Biosecurity-by-Design to Safeguard Emerging Bioeconomies

INTEGRATING BIOSECURITY CONSIDERATIONS INTO THE COMPLETE BIOTECHNOLOGY INNOVATION AND DEVELOPMENT PIPELINE

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Executive Summary

Rapid advances in bioscience research have the potential to drive sustainable economic development and growth. However, the safe and thoughtful scale-up of biotechnology is essential to mitigate potential risks. We conducted a literature review, consulted subject matter experts, and analysed data from the Global Health Security Index (GHSI) to propose a set of policy approaches to reinforce biosecurity norms at every stage of research and development (R&D). We recommend a biosecurity-by-design approach, which integrates biosecurity into the design of research projects and across the R&D pipeline without hampering innovation. First, we suggest incorporating biosecurity-by-design as part of a culture of responsibility among scientific communities. Fostering a culture of responsibility has been a consistent biosecurity theme over recent decades, and focusing efforts here could propagate a global and standardised code of conduct for scientists as new bioeconomies emerge and grow. Second, targeting the private sector, we encourage using market levers to incentivise biosecurity in the design of products. This should ensure biosecurity is built into the initial stages of product conceptualisation and becomes an integral part of innovation. Finally, we encourage leveraging existing international venues, such as the Biological Weapons Convention (BWC), to target governments globally. This aims to promote international norms and values among stakeholders involved in bioeconomy development. Taking this broad view is essential to capture the entire research pipeline and include the various stakeholders involved in biosecurity, from individual scientists to private industry to governments. Biosecurity must be seen as an intrinsic part of sustainable innovation (as opposed to a threat to growth) and a critical component of a prosperous global bioeconomy.

Background

THE RISE OF THE GLOBAL BIOECONOMY

Globally, nations are increasingly investing in the promise of the bioeconomy, and at least 50 countries have adopted new bioeconomy strategies or policies in the past decade (**Figure 1**).[1–3] The term *bioeconomy* has historically had an inherent sustainability focus, referring to a push toward circular economies that use renewable biological resources and reduce reliance on fossil fuels.[4] The bioscience landscape has dramatically transformed in the past two decades, driven by breakthroughs in genetic engineering and the advent of synthetic biology.[5, 6] These advances have given rise to a new *emerging bioeconomy*—economic activity driven by biotechnology across all sectors, including human health, agriculture, manufacturing, and the environment.[7] During the next 10 years, global bioeconomic activity is estimated to have a direct economic impact of up to US$4 trillion annually.[8] Moreover, biotechnology is predicted to be a key driver of the Fourth Industrial Revolution, which according to the chair of the World Economic Forum, will involve the "fusion of technologies […] blurring the lines between the physical, digital, and biological spheres."[9]

Public investment and national commitments have substantially increased to realise the opportunities of the emerging bioeconomy. In 2013, the UK government announced its intention to become a world leader in synthetic biology, investing £60 million in additional funding.[10] The European Union (EU) has also made substantial commitments, with €10 billion proposed for investment in food and natural resources in the bioeconomy, 10 percent of the total Horizon Europe budget (2021–2027).[11] Malaysia is also strategically developing its bioeconomy, which comprised 13.4 percent of the national gross domestic product (GDP) in 2010[12] and is projected to grow 15 percent annually to 2030.[13] Similarly, Brazil's bioeconomy could generate US$284 billion annually by 2050, accounting for 67 percent of its total GDP.[14, 15] Furthermore, the publication of an East African Regional Bioeconomy Strategy in 2022 demonstrates a commitment to bioeconomic development.[16] The Partnerships for African Vaccine Manufacturing (PAVM) Framework for Action, for instance, aims to increase local vaccine production from currently less than 1 percent of vaccines produced in the region to 60 percent by 2040, aiming to create up to 14,000 full-time jobs, with 40 percent of new trainees being female.[17, 18]

