Safeguarding the South African Bioeconomy

Quick Read

This report highlights that robust safeguards are crucial for enabling responsible bio-innovation and building public trust. It addresses the evolving risk landscape, including natural threats, disruptive technologies like synthetic biology and AI, and dual-use concerns, noting South Africa's established biosafety systems but also systemic weaknesses in governance and oversight of advanced technologies.

Key points include:

- Safeguarding is an enabler of responsible bio-innovation, fostering public trust through transparency and clear risk management.
- The risk landscape is evolving due to natural biological threats, disruptive technological changes, e.g., synthetic biology and AI-enabled biological design, and dual-use concerns.
- While South Africa has established biosafety and biosecurity governance frameworks, systemic weaknesses persist, particularly in oversight of enabling technologies and in fragmented regulatory authority.
- Policy reforms should focus on updating legislation and strategies, guided by risk-benefit analysis for fit-for-purpose regulation.
- DNA synthesis screening can be a cornerstone for safeguarding national biosecurity, preventing foreign policy imposition, and strengthening traceability.
- The establishment of a national or regional safeguarding platform, such as a bioeconomy council, is strongly supported to coordinate activities and guide the implementation of safeguards.

Background

The International Biosecurity and Biosafety Initiative for Science (IBBIS), in partnership with the Biosafety South Africa, convened a two-day strategic meeting in Pretoria on 9-10 October 2025 under the theme Safeguarding the South African Bioeconomy. The meeting convened government officials, scientists, public health experts, and representatives from academia and industry to examine how South Africa's bioeconomy can be advanced in a manner that fosters innovation while ensuring security. The discussions reflected South Africa's ambition to harness biotechnology for national development while embedding safeguards that meet both domestic needs and international obligations. Particular attention was paid to DNA

synthesis screening as a cornerstone measure to prevent potential misuse of emerging biotechnology, strengthen governance, and build public trust.

This report captures the key themes and recommendations from the meeting, providing a foundation for continued dialogue and collaboration.

The South African Bioeconomy: challenges and opportunities

Participants underscored that South Africa is operating at a pivotal moment in the evolution of its bioeconomy. The country has significant scientific assets that position it for leadership. These include exceptional biodiversity, world-class laboratory infrastructure, strong public research institutions, a globally connected academic community, and emerging capabilities in synthetic biology, precision medicine, and artificial intelligence-enabled biological design. Together, these strengths provide a powerful foundation for bio-innovation and long-term economic growth.

At the same time, participants acknowledged that South Africa faces structural constraints. Investment in research and development remains far below global benchmarks, limiting long-term planning, laboratory renewal and talent retention. Budget reductions across science and higher education institutions have slowed the growth of the national system of innovation. Private sector investment has declined due to low business confidence and macroeconomic uncertainty. Regulatory processes were often described as overly complex or unpredictable. Several participants noted that the absence of a stable, innovation-friendly regulatory environment constrains the translation of research into marketable products and reduces competitiveness.

Participants agreed that South Africa has significant scientific potential but faces a persistent disconnect between academic research output and commercial impact. The country is home to strong research programs in synthetic biology, precision medicine, indigenous knowledge and several emerging biotechnology fields. New initiatives such as the Council for Scientific and Industrial Research biofoundry development and partnerships between national research institutions and industry signal progress toward a more integrated innovation system.

However, several constraints limit the translation of innovation into societal and economic benefit. A longstanding challenge is the friction surrounding intellectual property rights in publicly funded research, which creates uncertainty for both researchers and industry. Participants emphasized the need for closer alignment between research activities and market needs. They described a growing need for a market-pull model in which industry priorities and societal needs shape research investments and academic activity.

Infrastructure gaps remain. Many samples are still sent overseas for sequencing and synthesis, indicating unmet domestic capability and raising concerns about responsiveness during future emergencies. Participants highlighted the need for more distributed capability across institutions, particularly for foundational biological materials, vaccines, diagnostics and analytical tools.

Participants also noted the need for stronger entrepreneurship pathways, improved access to domestic investment and expanded public-private collaboration. The bioeconomy was described as broader than pharmaceuticals, encompassing agriculture, food systems, biomaterials, soil health and environmental sustainability. Coordination with continental initiatives, such as the Africa Centres for Disease Control networks, was highlighted as an opportunity to exert regional influence.

Participants raised concerns about the acquisition of small South African biotechnology companies by international entities, noting that such acquisitions can reduce local competitiveness and constrain long-term national benefits. They underscored the importance of maintaining local ownership of scientific capability and ensuring that early-stage innovation provides tangible value to South Africa's economy and society.

Despite these challenges, participants stressed that South Africa retains important advantages. Its geographic and political position gives it significant regional influence and makes it a gateway for continental markets. The country also has a strong policy foundation in the form of the 2013 Bioeconomy Strategy, which emphasizes jobs and livelihoods alongside environmental and economic development. Related strategies in biodiversity, agriculture, forestry, wildlife and indigenous knowledge-based innovation create an ecosystem to support sustainable growth.

