

## Strengthening laboratory biological risk management

The Seventy-seventh World Health Assembly,

Having considered the consolidated report by the Director-General;<sup>1</sup>

Acknowledging the increasing risk of outbreaks of emerging and re-emerging diseases<sup>2</sup> and the need for strengthened global preparedness, including in the area of life science research and public health microbiology;

Recalling resolution WHA58.29 (2005) on enhancement of laboratory biosafety, which proposed actions to implement an integrated approach to biosafety, and other relevant resolutions;<sup>3</sup>

Recognizing the efforts and progress made in strengthening laboratory biosafety and structurally improving biocontainment conditions by both Member States and the Secretariat in collaboration with and alignment to relevant WHO technical guidance, as outlined in resolution WHA58.29;

Noting the implementation of specific programmes consistent with WHO guidance,<sup>4</sup> and development of national preparedness plans, mobilization of national and international resources and collaboration;

Noting also WHO's provision of technical support to Member States through the updating and publication of relevant guidance documents;

Stressing the importance of continuing implementation and strengthening of laboratory biological risk management, which includes institutional and personnel biosecurity measures;

Recognizing the critical role of relevant sectors'<sup>5</sup> laboratories in global health security and that the growing number of maximum-containment facilities engaging in research with high-consequence

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<sup>1</sup> Document A77/4.

<sup>2</sup> See WHO South-East Asia Dialogue. New Delhi: WHO Regional Office for South-East Asia; 2023 (<https://www.who.int/publications/i/item/9789290210955>, accessed 17 January 2024).

<sup>3</sup> Inter alia, resolutions WHA58.3 (2005), WHA71.16 (2018), WHA74.7 (2021) and WHA76.5 (2023).

<sup>4</sup> Including the Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists.

<sup>5</sup> See Advanced global health security: from commitments to actions. Geneva: World Health Organization; 2016 (<https://www.who.int/publications/i/item/WHO-HSE-GCR-2016.15>, accessed 17 January 2024).

pathogens<sup>1</sup> affecting humans, animals and other living organisms,<sup>2</sup> as well as the widespread use of new technologies, are changing the landscape of laboratory biosafety and laboratory biosecurity;<sup>3</sup>

Noting that the evolution of laboratory biological risk mitigation and management towards a more risk- and evidence-based approach requires Member States' effective control measures, practices and competencies as well as the strengthening of responsible conduct at all organizational levels;

Considering that research and development using high-consequence and other biological agents, as appropriate, in laboratories is critical for preventing, detecting and controlling outbreaks of emerging and re-emerging diseases and that their release from any type of containment facilities, including those belonging to pharmaceutical manufacturers and private entities, may have global ramifications;

Expressing concern regarding gaps in the implementation of laboratory biosafety and laboratory biosecurity measures, according to reports and evaluations under the International Health Regulations (2005),<sup>4</sup> and the additional appropriate actions required to minimize laboratory-associated biological risks;

Mindful also that the rapid advancement of technology, including easier access to genetic engineering, synthetic biology and research involving genetically modified pathogenic microorganisms, and those for which the highly contagious and/or virulent potential for humans, animals and other living organisms, as well as inter-species transmission, is not fully characterized and predictable;

Underscoring the importance of Member States' commitment to address the gaps as identified by evaluations under the International Health Regulations (2005), strengthen and raise the profile of laboratory biological risk mitigation and management as one of the necessary health security capacities for preventing, preparing for and responding to health emergencies, including pandemics and other emergencies,

1. CALLS on Member States<sup>5</sup> in accordance with national context and priorities:

(1) to comprehensively strengthen implementation of resolution WHA58.29 (2005) on enhancement of laboratory biosafety by including essential elements of biological risk mitigation and management within their national laboratory biosafety and laboratory biosecurity strategies, policies, programmes and mechanisms;

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<sup>1</sup> High-consequence material, technology and information is defined as a biological agent, biological material, technology and the information about it, capable of causing, direct or indirect, disease or other harmful effects in humans, animals, plants and/or the environment with severe or even catastrophic consequences. As per Biorisk management: laboratory biosecurity guidance, second edition. Geneva: World Health Organization (being finalized).

<sup>2</sup> High-consequence research is defined as biomedical research that uses or creates material, technology or information that could, besides its intended benefits, be misused to cause significant harm to humans, animals, plants and/or the environment. As per Biorisk management: laboratory biosecurity guidance, second edition. Geneva: World Health Organization (being finalized).

