The State of Biosafety and Biosecurity in South Africa

ASSAf
ACADEMY OF SCIENCE OF SOUTH AFRICA

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The Academy of Science of South Africa (ASSAf) was inaugurated in May 1996. It was formed in response to the need for an Academy of Science consonant with the dawn of democracy in South Africa: activist in its mission of using science and scholarship for the benefit of society, with a mandate encompassing all scholarly disciplines that use an open-minded and evidence-based approach to build knowledge. ASSAf thus adopted in its name the term 'science' in the singular as reflecting a common way of enquiring rather than an aggregation of different disciplines. Its Members are elected on the basis of a combination of two principal criteria, academic excellence and significant contributions to society.

The Parliament of South Africa passed the Academy of Science of South Africa Act (*Act 67 of 2001*), which came into force on 15 May 2002. This made ASSAf the only academy of science in South Africa officially recognised by government and representing the country in the international community of science academies and elsewhere.

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List of Acronyms

Abbreviation	Description
ARC	Agricultural Research Council
ASSAf	Academy of Science of South Africa
BSL	Biological safety level
CBEP	Cooperative Biological Engagement Programme
CDC	US Centres for Disease Control and Prevention
COC	Code of conduct
DAFF	Department of Agriculture, Forestry and Fisheries
DoH	Department of Health
DST	Department of Science and Technology
DTRA	United States' Defense Threat Reduction Agency
DUR	Dual-use research
FAO	Food and Agricultural Organisation of the United Nations
GIS	Geographic information systems
GMOs	Genetically modified organisms
HIV	Human immunodeficiency virus
HREC	Human Research Ethics Committee
IATA	International Air Transport Association
IHR	International Health Regulations
IAP	Interacademy Partnership
IP	Intellectual property
LMOs	Living modified organisms
MASSAf	Member of ASSAf
MRC	Medical Research Council
NHLS	National Health and Laboratory Services
NHREC	National Health Research Ethics Council of South Africa
NIAID	National Institute of Allergy and Infectious Diseases
NICD	National Institute of Communicable Diseases

Abbreviation	Description
NIH	National Institutes of Health
NMMU	Nelson Mandela Metropolitan University
NPW	Non-Proliferation of Weapons of Mass Destruction
NRF	National Research Foundation
NSABB	National Science Advisory Board for Biosecurity
NSI	National Security Information
OHSA	Occupational Health and Safety Act
OIE	*Office International des Epizooties* (International Office of Epizootics) World Organisation for Animal Health
R&D	Research and development
RHB	Regulations for Hazardous Biological Agents
REC	Research ethics committee
SABS	South African Bureau of Standards
SACIDS	Southern Africa Centre for Infectious Diseases
SADC	Southern African Development Community
SAPS	South African Police Services
SARS	Severe acute respiratory syndrome
SOPs	Standard operating procedures
the dti	Department of Trade and Industry
TIA	Technology Innovation Agency
TOR	Terms of reference
TRC	Truth and Reconciliation Commission
UCT	University of Cape Town
UK	United Kingdom
UN	United Nations
UNSCR 1540	United Nations Security Council Resolution 1540
USA	United States of America
WHO	World Health Organisation
WMD	Weapons of mass destruction

Definitions

Bioethics – The study of the ethical and moral implications of biological discoveries, biomedical advances and their applications, as in the fields of genetic engineering and drug research (World Health Organisation [WHO], 2006). Bioethics within the life sciences is not limited to animal and clinical research ethics, but encompasses many interlinking areas of responsible conduct of research including research misconduct, obligations to society, responsibilities towards creation of beneficial research and avoidance of maleficence.

Biological laboratory – A facility within which biological agents, their components or their derivatives, and toxins are collected, handled and/or stored. Biological laboratories include clinical laboratories, diagnostic facilities, regional and national reference centres, public health laboratories, research centres (including academic, pharmaceutical, environmental) and production facilities (including the manufacturing of vaccines, pharmaceuticals, large-scale genetically modified organisms [GMOs]) for human, veterinary and agricultural purposes (WHO, 2006).

Biosafety, or more specifically **laboratory biosafety –** In the context of this document 'biosafety' refers to practices, procedures and proper use of equipment and facilities, in order to assure the safe handling, storage and disposal of (potentially) harmful biological material (including pathogens and their products) (adapted from WHO, 2006). This includes measures to prevent harm caused by inadvertent or accidental exposure to dangerous pathogens and toxins (WHO, 2004 and European Commission for Standardisation, 2008). It should be noted that the term **biosafety** can also be used to describe the efforts to assess, manage and communicate the potential risks resulting from biotechnology and its products and in particular GMOs, but this falls outside the scope of this document.

