Legal Updates

Egypt Introduces a New Legal Framework for Biosafety and Biosecurity Facilities

Introduction

Law No. 76 of 2026 regulating the activities of Biosafety and Biosecurity Facilities classified as Biosafety Levels 3 and 4 (BSL-3 and BSL-4) establishes, for the first time in Egypt, a comprehensive legal framework for facilities engaged in research involving high-risk infectious agents and toxins.

The Law sets out an integrated regulatory regime governing the licensing, supervision and operation of such facilities. It represents a significant legislative development in response to the rapid advancement of biological research and the increasing need to balance scientific innovation with national security considerations.

I. Scope of the Law and Key Definitions

The Law begins by establishing a number of fundamental definitions that determine its scope of application. It distinguishes between Biosafety Level 3 (BSL-3) facilities, where research is conducted on infectious agents or toxins capable of airborne transmission and posing serious risks to human life, and Biosafety Level 4 (BSL-4) facilities, where research involves biological agents presenting an exceptionally high risk of laboratory-acquired infections through aerosols or airborne transmission.

The legislator also draws an important distinction between the concepts of Biosecurity and Biosafety, two terms that are frequently confused in practice.

Biosecurity refers to measures designed to protect biological agents and facilities against loss, theft, unauthorized access, diversion or deliberate misuse. Biosafety, by contrast, concerns the operational procedures, engineering controls and laboratory practices intended to prevent accidental exposure to hazardous biological agents or their unintended release.

This distinction is of considerable practical significance, as it directly affects the nature and extent of the obligations imposed upon regulated facilities and is expected to play a central role in the application of the forthcoming Implementing Regulations.

II. The National Center for Biosafety and Biosecurity and Its Institutional Character

The Law establishes a public service authority known as the National Center for Biosafety and Biosecurity, which enjoys legal personality and operates under the supervision of the Prime Minister.

Although the Law formally places the Center under the authority of the Prime Minister, its institutional structure reflects a predominantly national security-oriented approach. The

Center's Board of Directors is chaired by a person nominated by the Minister of Defense and includes representatives of the Ministry of Defense, the Ministry of Interior, the General Intelligence Service and other competent governmental authorities.

This institutional design is consistent with Article (4), which expressly classifies the activities regulated under the Law as activities of a special nature connected with national security. It also explains the repeated reference throughout the Law to "the requirements of national security", which serves as an overarching consideration governing the exercise of regulated biological activities.

The Center is entrusted with broad regulatory and supervisory powers, including the issuance of licenses and permits, inspection of regulated facilities, development of the National Biosafety and Biosecurity Program, and the establishment of several specialized units, including:

Specialized Units

- the Egyptian Isolates Bank Unit;
- the Automated Biological Surveillance, Monitoring and Early Warning Unit; and
- the Standard Biological Analysis and Research Laboratory.

Practical Regulatory Implications

From a practical perspective, research institutions, universities, healthcare providers and pharmaceutical entities seeking to conduct regulated activities will not be dealing solely with a scientific regulatory authority. Rather, they will be subject to an institution whose regulatory functions are significantly influenced by national security considerations.

This is reflected in the requirement to obtain security clearances for key personnel, including the Facility Director, Quality Manager and Laboratory Biosafety Officer, the designation of certain employees of the Center as judicial enforcement officers, and the Board's authority to classify information as confidential.

III. Licensing Regime and Regulatory Obligations

The Law prohibits the conduct of any biological activity that poses a direct threat to human, animal or plant health, or to the environment. It further prohibits any person or entity from carrying out regulated biological activities without first obtaining the requisite license.

To obtain such a license, applicants must satisfy a comprehensive set of technical and security requirements, including compliance with prescribed engineering specifications, the installation of negative-pressure ventilation systems, the use of biological safety cabinets, adherence to biosafety and biosecurity standards, and the acquisition of an international accreditation issued by an accrediting body approved by the Board of Directors of the Center.

The Law also authorizes the imposition of a facility licensing fee of up to EGP 1 million, in addition to an individual permit fee of up to EGP 20,000 for each person authorized to work within the facility. For institutions employing a significant number of personnel, these cumulative fees may represent a substantial financial burden.

From a practical standpoint, however, the most significant licensing requirement is the obligation to obtain international accreditation. The Law neither defines the nature of such accreditation nor specifies the internationally recognized accrediting bodies whose

accreditation will be accepted. Instead, these matters have been left entirely to the discretion of the Board of Directors.

