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## **АСЕАН и законодательство в сфере биозащиты: опыт Юго-Восточной Азии**

**Н.Д. Осман, Н.З. Чоу Джен Т-чанг**

*Аннотация.* Вопросы биобезопасности, биозащиты и общественного здравоохранения сегодня регламентируются множеством правовых документов и норм. В статье рассматривается законодательная база, обеспечивающая биобезопасность АСЕАН, в том числе системную защиту от вирусов, болезней и организмов, потенциально опасных для здоровья человека, животных, растений и окружающей среды. В работе анализируются и определяются альтернативные методы управления этой сферой с помощью доктринальных правовых исследований. Парадигма биозащиты позволит государственным и коммерческим структурам лучше интегрироваться с различными инструментами защиты от пандемий и биологического оружия. В то же время все звенья, задействованные в регулировании, должны иметь общую основу или, возможно, специальный орган для координации работы всех акторов с целью предотвращения различных угроз в будущем. Предлагается разработать комплексный подход АСЕАН к вопросам биобезопасности, пандемии и биологического оружия. Общий стандартный протокол в регионе АСЕАН позволит обеспечить неограниченное передвижение людей, торговлю, туризм и другие услуги.

*Ключевые слова:* АСЕАН, биозащита, биобезопасность, экологическое право, общественное здравоохранение.

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## **ASEAN and Biosecurity Law: Experience of Southeast Asia**

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*Abstract.* A plethora of legal instruments and agencies currently control and enforce various biosafety, biosecurity and public health issues. This article proposes a regional ASEAN model of biosecurity

regulations that include viruses, diseases, and biological agents as potentially dangerous organisms to protect human health, animals, plants and the environment. This work analyses and defines alternative methods of biosecurity governance through doctrinal legal research. This biosecurity paradigm will enable these bodies and organisations to better integrate with the various instruments charged with controlling biosafety, biosecurity, pandemics, and bioweapons. All actors involved in regulating should have some common ground or perhaps a new different body to coordinate all the various threats in the future. It is proposed to develop an integrated ASEAN approach to biosecurity, covering biosafety, pandemic and biological weapons issues. Despite pandemics and other potential threats, a common standard protocol in ASEAN region will allow unrestricted movement of people, trade, tourism, and other services.

**Keywords:** ASEAN, biosecurity, biosafety, environmental law, public health.

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## Introduction

Biosecurity risks in a broad sense include the introduction or spread of harmful organisms to human, animal, and plant life, typically in the form of infectious diseases, lethal pathogens, toxins, and biochemical weapons. The recent COVID-19 pandemic has resulted in several achievements, quandaries, and challenges in combating the pandemic and other biosecurity issues. While the movement of people, goods, and services at the international ASEAN border has been hampered, many areas of international cooperation and economic aspects that have a significant impact on ASEAN have been halted, even though they are neighbouring countries. As a result, it is time for the ASEAN region to develop a biosecurity model that relies on shared resources and support rather than external input.

ASEAN was unable to impose a collective will on member states who disagreed on policies during the previous SARS crisis due to a lack of clear leadership. Most of the multilateral interaction occurred with ASEAN Plus Three, a coalition of China, Japan, and South Korea that utilised existing East Asian resources and protocols to combat the disease. Instead, ASEAN members concentrated on developing their policies for quarantine, international travel, and work suspension to limit the virus's spread within national borders.

During informal discussions on emerging regional biosecurity challenges, Southeast Asian participants expressed concerns about a perceived decline in the US interest in international programmes and global collaborations.

The ministries of defence, health, and foreign affairs of each ASEAN member state will need to coordinate the initiative. Diplomatic engagement is required for governments to communicate intentions, expectations, and decision-making mechanisms, which can strengthen non-governmental organisation input (NGOs).

Transparency and consistency in informing macro-policy decisions are enabled by data analytics and information-sharing protocols that strengthen ASEAN's response capabilities to naturally occurring or artificial biological threats. Efforts to standardise vaccine recognition and cross-border movement policies in health crises will benefit businesses and individuals dealing with the COVID-19 pandemic immediately. As the only developed country among ASEAN members, Singapore was asked to spearhead this initiative.

This ASEAN statement considers two major issues in biosecurity, highlighting ASEAN's reliance on superpowers. Another fact is that Singapore is frequently tasked with leading the way for the ASEAN region in science and technology, specifically biosecurity. As a result, this study proposes an ASEAN model of biosecurity while preparing for a future pandemic or similar threats. COVID-19 could be an excellent starting point for testing the water of ASEAN preparedness.

### Methodology

This study is conducted through a doctrinal type of research whereby desktop research is employed. The legal-doctrinal analysis is mainly to the primary and secondary sources of law, namely the statutes, acts, regulations, and case laws. The secondary sources that are being utilized are journal articles, reports, websites, magazines, and various materials. The focus of doctrinal legal research is on analysing legal rules, principles, or doctrines in contrast to non-doctrinal legal research, which focuses on the relationship of law to society, groups, and people. It entails an empirical investigation into the operation of law, specifically how the doctrine or principle has been adopted in real-world settings.

