfer; personnel reliability; information security; and an integrative review of the program and the scientific research"<sup>3</sup>. Alongside maintaining biological security, it is important to ensure that scientific research is not compromised, nor the essential values embodied in the publication of scientific articles based on such research.

The concern over the development of biological weapons within institutions conducting medical, biological, and microbiological research, as well as the concern regarding the leakage of pathogens or knowledge related to their use for biological terrorism, necessitated the introduction of supervision and restrictions on research involving biological agents, as well as oversight of the identity of participants in such research. In order to regulate the possession of pathogens and the research activity conducted, or that could be conducted, regarding biological agents, the Knesset enacted the Regulation of Research into Biological Disease Agents, 5769-2008 (the Biological Disease Agents Research Law or the Law), whose purpose

- 1 Pathogens are organisms such as bacteria and fungi, as well as other disease-causing agents, such as viruses, that cause illness and challenge the body's defense systems.
- 2 Biotechnology is the integrative scientific activity of microbiology, biochemistry, molecular biology, and biochemical engineering, focused on the technological (industrial) application of the biological potential inherent in microorganisms, plant and animal cells, and their components, including the production of pharmaceuticals by these methods. (Hebrew University website).
- 3 The Israel Academy of Sciences and Humanities / National Security Council, *Biotechnological Research in the Age of Terror* (2008), pp. 16 and 20.



is to establish the basic arrangements for the possession of pathogens and for conducting research involving them, due to the concern of biological weapon development within institutions in the course of research, even without intent to develop such weapons. The Minister of Health is in charge of the Law's implementation and for issuing directives regarding its execution.



Key Figures

43 institutions

in the State of Israel, as of the end of the audit (November 2024), which are authorized as "recognized institutions" to hold biological pathogens or conduct research with them. These include hospitals, universities and research institutes, companies, and public health laboratories

4 biosafety levels

are set by the Work Safety Regulations<sup>4</sup>. The lowest is BSL-1, and the highest is BSL-4. Each laboratory is assigned the biosafety level required, according to the type of biological agent it handles

22 recognized institutions (approx. 51%)

(of the 43 existing) have not established an internal institutional committee authorized to approve the possession of pathogens and research involving them within the institution

In some of

the laboratories examined, gaps were found regarding the declaration of no prior convictions for security offenses

In a number of laboratories

deficiencies were found in conducting risk surveys

In a number of laboratories

deficiencies were found in security measures

Since 2008

when the Biological Disease Agents Research Law was enacted and until the end of the audit in November 2024, the Ministry of Health failed to issue regulations regarding the Law's implementation and the oversight of the laboratories required under it

4 Work Safety Regulations (Occupational Safety and Hygiene in Work with Hazardous Agents in Medical, Chemical, and Biological Laboratories), 2001.



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## Audit Actions



From August 2024 through November 2024, the State Comptroller's Office examined the oversight exercised by enforcement authorities over various research institutions (43 recognized institutions<sup>5</sup>), hospitals, and private companies in which research involving pathogens is conducted, or pathogens are held without research activity; the activities of several institutions operating laboratories<sup>6</sup>; and the advancement of the required regulation in this field. The audit was conducted in the Ministry of Health (MOH): in the Office of the Chief Scientist, in the Council for Regulating Research on Biological Pathogens, and in the External Institutional Committee; in the National Security Council (NSC); in the Ministry of Defense (MOD): in the Office of the Assistant Home Front Defense Minister; and in the Israel Police.






The audit team, through the Ministry of Health, sent questions concerning the measures taken to ensure biological security to all 43 laboratories of the recognized institutions: to four laboratories at biosafety level BSL-3 and to the remaining 39 supervised laboratories. Twenty-four of the 43 laboratories provided responses to the questions. Six laboratories replied that they do not hold biological pathogens. The other 18 laboratories addressed the questions in detail (four of them at biosafety level BSL-3 and 14 at lower biosafety levels).

The Subcommittee of the Knesset State Control Committee, in consultation with the State Comptroller, decided not to table this report in its entirety to the Knesset, and to publish only parts of it, in order to protect state security, in accordance with Section 17(a) of the State Comptroller Law, 1958 [Consolidated Version].

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- 5 The audit team sent questions concerning the measures taken to ensure biological security to four laboratories at biosafety level BSL-3 and to the remaining 39 supervised laboratories. Twenty-four of the 43 laboratories responded to the questions, and from their responses it emerged that six of them neither hold biological pathogens (although they are recognized by the Council as institutions authorized to hold pathogens) nor engage in research in the field.
- 6 Belonging to recognized institutions that have been authorized to hold biological pathogens.



