# EMERGING BIOSECURITY LANDSCAPE IN SOUTHEAST ASIA SUMMARY OF KEY FINDINGS

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# **Glossary of Terms**

Accident	An unintended occurrence that results in harm, such as infection, illness or injury in humans, nonhuman animals, plants and agriculture, or contamination of the environment. <sup>a</sup>
Agro-bioterrorism	The deliberate release of biological agents, in particular plant or animal pathogens, to cause devastating disease in plants and animals in the agricultural sectors and thereby disrupt or destroy the agricultural industry and/or food supply system of a population. The intents may be to intimidate or coerce governments or civilian populations, so as to further economic, political, social or other objectives. <sup>b</sup>
Biocrime	The intentional use of biological agents against a specific individual. <sup>c</sup>
Biological Agent	A microorganism, virus, biological toxin, particle or otherwise infectious material, either naturally occurring or genetically modified, which may have the potential to cause infection, allergy, toxicity or otherwise create a hazard to humans, nonhuman animals or plants. <sup>a</sup>
Biological Diversity (Biodiversity)	The variability among living organisms from all sources, including terrestrial, marine and other aquatic ecosystems, and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems. <sup>a</sup>
Biological Weapons	Biological and toxin weapons are either microorganisms like virus, bacteria or fungi, or toxic substances produced by living organisms that are produced and released deliberately to cause disease and death in humans, animals or plants. <sup>d</sup>
Biorisk	The probability or chance that an event caused by accidents, inadvertent or deliberate misuse of the life sciences can adversely affect the health of humans, nonhuman animals, plants and agriculture, and the environment. <sup>a</sup>
Biorisk Management	An integrated, overarching approach to address the risks associated with the life sciences research enterprise, from accidents and inadvertent actions to deliberate misuse. Biorisk management relies on three core pillars: biosafety, laboratory biosecurity and the oversight of dual-use research. Biorisk management involves the quantitative or qualitative forecasting and evaluation of the probability of harm occurring and subsequent consequences (risk assessment), together with the identification and implementation of technologies, measures or practices to avoid or minimize their likelihood or impact (risk mitigation). <sup>a</sup>
Biosafety	Containment principles, technologies, measures and practices that are implemented to prevent unintentional exposure to biological agents or their inadvertent release. <sup>a</sup>
Biosecurity	Principles, technologies, measures and practices that are implemented for the protection, control and accountability of biological agents, data or equipment, biotechnologies, skills and information related to their handling. Biosecurity aims to prevent their unauthorized access, loss, theft, misuse, diversion or release. <sup>a</sup>
Biological Threats / Biosecurity Threats	Threats from biological agents that can be harmful to humans. <sup>e</sup>

Biotechnology	The integration of the new techniques emerging from modern biotechnology with the well-established approaches of traditional biotechnology. It is a set of enabling techniques for bringing about specific human-made changes in DNA, or genetic material, in plants, animals and microbial systems, leading to useful products and technologies. <sup>f</sup>
Bioterrorism	Bioterrorism refers to the intentional release of biological agents or toxins for the purpose of harming or killing humans, animals or plants with the intent to intimidate or coerce a government or civilian population to further political or social objectives. <sup>9</sup>
Confidence-Building Measures (CBMs)	Planned procedures to prevent hostilities, to avert escalation, to reduce military tension, and to build mutual trust between countries. In the context of biosecurity, the objective of CBMs is to prevent or reduce the occurrence of ambiguities, doubts and suspicions and to improve international cooperation in the field of peaceful biological activities. <sup>h</sup>
Cyberbiosecurity	Developing understanding of the vulnerabilities to unwanted surveillance, intrusions, and malicious and harmful activities which can occur within or at the interfaces of comingled life science, cyber, cyber-physical, supply chain and infrastructure systems, and developing and instituting measures to prevent, protect against, mitigate, investigate, and attribute such threats as it pertains to security, competitiveness, and resilience. <sup>1</sup>
Deliberate act / misuse	Malicious acts with the intention to cause harm. The scope includes traditional chemical, biological and radio-nuclear agents and emerging threats such as cyber-attacks and dis-information campaigns. <sup>j</sup>
Dual-use	Knowledge, information, methods, products or technologies generated by peaceful and legitimate research that may be appropriated for non-peaceful or harmful purposes. <sup>a</sup>
Dual-use Research, "DUR"	Research conducted for peaceful and beneficial purposes that has the potential to produce knowledge, information, methods, products or technologies that could also be intentionally misused to endanger the health of humans, nonhuman animals, plants and agriculture, and the environment. In the context of this framework, it refers to work in the life sciences, but the principles are also applicable to other scientific fields. <sup>a</sup>
Dual-use Research of Concern (DURC)	Dual-use research of concern (DURC) describes research that is conducted for peaceful and beneficial purposes but could easily be misapplied to do harm with no, or only minor, modification. This term has generally been used for research in the life sciences. DURC covers everything from information to specific products that can create negative consequences for the health of humans, nonhuman animals, plants and agriculture, and the environment. <sup>a</sup>
Emerging Infectious Disease (EID)	A new disease that is affecting a population for the first time, or an existing disease that is rapidly spreading geographically or affecting an increasing number of people. <sup>k</sup>
Gain-of-Function (GoF) Research	Research that results in the acquisition of new biological phenotypes, or an enhancement of existing phenotypes. Gain-of-function research that is anticipated to enhance the transmissibility or virulence (or both) of potential pandemic pathogens raises significant biosafety and biosecurity risks, as well as dual-use concerns that may warrant additional oversight. <sup>a</sup>

Global Health Security	The multisectoral activities required, both proactive and reactive, to minimize the risk of public health events that endanger the health of humans, nonhuman animals, plants and agriculture, and the environment, across national boundaries, geographical regions and generations. <sup>a</sup>
Governance	The norms, values and rules of the processes through which public affairs are managed so as to ensure transparency, participation, inclusivity and responsiveness. Governance also represents the structures and processes that are designed to ensure accountability, transparency, responsiveness, adherence to the rule of law, stability, equity and inclusiveness, empowerment, and broad-based participation. <sup>a</sup>
Hazard	An object, situation or information that has the potential to cause harm to humans, nonhuman animals, plants and agriculture, or the environment. A hazard does not become a "risk" until the likelihood and consequences of that hazard causing harm are taken into account. <sup>a</sup>
Incident	An occurrence that has the potential to cause, or results in, the exposure of laboratory personnel to biological agents or the release of those agents into the environment, which may or may not lead to actual harm. <sup>a</sup>
Laboratory Accidents	Unintended occurrences in laboratories that result in harm, such as infection, illness or injury in humans, nonhuman animals, plants and agriculture, or contamination of the environment. <sup>a</sup>
Life Sciences	All sciences that deal with living organisms, including humans, nonhuman animals, plants and agriculture, and the environment, or products of living organisms or that incorporate components derived directly or synthetically from living organisms; the life sciences include but are not limited to biology, biotechnology, genomics, proteomics, bioinformatics, pharmaceutical and biomedical research and technologies. <sup>a</sup>
Misinformation	Information that is false, but not intended to cause harm. Determining the veracity of information or misinformation relies on assessing the state of evidence and expert consensus on the topic. The person disseminating it may believe it to be true. It involves two dimensions: intentionality (harm/benefit – as variously defined) and knowing or not knowing that the content is false. It is not about opinion, because that cannot be fact-checked. <sup>a</sup>
One Health	An integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems. It recognizes the health of humans, domestic and wild animals, plants and the wider environment (including ecosystems) are closely linked and interdependent. The approach mobilizes multiple sectors, disciplines and communities at varying levels of society to work together to foster well-being and tackle threats to health and ecosystems, while addressing the collective need for clean water, energy and air, safe and nutritious food, taking action on climate change and contributing to sustainable development. <sup>a</sup>
Pathogen	An infectious agent (a germ) that is capable of causing disease in a human, animal or plant host. <sup>a</sup>
Re-emerging Infectious Disease (REID)	An infectious disease that is increasing in prevalence in an area where it was previously absent or controlled. $^{\rm k}$