<sup>3</sup> Laboratory biosecurity is defined as preventing unauthorized access, loss, theft, misuse, diversion or release, including protection, control and accountability of biological materials and/or the equipment, skills and data related to their handling. See Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (<https://www.who.int/publications/i/item/9789240011311>, accessed 17 January 2024).

<sup>4</sup> Including the State Party Self-Assessment Annual Reporting Tool and other voluntary tools, as appropriate.

<sup>5</sup> And, where applicable, regional economic integration organizations.

(2) to approve, strengthen and implement, within the capacities and priorities of each sovereign Member State, whole-of-government, multisectoral national laboratory biosafety and laboratory biosecurity strategies, policies, programmes and mechanisms, including research and transportation, in line with WHO guidelines, involving high-consequence biological agents,<sup>1</sup> that would, in case of release or exposure, cause significant harm or potentially catastrophic consequences;

(3) to strengthen training and continual development of competent human resources, including in the areas of research, data and incident-management systems on laboratory biological risk mitigation and management;

(4) to promote a risk-based approach in support of a sound technical foundation through evidence-based measures, a sound culture of biosafety and biosecurity<sup>2</sup> at all institutional levels, and appropriate awareness, including cultural and behavioural approaches, practices and interventions that support transparent communication with prevention of and resilience to misinformation and disinformation;

(5) to develop and align, as appropriate with relevant international standards, legislation and/or regulation and policies around laboratory biological risk mitigation and management, including involving possession, use or transfer of high-consequence biological agents and relevant containment facilities, the handling of research data, methodologies in synthetic and other newly developed fields of biology and their products, where legislation, regulation and policies should support inclusivity in the context of promoting people-centred health, disease prevention, early detection of and response to health emergencies and to reduce the burden on health systems;

(6) to augment and secure international cooperation, development of technical tools and sharing of information about laboratories and incidents to implement practically, in line with the International Health Regulations (2005), laboratory biological risk mitigation and management with considerations for information security and potential risks of international spread;

## 2. REQUESTS the Director-General:

(1) to provide technical assistance and normative guidance to Member States, on request, in developing comprehensive, biological risk-management strategies, measures and oversight systems, including for laboratory containment, research and the responsible use of the sciences, and for scaling up the implementation based on the needs and priorities of Member States;

(2) to assist Member States' development and implementation of laboratory biosafety and biosecurity national strategies in line with national legislation and the applicable general programme of work with the appropriate structure, resources, assets and capabilities in alignment with financial support based on the structure at country-level strategy;

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<sup>1</sup> See WHO consultative meeting on high/maximum containment (biosafety level 4) laboratories networking: meeting report, Lyon, France, 13–15 December 2017. Geneva: World Health Organization; 2018; Biorisk management: laboratory biosecurity guidance, second edition. Geneva: World Health Organization (being finalized).

<sup>2</sup> Biosafety culture is the set of values, beliefs and patterns of behaviour instilled and facilitated in an open and trusting environment by individuals throughout the organization who work together to support or enhance best practice for laboratory biosafety. See Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (<https://www.who.int/publications/i/item/9789240011311>, accessed 17 January 2024).

- (3) to ensure that WHO builds on its strengths, by developing and updating guidance for laboratory biological risk management in cooperation with other international organizations, including, but not limited to, convening discussions for proposing consensus-based baselines for enabling objective assessment and incident reporting under the International Health Regulations (2005) of facilities working with microbiological agents through the identification and promotion of best practices, such as evidence- and risk-based interventions, in the context of each Member State and its current phase in the development of the national laboratory biosafety and biosecurity programme;
- (4) to monitor at all levels of WHO and to report to the Health Assembly developments, evidence and trends in laboratory biosafety- and laboratory biosecurity-related tools, technologies, methodologies and standards in health systems, public health, training programmes of all stakeholders, including academic institutions and the private sector, and data science, and to analyse their implications and possible use for the achievement of the health-related Sustainable Development Goals with the engagement of all relevant sectors;
- (5) to promote WHO's collaboration with other organizations and relevant stakeholders in line with the Framework of Engagement with Non-State Actors in a manner cohesive to strengthening the implementation of laboratory biological risk mitigation and management by leveraging their capabilities through WHO collaborating centres and other relevant technical partners or national and international voluntary partnerships;
- (6) to enable continued discussion among Member States and relevant international organizations or stakeholders on possible additional proposals to strengthen biological laboratory risk mitigation and management comprehensively;
- (7) to report on progress made in the implementation of this resolution, and challenges faced, to the Health Assembly in 2026, 2028 and 2030.

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A77/VR/8

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