## Key Findings

-  **Issuing Regulations for Implementing the Provisions of the Biological Disease Agents Research Law** – In 2017 and 2020, the Minister of Health issued regulations pursuant to Section 24 of the Law, which governs the updating of the list of biological pathogens included in the Law's appendix<sup>7</sup> (see Appendix A for the list of pathogens established under the Biological Disease Agents Research Law). It should be emphasized that these regulations were issued solely for the purpose of updating the list of biological pathogens, and do not address enforcement of the Law or the oversight aspects required under Section 25 of the Law. The audit found that from the enactment of the Biological Disease Agents Research Law in 2008 through the conclusion of the audit in November 2024, the Minister of Health did not issue regulations regarding the Law's implementation or the oversight of laboratories<sup>8</sup> as required under it. Nor have regulations yet been issued establishing conditions for recognizing an institution as authorized to hold pathogens. In addition, the work rules issued by the Council for Research into Biological Disease Agents, as well as the Security Procedure for Repositories, were not anchored in formal regulations. The failure to issue such regulations may compromise the implementation of the Law and the oversight of recognized institutions, thereby increasing the risk of the leakage of knowledge and pathogens into hostile or criminal hands.
-  **Assessment of Biological Security Risks in Laboratories Operating in Recognized Institutions** – The audit found that despite the importance attached to conducting risk surveys, as detailed in the Security Procedure for laboratories holding pathogenic materials published by the Council for Research into Biological Disease Agents, in some laboratories deficiencies were found in the conduct of risk survey.
-  **Activity of Security Units in Recognized Institutions** – In several laboratories, deficiencies were found regarding the establishment of security procedures for laboratories.
-  **Provision of Security Procedures by the Institutional Security Unit** – In several laboratories, deficiencies were found in the provision of security procedures by the institutional security unit.
-  **Security Screening of Authorized Personnel** – In several laboratories, deficiencies were found in the security screening of individuals authorized for access to laboratories.

<sup>7</sup> Biological Disease Agents Research Regulations (Amendment of the Law's Appendix), 2017; Biological Disease Agents Research Regulations (Amendment of the Law's Appendix), 2020.

<sup>8</sup> Laboratories of recognized institutions that have been authorized to hold biological pathogens.



-  **Declaration of No Security Convictions** – The audit found that in some institutions examined, deficiencies were found regarding the declaration of no prior convictions for security offenses.
-  **Security and Conduct of Drills** – Deficiencies were found regarding laboratory security and the conduct of security drills.
-  **Emergency Response Plans in Institutions Holding Pathogenic Materials** – Contrary to the requirements set out in the Repository Security Procedure and the rules, deficiencies were found in several laboratories in the preparation of plans for responding to emergency events.
-  **Transmission of Intelligence Information to the Council for Research into Biological Disease Agents** – The Council has 15 members, including a representative from the Israel Police, the Ministry of Defense, and the National Security Council. The audit found that no arrangement exists regarding the transfer of intelligence information that may be relevant to the threat of biological terrorism or to the development and production of biological weapons related to pathogens, from representatives of the security agencies to the Council. The absence of an orderly process for transmitting intelligence information among the agencies may compromise biological security in recognized institutions. The responses of the Israel Police and the National Security Council to the draft audit report further underscored the difficulties created by the absence of such an arrangement for transferring relevant intelligence information to the Council.
-  **Regulation of Synthetic Biology** – Synthetic biology is a scientific-technological field involving the design and construction of new biological systems, elements, and components, or the redesign of existing natural biological systems for practical purposes. The Minister of Health is responsible for the implementation of the Biological Disease Agents Research Law and for issuing directives concerning its execution. The audit found that despite the conclusions of the Council for Research into Biological Disease Agents and the recognized need to examine the promotion of activity in the field of synthetic biology in Israel – including controls on the purchase and use of potentially hazardous DNA sequences, as practiced in the European Union, the United States, and Australia – the Ministry of Health took no action to regulate this field.
-  **Publication of Scientific Articles That May Contribute to the Development and Production of Biological Weapons by Unauthorized Actors** – In scientific articles, the findings of studies, experiments, or reviews in a particular field are detailed, and their publication is intended to contribute to existing scientific knowledge and to share it with the global scientific community and with the public at large. The issue of biosecurity is complex, embodying the need to balance between two domains: security versus freedom of scientific research. The audit found that since 2008, the year in which the Knesset





enacted the Biological Disease Agents Research Law, the Council has not discussed the issue of regulating the publication of the findings of dual-use biological research. The audit further found that a dispute exists between the Israel Police and the National Security Council regarding responsibility for handling the security aspects involved in the publication of scientific articles concerning pathogens. The absence of oversight and control over the publication of dual-use biological research may assist hostile actors and terrorist organizations in planning and implementing an effective biological terror attack, and may harm state security, public safety, or public health. This issue assumes added significance at this time, when technology is available to nearly every person and is developing at a rapid pace. In addition, the absence of such oversight and control may enable unauthorized actors to produce and use biological weapons with greater ease.







**Security Units in the Recognized Institutions** – All of the recognized institutions in which the four BSL-3 laboratories operate have an institutional security unit.