Risk	A combination of the probability of harm occurring and the severity (consequences) of that harm if it were to occur. <sup>a</sup>
Risk Assessment	A systematic process – quantitative or qualitative – of gathering information and evaluating the nature, probability and magnitude of potential harms and determining the appropriate control measures to minimize or otherwise mitigate the risks. <sup>a</sup>
Risk Management	The quantitative or qualitative forecasting and evaluation of the probability of harm occurring and subsequent consequences (risk assessment) together with the identification and implementation of technologies, measures or practices to avoid or minimize their likelihood or impact (risk mitigation). <sup>a</sup>
<b>Risk Perception</b>	The subjective judgment(s) about the severity of a risk that accounts for the experiences of individuals in different contexts. These risks may include natural or man-made biological threats such as pandemics, bioterrorism, or accidental release of harmful biological agents. <sup>1</sup>
Security Sector	The structures, institutions and personnel responsible for security provision, management and oversight at national and local levels. The security sector includes both actors that use force and those responsible for controlling how force is used through management and oversight. <sup>m</sup>
Stakeholders	Persons or groups that have an interest in a policy or activity. They include scientists, the scientific community, ethics committee members, institutional and repository managers, biosafety officers, funding bodies, publishers, editors, security officials, regulators, institutional and other authorities, civil society networks, the private sector, other relevant organizations and publics. <sup>a</sup>
Zoonosis / Zoonotic Disease	An infectious disease that has jumped from a non-human animal to humans. Zoonotic pathogens may be bacterial, viral or parasitic, or may involve unconventional agents and can spread to humans through direct contact or through food, water or the environment. <sup>n</sup>

Adapted from various sources and team synthesis, including:

- <sup>a</sup> World Health Organization (WHO), *Global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research*, Geneva: WHO, 2022.
- <sup>b</sup> Team synthesis, following 1) International Standards Organisation (ISO) definition of agro-terrorism in ISO, "Terms and Definitions", item 3, *ISO 26683-3:2019: Intelligent transport systems, ISO Browsing Platform (IBP)*, 2019; and 2) World Organization for Animal Health (WOAH) definition of agro-bioterrorism in WOAH, "Agro-crime and Agro-terrorism," *WOAH Website*, 2024, retrieved 8 September 2024, https://www.woah.org/en/what-we-offer/emergency-preparedness/agro-crime-and-agro-terrorism/.
- <sup>c</sup> Oliveira M, Mason-Buck G, Ballard D, Branicki W, Amorim A., "Biowarfare, bioterrorism and biocrime: A historical overview on microbial harmful applications," *Forensic Sci Int.* 2020 Sep;314:110366. doi: 10.1016/j.forsciint.2020.110366.
- <sup>d</sup> WHO, "Biological Weapons," retrieved 8 September 2024, https://www.who.int/health-topics/biological-weapons#tab=tab\_1.
- <sup>e</sup> Definition synthesized by the team for the purpose of the report.
- <sup>f</sup> United Nations, "Sustainable Development Topics," retrieved 8 September 2024, https://www.un.org/esa/sustdev/sdissues/biotechnology/biot.htm.

<sup>g</sup> Interpol, "Bioterrorism," Retrieved 8 September 2024, https://www.interpol.int/en/Crimes/Terrorism/Bioterrorism.

- <sup>h</sup> United Nations, "Confidence Building Measures," retrieved 8 September 2024, https://disarmament.unoda.org/biologicalweapons/confidence-building-measures/.
- <sup>1</sup> Lauren C. Richardson et al., "Cyberbiosecurity: A Call for Cooperation in a New Threat Landscape," *Front Bioeng Biotechnol* 7 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6562220/.
- <sup>1</sup>WHO, "Deliberate Events," retrieved 8 September 2024, https://www.who.int/news-room/fact-sheets/detail/deliberate-events.

<sup>k</sup> WHO, " Glossary of terms", A brief guide to emerging infectious diseases and zoonoses," (2014).

<sup>m</sup> DCAF – Geneva Centre for Security Sector Governance, "The Security Sector," SSR Backgrounder Series, Geneva: DCAF, 2015.

<sup>n</sup> World Health Organization, "Zoonoses," retrieved 29 July 2020, https://www.who.int/news-room/fact-sheets/detail/zoonoses

<sup>&</sup>lt;sup>1</sup>Jason Dean-Chen Yin and Juliana Nga-Man Lui, "Factors influencing risk perception during Public Health Emergencies of International Concern (PHEIC): a scoping review," *BMC Public Health* 24 (2024), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11110302/.

### **1. Introduction**

In Southeast Asia, porous borders are closely associated with transnational security challenges, including environmental degradation, irregular migration, smuggling and human trafficking of women and children. Against a rapidly changing environment, the concept of security has evolved further encompassing not only traditional human security challenges but also unseen threats. One such 'novel' threat comes from lethal biological diseases, pathogens, toxins, and weapons, also commonly referred to as biosecurity threats.

Unlike in the West, where biosecurity is primarily focused on the proliferation of biological weapons and bioterrorism,<sup>1</sup> in the Asia-Pacific, particularly Southeast Asia, biosecurity originated as a critical component of national health strategies aimed at combating infectious diseases within a country's borders. Its initial focus was on preventing the spread of diseases that could affect human populations, animals, and plants. Over time, the concept of biosecurity has evolved to cover a broader spectrum of protective measures, acknowledging the interconnectedness of human, animal and environmental health (One Health) and the potential for disease transmission across species and borders. The 2003 severe acute respiratory syndrome (SARS) epidemic, which caused over 750 deaths in Indonesia, Malaysia, the Philippines, and Singapore, highlighted the region's vulnerability to these infectious diseases.<sup>2</sup> The epidemic initiated discussions on pandemic preparedness and health security. Although not explicitly highlighted, biosecurity was an integral part of the broader conversation.

However, because of conflicting priorities, lack of awareness and resource constraints, the focus on biosecurity waned years after the 2003 SARS epidemic. It continued to be discussed among professionals, experts, and other stakeholders, but this did not result in any significant policy development. It was not until the COVID-19 pandemic, with its higher impacts and casualties, that discussions on biosecurity were revived in Southeast Asia. The impact of the 2019 Coronavirus pandemic on the discourse and prioritisation of biosecurity is evident in several ways as it highlighted: the critical role of laboratory capacity in public health surveillance and research; the threats posed by dual-use research of concern (DURC) and gain-of-function (GoF) studies; the potential for laboratories to be sources of biological agents; and concerns about cyberbiosecurity. <sup>3</sup>

The rapid development of biotechnology has spurred increased discussions on biosecurity, as it brings significant advancements and new capabilities in various fields, including medicine, agriculture, and environmental science. These advancements, while beneficial, also pose potential risks if not properly managed, as they involve manipulating biological materials that could be harmful if misused or accidentally released. For instance, the 2001 Anthrax Attacks in the United States, whereby the postal system was leveraged as a means of distributing bacillus anthracis or anthrax spores served as a glaring example for the importance of establishing and maintaining robust biosecurity mechanisms; lessons from this incident need to be heeded in Southeast Asia as well.

In addition to the developments in conventional biotechnology, the global movement of Do-it-Yourself Biology or DIYBio is contributing to heightened biosecurity awareness. This trend involves amateurs, enthusiasts, students, and trained scientists working outside traditional scientific institutions.<sup>4</sup> While DIYBio promotes innovation and democratises scientific research, it undoubtedly raises new biosafety and biosecurity concerns, including the potential misuse of biological materials by individuals who lack the necessary training and oversight.<sup>5</sup> Amidst the recent advancements in biosecurity, the main objective of this summary report is to provide an overview of the biosecurity landscape in Southeast Asia. The analysis is guided by five major questions:

- 1. *How* has the concept and definition of biosecurity evolved over time in each Southeast Asian country?
- 2. *What* are the primary biological threats, concerns and risks in each country in the region?
- 3. What are the key biosafety and biosecurity policies and responses in Southeast Asia?
- 4. What are the key challenges to biosecurity governance in Southeast Asia?
- 5. How can ASEAN member states strengthen biosecurity governance and cooperation?

This summary report will examine the evolution of the distinct concept and definition of biosecurity over time in Southeast Asian countries. It will assess different perceptions of threats associated with biosecurity from emerging/re-emerging diseases, dual-use research of concern, accidental release of biological agents, and the deliberate misuse of biological materials or bioterrorism. Preliminary findings draw from field research interviews with biosecurity experts in Indonesia, Thailand, Malaysia, the Philippines and Singapore. These are supplemented by a comprehensive review of related literature as well as national statements delivered by ASEAN member states' permanent representatives at United Nations-organised review conferences and meetings on the Biological Weapons Convention (BWC).

## 2. Biosecurity: An Evolving Field with Diverse and Emerging Priorities

Globally recognised definitions of biosecurity, established by major international organisations such as the World Health Organization (WHO), the Food and Agriculture Organization (FAO), and the World Organization for Animal Health (WOAH), provide a foundational understanding of biosecurity. These definitions emphasise various aspects, including the protection of public health, laboratories, animals, and the environment from biological threats.