Biosecurity – refers to measures to protect against the inadvertent, inappropriate, intentional and malevolent use of (potentially) dangerous biological material (including pathogens and their products) or the malevolent use of biotechnology against humans, livestock or crops. This also includes the protection of valuable biological material (adapted from WHO, 2006).

Biorisk – The risk (risk is a function of likelihood and consequences) of occurrence of a particular biological event (including naturally-occurring diseases, accidents, unexpected discovery, or deliberate misuse of biological agents and toxins) which may adversely affect the health of human populations (WHO, 2004 and 2007a). An assessment of these risks can be both quantitative and qualitative.

Biorisk spectrum – A continuum of biorisks ranging from naturally-occurring diseases (chronic and infectious diseases) to accidents, to the deliberate misuse of biological agents and toxins with the intention to cause harm (WHO, 2007a).

Biorisk reduction – The reduction of the occurrence of risks associated with exposure to biological agents and toxins, whatever their origin or source, encompassing the full spectrum of biorisks (WHO, 2007a).

Laboratory biosafety – The containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents and toxins, or their accidental release (WHO, 2004 and European Commission for Standardisation, 2008).

Laboratory biosecurity – The protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorised access, loss, theft, misuse, diversion or intentional release (WHO, 2006).

Dual-use life sciences research – Knowledge and technologies generated by legitimate life sciences research that may be appropriated for illegitimate intentions and applications (WHO, 2005 and 2007a).

Life sciences – All sciences that deal with organisms, including humans, animals and plants, and including but not limited to biology, bio-technology, genomics, proteomics, bioinformatics, pharmaceutical and biomedical research and techniques.

Global health security – The activities required, both proactive and reactive, to minimise vulnerability to acute public health events that endanger the collective health of populations living across geographical regions and international boundaries (WHO, 2007b).

Public health – The science and art of preventing disease, prolonging life, and promoting health through the organised efforts and informed choices of society, organisations, communities and individuals in both the public and private spheres (Winslow, 1920). Health is defined by the Constitution of the World Health Organisation as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

Research excellence – Research that is of high quality, ethical, rigorous, original and innovative.

Foreword

The Academy of Science of South Africa (ASSAf) has a mandate to provide evidence-based scientific advice to South African policymakers and this consensus report is in fulfilment of this mandate.

This consensus study was initiated by the ASSAf Standing Committee on Biosafety and Biosecurity. The key objective was to undertake a consensus study in which the findings and recommendations will contribute to policy development/modification and to inform practice in relation to the improvement of biosafety and biosecurity in the country.

This consensus report provides a review of the state of the biosafety and biosecurity in South Africa. This review includes an overview of existing legislation, regulations and practices as they relate to biosafety and biosecurity; an evaluation of existing measures and capacity to detect, control and prevent the natural, accidental and spread of infectious agents; and a critical overview of current practice in relation to the implementation of biosafety and biosecurity measures and the application of ethics in South African laboratories.

Key findings from the study include the poor education and/or training on research ethics for life scientists, inadequate compliance with the statutory obligations to report Notifiable Medical Conditions, the lack of a database of both public and commercial laboratories in the country and a low level of awareness among life scientists about national and international conventions, laws and regulations related to their research.

Based on these findings, the report makes a number of recommendations which are under these four themes:

1. Improving the capacity to detect and respond to infectious disease outbreaks.
2. Education and awareness raising.
3. Ethics review.
4. Scientific openness and transparency.

The report provides guidance on how the relevant stakeholders can implement these recommendations in a manner that can improve the state of biosafety and biosecurity in South Africa.

This report is the product of the work of a 10-member consensus study panel. The ASSAf Council would like to extend its appreciation to this panel for their expert contributions to the study and the development of this report.

The report was peer-reviewed by three experts: Prof Barry Schoub, former National Institute of Communicable Diseases (NICD) Executive Director and Emeritus Professor at the University of the Witwatersrand (South Africa); Prof Eucharia Kenya, Deputy Principal at Embu University College (Kenya); and Prof Malcolm Dando, Professor of International Security at the University of Bradford (United Kingdom). The ASSAf Council wishes to extend its gratitude to the reviewers for providing valuable inputs that have greatly improved the report.

The ASSAf Council trusts that the report's recommendations will be implemented in a manner that will improve the state of biosafety and biosecurity in South Africa.

The ASSAf Council wishes to express its appreciation to the United States' Defense Threat Reduction Agency's (DTRA) Cooperative Biological Engagement Programme (CBEP) for funding the study.