Thus, doctrinal legal research focuses on the letter of the law, whereas non-doctrinal legal research focuses on research about law, with the researcher interested in learning about the law in action. The former is known as armchair research or fundamental research, while the latter is known as empirical research. It starts with a proposition, then it moves to locate the law in statutes, judicial pronouncements, and discussions in commentaries, textbooks, journals, and debates. These sources will be read and analyzed thoroughly. Based on the analysis, the set of formulations is advanced, or the objective behind the proposition will be highlighted and proposed as what it should be<sup>1</sup>.

The doctrinal legal research has been redefined as 'doctrinal restatement' and 'recasting' as follows [Hutchinson, Duncan 2012].

1. Doctrinal Restatement.
2. Recasting Project.
3. Policy Analysis.
4. Test a proposition.
5. The study, Explain, and Assess Legal Institutions, Systems, or Institutional Actors.
6. Critical Projects.
7. Comparative and Historical Inquiries.
8. Jurisprudence, Philosophy of Law.
9. Combinations of any of those methods.

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<sup>1</sup> Ranbir Singh et.al. (n.d.). Qualitative and Doctrinal Methods in Research. Retrieved June 1, 2022. URL: [https://epgp.inflibnet.ac.in/epgpdata/uploads/epgp\\_content/law/09.\\_research\\_methodology/08.\\_qualitative\\_and\\_doctrinal\\_methods\\_in\\_\\_\\_research/et/8155\\_et\\_et.pdf](https://epgp.inflibnet.ac.in/epgpdata/uploads/epgp_content/law/09._research_methodology/08._qualitative_and_doctrinal_methods_in___research/et/8155_et_et.pdf) (accessed: 20.09.2022).

The doctrinal legal research in this study also applies social science research norms such as qualitative research, literature review, and content analysis. Nevertheless, the application of these methods is still subject to the legal primary and secondary sources of laws.

The finding of this research highlights some pertinent issues at hand, namely the achievements, challenges, and dilemmas faced by ASEAN countries in biosecurity.

### **Achievements**

While ASEAN has no ASEAN Biosafety Association, together with Asia Pacific countries the Organization has established Asia Pacific Biosafety Association (APBA). The full APBA membership can be illustrated as follows: Afghanistan, Australia, Bangladesh, Belgium, Benin, Brunei, Cambodia, Canada, Chad, Chile, China, Hong Kong China, Macau China, France, Germany, India, Indonesia, Ivory Coast, Japan, Kenya, Korea, Lao PDR, Malaysia, Mali, Mexico, Myanmar, Netherlands, New Zealand, Pakistan, Philippines, Singapore, Sri Lanka, Sweden, Switzerland, Thailand, Uganda, United Arab Emirates, United Kingdom, USA, Vietnam, and Zambia. APBA's goal is to provide a professional forum reflecting the regional interests and concerns of biological safety practitioners, as well as a platform for productive dialogue between the research world, governments, civil society, and the private industry.

Apart from APBA, ASEAN has its own Biosafety & Biosecurity Network, which served as a platform for sharing information, protocols, and documentation, as well as a pool of specialists for prospective cooperative actions across the ASEAN member states. This network is more focused on the lab and environmental biosafety, and biosecurity-related animals that cause a pandemic. It is hoped that in the future this scope should be widened to include bioweapon and possible bioterrorism.

In 2017–2018 Thailand launched the Biosafety Engineering and Control for Health Laboratories in ASEAN project as part of MBT Phase 1, which formed the foundation for key networking activities among ASEAN member states on enhancing biosafety and bioengineering in every country. It was regarded as one of the efforts to harmonise biosafety and biosecurity guidelines in ASEAN.

The International Federation of Biosafety Associations (IFBA) has collaborated with Global Affairs Canada and the ASEAN Secretariat to promote sustainable biosafety and biosecurity in Southeast Asian laboratories. This is for:

- increasing the number of certified professionals in the region who handle biological materials;
- developing cost-effective validation methods for biological safety cabinets in collaboration with the Asia-Pacific Biosafety Association and NSF International;
- creating institutional models for biorisk management that are based on local resources<sup>2</sup>.

### **ASEAN and Canada**

ASEAN maintains a strong relationship with Canada concerning biosafety and biosecurity as they are important components of Canada's commitment to the Global Health Security Agenda's

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<sup>2</sup> IFBA in the ASEAN Region. URL: <https://internationalbiosafety.org/program-activities/biosafety-and-public-health-2-copy/> (accessed: 20.09.2022).

biosafety and biosecurity (Prevent-3) Action Package and efforts to mitigate biological threats in the ASEAN region. Consequently, an agreement was made at the ASEAN-Canada Global Partnership Program Forum in Lao capital Vientiane in 2017.