WHO's definition of biosecurity focuses heavily on laboratory biosecurity and defines it as "policies, principles, technologies and practices implemented for the protection and control of and accountability for biological material, technology, and information or the equipment, methods, skills and data related to their handling."<sup>6</sup> It aims to prevent the loss, theft, misuse, diversion or intentional release of biological agents being handles in laboratory.<sup>7</sup> This definition is primarily laboratory-focused because laboratories are key environments where high-risk biological agents are handled, researched, and stored. This focus also aligns with the WHO's mandate to protect global public health and to prevent the spread of communicable diseases.

The FAO and WOAH define biosecurity in ways that align with their specific mandates. The FAO refers to biosecurity as "a strategic and integrated approach to analyse and manage risks in food safety, animal and plant life and health."<sup>8</sup> In contrast, biosecurity is defined by the WOAH *Terrestrial Animal Health Code* as "a set of management and physical measures designed to reduce the risk of introduction, establishment and spread of animal diseases, infections or infestations to, from and within an animal population."<sup>9</sup>

The differing priorities reflected in the definitions adopted by these global organisations bring both advantages and disadvantages in dealing with catastrophic biological events. The diverse definitions ensure comprehensive coverage of various aspects of biosecurity, including human health, animal health and agricultural safety. They also offer opportunities for specialisation, leading to more detailed and effective strategies within specific domains and tailored responses. However, these differing definitions also come with significant disadvantages. One of the more obvious issues is the fragmentation of efforts and lack of coordination among organisations, which hinders a unified response to catastrophic biological events. This fragmentation can result in inconsistent policies and practices, complicating international cooperation. Resource allocation is another major concern, as some areas might receive more attention and funding while others are neglected, potentially leaving critical vulnerabilities unaddressed.

While the term *biosecurity* has become more widespread, certain institutions may still opt to substitute it with the term *biosafety*. It is noteworthy that, compared to *biosecurity, biosafety* is a more well-established concept with widely accepted definitions and international guidelines for implementation at the national level.<sup>10</sup> The WHO Laboratory Biosafety Manual (LBM), for example, defines biosafety as "containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents or their inadvertent release,"<sup>11</sup> thus focusing more on the safe procedures involved in managing biological materials, especially infectious agents. In this manual, the WHO emphasises that laboratory biosafety forms the foundation for establishing laboratory biosecurity.<sup>12</sup> The manual strongly urges WHO Member States to assess the safety of their laboratories, enact safety initiatives, improve adherence to fundamental guidelines, and promote training efforts.<sup>13</sup> In fact, some scholars suggest that while biosecurity and biosafety share many common concepts and sometimes used interchangeably, they are not entirely identical terms. The United States National Research Council summarises these differences as:

Biosafety is about protecting people from bad 'bugs'; biosecurity is about protecting 'bugs' from bad people.<sup>14</sup>

#### (i) Brief Overview of Biosecurity Definitions Adopted in this Report

In this report, we consider "**biological threats**" and "**biosecurity threats**" interchangeably, as representing threats from biological agents that can be harmful to humans." We follow the WHO's definition of **biological agents** in its "Global Guidance Framework for the Responsible Use of the Life Sciences" (hereafter "Global Guidance Framework"), as "A microorganism, virus, biological toxin, particle or otherwise infectious material, either naturally occurring or genetically modified, which may have the potential to cause infection, allergy, toxicity or otherwise create a hazard to humans, nonhuman animals or plants."<sup>15</sup> The WHO's 2014 guide to EIDs and zoonoses, also considers that "different pathogen classes include viruses, bacteria, fungi and prions,"<sup>16</sup> and that a **pathogen**, is as "**an infectious agent (a germ) that is capable of causing disease in a human, animal or plant host**".

Given these definitions, our coverage of biosecurity/biological threats encompasses risks of emerging/re-emerging infectious diseases; laboratory accidents; biotech/dual use research of concern; and deliberate/bioterrorism, which may cause harm to humans. Each of these will be subsequently defined.

Under the first category of biosecurity threats, namely emerging/re-emerging infectious

**diseases (EIDs/REIDs)**, we define an **EID** as "a new disease that is affecting a population for the first time, or an existing disease that is rapidly spreading geographically or affecting an increasing number of people", while an REID is "an infectious disease that is increasing in prevalence in an area where it was previously absent or controlled", building on the WHO's guide to EIDs and zoonoses.<sup>17</sup> A key source of novel EIDs are or **zoonotic diseases** or "diseases that are transferable between animals and humans, and vice versa".<sup>18</sup>

Under the second category of biosecurity threats, we define **laboratory accidents** as "unintended occurrences in laboratories that result in harm, such as infection, illness or injury in humans, nonhuman animals, plants and agriculture, or contamination of the environment,"<sup>19</sup> building on the WHO's 2022 Global Guidance Framework definition. These occur within containment laboratories, which are "designated facilities established for the handling and investigation of infectious agents or toxins." Containment labs are classified into four levels, ranging from biosafety level (BSL) **1 to BSL 4**, whereby the categorization is primarily based on the types of microorganisms which they study and the level of risk, or the "risk groups" of these micro-organisms. There are four risk groups, based on "factors such as the transmissibility, severity, and origin of the studied microorganisms."<sup>20</sup> The BSL classifications, and the risk groups, are illustrated below.

#### Figure 1: Illustration of Microorganisms of Varying Risk Group Levels, and the Biosafety Level (BSL) of the Corresponding Containment Laboratories that Handle these Microorganisms



Source: Jeselyn (2024), "Biosafety Labs in Asia," NTS Fast Facts March 2024.

The third category we refer to is from dual use research of concern (DURC). Following the WHO's 2022 Global Guidance Framework, DURC "describes research that is conducted for peaceful and beneficial purposes, but could easily be misapplied to do harm with no, or only minor, modification;" "generally (...) used for research in the life sciences"; "encompasses everything from information to specific products that have the potential to create negative consequences for health of humans, nonhuman animals, plants and agriculture, and the environment." One of potential ways by which DURC can have negative impacts, is through Gain-of-function (GoF) research, defined as "[r]esearch that

results in the acquisition of new biological phenotypes, or an enhancement of existing phenotypes," which may include enhancement of "the transmissibility or virulence (or both) of potential pandemic pathogens."<sup>21</sup>

Under the fourth category, we define bioterrorism as "the intentional release of biological agents or toxins for the purpose of harming or killing humans, animals or plants with the intent to intimidate or coerce a government or civilian population to further political or social objectives," following the definition by the International Criminal Police Organization (Interpol).<sup>22</sup>

Given our expansive definition of biosecurity threats, we scope our consideration of "biorisk" to "human biorisk", in particular, "the probability or chance that a biosecurity/biological threat can adversely affect the health of humans." This builds on the WHO's earlier definition of Biorisk, while being narrowed down to humans, and in this report, we only consider further effects on animals, plants and agriculture, and the environment, **to the extent that these are harmful to humans**.

#### (ii) Assessing Biosecurity Risk Perceptions in Southeast Asian Countries

Following the definitions above, the table below indicates the ranking of biosecurity risk perceptions in Southeast Asia, based on our interviews with experts in five ASEAN countries, namely Indonesia, Malaysia, the Philippines, Singapore and Thailand. The prioritisation of biosecurity risks is ranked on a scale with "high" (red fill), "moderate" (yellow fill) and "low" (blue fill) levels.

The table shows that experts ranked i) emerging infectious diseases highest across all countries, while the risk of ii) laboratory accidents are perceived to be high in Malaysia and the Philippines, moderate in Indonesia, and low in Thailand and in Singapore. Next, Indonesia places a high-risk perception on iii) dual use research of concern (DURC) within the biotechnology industry/research clusters, while this risk is perceived as moderate in the Philippines, low in Malaysia and Singapore, and less significant in Thailand. Finally, the risk perception on iv) deliberate misuse/bioterrorism is moderate in Malaysia, the Philippines and Singapore, but low in Indonesia and Thailand. It must be noted that risks, such as bioterrorism or breaches of laboratory biosafety, are perceived to be low/moderate because of established health and security systems and regulations that can mitigate or prevent the said risk, but not low in terms of the prioritisation by the state.

	i) EIDs/ REIDs	ii) Laboratory Accidents	iii) Biotech / DURC	iv) Deliberate misuse/ Bioterrorism
Indonesia	High	Moderate	High	Low
Malaysia	High	High	Low	Moderate
Philippines	High	High	Moderate	Moderate
Singapore	High	Low	Low	Moderate
Thailand	High	Low		Low

 Table 1: Summary Table of Southeast Asia's Biosecurity Risk Perceptions

Note: Other types of risk will be further explored in later editions/versions of this report, as the research is ongoing for ASEAN countries.