Professor Daya Reddy
President: Academy of Science of South Africa

Acknowledgements

This consensus report is collaborative work of a 10-member study panel of experts that was appointed by the ASSAf Council. They were: **Prof Jill Farrant** (MASSAf), University of Cape Town, Panel Chairperson; **Prof Daniel du Toit**, Tshwane University of Technology; **Dr Chandré Gould**, Institute for Security Studies; **Dr Petrus Jansen van Vuren**, National Institute for Communicable Diseases; **Dr Shadrack Moephuli**, Agricultural Research Council; **Dr Nhlanhla Msomi**, Independent Consultant; **Prof Iqbal Parker** (MASSAf), the International Centre for Genetic Engineering and Biotechnology; **Dr James Southern**, Independent Consultant; **Prof Anton van Niekerk** (MASSAf), Stellenbosch University and **Ms Delille Wessels**, Agricultural Research Council – Onderstepoort Veterinary Institute. These members generously donated their time for execution of this report and they are gratefully acknowledged.

Panel members were each allocated different sections within the scope of the brief and were assisted by contracted researchers appointed by ASSAf for this purpose. Data were collected, analysed and discussed electronically at six meetings held between November 2012 and June 2014. Issues raised by the findings were deliberated upon and this report reflects the findings, conclusions and recommendations of the panel.

The panel would like to acknowledge the following individuals for their different contributions to the study and the report: Dr Louise Bezuidenhout, Consultant; Mr Shaun Edge, Embassy of Japan; Ms Andrea Palk, Stellenbosch University; Dr Nandi Siegfried, Consultant; Ms Katya Mauff, University of Cape Town; Prof Janusz Paweska and Dr Jacqueline Weyer, NICD; Prof Zeblon Vilakazi, University of the Witwatersrand and Dr Rachel Chikwamba, Council for Scientific and Industrial Research.

The panel would also like to thank the following government department personnel for their inputs prior to the initiation of the study: Mr Ben Durham, Department of Science and Technology; Ms Wadzi Mandivenyi, Department of Environmental Affairs; Dr Frew Benson, Department of Health; Ms Nompumelelo Mkhonza, Dr Julian Jaftha and Dr Botlhe Modisane, Department of Agriculture, Forestry and Fisheries.

All personnel who participated in the information gathering process for the study are also acknowledged. Sincere appreciation also goes to the institutions and organisations that participated and contributed. The research ethics committees from the University of Cape Town, Nelson Mandela Metropolitan University and the National Health Laboratory Services are thanked for granting ethics approval.

The three independent peer reviewers were: Prof Barry Schoub, former National Institute of Communicable Diseases (NICD) Executive Director and Emeritus Professor at the University of the Witwatersrand (South Africa); Prof Eucharia Kenya, Deputy Principal at Embu University College (Kenya); and Prof Malcolm Dando, Professor of International Security at the University of Bradford (United Kingdom). The panel wishes to express its gratitude for their inputs which have enriched the report.

Dr Hennie Groenewald's invaluable contributions in finalising the report are greatly acknowledged.

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The publisher for the report was Kashan Advertising.

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Professor Jill Farrant
Panel Chairperson: The State of Biosafety and Biosecurity in South Africa

Executive Summary

This consensus study report presents the findings of a systematic assessment of the state of biosafety and biosecurity in South Africa, including an evaluation of legislation, regulations and practices at both national and institutional levels. The findings report on strengths, weaknesses and gaps in the laws and in their implementation, and the practices relating to biosafety and biosecurity at laboratory level. Recommendations are made to address the weaknesses and gaps identified.

Research and development in the life sciences are important elements of South African growth and development and are essential to address the needs of the country. It was thus imperative that ASSAf contributes towards ensuring that life science research in South Africa is conducted safely, securely and ethically. This is in the interests of all South Africans and in the interests of the life science community.

With this broad objective, ASSAf constituted a Biosafety and Biosecurity panel of experts to assess and comment on the relationship between science and security in South Africa. While it is deemed important to extend an assessment of biosafety and biosecurity to the greater southern African region, this was not possible in the timeframe permitted for the study, but remains an important objective in the long term.

The research conducted for this consensus study included:

1. An investigation into the applicability and balance of relevant ethical principles through a review of literature in order to establish a context for biosafety and biosecurity considerations.
2. An assessment of existing, relevant legislation and regulations in relation to biosafety and biosecurity in order to identify strengths, weaknesses and gaps in laws and in their implementation.
3. A critical overview of the implementation of biosafety and biosecurity measures in laboratories in South Africa and an assessment of the extent to which laboratory practices address safety and security concerns.
4. An evaluation of existing measures and capacity to detect, identify, control and prevent the natural, accidental or deliberate spread of infectious agents.

The panel used a variety of methods to conduct the research, including but not limited to:

1. Convening a series of panel discussions on biosafety and biosecurity.
2. Assessing existing legislation and regulations in relation to biosafety and biosecurity to identify strengths, weaknesses and gaps in laws and in their implementation.