The agreement also intends to strengthen global health security as a global top priority, as well as to build capacity forward into successful integration of the World Health Organization's (WHO) International Health Regulations 2005 (IHR), the World Organization for Animal Health's (OIE) Performance of Veterinary Services (PVS) pathway, as well as other relating global health security frameworks.

The goal of Action Package Prevent-3 (APP3) is to promote national biosafety and biosecurity by providing tools and training for developing, implementing, and maintaining national biosafety and biosecurity frameworks and monitoring supervision systems<sup>3</sup>.

Furthermore, ASEAN successfully developed ASEAN Strategy for Exotic, Emerging, Re-emerging Diseases and Animal Health Emergencies, which was finalized in May 2021.

### **ASEAN Plus 3 – China, Korea, and Japan**

Apart from ASEAN members, there were ASEAN Plus 3 collaborations with China, South Korea and Japan in curbing communicable diseases and pandemic preparedness and response. There were achievements made in implementing the Year 1 Action Plan (July 2007-June 2008) of the ASEAN Plus Three Emerging Infectious Diseases (EID) Program, which aims to improve regional contingency planning and capabilities through integrated approaches to prevention, surveillance, and timely response to emerging infectious diseases such as SARS and avian influenza.

The ASEAN Plus Three Cooperation in Health includes policy coherence for health and social welfare development concerning public health issues.

China, for example, supported regional activities and ASEAN capacity building in communicable disease prevention and control, traditional medicinal resources, laboratory diagnosis, and food safety.

Government of Japan supported the ASEAN-Japan Project on Regional Stockpiling of Oseltamivir (Tamiflu), which provided 500 000 courses and Personal Protective Equipment (PPE) for 700 000 people against a potential influenza pandemic, as well as 500 000 courses of antivirals for country-level stockpiling for rapid response and rapid containment purposes.

Phase 2 of the ASEAN-Republic of Korea Home Care for Older Persons Agreement focuses on providing care to older people by utilising untapped resources such as older people themselves and communities. The Ministers acknowledge HelpAge Korea's proposal to extend Phase 3 of the project from 2009 to 2012<sup>4</sup>.

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<sup>3</sup> ASEAN to strengthen cooperation in bio-safety and bio-security. Xinhua. 15 March 2017. URL: [http://www.xinhuanet.com/english/2017-03/15/c\\_136131852.htm](http://www.xinhuanet.com/english/2017-03/15/c_136131852.htm) (accessed: 20.09.2022).

<sup>4</sup> Joint Statement of the Third ASEAN Plus Three Health Ministers Meeting Manila. The ASEAN Secretariat. URL: <https://asean.org/joint-statement-of-the-third-asean-plus-three-health-ministers-meeting-manila/> (accessed: 20.09.2022).

## ASEAN and the United States

The Southeast Asia Strategic Multilateral Biosecurity Dialogue was held with the participation of Indonesia, Malaysia, the Philippines, Singapore, Thailand, and the United States. Following the COVID-19 pandemic, this meeting took place to discuss each country's biosecurity capabilities and limitations in public health issues. Countries have revised COVID-19 regulations, restrictions and policies, as well as their biosecurity system, in preparedness for the introduction of vaccines in late 2020, first for high-priority groups, then for the public. This was a coordinated work of ideas from all countries attempting to effectively implement it [Health Security 2019].

These are among the forum on strengthening biosecurity in the ASEAN region.

### ASEAN individual country's biosafety/biosecurity laws

Next, we should look at each country in strengthening biosafety and biosecurity efforts.

*Malaysia.* Next, the discussion focuses on every 10 countries' different biosafety and biosecurity laws. Malaysia for instance enforced the Prevention and Control of Diseases Act 1988 (Act 342), COVID-19 Regulations 2020/2021, and the Police Act 1967 (Act 344) for the control of COVID-19. The former gives a wider power to the Ministry of Health, whereas the latter gives the police the power to control the movement of people that in consequence affects the movements of goods and services, within and outside Malaysia. Malaysia is in the process of enacting the biosecurity act to regulate the bioweapon rules as part of the compliance towards being a member of the Biological Weapons Convention. Malaysia as part of the compliance with Cartagena Protocol on Biosafety on the transboundary movement of living modified organisms (LMO) has enacted Biosafety Act 2007 (Act 678).

*Singapore* has a more comprehensive law in regulating both biosafety and biosecurity issues – the Biological Agents and Toxins Act (BATA) (Act 36) was passed in 2005. BATA 2005 is a law that prohibits or regulates the ownership, use, import, transshipments, transfer, and transit of biological agents, inactivated biological agents and toxins, as well as providing for safe handling standards. The goals are to include avoiding acts of bioterrorism, fostering a strong national biosafety culture, and assisting Singapore's growing bioscience industry [Tun, Sadler, Tam 2007].

*Brunei* seems to have its comprehensive system of biosecurity in place. The objectives of the Biosecurity Division, Department of Agriculture, and Agri-food are as follows:

- to safeguard the economy, the environment and local agricultural production, as well as social amenity and human health from exotic plant and animal pests and diseases;
- to improve pre-border, border and post-border sanitation and phytosanitary measures (SPS);
- to facilitate the agricultural trade by providing an internationally recognised certification service.