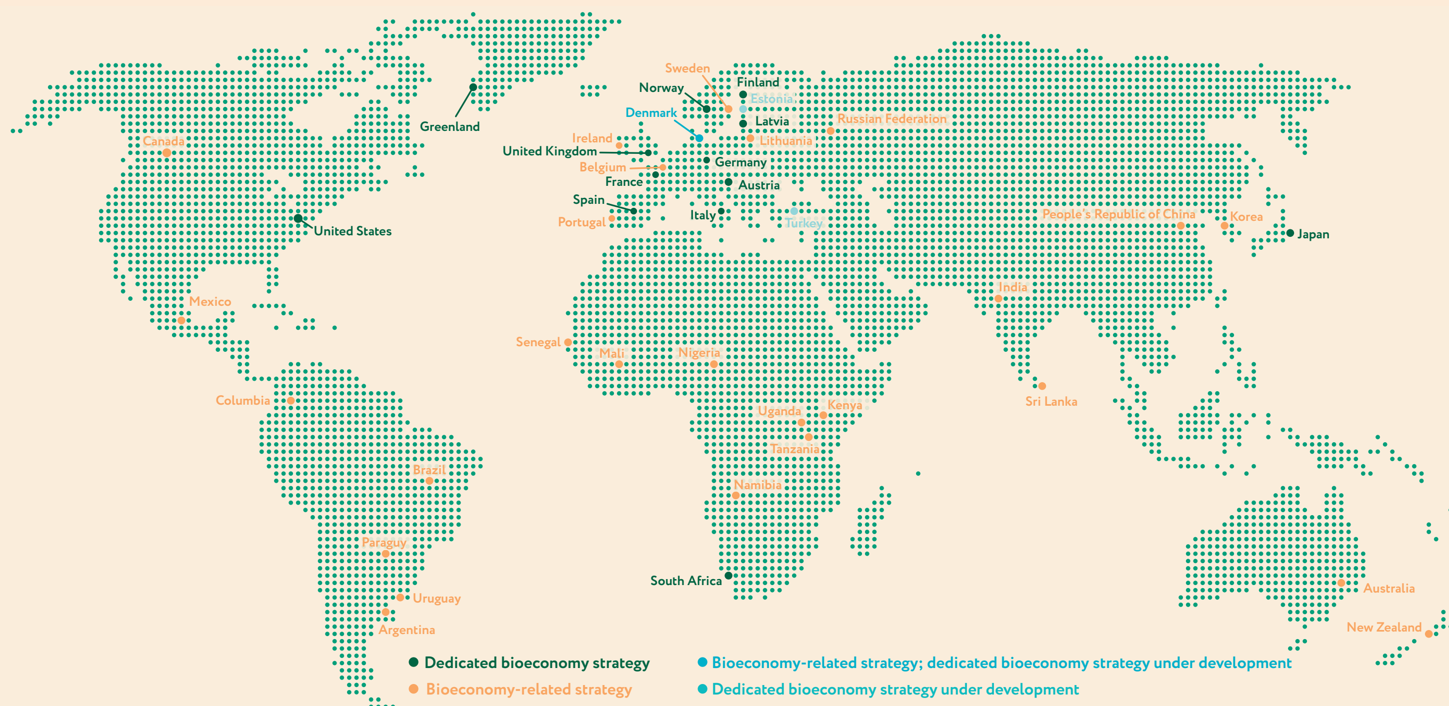
A country's bioeconomic activity often draws on locally available natural resources. For example, Thailand's bioeconomy strategy promotes using sugarcane and cassava for valorisation to products such as bioplastics and biofuels.[19] Furthermore, as the most biodiverse region of the world, Latin America's main ecosystem services are estimated to have an economic value of US$15.3 billion. Varying foci in bioeconomic activity, therefore, result in different definitions of the bioeconomy. For example, the European Commission broadly defines *bioeconomy* as using "renewable biological resources from land and sea, like crops, forests, fish, animals and microorganisms to produce food, materials and energy."[11] However, the EU definition fails to capture the influence of recent biotechnological advances that have propelled significant public investment, as well as growing investments from the private sector.

Private sector interest in the commercial potential of biotechnology is illustrated by the stark rise in entrepreneurial activity in this area. Global venture capital investment into the biotechnology sector increased sixfold to US$19 billion from 2010 to

2019.[20] During the same time frame, private sector biotech R&D investment in the United States tripled to reach US$88 billion and, in 2022 alone, the 11 largest pharmaceutical companies invested US$104 billion into biotech R&D.[21,22] The scale of private sector interest and investment in the industry is becoming increasingly significant, with private sector companies becoming key stakeholders within the bioeconomy.

Given these advances and increased global investment in bioinnovation, the bioeconomy warrants a new working definition. **We define the emerging bioeconomy as encompassing economic activity arising from bioscience R&D and innovation across sectors, enabled by advances in technology.** This also encompasses economic activity arising from intersections with other emerging technologies that further catalyse

FIGURE 1. Countries are increasingly publishing bioeconomy strategies, demonstrating the rise of the global bioeconomy.



Note. Countries that have a dedicated bio economy strategy (dark green), a bioeconomy-related strategy (orange), a bioeconomy-related strategy with a dedicated bioeconomy strategy in development (blue), or a dedicated bio economy strategy in development (light blue). Adapted from Gardossi et al. (2023).[1]

biotechnological innovations, such as computing and engineering. These activities have the potential to significantly foster economic growth and development; contribute to sectors such as health, food, energy, and manufacturing; and promote ecological, social, and economic sustainability.

EXPANSION OF THE BIOECONOMY MAY CHANGE THE RISK LANDSCAPE

The rapid scale-up of biotechnology research can pose unique risks. One such risk is the accidental release of biological agents, which may become more likely with expanding laboratory and manufacturing infrastructure worldwide. Previous incidents of accidental release have had high economic and social costs; for example, the United Kingdom's accidental leak of the foot-and-mouth disease agent through laboratory discharge cost an estimated £47 million in containment costs and livestock loss.[23] Despite high-profile events of accidental release, recent findings exposed there have still been 100 safety breaches or near misses in high-security UK labs over five years,[24, 25] demonstrating a need for greater biosafety. Furthermore, in a thriving emerging bioeconomy, a deepened reliance on specialised supply chains could make biomanufacturing infrastructure a target for physical and cyber attacks. This technological fragility threatens health and food security and may have global economic and social consequences.[1, 26]

Emerging bioeconomies will also require more trained biotechnological personnel, increasing the probability that actors with intent to harm are equipped with relevant technical and tacit knowledge. This risk is compounded in cases where countries with emerging bioeconomies may lack adequate biosafety and biosecurity training and capacities. At the beginning of a Synthetic Biology (SynBio) Africa biosecurity workshop, more than 90 percent of attendees were unfamiliar with the concept of "dual-use research of concern," showing the importance of biosecurity educational programs.[27]

Given rising private sector investment in bioeconomic activities, unique risks may also arise in private labs, including biotechnology startups. Unlike state-funded or academic research labs, these may not have government-mandated biorisk management regulations in place. Private sector industries may also be more hesitant regarding government intervention and taking on additional costs relating to biosecurity.