## Key Recommendations

- 💡 The Ministry of Health should issue regulations regarding the Law's implementation, including the procedure for submitting research applications and granting approvals, as stipulated in Section 25 of the Law, and including the method of holding pathogens and conducting research on them. It is further recommended that the Council for Research on into Biological Disease Agents assist in formulating the text of the regulations in order to advance their enactment.
- 💡 The Minister of Health should act in accordance with Section 25 of the Law, which stipulates that the Minister of Health, after consulting with the Minister of Defense, shall issue regulations establishing conditions for recognizing an institution as authorized to hold pathogens. Such consultation with the Minister of Defense is important in view of the potential security risks involved in holding pathogens, particularly when setting the rules governing the recognition of institutions authorized to hold them.
- 💡 It is recommended that the Council for monitoring research into biological disease agents also stipulate in its procedures the frequency of conducting risk surveys.
- 💡 It is recommended that the Council for Research into Biological Disease Agents establish procedures for examining the security suitability of those authorized to access biological pathogens.
- 💡 The Council for Research into Biological Disease Agents should complete the establishment of security directives for laboratories.



-  The inspector at the Ministry of Health should ensure a process of drawing lessons and correcting deficiencies identified in exercises conducted in the laboratories.
-  The relevant institutions should act to correct the deficiencies identified in this report.
-  It is recommended that the representatives of the security agencies on the Council – the Israel Police, the Ministry of Defense, and the National Security Council – take measures to regulate the transfer of relevant intelligence information from the security agencies to the Council and establish a normative framework that determines the authority responsible for the matter, its powers, and its modes of action. In this way it will provide a solution to the disputes that exist between the Israel Police and the National Security Council.
-  It is recommended that the Ministry of Health establish a regulatory framework that applies both to the use of synthetic biology and to research on pathogens that may result from its use, and coordinate this with the Ministry of Defense and other relevant government ministries. It is recommended that the Council examine the issue of publishing research on biological pathogens where there is concern that such publication could harm state security or public safety, health, or security. As part of this examination, consideration should be given to the implications of using AI tools for searching and analyzing information, and to the potential use of the information contained in research published on biological pathogens. To ensure the necessary balance between freedom of scientific research and biosecurity, the Council should also ascertain the views of the relevant academic community, as well as of the Israel Police, the Israel Security Agency (ISA or Shin Bet), the National Security Council, and the Israel Institute for Biological Research. It is recommended that the Council submit the findings of its examination to the Minister of Health and to the Knesset Science and Technology Committee and, in accordance with these findings, formulate courses of action. It is recommended that the representatives of the security agencies on the Council – the Israel Police, the Ministry of Defense, and the National Security Council – act to resolve the disagreements between the Police and the National Security Council.



## Summary

A biological terrorism incident could occur, among other scenarios, if a perpetrator were to obtain a disease-causing biological agent and possess basic knowledge of its properties, its methods of cultivation or preservation, and the means by which it could be employed to achieve the objective of effectively infecting human beings with disease. The concern over the development of biological weapons in various institutions in the course of conducting research, as well as the concern over the leakage of pathogens or knowledge related to their use for purposes of biological terrorism, necessitates the imposition of supervision and restrictions on conducting research involving biological agents, as well as oversight of the identity of participants in such research. This must be done without compromising scientific research and the important values inherent in the publication of scientific articles based on such research.

The audit found that the enactment of the Biological Disease Agents Research Law, 2008, led to the establishment of mechanisms and a regulatory framework to enable oversight of institutions that hold biological pathogens for research purposes. However, it also found gaps in the oversight mechanisms and in the manner of implementing the rules set out in the procedures of the Council for Research into Biological Disease Agents. The findings of this report indicate that some provisions of the Law have not been implemented, including the failure to issue regulations under the Law, as well as gaps in oversight of the Law's implementation and in compliance with the rules governing the activity of the external institutional committee. In addition, the findings attest to only partial implementation of the work rules and the repository security procedure by research laboratories.

At the conclusion of the audit, 16 years after the enactment of the Law, arrangements regarding the oversight of research in the field of synthetic biology had still not been examined or regulated, nor had aspects concerning the publication of research on biological pathogens – where publication may pose a risk to state security or to public safety, health, or security – been regulated. This is particularly pertinent given the implications of using AI tools for searching and analyzing information. This deficiency assumes added significance in the present era, in which technology is accessible to almost anyone, is developing rapidly, and may even enable the production and use of biological weapons with relative ease through the use of artificial intelligence (AI).

It is recommended that the Ministry of Health establish regulation concerning the use of synthetic biology as well as the regulation of research on pathogens that may result from its use, and coordinate this with the relevant government ministries. The gaps identified in the performance of oversight and control of laboratories, and regarding the publication of dual-use biological research, may increase the risk of leakage of knowledge and pathogens into criminal or hostile hands, thereby assisting hostile actors and terrorist elements in planning and carrying out an effective biological terrorist attack, and causing harm to state security or to public safety, health, or security.