The biosecurity divisions seem to cover the essential elements of biosecurity, namely border control, plant, animal, and data<sup>5</sup>.

The report on the Joint External Assessment (JEE) of the main capabilities of the International Health Regulations (IHR) states says that Brunei Darussalam is able to protect, detect and respond to threats to public health (which may be biological, chemical or radiological in nature), as well as a

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<sup>5</sup> Biosecurity Division, Department Of Agriculture And Agrifood. Department of Agriculture and Agrifood Brunei. URL: <http://www.agriculture.gov.bn/SitePages/Biosecurity.aspx> (accessed: 20.09.2022).

joint review of the country in the report on the Joint External The Assessment (JEE) of the basic capabilities of the International Health Regulations (IHR) <sup>6</sup>. This shows Brunei's commitment to the wider spectrum of biosafety and biosecurity issues.

*Indonesia* has also published a report on the status of biosafety and biosecurity implementation in health laboratories, as well as its level of capacity in this field since 2005. In terms of the various regulations and laws currently in place, this research has focused on the Joint External Evaluation Tool and their priority actions to finalise a broader National Strategic Plan for biosafety and biosecurity in Indonesian laboratories. It also discusses how to improve coordination and collaboration among stakeholders such as the ministries of health, agriculture and defence, among others.

Among many of the activities undertaken in this regard are biosafety and biosecurity training, the development of a national biorisk strategy plan, a meeting on biorisk dissemination to the Indonesian EID laboratory network, the development of a national standardisation on biosafety laboratories, and the TOT Biosafety Implementation and Biorisk Analysis<sup>7</sup>.

*Cambodia*. The Laboratory Biosafety and Biosecurity Legislation Workshop Strengthening laboratory capacities are a multi-step process that frequently includes workforce training, the implementation of new diagnostics, and the development of laboratory protocols. In November 2017, the Cambodian Ministry of Health (MOH) laboratory leadership collaborated with technical experts from CGH, the CDC's National Center for Emerging and Zoonotic Infectious Diseases, and CDC Cambodia to facilitate a workshop aimed at strengthening biosafety and biosecurity practises across Cambodia's national laboratory network.

Technical experts from the CDC and Cambodia's public health system participated in this successful workshop and subsequent ongoing collaboration. A Prakas is a ministerial proclamation that establishes policies and procedures within its facilities. When passed, the Prakas will be the first regulation created by the Cambodian Ministry of Health to improve laboratory safety involving the possession, use, storage, and transfer of dangerous biological pathogens in Cambodian public health laboratories<sup>8</sup>.

*Myanmar*. Myanmar has recently increased its efforts to join and ratify several international agreements as it continues its political and economic liberalisation. It ratified the Biological and Toxin Weapons Convention (BTWC) in December 2014 and the Chemical Weapons Convention in July 2015. Recognizing that biosecurity is becoming a major international issue and exploring avenues for collaboration will allow Myanmar to benefit from pooled resources and expertise in identifying issues, weak points, and opportunities. Myanmar aspires to achieve universal health coverage by 2030, and the expansion of public health infrastructure to achieve this goal can include guidelines and resources that can be quickly mobilised in the event of a biosecurity emergency.

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<sup>6</sup> 2020 United Nations High Level Political Forum on Sustainable Development. Voluntary National Review Report of Brunei Darussalam. URL: [https://sustainabledevelopment.un.org/content/documents/26412VNR\\_2020\\_Brunei\\_Report.pdf](https://sustainabledevelopment.un.org/content/documents/26412VNR_2020_Brunei_Report.pdf) (accessed: 20.09.2022).

<sup>7</sup> Kementerian Kesehatan Republik Indonesia. Current State of Biosafety and Biosecurity Regulatory Framework in Indonesia. URL: <https://www.kemkes.go.id/index.php?lg=LN02> (accessed: 20.09.2022).

<sup>8</sup> CDC in Cambodia – Strengthening laboratory biosafety and biosecurity through legislation. CDC Cambodia. 5 April 2018. URL: [https://www.cdc.gov/globalhealth/stories/strengthening\\_laboratory\\_biosafety.html](https://www.cdc.gov/globalhealth/stories/strengthening_laboratory_biosafety.html) (accessed: 20.09.2022).

Because of the staggering number of people affected each year, the focus in health will be on familiar communicable diseases<sup>9</sup>.

*The Philippines* has its own national Biosafety Framework Project (NBFP). The primary goal of the Philippines National Biosafety Framework Project (NBFP) is to evaluate/review existing national policies on modern biotechnology/biosafety and to integrate, update and/or revise these policies to produce an NBF that is consistent with the relevant provisions of the Cartagena Protocol on Biosafety. As a result, the nation will be better equipped to meet its commitments under the Protocol, once it is ratified<sup>10</sup>.