Accordingly, the forthcoming Implementing Regulations will be of critical importance in determining the practical application of this requirement. In the absence of clear and transparent criteria, the accreditation requirement could become a significant regulatory obstacle for existing facilities, even where they already operate in accordance with internationally recognized biosafety standards.

The Law further requires all personnel working in regulated facilities to obtain individual permits issued by the Center and establishes detailed qualification requirements for key positions. In particular, the Facility Director must hold a doctoral degree, possess no less than five years of relevant professional experience, and maintain membership in an internationally recognized biosafety organization. Separate qualification requirements are also prescribed for the Quality Manager and the Laboratory Biosafety Officer.

Existing facilities are required to regularize their legal status within one year from the date on which the Implementing Regulations enter into force. This period may be extended for an additional year by a decision of the Prime Minister upon the recommendation of the Minister of Defense.

Given that the Implementing Regulations must themselves be issued within six months from the Law's effective date, existing facilities may, in practice, benefit from an overall compliance period of approximately eighteen months, subject to a possible extension of an additional year.

IV. Ownership of Data and Research Outputs

Article (38) provides that all information and data generated through licensed biological activities shall be owned by the license holder. This constitutes a positive legislative approach from the standpoint of protecting research outputs and the intellectual property rights of research institutions and commercial operators active in this sector.

That ownership, however, is subject to significant statutory limitations.

The Law prohibits the dissemination or disclosure of such information except with the authorization of the Board of Directors. It also empowers the Center to issue binding instructions restricting the use of such data whenever this is deemed necessary for the protection of national security or the safeguarding of human health, animal health, plant health, property or the environment.

Furthermore, Article (39) prohibits the transfer of ownership of a licensed facility, or of research results arising from regulated biological activities, to any person or entity unless the transferee satisfies the applicable licensing requirements and prior approval is obtained from the Board of Directors.

Accordingly, although research data and research outputs are legally vested in the license holder, the exercise of ownership rights remains subject to extensive regulatory controls. These restrictions should be carefully considered when negotiating research collaboration agreements, technology transfer arrangements, licensing transactions or any commercial exploitation of research outcomes.

V. Penalties

The Law adopts a stringent enforcement regime reflecting the high-risk nature of the activities it regulates. It prescribes severe criminal sanctions, including rigorous imprisonment and fines of up to EGP 50 million, for a number of serious offences.

These offences include conducting regulated biological activities without the required licence, importing biological research equipment or devices without the Center's prior approval, importing or introducing microbial agents into the Arab Republic of Egypt without authorization, and removing Egyptian biological isolates from the country without the approval of the Board of Directors.

Article (45) further criminalizes the unauthorized disclosure of classified information. Where such disclosure is committed with the intent to prejudice national security, the penalty is aggravated to rigorous imprisonment for a term of not less than five years.

Conversely, Article (55) establishes a statutory exemption from criminal liability for offenders who voluntarily report the offence to the competent administrative or judicial authorities before its commission and prior to the commencement of any investigation. The Law also grants the court discretionary authority to exempt an offender who reports the offence after its commencement where such disclosure enables the authorities to apprehend the remaining offenders or otherwise facilitates the investigation.

This approach is consistent with the legislative policy commonly adopted in relation to offences involving significant threats to public safety and national security and may also serve as an effective mechanism for encouraging internal reporting within regulated facilities.

Our Perspective

In our view, Law No. 76 of 2026 represents a significant legislative development in establishing a comprehensive legal framework governing high-containment biological activities in Egypt. The Law aligns the country's regulatory landscape with evolving international standards in the fields of biosafety and biosecurity while introducing a specialized regulatory regime applicable to research institutions, universities, healthcare providers and pharmaceutical companies operating in this sector.

At the same time, the practical impact of the Law will depend largely on the content of its Implementing Regulations. Several fundamental issues — including licensing procedures, international accreditation requirements, applicable fees, and the grounds and procedures for the suspension or revocation of licences — have been expressly left for future regulation rather than being comprehensively addressed in the Law itself.

Accordingly, it is the Firm's view that the Implementing Regulations will ultimately determine the practical effectiveness of the new legislative framework. The manner in which they address these fundamental issues will shape the balance between regulatory oversight and operational flexibility and will, in turn, define the Law's practical impact on research institutions and commercial operators engaged in regulated biological activities.