### 3. Understanding Risks from National Perspectives

#### (i) Emerging and Re-emerging Diseases

Reflecting the growing importance of emerging and re-emerging diseases at the regional level, our interviews reveal that these diseases are also a significant concern in the five Southeast Asian countries where interviews were conducted.

The recent COVID-19 pandemic revealed the vulnerabilities of all countries concerned, showing that diseases can significantly debilitate lives, livelihoods, and economies at large. As such, all countries recognise the risk of diseases being "imported" through international travel, learning from the COVID-19 pandemic experience. In fact, the five countries have setup additional structures for centralising the control of the pandemic.

In the archipelagic countries of Indonesia and the Philippines, a primary concern is monitoring the emergence and re-emergence of diseases that may arise from their rich biodiversity or enter through sea or air travel routes. Within Indonesia, four new pathogens have crossed its borders over the past four years, primarily through international air and sea travel routes. These are COVID-19, African Swine Fever, Foot-and-Mouth disease, and Lumpy Skin disease.<sup>23</sup> In the case of the Philippines, there is also concern over the potential for zoonosis, or the transmission of diseases from animals to humans, as a result of environmental perturbation and increased interactions between humans and wildlife. Experts have noted that animal and human health have become closely connected, owing to more frequent human-wildlife interaction.

Climate change plays an important role in zoonosis, given that shifts in climate and weather patterns can trigger climate-induced animal movements and habitat changes, thus calling for greater attention to facing up to climate-induced zoonotic threats.<sup>24</sup> A recent study found that even in a "below 2°C" global warming scenario, there would still be more than 300,000 new interactions amongst different species of wildlife, and 15,000 transmission events across species heading up to 2070.<sup>25</sup> This translates practically to 300 new transmission events per year, or between 5 and 6 per week. Faster rates of movement observed in bats as a key driver for new "first encounters."<sup>26</sup>

Another concern is the potential for wildlife crimes through illegal wildlife trafficking (IWT). The importance of IWT was noted in an earlier report by the Global Initiative against Transnational Crime, highlighting that "fragile environments are placed under enormous pressure, and this intensifies the emergence and spread of zoonotic infections, as well as other biological threats"<sup>27</sup> Areas with higher wildlife biodiversity, also made for richer breeding ground for emerging infectious diseases EIDs.<sup>28</sup>

Our field interviews have supported the concern by countries over the potential migration of animals which can carry zoonotic diseases. In the case of Thailand, which shares land borders with multiple countries (Myanmar, Laos, Cambodia and Malaysia), the threat of land border entry of such diseases was highlighted.<sup>29</sup> One of the examples is the March 2024 Anthrax threat in the Laos-Thailand border, which impacted 54 persons in Laos and Thailand, and which owed to a buffalo infection. Similarly, in Malaysia, which shares borders with Thailand, Indonesia, and Brunei, significant attention is given to the "gazettement" or protection or natural areas of concern.

The risk of food borne pathogens was highlighted as an important concern in Singapore, given

that more than 90% of its food supplies are imported from overseas. The Singapore Food Agency (SFA) conducts safety checks for imported food, to guard against bacteria (e.g., Salmonella, Listeria, Campylobacter, Gastroenteritis-causing bacteria, E. coli). Similarly, in Malaysia, Indonesia and the Philippines, there is visible concern over plant products that can pose threats to the health of plants. Within these countries, the risk of plant pathogens potentially falling into the wrong hands and leading to agro-bioterrorism was highlighted. The Philippines, for instance, has raised the importance of enhanced border security measures including rigorous plant quarantine protocols to monitor all imported plant products. Similarly, Malaysia conducts thorough pre- and post-border inspections, especially for products imported goods from high-risk countries. One of the issues highlighted was the potential for invasive alien species (IAS) being imported through e-commerce and postal companies.

#### (ii) Deliberate Misuse and Bioterrorism

In various meetings and conferences convened by the UN on Weapons of Mass Destruction (WMD) disarmament and the Biological Weapons Convention (BWC), ASEAN Member States (AMS) have also repeatedly and strongly expressed their collective commitment to the BWC as well as their concerns over the development and possible use of biological weapons by non-state actors.<sup>30</sup> Biological terrorism is a common concern for AMS. But this concern appears to be expressed within the security sector alone (i.e., "actors involved in the provision, management and oversight of security in a country,"<sup>31</sup> further elaborated in the glossary) and articulated during ASEAN Chemical, Biological, Radiological and Nuclear (CBRN) and WMD meetings as well as in BWC Conference of States Parties, but the level of concern is unlikely to be shared by civilian agencies. AMS have nonetheless called for enhanced international cooperation and information-sharing to prevent terrorists and other non-state actors from developing, obtaining and distributing biological weapons.<sup>32</sup>

While most Southeast Asian countries have a low-risk perception of bioterrorism, in comparison to traditional biological threats such as pandemics and emerging/re-emerging diseases, experts in the region argued that bioterrorism is a serious threat that should not be ignored and must be considered a significant biosecurity threat requiring government attention. The potential for disruptions from intentional misuse should be taken very seriously, as it can have far-reaching consequences. Exposure to designed or leaked pathogens can lead to deaths, with severe and far-reaching implications such as economic collapse and border closures. Yet, the malicious intent behind such acts often remains hidden. Bioterrorism is not limited to lab-created or imported biological agents; it is particularly challenging because it can involve naturally occurring toxins and other biological materials from natural environments.<sup>33</sup>

Even though the region has not yet been hit by any mass-casualty CBRN terror attack, Singapore views the potential for bioterrorism not as a question of "if" but rather "when". Singapore's Defence Minister, Mr Ng Eng Hen, argued that terror movements and lone-wolf actors have contemplated on misusing biological agents, following an attempt in 2019 by a pro-Islamic State Jamaat Ansharud Daulah cell to use abrin-filled explosives. Indonesian authorities had foiled such planned biological attack.<sup>34</sup> Indonesia's law enforcement agencies such as the National Counterterrorism Agency and the State Intelligence Agency acknowledged that the potential threat of bioterrorism in Indonesia exists albeit on a "manageable" scale. Even if biological agents can be easily sold and purchased in the absence of strict regulatory requirements,<sup>35</sup> the perception among some Indonesian security sector experts interviewed is that terrorist groups have limited capacity to weaponise these materials.

Malaysia has been mindful of the need to prevent malicious and terrorist organisations from developing or acquiring biological weapons in its annual national statements at UN WMD disarmament meetings.<sup>36</sup> For instance, agro-bioterrorism, particularly deliberate contamination of food and water sources, presents as a serious threat to Malaysia, and there has been a past attempt by a militant group to use biological agents. Concern over the deliberate sabotage of their food supply chain using biological agents was shared by experts from Singapore, the Philippines and Indonesia.<sup>37</sup> Concern over the deliberate sabotage of their food supply chain using biological agents from Singapore, the Philippines and Indonesia.<sup>38</sup>

While Thailand has also considered the threat of bioterrorism, it is currently not a top priority. Nonetheless, in its national statement at the Ninth Review Conference of the BWC, Thailand stated that even if the development of biotechnologies for peaceful purposes are encouraged by the BWC, the same technologies have also increased the risk of non-State actors acquiring and misusing biological weapons.<sup>39</sup>

Although the experts' risk perception of bioterrorism is currently moderate in the Philippines, the security situation in Mindanao (southern Philippines) provides potential training grounds for terror groups using biological materials.<sup>40</sup> For the security sector, bioterrorism is a key biosecurity concern.<sup>41</sup> Reports indicate that terror groups in Mindanao have been trying to recruit university students. There are concerns in universities that these students enrolled in science courses can have access to hazardous biological materials.<sup>42</sup>

#### (iii) Advances in Biotechnology and Dual-Use Research of Concern

DURC refers to research intended for beneficial purposes, but with the potential to be misapplied, thus posing a threat to the health of the public, animals and the environment.<sup>43</sup> In Southeast Asia, research that eventually gets categorised as DURC was initially conducted for good purposes. In some countries in the region, certain scholars have engaged in research studies without realising that these can be a DURC; this reflects a low level of awareness of DURC among researchers in the region.<sup>44</sup> This low awareness can stem from the absence of comprehensive biosafety protocols and laws, as well as varying capabilities and capacities of Institutional Biosafety Committees (IBCs) responsible for evaluating the potential dual-use risks associated with research. Furthermore, some universities and private entities lack established research protocols or oversight committees such as IBCs altogether.<sup>45</sup>

Regional biosecurity experts also pointed out that Genetically Modified Organisms (GMOs) can be used as a platform for bioterrorism and biocrime. The malicious genetic editing of seeds in agriculture can make them harmful, as these can be used for agro-bioterrorism through the unauthorised planting of GMO seeds with the intent to cause damage. The inability to detect unauthorised GMOs (UGMOs) creates an entry point for the distribution of GMO-based weapons.