The National Training Centre for Biosafety and Biosecurity (NTCBB) was established in February 2018. It is the newest Centre formally established under the NIH and approved by the UP Board of Regents. The NTCBB is the Philippines' first biosafety and biosecurity training centre, promoting and developing biorisk management principles in various institutions to ensure the safety of all laboratories and other institutions that handle biological hazards across the country.

The Centre aspires itself as a source of relevant information and expertise related to biosafety and biosecurity practice in the Philippines, as a potential for training for biosafety and biosecurity practitioners in the Philippines, and as the country's focal training centre that will link with counterpart organisations globally.

As the COVID-19 pandemic continues to claim lives and devastate the country's healthcare system, the Centre undertook and led free biosafety pieces of training online to educate lab technicians and healthcare workers on the importance of biorisk management when handling COVID-19 samples<sup>11</sup>.

*Vietnam* has laboratory guidelines that have been enforced by the government for years, such as the List of Infectious Microorganisms and Requirements of a Biosafety Laboratory. In 2011, biosafety and biorisk assessments were performed in selected BSL2 laboratories in Vietnam to update biosafety procedures and practises, along with decontamination and infectious waste management.

In addition, risk assessment and quality control were implemented in 2012 for assessing national-level response and external quality assurance (EQA). There is also a report on International Health Regulation (IHR) regarding Vietnam biosafety, as well as some other legislation enacted to protect human life from many diseases around the world [Sandia National Laboratories 2018].

In *Thailand* the biological safety cabinets (BSCs), as stated by the Director-General, are the primary engineering control for minimising exposure to potentially infectious materials, as well as the containment device required to protect workers, products and the environment. The BSC must be maintained and re-certified regularly to ensure that the equipment works properly<sup>12</sup>.

*Lao People's Democratic Republic* (Lao PDR) has its own set of National Biosafety Regulations, which establishes biosafety and biosecurity guidelines for all laboratories, and

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<sup>9</sup> Wai K.S. (2016). Bolstering Myanmar's biosecurity. Bangkok Post. 5 January. URL: <https://www.rsis.edu.sg/media-highlight/rsis/bolstering-myanmars-biosecurity/> (accessed: 20.09.2022).

<sup>10</sup> Developing the National Biosafety Framework for the Philippines. Department of Environment and Natural Resources Protected Areas and Wildlife Bureau. URL: <https://bch.cbd.int/en/database/41666> (accessed: 20.09.2022).

<sup>11</sup> National Training Center for Biosafety and Biosecurity. National Institutes of Health. URL: <https://nih.upm.edu.ph/institute/national-training-center-biosafety-and-biosecurity> (accessed: 20.09.2022).

<sup>12</sup> The Department of Medical Sciences promotes health laboratory capacity building for ASEAN in responding with highly pathogenic infection and life threatening agents. Department of Medical Sciences, Ministry of Public Health, Thailand, 2017. URL: <https://www3.dmsc.moph.go.th/en/post-view/128> (accessed: 20.09.2022).



National Quality Standards. These standards apply to all aspects of laboratory operations and management, from personnel competencies to equipment quality. Laos PDR was thankful to the US Defense Threat Reduction Agency for their assistance in developing these critical documents.

As the same goes for other ASEAN countries according to the 2021 Global Health Security Index, Laos also reports biosafety issues. This document is a collection of all questions, justifications, and sources used to calculate Laos's 2021 Global Health Security Index scores, particularly in biosafety. This report discussed the availability of any biosafety research, legislation, biosafety enforcement, and the government's biosafety efforts.

From each individual ASEAN 10 countries report, it seems that every country has its capacities, biosafety and biosecurity regulations to comply with the intended international obligations that they wish to sign or ratify. This could be summarised as follows (pic. 1).

COUNTRY	CARTAGENA PROTOCOL ON BIOSAFETY 2000	BIOLOGICAL WEAPON CONVENTION 1972	WHO INTERNATIONAL HEALTH REGULATIONS 2005
MALAYSIA	/	/	/
SINGAPORE	X	/	/
BRUNEI	X	/	/
INDONESIA	/	/	/
CAMBODIA	/	/	/
MYANMAR	/	/	/
PHILLIPINES	/	/	/
VIETNAM	/	/	/
THAILAND	/	/	/
LAOS	/	/	/

**Pic. 1.** ASEAN countries membership status towards important international biosafety/biosecurity/public health agreements.

*Source:* Biological Weapons Convention Signatories and States-Parties. Arms Control Association. URL: [https://www.armscontrol.org/factsheets/bwcsig#:~:text=The%20Biological%20Weapons%20Convention%20\(BWC,So uth%20Sudan%2C%20and%20Tuvalu\)](https://www.armscontrol.org/factsheets/bwcsig#:~:text=The%20Biological%20Weapons%20Convention%20(BWC,So%20uth%20Sudan%2C%20and%20Tuvalu)) (accessed: 20.09.2022); Parties to the Cartagena Protocol and its Supplementary Protocol on Liability and Redress. URL: <https://bch.cbd.int/protocol/parties>(accessed: 20.09.2022) ; International Health Regulations. URL: [https://www.who.int/health-topics/international-health-regulations#tab=tab\\_1](https://www.who.int/health-topics/international-health-regulations#tab=tab_1) (accessed: 20.09.2022); World Health Organisation: Countries. URL: <https://www.who.int/countries> (accessed: 20.09.2022).