Additionally, the same infrastructure that facilitates legitimate research and production also presents opportunities for creating bioweapons.[25,26] Although historical incidents of deliberate biotechnology misuse—such as the 2001 anthrax attacks linked to spores from the U.S. Army Medical Research Institute of Infectious Diseases[28]—have been relatively rare, the landscape is changing. Advances in biotechnology over recent decades have expanded capabilities to engineer pathogens with pandemic potential, potentially outpacing existing medical countermeasures.[26] Moreover, the convergence of engineering biology with other emerging technologies, such as artificial intelligence and robotics, may aid a malicious actor in designing and constructing more dangerous pathogens and create information hazards.[29–32]

TRADE-OFFS BETWEEN BIOECONOMIC GROWTH AND SECURITY CONCERNS WARRANT CAREFUL BALANCING

Biotechnology holds the transformative potential to improve food security and public health and to drive broader socioeconomic benefits.[33–35] To illustrate, the widespread deployment of genetically modified (GM) crop technology to make insect-resistant cotton in India has decreased food insecurity by 15–20 percent in cotton-farming households.[36] On the other hand, some beneficial biotechnologies may have unintended risks; for example, CRISPR gene drive technology may aid in controlling disease transmission but was flagged as a potential area of dual-use research of concern (DURC) in a working paper by the United States at the Biological Weapons Convention (BWC) Meeting of Experts.[37]

As the global bioeconomic market expands, countries may have strong incentives to rapidly grow their own bioeconomies, particularly when development contributes significantly to GDP.[39] However, focusing purely on rapid bioeconomic growth could risk neglecting the implementation of safeguards in infrastructure and personnel training and cause a lack of oversight for DURC research and publication. To balance this, organisations such as SynBio Africa raise awareness of risks through biosecurity and biosafety training, encouraging biosecurity measures to be considered "as we develop the concept for the project before we even start the work."[27]

Conversely, an excessive focus on biosecurity may hinder bioeconomic growth. One expert suggested that in countries launching their biotechnology sector, emphasising the promise of the bioeconomy is important instead of overfocusing on risks. This is especially practical where the technical risks are well characterised (for example, projects using relatively safe recombinant protein expression protocols in model organisms such as *E. coli*).[40] Additionally, existing security regimes, such as strict export controls on genetic material, substantially delay R&D timelines.[39]

As a case study, the International Genetically Engineered Machine (iGEM) Competition exemplifies how promoting biosecurity does not have to come at the cost of hindering innovation. The competition—which incentivises participants to consider biosecurity and biosafety as a priority and in the design of their projects—has incubated more than 150 startups in its 20-year history.[38] One of these companies, Ginkgo Bioworks, is now a globally leading biotech company with a dedicated biosecurity unit, Concentric by Ginkgo. iGEM uses an adaptive risk management approach and promotes biosecurity through the Human Practices program, working with teams to make their projects safer while still achieving their goals.[41,42] This generates a culture of responsibility by requiring teams to engage with stakeholders at all stages of their project, similar to the Lean LaunchPad entrepreneurship approach, which emphasises engagement with customers for a strong product-market fit.[43] Elements of this model may inspire international and national policies. Therefore, the iGEM model illustrates how governments and funders could design biosecurity measures into the research process while encouraging innovation.

INTERNATIONAL COOPERATION AND COLLABORATION ARE ESSENTIAL FOR PROMOTING BIOECONOMIC DEVELOPMENT AND MANAGING ASSOCIATED RISKS

Biological agents can pose a unique global threat, as they may rapidly spread across borders. Therefore, international cooperation, regulations and standards, and investments in global health security are vital as countries scale-up their bioeconomies. Formal mechanisms, such as legally binding conventions and country participation in international fora, can help to address potential biosafety and biosecurity risks and reinforce global norms.

Strong norms have been generated through the BWC—only eight States Parties have not signed or acceded to the convention—and the legally binding International Health Regulations, of which 196 countries are members. The BWC is a treaty between States Parties that bans developing and using biological weapons and toxins and prompts discussing standards for research with the potential for misuse. The BWC also sets out commitments for assistance and cooperation between States, such as Article VII, which mandates that States Parties provide assistance to another State Party if it is affected by violations of the Convention. Article X encourages the international exchange of equipment, materials, and scientific and technological information for peaceful purposes and is implemented through the BWC Assistance and Cooperation Database, which helps to encourage biorisk management, as well as capacity building and scientific cooperation.[44,45] Further, in 2004 the adoption of the UN Security Council Resolution 1540 bridged an important gap in international law, requiring UN member states to adopt effective measures to prevent the acquisition of nuclear, chemical, and biological weapons by non-state actors.[46]

International cooperation and global health security are also promoted through the International Health Regulations, which define countries' obligations to handle public health emergencies with pandemic potential, emphasising the responsibilities of countries to curb accidental or deliberate biological risks.[47] Other international agreements, such as the Nagoya Protocol on Access and Benefit-Sharing and the Cartagena Protocol on Biosafety, reinforce international cooperation on bioeconomic development and encourage careful management of risks.[48,49] Efforts such as the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction are also effective ways to strengthen biosecurity and enhance cooperation. Together, these conventions and fora provide tangible formal mechanisms through implementation guidance and tools and are complemented by more intangible elements such as establishing and strengthening norms for biosafety and biosecurity.