Furthermore, biotechnology-related biosecurity threats, particularly those associated with gene editing technologies like CRISPR, present significant challenges. One major issue is the current inability of current technologies to precisely trace molecular scars left by genetic modifications. This makes it difficult to determine whether an organism has been modified or is naturally occurring.

In Southeast Asia, the state of biotechnological development and awareness of DURC varied from country to country, leading to different challenges and gaps. Indonesia's biotechnological development was rarely a national priority given the country's low ranking in Asia in terms of human resources and R&D in biotechnology.<sup>46</sup> The government's reluctance to engage in biotechnological development is partly due to the controversies surrounding biotechnology products and the false misinformation and campaigns suggesting they are unsafe to consume or use. Additionally, biotechnology products are often seen as being dominated by multinational corporations from Western countries, a sentiment that is not commonly welcome among local communities.<sup>47</sup> The same issue is faced in the Philippines; although the country is known for championing biotechnology development, it too faces resistance from advocacy groups (mostly environment-related) against the use of GMOs. This challenge makes the commercialisation of biotech-engineered products particularly difficult.<sup>48</sup>

Indonesia's lack of prioritisation of biotechnological developments does not mean that these are not a concern, though. The secretive nature of big pharmaceutical companies, which possess the technology to conduct Gain-of-Function (GoF) research, makes it more difficult to regulate them.<sup>49</sup> By not sharing vaccine formulas and restricting information exchanges, these companies create "economic dependency" wherein governments are dependent and beholden to companies for their specialised products. This secrecy and lack of transparency have made it more challenging to regulate the biotech industry in Indonesia, resulting in an increased risk of misuse.<sup>50</sup>

Malaysia launched the National Biotechnology Policy 2.0 in September 2022, aiming to further develop the national biotechnology industry and transform Malaysia into a progressive, prosperous, inclusive and sustainable high-tech bio-innovation nation by 2030.<sup>51</sup>However, it has similarly experienced pushback from certain interest groups against the use of GMOs in some agricultural sectors.<sup>52</sup> Additionally, the lack of resources in Malaysia has resulted in limited commercial production of biotech or genetically engineered products. Some experts even argued that government policies on biotechnology in Malaysia are insufficient and unable to keep pace with the rapid advancements in the field and that contrary to popular belief, the biotech industry desires regulation, as it provides funding and collaboration opportunities.<sup>53</sup>

Unlike countries where the population is less receptive to biotechnology, Thailand and Singapore have embraced biotechnological development for decades. In Thailand, the National Center for Generic Engineering and Biotechnology (BIOTEC) plays a crucial role in supporting and transferring technology for the development of industry, agriculture, natural resources and the environment, thereby enhancing the social and economic well-being of the Thai people.<sup>54</sup> The Thai government managed to secure support from the population through tax incentives, grants, subsidies for research and development activities, and efforts to simplify regulatory processes and promote technology transfer.<sup>55</sup> In Singapore, support for biotechnological development is evident in the sector's substantial market size, which reached \$823.5 billion in 2021, with an expected annual growth rate of 8.0%. Currently, there are 52 biotech companies, projected to increase to 84 by 2032.<sup>56</sup>

#### (iv) Laboratory Biosafety and Biosecurity

Most Southeast Asian countries have been transparent with the existence and operation of their national containment laboratories of various BSL categories (BSL-1 to BSL-3), as well as their new plans to build additional laboratories. Such national facilities are publicly reported including their health security-related functions. For instance, all five countries operate BSL-3

national containment laboratories. They also have several BSL-1 and BSL-2 containment laboratories, although, there is currently no BSL-4 laboratory in the region (for further information, please refer to section 2.i). Top research-intensive universities in the five countries have well-managed, international/ISO-certified and highly secure BSL-3 laboratories. A majority of these are run by medical schools, tertiary hospitals, and public health training institutions of these universities as well as by tropical medicine research institutes affiliated with government agencies such as the Ministry of Health. They are self-regulated in the sense that the oversight of these laboratories is under the respective medical/educational institutions which they are part of; these institutions in turn create guidelines on good practices for maintaining sufficient laboratory biosafety. While there is no general legislative framework that requires these laboratories to have annual international certification, it has been a norm across the five ASEAN countries for their BSL-3 containment laboratories to have annually updated international certification.<sup>57</sup>

Experts argued that with effective practices established in high-containment research laboratories in the region (i.e., BSL-3), these facilities would not be easy targets for terror groups or insider threats seeking to steal biological agents. Instead, ordinary laboratories in hospitals, as well as clinical and diagnostic laboratories (i.e., where research is not conducted), might be more vulnerable to the theft of biological samples due to lack of biosecurity awareness and lack of a security culture. In biosecurity, a security culture is an assembly of beliefs, attitudes, and patterns of behaviour of individuals and organisations that can support and implement policies, practices and norms intended to prevent the loss, theft, misuse, and diversion of biological agents.<sup>58</sup>

Monitoring and oversight should extend beyond high-containment labs, which undergo rigorous international certification processes annually. The primary concern lies with small, clinical and diagnostic labs that operate without a strong security culture. Countries in the region already have various regulations and guidelines governing all types of laboratories. Hence, the absence of regulations does not contribute to vulnerability. Instead, these labs pose a potential risk due to their staff's limited adherence to safety protocols and biosecurity measures as well as lack of biosecurity awareness. Laboratories may be vulnerable to theft, insider threats or unauthorised access to dangerous pathogens, posing a risk of bioterrorism or accidental release of infectious agents.<sup>59</sup> Insider threats arise when individuals within the organisation with authorised access to biological agents and toxins for research purposes misuse that access for malicious intent.<sup>60</sup>

Experts in Southeast Asia viewed accidental leaks or releases from laboratories as a minimal threat, indicating a low likelihood of occurrence. Attention is primarily directed towards naturally-occurring and (re)emerging infectious diseases, insider threats, and the intentional use of biological agents for purpose of bioterrorism. The region's low risk perception of laboratory accidents mainly stems from robust national and international biosafety regulation and the adoption of stringent due diligence measures.<sup>61</sup> Furthermore, there are different laboratory types, whether it is a clinical diagnostic lab (primary, secondary and tertiary), an academic research lab, or an industrial laboratory. It is potentially beneficial to tailor policies so that the concerns and risks related to these different labs are addressed accordingly.

### 4. National Frameworks, Approaches and Practices

#### (i) Existing Policy Frameworks

The table below includes a brief snapshot of biosecurity policies in place or pending/under discussion across the five countries where experts were interviewed. It includes both the comprehensive policies as well as other relevant frameworks applied at the national level. This list of national regulations and frameworks is non-exhaustive and will be further expanded in the succeeding reports.

Countries	Comprehensive	Other relevant frameworks
Indonesia	Draft biosecurity/BWC bill (pending)	Ministry of Agriculture Decree No. 85/KPTS/HK.330/9/1997, Government Regulation No. 21 of 2005, 2019 Institution Biorisk Laboratory Manual
Malaysia	Draft biosecurity/BWC bill (pending): A Policy Paper on BWC has been introduced	The Biosafety Act of 2007, Medical Act 1972, Prevention and Control of Infectious Disease Act 1988, National Security Council (NSC) Act Directive No. 20, Plant Quarantine Act, 2013 Malaysia Laboratory Biosafety and Biosecurity Policy and Guideline
Philippines	Draft biosecurity and biosafety bill (pending)	<ul> <li>1991 Biosafety Guidelines, Executive Order No.</li> <li>514, Joint Department Circulars 2016 (recently revised in 2021), Anti-terrorism Act of 2020 Section 4(d), 2023 Manual of Laboratory Biosafety and Biosecurity Standards</li> </ul>
Singapore	Biological Agents and Toxins Act 2005	Strategic Goods Act, 2002 Singapore Standard: Biorisk Management for laboratories and other related organisations, Singapore Biorisk Code of Conduct for the Life Sciences Industry and Professionals
Thailand	Pathogen and Animal Toxins Act 2015 (focusing mostly on lab biosafety)	Communicable Diseases Act, Animal Epidemics Act, Plant Quarantine Act, 2019 Biodiversity Act (Draft)

#### **Table 2: Key Biosecurity Policies**

Singapore has established a robust biosafety and security regime, underpinned by the Biological Agents and Toxins Act (BATA). Its government regularly reviews and amends its legislation, practices, and procedures to ensure they remain relevant and aligned with international best practice. Singapore implements the BWC primarily through the BATA. Any person who violates these provisions can be punished with a fine, imprisonment (extendable to life-imprisonment), or both. Participation in offences such as those related to biological weapons is prohibited by Chapter 5 of the Penal Code.<sup>62</sup> The Act is a key achievement of Singapore, as compared to most of its Southeast Asian neighbours which have yet to codify their national implementation of the BWC through a comprehensive legal framework.