However, they encountered some dilemmas in achieving the biosafety/biosecurity goals and objectives.

### Dilemmas

Perhaps, the main dilemmas apart from different capacities in biosafety/biosecurity among ASEAN member states, are the various levels of relationships with the superpowers such as the United States, China, and the European countries, especially during COVID-19.

ASEAN countries have been criticised as retreated from multilateralism by withdrawing from regional institutions and concentrating on national policy responses such as lockdowns and secure borders. ASEAN's collective ability to address member states' security has been put to the test.

Singapore, for instance, as a regional economic leader, has been suggested to assume a larger role in initiatives to strengthen ASEAN's capacity for multilateral biosecurity engagement to implement successful prevention and response mechanisms, as non-traditional threats (such as the pandemic) have repeatedly tested the region's resilience.

It is suggested that regional self-sufficiency in biosecurity should be achieved by a design of a biosecurity model that is not reliant on external input but instead makes use of common resources and support. It was reported that Southeast Asia has a long history of insufficient regional capacity to combat the spread of infectious diseases, which has hampered the region's development. Instead, ASEAN members concentrated on developing their policies for quarantine, international travel, and work suspension to limit the virus's spread within national borders. These were the dilemma faced by the ASEAN member countries.

The Southeast Asia Strategic Multilateral Dialogue on Biosecurity priorities, which was established in 2014, was held to discuss the challenges and developments related to biosecurity risks in Southeast Asia [Cicero et al. 2019]. Concerning ASEAN and the United States, discussions focused on mechanisms for detecting, mitigating and responding to biosecurity risks, as well as emphasising biosecurity issues for national leadership. Participants also recognized factors that could boost regional and global biosecurity, such as increased engagement and collaboration throughout relevant ministries and agencies, financially viable funding for biosecurity programmes, improved information sharing for communicable diseases, and increased participation in international biosecurity forums. This shows that the public health-related threats have been earlier identified by this medium of dialogue. Only effective and reliable strategies and plans of action were to be harmonised across the ASEAN member states.

The United States has lent a generous hand in supporting ASEAN in combatting COVID-19. In this regard, 23 million vaccine doses and over \$158 million in an emergency have been spent provided to ASEAN.

As for China, ASEAN – China have issued a Joint Statement on Cooperation in Support of the ASEAN Comprehensive Recovery Framework at the 24th ASEAN-China Summit<sup>13</sup>. In this regard, China has expressed its commitment to strengthen the cooperation with ASEAN on public health.

ASEAN governments are said to have more clout in dealing with potential quandaries because of the competition between the United States and China, which has been on display in the tumultuous vaccine diplomacy of the past year<sup>14</sup>.

Team Europe has been supporting ASEAN in COVID-19. European Union (EU) for instance invested €3, 5 million (5, 65 billion MMK) in biosecurity in Southeast Asia<sup>15</sup>.

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<sup>13</sup> ASEAN-China Joint Statement on Cooperation in Support of the ASEAN Comprehensive Recovery Framework. ASEAN. 26.10.2022. URL: <https://asean.org/asean-china-joint-statement-on-cooperation-in-support-of-the-asean-comprehensive-recovery-framework> (accessed: 20.09.2022).

<sup>14</sup> Now is the time for Singapore to lead regional biosecurity efforts. URL: <https://southeastasiaglobe.com/now-is-the-time-for-singapore-to-lead-regional-biosecurity-efforts/> (accessed: 20.09.2022).

<sup>15</sup> Team Europe COVID-19 response: EU announces €20 million to support health systems in ASEAN. European Commission. URL: [https://ec.europa.eu/commission/presscorner/detail/lv/ip\\_20\\_2242](https://ec.europa.eu/commission/presscorner/detail/lv/ip_20_2242) (accessed: 20.09.2022).

Russia would like to exchange experience on the practical aspects of combating infectious diseases with interested countries. Kremlin has also expressed the initiatives to broaden the training programme for ASEAN epidemiologists at the Vladivostok Research Centre of Biosecurity in the Asia-Pacific region<sup>16</sup>.

Whilst all these dilemmas, due to the different parties involved, conflicting factors and interests, as far as the ASEAN region is concerned, the benefits from these good and harmonious relationships should be reaped and put aside all possible differences. This will benefit not only the individual ASEAN countries but the entire region during these COVID-19 difficult times.