Data Analysis

BIOSAFETY AND BIOSECURITY PRACTICES NEED TO BE STRENGTHENED ACROSS EMERGING BIOECONOMIES

To understand whether countries are prepared for the risks that may arise from rapid bioeconomic development, we performed data analysis using the Global Health Security Index (GHSI) to explore how 15 countries with emerging bioeconomies scored on metrics relating to biosafety and biosecurity.

A broad range of definitions of the bioeconomy have been adopted at the national and international level, resulting in the lack of a unified metric to quantitatively compare overall bioeconomic activity.[1] To identify countries with emerging bioeconomies, we examined three representative key sectors of the bioeconomy. We included data that ranked leading countries in the following sectors: (1) agriculture (GM acreage per country in 2019, **Supplementary Figure 1**), (2) bioenergy (biofuel production per country in 2022, **Supplementary Figure 2**), and (3) a research-and innovation-focused ranking for the biotechnology industry at the country level incorporating public biotech company activity, investor activity, research and translation activity, and education as well as fundamental research.[50] The limitation of this approach is that a focus on different sectors within the bioeconomy may substantially change the country selection. However, we intended to describe a sample of countries across the broad spectrum of bioeconomic activity and the extent to which they address biorisk mitigation.

We selected the top five leading countries in each metric (**Table 1**). Furthermore, we included South Africa and Kenya, which experts in our interviews highlighted as focusing on their bioeconomy. Thus, we identified 15 countries to be a globally representative subset of emerging bioeconomies: Argentina, Brazil, Canada, China, Finland, Germany, India, Indonesia, Kenya, Singapore, South Africa, Sweden, Switzerland, the United Kingdom, and the United States.

TABLE 1. Emerging bioeconomies across different metrics and key sectors of the bioeconomy

Agriculture and GM Crops	Bioenergy	Health Biotech Innovation	Additional from Expert Consultation
United States	United States	Switzerland	South Africa
Brazil	Brazil	Sweden	Kenya
Argentina	Indonesia	Singapore	
Canada	China	Finland	
India	Germany	United Kingdom	

We analysed the GHSI, Joint External Evaluations (JEE), and Confidence-Building Measures (CBM) submissions data of these 15 countries. We selected three metrics from the GHSI representing the capacity of countries to prevent biological risks arising from their bioeconomic activity—biosecurity, biosafety, and DURC and culture of responsible science—and included additional metrics on international commitments and completion of JEE and CBM submissions.

Overall, the global average GHSI score for biosecurity has marginally improved from 16.0/100 in 2019 to 18.7/100 in 2021; however, this figure remains alarmingly low for all 195 countries. Notably, the GHSI score for DURC and culture of responsible science—evaluating DURC national-level oversight measures and requirements for DNA synthesis screening—averages globally at 2.7/100, with only 12 countries (6 percent) fulfilling this.

TABLE 2. Performance metrics of 15 selected emerging bioeconomies and their global average scores across the most Important dimensions to mitigate biological risks, as evaluated in the Global Health Security Index

	Argentina	Brazil	Canada	China	Finland	Germany	India	Indonesia	Kenya	Singapore	South Africa	Sweden	Switzerland	UK	US	AVG	AVG (all GHSI)
OVERALL GHSI SCORE	54.4	51.2	69.8	47.5	70.9	65.5	42.8	50.4	38.8	57.4	45.8	64.9	58.8	67.2	75.9	57.4	40.0
Dual-use research and culture of responsible science	0.0	33.3	50.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	33.3	0.0	33.3	50.0	13.3	2.7
Biosecurity	44.0	48.0	86.7	52.0	44.0	54.7	24.0	24.0	0.0	28.0	4.0	78.7	24.0	69.3	89.3	44.7	18.7
Biosafety	0.0	25.0	100.0	50.0	100.0	25.0	0.0	0.0	50.0	100.0	50.0	100.0	50.0	50.0	100.0	53.3	20.9
International commitments	100.0	50.0	100.0	50.0	100.0	100.0	100.0	84.4	90.6	100.0	50.0	100.0	100.0	100.0	100.0	88.3	56.1
Completion and publication of a JEE assessment and gap analysis	0.0	0.0	50.0	0.0	50.0	0.0	0.0	100.0	50.0	50.0	50.0	0.0	50.0	0.0	100.0	33.3	30.5
Consistent CBM submission (2019-2023)	Yes	Yes	Yes*	Yes	Yes*	Yes*	Yes	No	Yes	Yes	Yes	Yes*	Yes*	Yes*	Yes*	93.3	45.4

100.0

0.0

Note. Consistent submission of Confidence-Building Measures to the BWC denotes annual submission every year during 2019–2023.