Singapore has also established a BWC National Contract Point. Relevant organisations for implementation of the BWC include the Biosafety Branch of the Ministry of Health, the Ministry of Home Affairs and the Director-General of Customs. Singapore has organised outreach related to biosecurity and biosafety, including for example through the development of guidance

documents which do not mandate but rather inform on ideal biosecurity/biosafety practices, as well as procedures mandated by other laws, such as the Security Recommendation for Facilities Possessing, Storing or Working with Biological Agents and Toxins under the Biological Agents and Toxins Act from the Biosafety Branch of the Ministry of Health and the Ministry of Home Affairs.<sup>63</sup> To ensure the integrity of its export control system, which regulates the export of biological and chemical items, Singapore maintains a "control list" of that can be exported under its Strategic Goods Act.<sup>64</sup> This list includes all items listed under four existing multilateral export control regimes (e.g., treaties, conventions, frameworks) – the Australia Group, the Missile Technology Control Regime, the Nuclear Suppliers Group and the Wassenaar Arrangement, from which its trans-shipment and transit control lists are also derived. Singapore regularly reviews and updates its control lists to ensure that its system is in line with international practices.<sup>65</sup>

In Thailand, apart from the main legal framework under the Pathogens and Animal Toxins Act (PATA) B.E. 2558 of 2015, there are other existing Thai national laws related to biosecurity and biosafety such as Plant Quarantine Act, Public Health Act, Hazardous Substance Act, and Animal Epidemics Act. However, Thai experts argued that PATA does not focus on detection, but mostly on laboratories; as such, monitoring/detection of naturally occurring diseases and other emerging biosecurity threats was deemed a gap in Thailand's legal framework. Furthermore, there are Biosafety Guidelines for laboratories and research purposes. A Biodiversity Act, as a major legislative piece to support the PATA, has been proposed, and received approval from Thialand's Cabinet, and it is currently pending in the parliament.<sup>66</sup>

Concerning the prohibition of biological weapons, Thailand implements the BWC through a number of laws and other related normative instruments. These include the Control of Item in Relation to the Proliferation of Weapons of Mass Destruction Act B.E. 2562 (2019), which practically serves as the country's strategic export control legal framework, and the PATA.

Currently, Malaysia does not have a BWC implementation law as the proposed legislation has been pending since 2015 while a list of sensitive biological agents is still being reviewed by the country's biosecurity experts. In order to strengthen the implementation of the BWC at the national level, sans a national legislation, the Malaysian Science and Technology Research Institute for Defence (STRIDE), an agency of the Ministry of Defence, has drafted a policy paper on the BWC and submitted it for endorsement by Malaysia's Cabinet in 2023. STRIDE is the focal agency for the national implementation of the BWC. The official dissemination of this BWC policy paper is currently pending. The policy paper outlines strategies to strengthen national implementation, increase awareness and understanding on comprehensive biosecurity culture, enhance oversight mechanisms in science and technology, and ensure the effective multi-agency coordination in responding to deliberate biological incidents. Malaysia has an export control regime, the Strategic Trade Act 2010, Arms Act 1960, Customs Act 1967. Other related regulations and Malaysian laws relating to import and export, human, plant and animal health, environment and biological diversity can be referred to while a comprehensive BWC bill has yet to be legislated.

The Philippines currently lacks a national law that specifically addresses biosecurity and the BWC, despite having some executive and administrative orders in place which are mainly on biosafety. A draft BWC law has been pending in the Philippine Congress since it was first introduced in 2013.<sup>67</sup> Nonetheless, several legislative measures are used to implement the BWC within the criminal legislation of the Philippines. Notably, Section 4(d) of the Anti-

Terrorism Act of 2020 bans the development, possession, export, supply, and use of biological weapons when carried out with a terrorist intent.<sup>68</sup> Additionally, the Strategic Trade Management Act (STMA) and its Implementing Rules and Regulations provide a legal framework for export control and the transfer of strategic goods, thereby bolstering BWC implementation.<sup>69</sup>

In Indonesia, the National Institute of Health Research and Development's Institution Biorisk Laboratory Manual, which was published in 2019, covers general biosafety and biosecurity requirements to be utilised in the country's containment laboratories but it does not contain details on specific system requirements for physical containment, reporting or cybersecurity in handling especially dangerous pathogens. Just like its Southeast Asian neighbours, Indonesia has prevailing regulations and frameworks covering environmental, plant and animal health, complementing human health. However, there is no biosecurity or BWC implementation law in Indonesia. Existing domestic laws can only partly execute BWC, such as the Law on Criminal Acts of Terrorism; various legislations on Quarantine; the Law on the Outbreak of Diseases; Law on Customs; and its Penal Code. Indonesia currently has patchy ministerial level regulations on strategic goods subject to export prohibition and on the control over importation and distribution of hazardous materials, but it has no comprehensive export control legislation.<sup>70</sup>

#### (ii) A One Health Systems Approach in Tracking Diseases

Processes for tracking the emergence/re-emergence of such diseases are critical, and this needs to be done at multiple stages, from before a disease becomes zoonotic, until after it has started affecting humans. The One Health approach will ideally help attain optimal health for people, animals and our environment. Thailand, the Philippines, Indonesia, Malaysia and Singapore, for instance, were among those with gene sequencing technologies for conducting such analysis. Thailand is mostly focusing on diseases after they have zoonised, i.e., once they can infect humans; its goal is to prevent "DiseaseX" from having a significant impact, although sequencing focuses more on human DNA rather than animal DNA. By contrast, Singapore, Indonesia, Malaysia and the Philippines are conducting Whole Genome Sequencing (WGS) of human and animal viruses, including analysis of pre-zoonosis, to study how viruses evolve even within animal hosts. This approach is more foresighted and helps to better track future hotspots for disease (re)emergence, premised also on animal behaviours and migration patterns amid climate change. There are trade-offs, however, given the perception that doing more animal gene sequencing could dilute efforts at human gene sequencing given resource constraints.

#### (iii) Raising Biosecurity Awareness and Expertise among Policymakers and Across Sectors

The prioritisation of disease surveillance requires policy support, and so efforts are needed to raise awareness among policymakers and the general public alike. In the Philippines, one expert viewed that the country lacks sufficient capacity to manage emerging or re-emerging infectious diseases. In the expert's view, this lack of capacity owes to its government's underestimation of the potential impact of pandemics, given that the country was not severely affected during the earlier SARS outbreaks. This led to underdeveloped primary care systems; inadequate testing capabilities; insufficient documentation for reference, limiting their readiness to respond effectively to health crises; heavy reliance on volunteers, resulting in late reporting of diseases; and under-resourced local health agencies.<sup>71</sup> The concern of underdevelopment of health systems is also shared in Indonesia's biosecurity experts called

for educating policymakers on the importance of plant and animal biosecurity frameworks given that country is considered the "megabiodiversity" zone of the world.

Experts have pointed out the need to also include the agricultural sector, particularly farmers, in biosecurity education. For instance, as with other large countries, Indonesia's large size and decentralised command structures also make it challenging to ensure uniform knowledge of biosecurity across all levels of society. It is perceived that many farmers still likely lack awareness of the potential pathogens that can enter through their livestock and the threat of new or re-emerging plant-related diseases that could reduce farms' crop yields. Consequently, the effectiveness of even the most robust regulations, is undermined if people lack the knowledge to implement them.

There is a significant disparity between biosafety awareness and biosecurity awareness. Scientists, medical professionals, the health security community, academics, and laboratory personnel are traditionally more familiar with biosafety; by contrast, the concept of biosecurity is still new to many of these actors. It is crucial to increase their awareness of biosecurity to be able to respond to biological security threats and incidents. More needs to be done to raise awareness on biosecurity, to match the awareness of biosafety. While biosafety awareness and compliance are relatively high, this owes largely to biosafety requirements being mandated by the government and IBCs. When it comes to biosecurity awareness, it is considerably lacking due to the absence of specific biosecurity provisions in the existing national regulations. Therefore, there is a substantial need for improvement in biosecurity awareness and regulatory development. Currently, there is low awareness in the legislative bodies on the importance of a comprehensive biosafety and biosecurity legal framework or BWC national implementation bill.