### Challenges

Despite all these achievements and challenges, there were some known difficulties in regulating this immense aspect of biosecurity. The worldwide biological threat is exacerbated by the possibility of rogue nations and/or terrorists using biological agents as weapons of war on purpose. Any recourse to a biological agent (whether explicit or subtle) could have disastrous consequences for public health or the environment. Because infectious disease knows no borders, ensuring good, comprehensive biosecurity to detect unauthorized possession, loss, theft, misuse, diversion, or intentional release of biological agents and toxins is a collaborative effort at the international level [Bakanidze, Imnadze, Perkins 2010].

To begin, the definition of biosecurity at the national and international levels is ambiguous and limited. The above-mentioned broad definition of biosecurity could include animal health, human or public health, food, and the environment, whereas the definition of biosecurity only extends to biological weapons and the related convention, which some countries must comply with. The main international agreements that regulate biosecurity are the Biological Weapons Conventions 1972 and United Nations Security Council Resolution 1540 (2004). The Biosafety definitions at the international and national levels mostly refer to living-modified organisms (LMO) or genetically modified organisms (GMO), as stated in the Cartagena Protocol on Biosafety. However, the COVID-19 pandemic, which has affected public health, has broadened the scope of perception toward the conception of biosafety and biosecurity.

Because of these specific definitions of biosafety and the various international agreements that govern the various bodies/agencies, the definition and scope between biosafety and biosecurity will become a pressing issue. In a broader sense, biosafety refers to the intentional release of organisms from a contained environment, such as a laboratory. Meanwhile, biosecurity refers to the unintentional release of pathogenic organisms. COVID-19 as declared by WHO as a pandemic is also part of a biosecurity issue. But the virus as part of the pandemic is under WHO International Health Regulation (pic. 2).

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<sup>16</sup> East Asia Summit. President of Russia. URL: <http://en.kremlin.ru/events/president/news/67010> (accessed: 20.09.2022).

	WHO International Health Regulations (2005)	UN Security Council Resolution 1540 (2004)	Biological Weapons Convention (1972)
<b>Applicability:</b>	All 192 UN Member States	All 192 UN Member States	163 States Parties
<b>Purpose:</b>	"to prevent, protect, protect against, control and provide a public health response to the international spread of disease..."	To prohibit <b>non-State actors</b> from developing, acquiring, manufacturing, possessing, transporting, transferring or using nuclear, chemical or biological weapons and their delivery systems.	To prohibit the development, production, acquisition, transfer, stockpiling and use of biological and toxin weapons
<b>Requirements:</b>	8 core capacities "to detect, assess, notify, and report events" [Laboratory core capacity includes biosafety / biosecurity]	Domestic controls to prevent the proliferation of nuclear, chemical and biological weapons, their means of delivery, and related materials	Any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, retention, transfer or use of biological weapons
<b>Entry into force:</b>	15 June 2007	28 April 2004	26 March 1975
<b>Mandated reporting / where / when:</b>	Status of implementation / WHO/"As soon as possible but no later than five years from entry into force ..."	Status of implementation / 1540 Committee / "without delay"	None* "CBM voluntary reporting/ BWC ISU/ annually by 04/15"

**Biosafety / Biosecurity**

**Pic. 2.** WHO International Health Regulation.

Source: [Bakanidze, Imnadze, Perkins 2010].

### **Adopted ASEAN laws and organisations in the field of biosafety/biosecurity**

It is important to highlight here that the fundamentals of most ASEAN laws differ from European laws, as they resemble a more rules-based order [Hsien-Li 2021]. The same applies for the adopted laws in the field of biosafety/biosecurity and organizations working in the field in ASEAN countries. The biosafety/biosecurity laws are very much dependent on the individual countries' compliance towards the related international conventions and agreements as shown in Pictures 1 and 2 above. In the Southeast Asian region, ASEAN develops a more detailed policy guidelines, for instance, ASEAN Guidelines on the Regulation, Use and Trade of Biological Control Agents (BCA) (2014) for harmonisation among ASEAN countries. There is no single ASEAN body that regulates biosafety/biosecurity aspects but rather several organisations/institutions. It is important to note here that regional cooperation such as within ASEAN must be driven by countries rather than by an externally imposed agenda. As a result, for many countries, initial attempts at regional cooperation have taken the form of regional meetings to identify potential areas for collaboration [Segger et al. 2013].

### **ASEAN latest cooperation with partners on biosafety/biosecurity**

As part of ASEAN cooperation with partners (Plus Three in this case) the work plan strengthens cooperation in public health through combating the COVID-19 pandemic in the region and mitigating its socio-economic impacts. Among others, we should mention the establishment of the ASEAN Centre for Public Health Emergencies and Emerging Diseases (ACPHEED), the COVID-19 ASEAN Response Fund, the ASEAN Regional Reserve of Medical Supplies for Public Health Emergencies (RRMS), the ASEAN Comprehensive Recovery Framework (ACRF) and its

Implementation Plan, and the ASEAN Strategic Framework for Public Health Emergencies, encouraging further consultation on the APT Reserve of essential Medical Supplies (APT RMS) for public health emergencies.