Emerging risk landscape

Participants described an evolving risk landscape shaped by natural biological threats, disruptive technological change and growing dual-use concerns. South Africa continues to face a high burden of infectious diseases, including multidrug-resistant tuberculosis, HIV and periodic surges in vaccine-preventable illnesses. These ongoing pressures underscore the importance of strong surveillance systems, rapid outbreak detection and coordinated national response mechanisms. They also highlight the need to ensure that new biological activities do not unintentionally strain an already burdened public health system.

Participants noted that synthetic biology and artificial intelligence-enabled biological design are transforming what is technically possible. Tools for protein, genome and pathogen design are becoming more accessible and automated. The speed of scientific progress has outpaced risk awareness in parts of the research community. Several gaps were identified. These included limited understanding of dual-use implications, insufficient oversight of enabling technologies, the lack of external auditing for many laboratories and gaps in monitoring equipment that could be repurposed for harmful use. Some institutions rely on informal expectations rather than formal compliance systems.

The convergence of technological capability and increased research throughput was highlighted as a concern. Activity is expanding across universities, startups, and private laboratories, while safeguards have not grown proportionately. Participants expressed the need for stronger risk awareness and improved systems for monitoring, training and compliance. Climate change, supply chain fragility and geopolitical instability were described as amplifiers of biological risk. Together, these factors create an environment in which both natural and human-made threats may become more frequent or more severe.

Safeguarding as an enabler of responsible innovation

Across discussions, there was broad agreement that safeguarding should be positioned as an enabler rather than a barrier to innovation. Participants emphasized that strong safeguards build public trust by ensuring transparency, proportionality and clear communication about

how risks are managed. Responsible governance allows society to capture the benefits of biotechnology while reducing potential harms. DNA synthesis screening was highlighted as a central element of this approach because it provides a practical, non-intrusive mechanism to reduce risk, enhance social legitimacy and demonstrate that advanced biotechnology can be pursued safely.

Governance and institutional capacity

Participants discussed both the strengths and structural gaps within South Africa's biosafety and biosecurity governance frameworks. The country has established systems for detecting natural outbreaks, strong public health laboratories and well-coordinated emergency operations committees. These foundations provide significant capability for detecting unusual biological events. The most recent Joint External Evaluation conducted under the World Health Organization was described as a useful instrument for identifying strengths and gaps through a structured, checklist-based methodology. Participants noted that the national action plan developed in response to the Joint External Evaluation provides a coherent roadmap for improvement and has strong political endorsement. The work packages related to biosafety and biosecurity were viewed positively because they align closely with identified priorities.

Despite these strengths, systemic weaknesses remain. Oversight continues to focus primarily on high-risk pathogens, with less attention to enabling technologies such as automated systems, DNA synthesis tools, cloud-based design platforms and other advanced capabilities. There is no comprehensive dual-use governance framework that addresses artificial intelligence, distributed manufacturing or modern genetic engineering. Regulatory authority is fragmented, and mandates can be unclear. Participants expressed the need for greater coordination across health, science, agriculture, security and higher education sectors.

Participants also observed that capacity is uneven across provinces and municipalities. Resource constraints at the subnational level weaken national surveillance, reporting, and response capabilities. Enforcement challenges were frequently mentioned, especially in

smaller private laboratories and academic institutions where biosafety oversight may be limited or inconsistent. Participants highlighted additional areas requiring capacity building. These included formalizing audit systems, expanding training in responsible research, creating more consistent guidance for laboratory practices and clarifying accreditation processes for biosafety facilities. The idea of a national biorisk database was introduced as a possible tool for mapping laboratories, tracking capacity and improving oversight.

Institutional biosafety committees were repeatedly highlighted as essential elements of governance. Participants described them as frontline structures that integrate risk awareness, project review, training, reporting and accountability. Participants emphasized the need for a full suite of tools to manage risks ranging from deliberate misuse to accidents and natural outbreaks. Strengthening institutional biosafety committees emerged as one of the most important elements of governance. Participants described these committees as essential structures that link training, project oversight, risk awareness, incident reporting and institutional culture. They argued that as research capabilities expand, institutional biosafety committees must be supported to effectively review activities and ensure compliance with both national guidance and international norms.

Participants discussed several areas for improved practice. These included harmonizing standard operating procedures across institutions, enhancing risk-benefit assessment methods, expanding training in responsible research, and improving communication between regulators and research communities. Participants emphasized that regulators must be seen as partners, not barriers. Clear and accessible communication is essential for building trust, reducing uncertainty and supporting compliance.

Policy pathways and national strategy alignment

Participants discussed how policy reform can support both innovation and safeguarding. They emphasized that new institutions are not needed. Instead, South Africa should update existing legislation to reflect modern technologies and align current strategies, including the science, technology and innovation white paper and the bioeconomy strategy, with contemporary realities. Participants emphasized the need for fit-for-purpose regulation that

avoids unnecessary burdens while ensuring responsible governance. They stressed that the extensive institutional memory within South Africa's biosafety community can help guide proportional and transparent approaches.