**States Parties that also submitted open, public-facing versions.*

Emerging bioeconomies are investing in expanding their bioeconomic infrastructure, increasing risks. We therefore sought to compare how the 15 selected emerging bioeconomies perform across the analysed metrics of biorisk mitigation with respect to global efforts. Although the 15 emerging bioeconomies, on average, score better for DURC and culture of responsible science than the global average, the scores remain low, with 10 countries scoring 0/100 (**Table 2**). This metric includes (1) evidence of national assessment of dual-use research, (2) national law/regulation on oversight of dual-use research, (3) existence of an agency responsible for oversight of dual-use research, and (4) screening requirements for providers of genetic material. The lack of investment into these safeguarding components by countries with emerging bioeconomies highlights an area of biosecurity that needs strengthening. The scores for biosafety and biosecurity for these selected countries are higher than the global average, with five countries scoring 100/100 for biosafety, and nine countries scoring more than 40/100 for biosecurity. We note that these above-average scores are not indicative of fulfilling desirable standards. Rather, the global average remains too low, with substantial room for improvement in the global landscape of biosafety and biosecurity. These metrics include factors such as biosafety legislation and requirements for biosafety training, which should be an important component of expanding bioeconomies.

The GHSI score for international commitments includes factors relating to the implementation of UN Security Council Resolution 1540 and commitments to the BWC, including CBM submissions. High scores across this metric demonstrate that countries are aware of the importance of upholding global norms and participating in international venues. This is also shown through consistent CBM submissions during the past five years, with some countries also producing an open, public-facing version. Contrastingly, many countries do not commit to the collaborative JEE submission and publication process, which encourages countries to assess gaps in their preparedness and response plans, with an average score of 33.3/100 among the selected 15 emerging bioeconomies.

BIOSECURITY INITIATIVES AND INVESTMENTS CONTRIBUTE TO SAFEGUARDING THE BIOECONOMY

Despite these low metrics across the GHSI, there are other ways that countries may contribute to safeguarding their bioeconomy. Although an important international venue, the BWC exclusively relies on contributions from States Parties. However, in 2021, 54 states contributed less than US$100,[51] and as of 31 August 2023, there is US$360.5 thousand owed in outstanding payments by States Parties. The top financial contributors are the United States, Saudi Arabia, France, the United Kingdom, Spain, and the Netherlands.[52] Outside of financial investment, countries may demonstrate their commitment to advancing global biosecurity and biosafety standards during the BWC by submitting working papers and hosting associated side-events at the Review Conferences (RevCons). For example, at the recent BWC RevCon, Canada, Germany, Mexico, and the United States submitted a working paper on "Reinforcing Laboratory Biosafety and Biosecurity Internationally," and Canada submitted a separate paper on "An Analytical Approach: Biosafety and Biosecurity Oversight Framework."[37]

Our expert interviews highlighted countries with dedicated policy documents to set out their biological security strategies. These countries include the United Kingdom, the United States, and South Africa.[53–55] The policy documents include specific commitments to safeguard the bioeconomy and minimise risks, such as the United Kingdom's Biothreats Radar and Biosecurity Leadership Council and South Africa's recommendations to improve its legislation and implement biosecurity practices in laboratories. One expert also noted that the Netherlands and Denmark have dedicated national authorities for biosecurity and biopreparedness.[56–58]

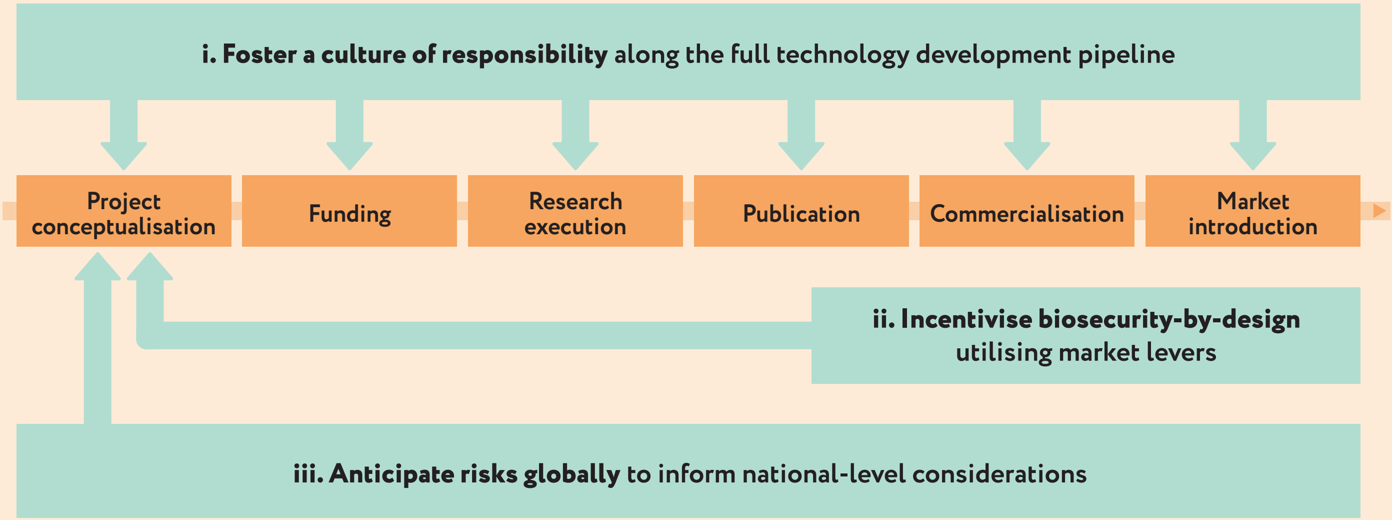
Overall, our analysis of GHSI data has highlighted areas that require greater attention, such as DURC and developing a culture of responsible science. Although governments are making efforts on the state level, it may be difficult to ensure that technology developing outside government oversight, such as in the private sector, balances innovation, safety, and security. Therefore, a culture of responsibility across the scientific community, as well as specifically targeting the private sector, and regular assessment of possible DURC science and technology advances are key areas that could benefit from targeted policy and technical interventions.