### **Mitigation of Biological Threats in the ASEAN Region Phase II Project**

This assistance activity aims to strengthen ASEAN member states' capacities to address critical vulnerabilities and essential regional capacities to prevent, detect, and respond to a variety of biological threats. Specific initiatives concentrate on:

- increasing regional capacity to respond to health-security threats;
- increasing the capacity and effectiveness of biosafety and biosecurity systems;
- expanding the network of ASEAN Emergency Operations Centres;
- increasing regional capacity for big data analytics and visualization in disease surveillance;
- ASEAN Secretariat's health-security interface capacity is being strengthened.

This project started in 2019 and will soon end in December 2022.

### **Suggestions and Recommendations**

This paper suggests the ASEAN Model of Biosecurity Law. It is proposed that the ASEAN regional biosecurity model includes viruses, illnesses, and biological agents as potentially dangerous organisms for the protection of human health, animals and plants, as well as food and the environment. In furtherance of these aims, there should be biosecurity governance strategies to better safeguard human health and the environment. It is hoped that the ASEAN biosecurity paradigm would provide future solutions not only for pandemics but also for biological and hazardous materials, as well as any other future threat, allowing for more extensive safeguards.

As highlighted above, as there were various sources of powers and organisations involved in regulating, they should have some common ground or perhaps a new different body to coordinate all potential threats.

Thus, the efforts in developing a conceptual model for the integration of biosecurity sectors are crucial. ASEAN integrated biosecurity approach with coverage of biosafety, biosecurity, pandemics, and bioweapons. In that biosecurity aspect, it will improve international and regional cooperation and coordination.

Despite pandemics and other possible threats, a uniform standard protocol could be beneficial for the whole ASEAN region, as it would allow unrestricted movement of people, trade, tourism, and other services in the future.

### **Conclusion**

Rather than taking an international legal approach, it is recommended that a regional integrated biosecurity strategy to be established, including biosafety, biosecurity, pandemic, and bioweapons coverage. A regionally integrated biosecurity approach, by contrast, would make it easier to implement in ASEAN countries. This is for international collaboration and coordination at the regional level.

As noted previously, it appears that various problems will be encountered in developing the conceptual model of biosecurity, such as the involvement of several ministries, as well as the

involvement and enforcement of various laws and regulations. As a result, it is proposed that a new biosecurity policy to be developed and implemented.

An integrated biosecurity framework or biorisk assessment and management that can reach across all relevant ministries is another option that may provide more flexibility than the hard rule. To create a viable integrated biosecurity body, a single body with single comprehensive legislation that can combine pandemic, biosecurity, biosafety and bioweapons should be created.

Nevertheless, in terms of governance, a smart regulatory strategy such as licencing, self-regulation, and so on should be used in addition to the command-and-control method supported by appropriate ministry rules. It is essential to devise a methodology for biorisk assessment and management that takes socioeconomic as well as bioethical factors into account. In the event of a state of emergency, which would render several laws impracticable and ineffective, as happened during the COVID-19 pandemic, this method will strengthen the new biosecurity law. As a result, once in place, these biosecurity mechanisms could offer a more flexible strategy and structure.

At the international level, some model national biosecurity laws could be adopted by the ASEAN region. For instance, there is the One Health concept developed by the WHO in integrating safety protection across animals, humans, and the environment (pic. 3).



**Pic. 3.** One Health Idea.

*Source:* One Health Graphics. URL: <https://www.cdc.gov/onehealth/resource-library/one-health-graphics.html> (accessed: 20.09.2022);

One Health. URL: <https://www.who.int/news-room/q-a-detail/one-health> (accessed: 20.09.2022).

China has already passed its Biosecurity law in October 2020. The biosecurity law contains ten chapters and 88 articles and calls for the establishment of 11 basic systems for biosecurity risk prevention and control, including biosecurity risk monitoring and early warning, risk investigation and assessment, information sharing and information release<sup>17</sup>.

<sup>17</sup> China's Biosecurity Law goes into effect. Xinhua. 15.04.2021. URL: [http://www.xinhuanet.com/english/2021-04/15/c\\_139882718.htm](http://www.xinhuanet.com/english/2021-04/15/c_139882718.htm) (accessed: 20.09.2022).

Australia enacted its Biosecurity Act 2015 to control illnesses and pests that may affect human, animal, or plant health or the environment [Australian Biosecurity Act, 2015]. Whereas biosecurity legislation in New Zealand creates a legal framework to help prevent hazardous organisms out of the nation by responding to and regulating them if they do get in, it covers pre-border risk management, standardisation, readiness, and border management response, as well as long-term pest control<sup>18</sup>.

In conclusion, the ASEAN model of biosecurity laws is timely to be developed, considering that COVID-19 has become endemic, but other pandemics might be taking place in the future. Regardless of whether ASEAN should develop based on which model, it should suit the requirements, nature, infrastructure, and reality of the ASEAN region.

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<sup>18</sup> New Zealand Biosecurity Act. URL: <https://legislation.govt.nz/act/public/1993/0095/latest/whole.html> (accessed: 20.09.2022).