

## Strengthening laboratory biological risk management<sup>1,2</sup>

### Draft decision proposed by the European Union and its 27 Member States and the United States of America

The Executive Board, having considered the reports by the Director-General,<sup>3</sup>

Decided to recommend to the Seventy-seventh World Health Assembly the adoption of the following resolution:

The Seventy-seventh World Health Assembly,

(PP1) Acknowledging the increasing risk of outbreaks of emerging and re-emerging diseases<sup>4</sup> and the need for strengthened global preparedness, including in the area of life science research and public health microbiology;

(PP2) Recalling the previous resolution WHA58.29 (2005) on the enhancement of laboratory biosafety, which proposed actions to implement an integrated approach to biosafety, and other relevant resolutions;<sup>5</sup>

(PP3) Recognizing the efforts and actual progress made in strengthening laboratory biosafety and structurally improving biocontainment conditions by both Member States and the WHO Secretariat in collaboration with and alignment to relevant WHO technical guidance, as outlined in resolution WHA58.29;

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<sup>1</sup> “Laboratory biological risk management” in this resolution refers to:

“Principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents and their inadvertent release (i.e. laboratory biosafety) as well as 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 (i.e. laboratory biosecurity)”. See WHO’s laboratory biosafety manual 4th edition (Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020, available at <https://www.who.int/publications/i/item/9789240011311>, accessed 17 January 2024).

<sup>2</sup> See document A74/18.

<sup>3</sup> Documents EB154/14 and EB154/15.

<sup>4</sup> WHO South-East Asia Dialogue. New Delhi: World Health Organization, Regional Office for South-East Asia; 2023 (<https://www.who.int/publications/i/item/9789290210955>, accessed 17 January 2024).

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

(PP4) Noting the implementation of specific programmes consistent with WHO guidance,<sup>1</sup> and development of national preparedness plans, mobilization of national and international resources and collaboration;

(PP5) Noting also WHO's provision of technical support to Member States through the updating and publication of relevant guidance documents;

(PP6) Stressing the importance of continuing implementation and strengthening of laboratory biological risk management, which includes institutional and personnel biosecurity measures;

(PP7) Recognizing the critical role of relevant sectors<sup>2</sup> laboratories in global health security and that the growing number of maximum containment and facilities engaging in research with high-consequence pathogens<sup>3</sup> affecting human, animal, and other living organisms,<sup>4</sup> as well as the widespread use of new technologies, are changing the landscape of laboratory biosafety and laboratory biosecurity;<sup>5</sup>

(PP8) 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;

(PP9) 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 manufacturing and private entities, may have global ramifications;

(PP10) 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>6</sup> and the additional appropriate actions required to minimize laboratory-associated biological risks;

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<sup>1</sup> Including the Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists.

<sup>2</sup> 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).

<sup>3</sup> As per WHO's document, Biorisk management: laboratory biosecurity guidance, 2nd edition (being finalized): High-consequence material, technology and information: 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.

<sup>4</sup> As per WHO's document, Biorisk management: laboratory biosecurity guidance, 2nd edition (being finalized): High-consequence research: 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.

<sup>5</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 WHO's laboratory biosafety manual 4th edition (Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020, available at <https://www.who.int/publications/i/item/9789240011311>, accessed 17 January 2024).

<sup>6</sup> Including the State Party Self-Assessment Annual Report (SPAR) and other voluntary tools, as appropriate.

(PP11) 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;

(PP12) Underscoring the importance of Member State 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,

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

- (1) to comprehensively strengthen implementation of WHA58.29 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;
- (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>2</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>3</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;

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<sup>1</sup> And, where applicable, regional economic integration organizations.

<sup>2</sup> WHO consultative meeting high/maximum containment (biosafety level 4) laboratories networking: meeting report; WHO document, Biorisk management: laboratory biosecurity guidance, 2nd edition (being finalized).

<sup>3</sup> As per WHO's laboratory biosafety manual 4th edition (Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020, available at <https://www.who.int/publications/i/item/9789240011311>, accessed 17 January 2024): 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.

(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 and response to health emergencies and to reduce the burden on health systems;

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

(OP)2. REQUESTS the Director-General:

(1) to provide technical assistance and normative guidance to Member States, upon 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;

(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 of the national laboratory biosafety and biosecurity programme development;

(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 academia and private sectors, and data science, and to analyse their implications and possible usage 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 the strengthening of laboratory biological risk mitigation and management implementation by leveraging their capabilities via 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 for possible additional proposals to strengthen biological laboratory risk mitigation and management comprehensively;

(7) to report back on progress in the implementation of this resolution, and challenges faced, to the Health Assembly in 2026, 2028 and 2030.

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