3. Conducting a survey of life scientists' experience and perceptions of biosafety and biosecurity measures in laboratories in South Africa.
4. Evaluating existing measures and capacity to detect, identify, control, and prevent the natural, accidental, or deliberate spread of infectious agents.
5. Consultation with experts from a variety of disciplines (including experts with proven biosecurity expertise).

Ultimately, the goal of the study was to:

1. Make sustainable and evidence-based recommendations to the South African government and the scientific community to address the identified weaknesses in: existing legislation; the implementation of biosafety and biosecurity in laboratories; existing measures and capacity to detect and control spread of infectious diseases; and to raise awareness about existing measures (including practices and legislation) to reduce the risks associated with dual-use research and to engage the life science community in a dialogue about biosafety and biosecurity.
2. Make recommendations to remove weaknesses and gaps in existing legislation and in the implementation of such legislation.

Outline of the report

Chapter 1 (background) introduces the context of the study and then continues to define its goals, approaches and methodologies.

Chapter 2 (ethical context) offers an introduction to the interface between science and social responsibility, both at the level of the individual scientist and the institutional. Morality and ethics are discussed and the distinction between these concepts is clarified. The dual-use problem, whereby science can be used for both good and bad purposes, is explained and examples pertinent to the biosafety and biosecurity field are provided. The chapter concludes with an overview of how ethics is currently institutionalised and managed in South Africa.

Chapter 3 (regulatory framework) presents the results of the studies undertaken to explore legislation relevant to biosafety and biosecurity in South Africa. A desktop review of legislation currently governing South African biological safety as listed in the governmental submission to the United Nations Security Council Resolution 1540 (UNSCR 1540) Committee is presented. The review also identified and analysed legislation and regulations pertinent to biological safety and security in the country not listed in the UNSCR 1540 submission, through consultations with government departments and ministries involved in the biological safety and security arena. The review revealed that the South African legislative framework is robust and comprehensive, but suffers from several limitations and challenges, including

coherence in the categorisation of pathogens, the lack of harmonisation of guidelines, and infrastructure and capacity challenges for implementation.

In addition, the results of a systematic review conducted to identify, collate and review current South African governmental regulations, policies and guidelines for detecting, identifying, controlling and preventing the natural, accidental or deliberate spread of infectious agents. The review identified a complex set of South African regulations governing the detection, identification, control, and prevention of human, animal and plant diseases caused by infectious agents. The panel noted that the development of a single, locally relevant list of infectious agents which is regularly updated could potentially enhance the utility and cross-referencing of future regulations.

Chapter 4 (implementation) outlines the survey used to map and compile a database of all functional life science facilities in the country. This included public and private sector facilities engaged in life science research, development or both. The final database comprises 979 facilities, of which 22% conduct research, 72% perform diagnostic services and 6% provide both.

At the start of this survey there was no comprehensive database of public and commercial life sciences facilities in South Africa. Therefore, the panel recommends that the database compiled during this survey be considered a national asset and that its ongoing development and maintenance (including the development of a geographic information system map of all facilities) becomes the responsibility of the Department of Science and Technology (DST). In the view of the panel, the DST is correctly placed to take on this responsibility because laboratories work in the fields of human, animal and plant health and thus fall neither neatly into the scope of the Department of Health (DoH) nor the Department of Agriculture, Forestry and Fisheries (DAFF). In the interim, the database is available from ASSAf on request, but not for commercial use.

In addition, a comprehensive overview is presented of the findings from a survey of 350 life scientists in South Africa regarding the safety and security rules and regulations pertaining to their work. The survey found significant gaps in the training of scientists pertaining to ethics, biosafety, biosecurity and dual-use issues, as well as in relation to how and where to report possible breaches. There also appear to be gaps in relation to the implementation of existing rules and regulations, including in relation to standard operating procedures (SOPs), tests of competence (in biosafety and biosecurity) and even in some instances in the maintenance of laboratory equipment. The panel agreed that this survey highlighted an urgent need to ensure that life scientists are informed about national and international laws and policies relevant to their work.

Chapter 5 (responsiveness) details the methods and results of a study of qualitative, key participant interviews, conducted with purposively-sampled experts in the field of infectious disease outbreaks in South Africa. The study highlighted the complexity of the systems required to manage infectious disease outbreaks in South Africa. The study participants identified significant strengths of the system, which provide a strong foundation for future improvements. Since many sectors and levels of workers are involved, it was often difficult to navigate these complex systems. The panel recognises that the voices of the participants provide clear advocacy for meaningful engagement between sectors with the shared aim of reducing the incidence of potential infectious disease outbreaks in the future.

Chapter 6 summarises the key findings and recommendations arising from the different chapters. Specific recommendations were made under four distinct themes:

1) Improving the capacity to detect and respond to infectious disease outbreaks.
2) Education and awareness raising.
3) Ethics review.
4) Scientific openness and transparency.