#### (iv) Security-Health Sectors Cooperation and Joint Training to Boost Enforcement

Even if countries may have robust biosafety and biosecurity laws, the lack of enforcement may prevent these from being followed consistently. A potential mechanism to strengthen enforcement is through the engagement of the security sectors (including the military, police, home affairs, etc.) in enforcing health- and biosecurity-related agenda. Within Thailand, for instance, there are some siloed distinctions between "Ministry of Health Jobs" and "Police Jobs." While there are sub-units within the police which could be involved in investigating health/biosecurityrelated incidents, the perception by one of the experts interviewed is that their efforts are currently focused on investigating top line issues such as drug smuggling, animal smuggling, and money laundering, among others. The police will need guidance from the health sector, which is conveyed in a language that is easier to operationalise on the types of biosecurityrelated incidents that the policy should be tracking/monitoring within their own sphere. For instance, the police cannot be expected to monitor the movements of biological materials without a prioritised list of biological materials and guidelines on how they are tracked. Nonetheless, in the five countries, the security and health sector agencies have begun enhancing their coordination mechanisms in responding to biosecurity events, whether accidental or deliberate, through their respective CBRN workshops and joint exercises.

It is also important to recognise that bioterrorists, or individuals involved in acts of bioterrorism, including insider threats as defined earlier, are rather hard to track. They are typically highly educated individuals with scientific expertise, and distinguishable only when they act on their strong ideological beliefs. They may appear and behave typically like the rest of the organisation/society they belong to, but their ideologies may drive them to misuse their

knowledge and skills towards creating or disseminating biological agents as weapons. As such, the security sector can also be tapped in the practical aspects of enforcement of lab biosecurity, such as through regular inspections, staff training, even as the health sector communicates the consequences of non-compliance.

#### (v) Developing National Control Lists and Inventories of Pathogens, Toxins and Security Sensitive Biological Agents

Countries need to develop their national inventories of dangerous pathogens and toxins, and security sensitive biological agents warranting specific monitoring regulations in order to mitigate potential health risks to humans, animals, and the environment. These national control lists and inventories need to be consistently monitored across all human and animal health laboratories, and tailored to their specific needs, to ensure adequate oversight mechanisms. The control of access to containment laboratories (or "access control") working with high-risk materials should be well-regulated to reduce vulnerability to theft, diversion, or misuse of dangerous pathogens.

The steps above are critical to ensure strict and effective control of pathogens, toxins and security-sensitive biological agents (or biological agents with a high "risk group" as defined in Section 2.i), which will help maintain national security and prevent potential threats to society and the environment. Singapore has fully developed a systematically categorised list of biological agents, which makes for better regulatory oversight by related ministries.<sup>72</sup> Meanwhile, some countries in Southeast Asia have just started developing such a list through national consultations and workshops with stakeholders and agencies involved in life sciences and biotechnology.

### 5. Recommendations for Enhanced Regional Cooperation

# (i) Promote Harmonisation of Biosecurity Protocols and Capacity Building through ASEAN Regional Networks

AMS strengthen their international cooperation and assistance through various capacity building programs. Through the Network of ASEAN Chemical, Biological and Radiological (CBR) Defence Experts, which was established in 2019, CBR experts actively organise workshops, table-top exercises and regular exchange of visits to build country experts' capacity and nurture cooperation in areas where CBR defence awareness remains relatively low. This includes the successful ASEAN CBR Defence Experts Technical Meeting for Harmonisation of CBR Sampling and Analysis Reporting Protocol held in Singapore in August 2023.<sup>73</sup> Under the ASEAN Regional Forum (ARF), the Philippines, in collaboration with the U.S. State Department, hosted several workshops and table-top exercises that tackled biological weapon risk mitigation measures such as biological threat reduction; bio-risk management; disease detection and surveillance; preparedness and response to a biological event; countering illegal/illicit trafficking of CBR materials; and raising awareness on CBR risk management, with a special focus on biological incidents.<sup>74</sup>

Building on the initial success of the ASEAN CBR Defence Experts Technical Meeting by developing standardised protocols for CBR sampling, analysis, and reporting across all member states, biodefense and biosecurity experts in the region can conduct **regular reviews and updates of biosecurity-related protocols** to incorporate the latest advancements and

best practices. The CBR Network can also consider joint reviews and initiatives with other related networks and institutions within the ASEAN system.

The **mutual recognition of biosecurity measures** across different institutions and countries can be explored. By standardising and acknowledging each other's biosecurity protocols, organisations and nations can build trust, improve collaboration, and create a more cohesive and effective regional defence against biological/biosecurity threats.

To encourage more collaborative initiatives under the ARF, AMS and their dialogue partners in the broader Asia- Pacific region can explore **the creation of expert working groups** in collaboration with the Council for Security Cooperation in the Asia-Pacific (CSCAP) to tackle specific issues such as biological threat reduction, disease detection, preparedness for biological events, and peace and security impact of advances in biotechnology.

Further **capacity building exercises through regional networks** will be needed for emerging infectious diseases, so that all AMS may achieve a minimum agreed level of surveillance, testing and monitoring to detect new pathogens. This has to do with the difficulty in responding collectively to biosecurity threats because the types of resources for different issues/threats which are available vary across countries, and there is often an absence of a framework that allows for the effective use of these resources at the national level. The most cost-effective approach is to implement a framework at the regional level. Forward-looking and action-based discussions will be needed on how to promote further investments in surveillance systems to ensure that robust testing protocols are in place.

#### (ii) Conduct Workshops on Biosecurity

Countries in the region have set up workshops on the implementation of the BWC and other relevant biosecurity and biosafety conventions, treaties and guidance documents. The purpose of these workshops has always been to deepen understanding of biosecurity. share effective practices related to the preparation of Confidence-Building Measures (CBMs; see glossary for further reference) as part of BWC requirements, and inform participants about capacity-building opportunities available to strengthen biosafety and biosecurity.<sup>61</sup> These workshops are beneficial as countries can learn not only from their regional counterparts but also from international partners such as the European Union CBRN Risk Mitigation Centres of Excellence Initiative (EU CBRN CoE).<sup>75</sup> These workshops may further **encourage countries** to submit their CBM reports, thus deepening their understanding of their own biosecurity capacities, enhance transparency, and foster greater trust and cooperation within the region. Regional workshops can also provide guidance to develop national frameworks that cover both naturally-occurring and man-made biosecurity threats, craft better risks communication strategies (science diplomacy and diplomacy in science), and strengthen biosecurity threatoriented intelligence work. These workshops can also be geared towards developing regional database to map, monitor, and track biosecurity threats. They can further promote mutual agreement and recognition of country-level biosecurity measures (as described in the previous recommendation), and improve the transparency of cross-country information exchange.

#### (iii) Develop Regional Research Networks for Information Exchange

A regional network for information exchange in Southeast Asia is essential for enhancing biosecurity by facilitating the **timely detection of disease outbreaks**, **development of** 

**treatments, and effective data sharing.** Such a network would allow countries to quickly share information on emerging biological threats, enabling coordinated responses and reducing the time needed to develop and distribute treatments. Through joint research initiatives, regional experts can collaborate on understanding pathogens, developing vaccines, and creating strategies to mitigate biosecurity risks.

**Strengthening regional research networks and partnerships on biosecurity** is key in balancing between research and development (R&D), security and health. While some information exchange and technological sharing partnerships have been established, they are not happening at a pace that meets the current biosecurity needs of the region. This type of cooperation could expand to regional sharing of information on emerging and re-emerging diseases, and to developing a regularly updated list of controlled pathogens, toxins and security-sensitive biological agents.

**Creating a country-specific list of biological agents unique to Southeast Asia or individual countries** is a crucial step in strengthening regional biosecurity. This list would differ from global or other regional lists by focusing on organisms that are particularly prevalent or pose significant risks within Southeast Asia, such as tropical diseases, endemic pathogens, or agricultural pests specific to the region. Identifying these organisms requires through research and collaboration among Southeast Asian countries to ensure that the list accurately reflects the biological threats that most affect the region. By prioritising these unique threats, countries in the region can develop targeted surveillance, prevention, and response strategies, better safeguarding public health, agriculture, and the environment against local biosecurity risks. Relative to developing national lists, a further step forward is to **develop national and regional inventories for such pathogens**; the challenge however is that there is limited authority on the part of health agencies to mandate or implement inventory reporting.