Recommendations

BIOSECURITY-BY-DESIGN TO SAFEGUARD EMERGING BIOECONOMIES

Safe-by-design approaches, exemplified by a recent Dutch initiative,[59] encourage researchers to consider safety at the earliest stages of product development. Similarly, we propose a paradigm of biosecurity-by-design in emerging bioeconomies while promoting and encouraging innovation through three main initiatives.

FIGURE 2. Biosecurity-by-design incorporates risk mitigation measures along the full research and technology development pipeline



Note. Three proposed initiatives would drive the adoption of biosecurity-by-design principles:(1) fostering a culture of responsibility; (2) incentivising biosecurity-by-design using market levers; and (3) anticipating risks globally to inform national-level considerations on risk mitigation measures.

1 Integrate biosecurity-by-design by fostering a culture of responsibility at all stages of the research and technology development pipeline

To foster a culture of responsibility among life scientists,[60,61] **we propose promoting the adoption of the Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists.**[62] The Tianjin Guidelines were not adopted at the 9th Review Conference of the BWC in December 2022 despite strong calls for endorsement.[63] With four years until the next opportunity for possible formal adoption at the upcoming RevCon, we note that more than 140 scientific academies worldwide already incorporate elements from the guidelines.[62] Therefore, **we encourage further global uptake and adoption of the Tianjin Guidelines across scientific academies and institutes.** This will cultivate a globally recognised standardised code of conduct for scientists as new bioeconomies emerge and grow, and it will create universal norms in the R&D workforce.

An R&D workforce trained by these guidelines should incorporate biosecurity considerations from the outset when conceptualising projects implemented through funding mechanisms. Inspired by the Netherlands' Safe-by-Design approach, projects should integrate technical biosecurity considerations, such as model organism choice, kill switches, and containment strategies.[64] **To incentivise biosecurity-by-design, we encourage bioscience funders to expand their structured biosecurity questionnaires as part of funding applications and implement review processes in their grant proposals and during the funding period as risks change and emerge.** Questionnaires should prompt scientists to consider the impacts of their work, both at the beginning and throughout the project, building on existing mechanisms such as the Anticipate, Reflect, Engage, Act (AREA) framework, which engages scientists in thinking about responsible research and innovation proactively.[65–67] More detailed review processes could approach biosecurity concerns on a case-by-case basis, where funders may learn from the iGEM model, which triages proposals with biosecurity concerns and engages in adaptive iterations with researchers to enable innovation while prioritising biosecurity.[42]

2 Incorporate biosecurity-by-design as an intrinsic part of innovation

Although expert opinion stressed the importance of targeting the private sector, regulating and encouraging the uptake of biosecurity measures are difficult because of a lack of market incentives and differing funding mechanisms than publicly funded research.[56] We propose promoting and rewarding biosecurity at early stages of innovation by using market levers.

We encourage adopting unified biosecurity standards and market access regulations in the largest markets, which incentivise and reward innovation.[56] These standards may include risk assessment and mitigation and technological approaches such as synthetic containment and kill switches. Proactive implementation of such standards during the design phase of products will provide a competitive advantage over retroactively fitting products to adhere to market access requirements. This will globally incentivise actors that develop commercialisable products to implement biosecurity standards at an early stage of R&D—and thereby foster biosecurity-by-design.[68]

Products of the bioeconomy, including biotechnologically produced commodities or products that entail live biological agents such as bacterial biosensors, commonly face substantial regulatory hurdles, delaying or even preventing market access.[69] **We propose establishing a framework to fast-track products to market that adhere to defined biosecurity requirements and standards.** This builds on U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) fast-track authorisation of medicines.[70] Products that meet biosecurity requirements using technologies, parts or whitelisted agents may undergo accelerated market approval processes. This incentivises risk-minimising design choices in the early stages of the product development process.

Brand reputation is also an important element within the biotechnology industry.[71] **We propose establishing reputational rewards as an industry incentive to incorporate biosecurity into product development.** Seals of approval—as proposed for DNA synthesis screening[72]—encourage the private sector to uphold voluntary standards and procedures that improve biosecurity.

3 Promote biosecurity-by-design as a global Norm through existing international venues

Given that the BWC is a strong venue for norm-setting and international discourse, **we encourage adopting a systemic science and technology (S&T) review mechanism with a diverse membership to raise awareness of emerging biotechnology risks.** Although States Parties widely support a systematic S&T review process in a manner similar to the Organisation for Prohibition of Chemical Weapons (OPCW) Scientific Advisory Board,[73,74] they have not yet reached any consensus on its implementation.[75] Emerging bioeconomies without sufficient in-house biosecurity expertise may particularly benefit from such mechanisms. S&T review findings enable the design of forward-looking and effective oversight measures and regulations for bioeconomy infrastructure. Furthermore, S&T review findings could highlight research opportunities that positively contribute to global health, food, and energy security. Ultimately, we envision international dialogue will drive proactive national regulations and standards, encouraging researchers to design biosecurity into the early stages of technology development.

Conclusion

The emerging global bioeconomy presents opportunities for sustainable economic development. However, biological systems pose unique risks from accidental release or deliberate misuse due to their ability to spread across borders. International cooperation and global health security are, therefore, vital for effective risk mitigation, and valuable lessons are yet to be learned from venues such as the BWC, which has established strong norms against bioweapons.