A recurring theme was the value of guidance. Participants emphasized that many improvements can be made through updated guidance and standards rather than new legislation. Guidance documents can be updated more rapidly and with greater flexibility than formal legislation, allowing regulators to keep pace with scientific change while minimizing administrative burdens. Participants described guidance as an important enabler that supports compliance, builds understanding across institutions and allows for nuanced approaches that reflect South Africa's diverse research and innovation landscape.

The Department of Science and Innovation presented the core pillars of its current strategy. These include improving coordination among diverse actors, creating an enabling environment through skills, infrastructure, and finance, and advancing strategic programs in agriculture, health, industry, and indigenous knowledge. Participants observed that ongoing reviews of strategy documents offer a timely opportunity to modernize safeguarding practices.

Improved coordination across government sectors was seen as essential for preparedness. Participants emphasized that biological risks do not fall neatly within single departments and that effective governance requires cross-sector communication, shared understanding of risk and mechanisms that link health, science, agriculture and security actors.

Participants also observed that public communication and engagement remain essential. They noted that public confidence can be weakened by misinformation or perceived opacity in regulatory decisions. Transparent communication and clear explanations of how risks are managed were described as essential for building trust and supporting the societal legitimacy of emerging technologies.

The role of DNA synthesis screening in national and international security contexts

Participants described DNA synthesis screening as a cornerstone safeguard for responsible biotechnology. They noted that the global risk landscape is shifting due to artificial intelligence enabling the accelerated design of proteins, genomes, and pathogens, the increasing availability of long, complex synthetic DNA molecules, and the wider commercial accessibility of advanced biological tools.

Implementing screening in South Africa was framed as important for two reasons. First, without domestic standards, the country risks having restrictive and costly foreign policies imposed on local providers. Second, an absence of domestic screening could force reliance on foreign DNA imports, undermining national responsiveness during emergencies and weakening supply chain sovereignty. Screening was described as a means of shaping South Africa's future trajectory as a scientific and economic leader by demonstrating responsible capability and self-sufficiency.

Participants also highlighted screening as a significant confidence-building measure within national and international security frameworks. Global governance instruments such as the Cartagena Protocol on Biosafety, the International Health Regulations, the Global Health Security Agenda and non-proliferation mechanisms, including United Nations Security Council Resolution 1540, set broad expectations for responsible practice but rely heavily on voluntary reporting and national implementation. These mechanisms lack verification systems and are not enforceable. They depend on countries demonstrating responsible intent through domestic safeguards and transparent information sharing.

Within this context, DNA synthesis screening strengthens traceability, enhances public protection and supports compliance with non-proliferation obligations by helping ensure that harmful sequences are not ordered or assembled without oversight. Participants noted that Resolution 1540 requires states to maintain domestic controls on biological materials and equipment, as well as oversight systems and access controls. Screening complements these

obligations by adding an upstream checkpoint before material enters a laboratory environment.

Participants discussed the alignment of screening with dual-use governance, pathogen oversight, laboratory integrity and biosafety practices. Screening interacts with institutional biosafety committees, sequence ordering processes and laboratory management systems, making it part of a broader safeguarding ecosystem. Many participants stressed that institutional biosafety committees are central to this ecosystem by connecting research oversight, training, approval processes and documentation.

Confidence-building measures were described as limited by the scope of what countries include in their reports. Participants noted that many states struggle to determine which risks should be included in reports to the Biological Weapons Convention. Artificial intelligence-enabled biological design was highlighted as an emerging area that is not yet reflected in reporting mechanisms but will increasingly shape the global risk landscape.

Participants acknowledged structural limitations in current confidence-building systems. There is no verification framework, reporting practices vary widely, and capacity inequalities across countries result in inconsistent submissions. They noted that the Biological Weapons Convention envisions contributions from all relevant sectors, including science, agriculture, public health and security. In practice, this multidisciplinary reporting is often incomplete.

These limitations reinforce the importance of strong domestic safeguards. Participants emphasized that while international instruments set expectations, domestic measures give them practical meaning. Screening is therefore not only a technical tool but a visible demonstration of responsible intent that strengthens both national biosecurity and South Africa's role in the global community.

Next steps

Participants expressed strong support for establishing a national or regional safeguarding platform, such as a bioeconomy council or consortium. Such a body would bring together stakeholders from science, industry, agriculture, health, security and defence to sustain dialogue, coordinate safeguarding activities and guide the implementation of tools such as

DNA synthesis screening. It would also reinforce South Africa's leadership role on the continent and provide a structured mechanism for harmonizing policy efforts following the Joint External Evaluation.

Participants emphasized the importance of building a community of practice for biosafety professionals, strengthening relationships between regulators and industry, and supporting platforms that facilitate communication across research institutions. Continuous engagement was viewed as the most important lever for shaping risk awareness and supporting the adoption of safeguarding measures. Participants expressed a shared commitment to maintaining momentum and using the insights from this meeting to advance strategy modernization, strengthen national resilience and ensure that South Africa's bioeconomy grows