To build confidence, foster information sharing and harmonise protocols, it is recommended that **a network of high-containment laboratories** be established in Southeast Asia. Sharing of biological samples, for instance, among these laboratories can be explored through this network.

#### (iv) Encourage Sharing of Best Practices on Security-Health Sector Cooperation

While sharing of best practices among relevant sectors is ongoing within ASEAN, a potential focus moving forward lies in health-security sector cooperation in managing biosecurity threats. For instance, Malaysia's ongoing use of the United States' model of **inter-agency biosecurity cooperation between law enforcement/security** (Federal Bureau of Investigation) and the health sector (Centre for Disease Control), presents a potential model to consider for ASEAN countries which have decentralised/sub-national levels of government. Each country will nonetheless need to determine which model suits it best. In Thailand, one suggestion was to establish a law enforcement unit within the Ministry of Public Health as the focal point for enforcement of the PATA. In contrast, Singapore works with existing structures within a "Whole-of-Government" approach, while encouraging greater collaboration among the health, security, veterinary, environment, food, water and trade sectors.

At the regional level, to **strengthen cooperation in the health sector within the ADMM-Plus**, it is beneficial to follow the framework established by the security cluster, particularly in Military Medicine. Although the security sector tends to be reserved when discussing sensitive security issues, it is notably open and vocal about health and biosecurity matters. In contrast, the health cluster, which plays an equally or even more crucial role in biosecurity management, has been secretive with limited information sharing. Similarly, the education cluster requires significant improvement, as many discussions occur, but information is not being adequately shared, especially in areas like research and innovation in health. Given that multiple networks cover different types of biosecurity threats differently, such as bio-crimes as opposed to naturally occurring diseases, a "networking of networks" is required to enable synergies across these networks.

**Sharing of best practices** is also critical in light of the emergence of new types of threats, such as cyberbiosecurity. There can be a lack of awareness and understanding of the potential cyber security risks and threats associated with digital lab data and digital information about biological samples inside laboratories. Regional research networks should prioritise molecular epidemiology and create opportunities for effective collaboration. Increased research activity will lead to more regulation, so it is crucial to build trust, engage in joint research, and facilitate policy dialogues between researchers and policymakers to ensure mutual benefit. A regional network for information exchange in Southeast Asia is essential for enhancing biosecurity by facilitating the timely detection, development of treatments, and effective data sharing. Such a network would allow countries to quickly share information on emerging biological threats, enabling coordinated responses and reducing the time needed to develop and distribute treatments. Through **joint research initiatives, regional experts can collaborate** on understanding pathogens, developing vaccines, and creating strategies to mitigate biosecurity risks. It is also important to engage all ASEAN pillars to further improve biosecurity governance in Southeast Asia.

# (v) Explore One Health Integration of Primary and Secondary Prevention Approaches to Biosecurity Threats

Given resource constraints, AMS today commonly prioritise early detection and response to diseases or vaccine preparedness (i.e., "procurement, distribution and information management" as well as "interlink(ing) supply, delivery and demand, and considers how these interlinkages could be anticipated"),<sup>76</sup> once diseases have evolved into zoonotic forms that can infect humans. However, given the significant uncertainty over what kind of "DiseaseX" (or the next infectious disease with pandemic potential) will emerge, a disease-centric approach may be insufficient. **A systems-level One Health approach** is required in preparing for "DiseaseX", which focuses on "primary prevention", or preventing systemic factors that lead to the occurrence of zoonosis, as opposed to "secondary prevention" which focuses on early detection of the problem once it has emerged.

The starting point of primary prevention should be in **monitoring and planning urban**, **ecological and land-use developments** in a manner that reduces the likelihood of new human-to-animal interactions through, and in turn, animal-to-human spillover events in future, hence a One Health approach. Beyond this, there is a need to advocate for a One Health approach that not only accounts for the human-animal-environment health interactions, but also human-induced biosecurity threats. This is given that biological threats cut across multiple functions and sectors and go beyond the conventional silos of disease outbreaks (medical/health perspective) and bioterrorism (security perspective).

There is a need to **study approaches beyond preparedness and response**. Lessons learned from the past indicate the need to add layers to current policies and practices, which

may include laboratory policies, environmental policies, and engagement with civil society. While current efforts are heavily focused on preparedness and response, it is crucial to integrate these additional layers to enhance overall effectiveness. Strengthening laboratory policies can ensure safer handling of biological materials, while environmental policies can mitigate the impact of degradation of ecosystems that may lead to biosecurity events. Involving civil society can improve community resilience and awareness, creating a more comprehensive approach to bioterrorism prevention and response.

# (vi) Encourage the Development of Guidelines on Responsible DURC and Managed Cyberbiosecurity

The regulation of DURC and cyberbiosecurity represents a critical opportunity to safeguard scientific advancements while mitigating potential risks. DURC necessitates stringent oversight to prevent misuse of biological agents for bioterrorism or other nefarious activities. Given the digitalisation of biological information, cyberbiosecurity measures need to be integrated within both cybersecurity and biosecurity frameworks. By **implementing comprehensive regulatory frameworks**, Southeast Asian states can ensure the responsible conduct of life sciences research, protect sensitive biological data from cyber threats, and foster public trust in scientific innovation.

Such regulations, however, will need to **consider the delicate balance that needs to be maintained between safety, and innovation**. If regulations are too strict, such as those concerning reporting and monitoring, these can decrease researchers' or industries' motivation to conduct further research on biotechnology. Hence, more regional forums are needed to discuss whether new law or regulations are required, or if such policies can be achieved within existing legal frameworks. A critical concern remains, though, on whether a new, separate agency would be better suited to providing monitoring and oversight of DURC.

A stakeholder analysis is therefore critical. Stakeholders in DURC, including principal investigators, researchers, students, and IBCs, must have their expectations holistically studied to understand the messages they need, who will communicate with them, and how to communicate effectively. Principal investigators, students, and researchers require clear guidelines, detailed protocols, and regular updates, typically communicated by IBCs and regulatory bodies. Additionally, industry stakeholders must be actively engaged through forums, partnership meetings, and collaborative initiatives to ensure awareness of DURC.

The WHO has already issued its own guidelines on "Global guidance framework for the responsible use of the life sciences: Mitigating biorisks and governing dual-use research" in 2022."<sup>77</sup> A **potential initiative for AMS is to explore pathways to align with the WHO's global guidance framework**, such as by developing national guidelines that are adapted to unique local country contexts.

#### (vii) Establish Regional Supply Chain Security Framework for Sensitive Pathogens, Toxins and Biological Agents

Supply chains are potential conduits to biosecurity threats from DURC, as well as threats from imported commodities (whether food, animals, or plants). By rigorously **monitoring vendors or primary sources of biological materials, maintaining a secure chain of custody, and implementing physical and information security measures**, regulatory institutions can prevent unauthorised access, theft, accidental releases or misuse of sensitive materials. In light

of the potential for "invasive alien species" and harmful products to be imported into ASEAN countries, which can pose threats to human, animal and plant health, it is important equally to explore measures which will allow countries to ban imports from selected high-risk countries. An **ideal Regional Supply Chain Security Framework** should encompass both traditional trade as well as digital trade/e-commerce, the latter being less regulated. Such approaches, while taking a more conservative stance to prevent threats to food safety (e.g., poisoning/contamination), can potentially conflict with the World Trade Organization's (WTO)'s stance against non-tariff barrier to trade. Nonetheless, a balance must be struck between stringent security measures for food safety, and adherence to global trade standards. In addition, given the potential of synthetic biology to be misused or weaponised, a supply chain security framework needs to **include genetic materials produced from synthetic biology** (e.g., gene editing/modification).

#### (viii) Promote and Institutionalise a Security Culture to Prevent Biosecurity Threats

Low biosecurity awareness and a lack of a security culture create security challenges and vulnerabilities in ordinary laboratories (i.e., those not involved in research). Given the potential for "insider threats" as defined earlier (section 3.iv), AMS will benefit from **promoting and developing strict personnel reliability standards** in this regard to be rolled out across AMS. Such standards include comprehensive screening of personnel and compulsory training and retraining of staff. Also important are fostering positive workplace cultures; enhancing biosecurity awareness among staff and managers; promoting adherence to security protocols; detecting potential issues early; and preventing accidental releases from labs. Maintaining such standards can promote greater accountability for laboratory-related biosecurity within borders and prevent incidents of transnational threats, thus contributing to regional biosecurity. Future research can explore how Southeast Asian countries' biosecurity efforts can be upped to increasingly recognise **the importance of integrating social and cultural approaches** to effectively manage biological risks. These approaches involve engaging local communities, respecting cultural practices, and fostering public awareness about biosecurity threats.

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