To realise the opportunities of the bioeconomy, trade-offs in prioritising safety and security against innovation and growth require careful balancing and tailored risk messaging in a context-specific manner. We highlight iGEM as a case study to promote biosecurity considerations within the technology development pipeline, where successful commercialisation proves that risk mitigation and innovation are mutually compatible.

Our data analysis highlights the need to further invest in safety and security. We demonstrated that emerging bioeconomies do not adequately implement biosafety and biosecurity best practices in R&D—with alarming shortcomings in DURC oversight measures. These weaknesses in countries' biosecurity and biosafety investments show the need for governments to be aware of biosecurity risks and committed to innovation that incorporates biosecurity concerns.

To implement biosecurity-by-design, our recommendations target governments, the private sector, and the scientific community. We first propose to integrate biosecurity-by-design as part of a culture of responsibility in training scientists and throughout the R&D pipeline, a vital action for diffusing norms and values to the communities that can enact change. Next, we use market levers to incentivise the private sector to incorporate biosecurity-by-design principles in technology development. We encourage governments to create a secure bioeconomic market environment through market access regulations and reputational rewards such that biosecurity considerations are incorporated into R&D from the outset. Finally, biosecurity-by-design requires the propagation of norms and values at an international level, and governments need to be fully aware of S&T risks. With a systematic S&T mechanism, we propose using the BWC's strong position in informing governments on biosecurity-relevant technology developments.

We encourage a positive vision of biosecurity-by-design interwoven with the exciting possibilities of innovation, as opposed to the potentially negative connotations of overly stringent risk management. Our proposal is a grand undertaking; however, the scale and urgency of the possible risks necessitate this. We need ambitious thinking that transforms standards, diffuses across relevant communities, and spreads a clear norm of biosecurity-by-design worldwide.

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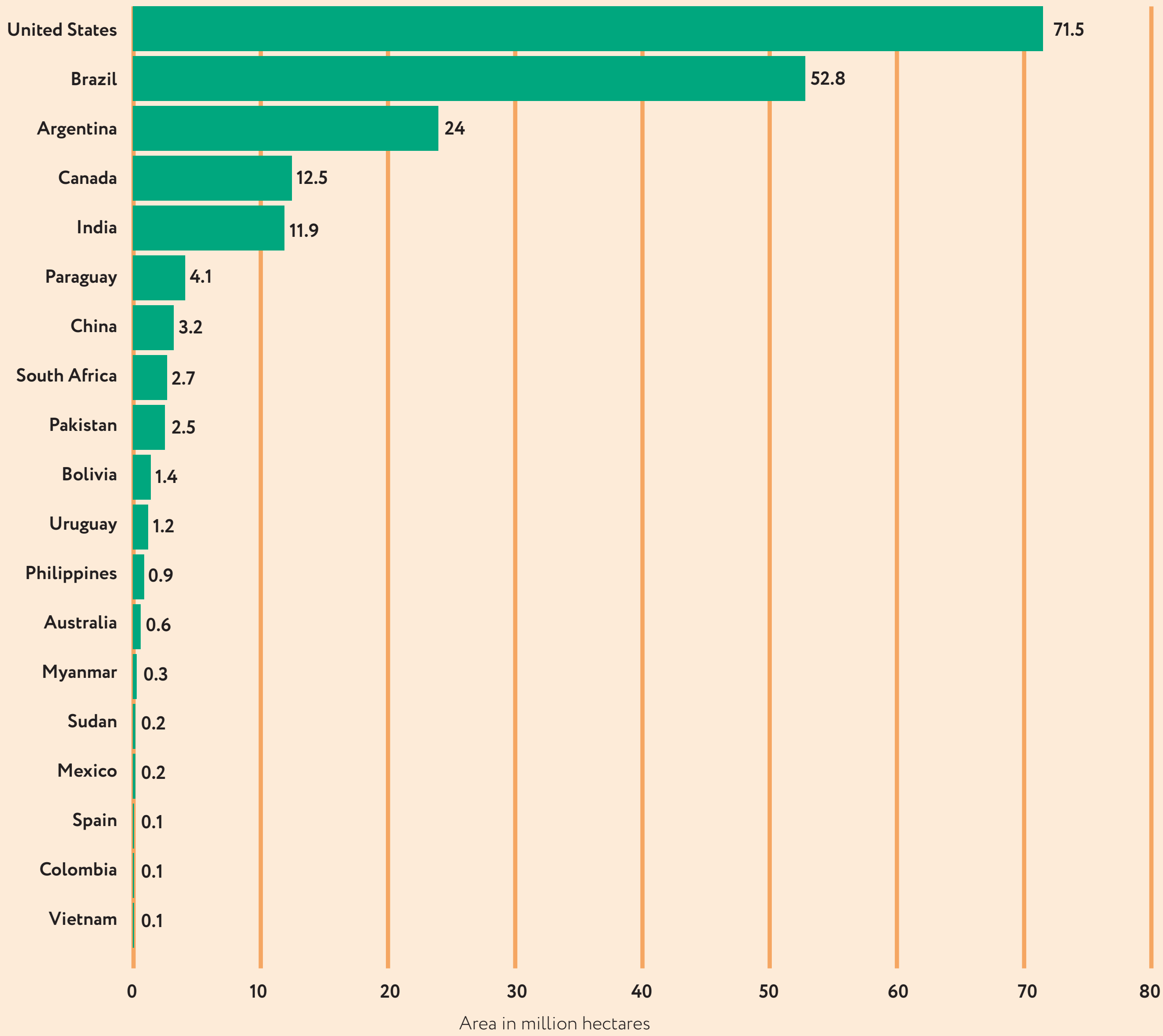
Abbreviations

AREA	Anticipate, Reflect, Engage and Act Framework
BWC	Biological Weapons Convention
CBM	Confidence-Building Measures
DNA	Deoxyribonucleic acid
DURC	Dual-use research of concern
EMA	European Medicines Agency
EU	European Union
FDA	U.S. Food and Drug Administration
GDP	Gross domestic product
GHSI	Global Health Security Index
GM	Genetically modified
iGEM	International Genetically Engineered Machine competition
IHR	International Health Regulations
JEE	Joint External Evaluations
OPCW	Organisation for Prohibition of Chemical Weapons
R&D	Research and Development
RevCon	Review Conference of the Biological Weapons Convention
S&T	Science and Technology
SynBio	Synthetic Biology
UK	United Kingdom
U.S.	United States of America
US$	United States Dollar

Supplementary Information

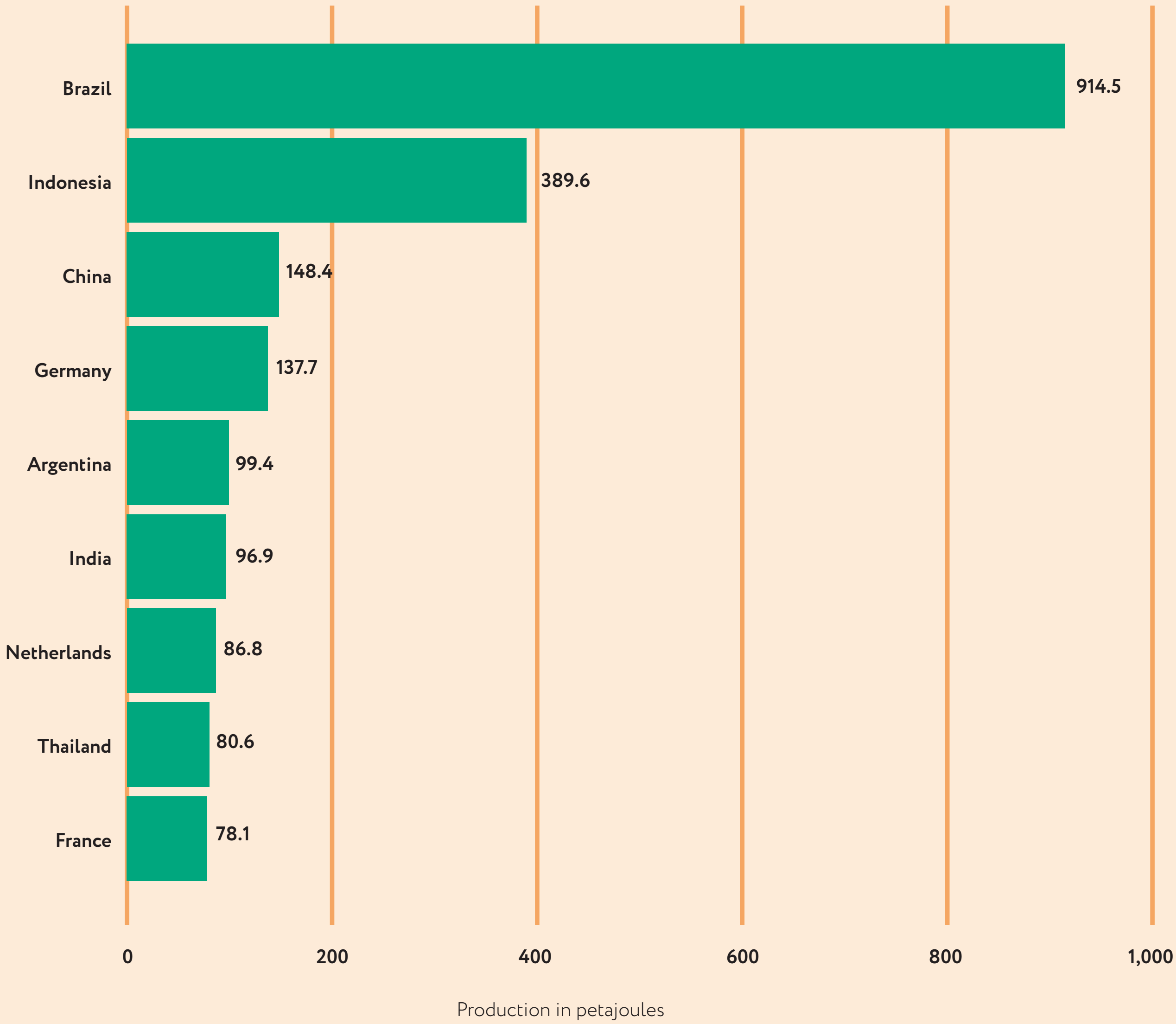
SUPPLEMENTARY FIGURE 1. Area of genetically-modified crops worldwide in 2019, by country



Source. Adapted from Statista.[76]

Supplementary Information (continued)

SUPPLEMENTARY FIGURE 2. Leading countries in biofuel production worldwide in 2022



Source. Adapted from Statista.[77]