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BACKGROUND

1.1 Introduction

Research and development (R&D) and service delivery within the life science sector in South Africa are important elements in ensuring the well-being of its citizens and the continued growth and development of the sector. Discovery and innovation within the life sciences hold great potential benefits to humankind, but also potential risks, which should be proactively considered and managed to ensure the safe, sustainable and ethical advancement of these sciences and their applications. The considered, safe and ethical conduct of life scientists is not only imperative to ensure safety within the R&D environment, but also that of the societies and world within which they work and live.

The concepts and practices of biosafety and biosecurity relate directly to the activities and conduct of life scientists and intend to safeguard against exposure to, or the deliberate or inadvertent development or release of, living organisms and/or biological material that may harm humans and/or the environment. Biosafety and biosecurity have a common, general goal, i.e. protecting people and the environment against hazardous living organisms and biological materials, but they mitigate different risks.

Biosafety, or more specifically *laboratory biosafety*, is a fairly well-established concept that refers to the containment principles, technologies and practices that are implemented to prevent unintentional exposure to (potentially) hazardous biological material, e.g. pathogens and toxins, or their accidental release.[1] More recently the term has also become synonymous with GMOs – specifically referring to the food/feed and environmental safety of these organisms. The *biosafety of GMOs* as assessed through food/feed and environmental risk assessments has developed into a separate discipline with related, but distinct, objectives, methodologies and regulatory frameworks. Although there are references to GMO biosafety, this consensus study focuses on *laboratory biosafety*.

Biosafety and biosecurity measures safeguard against exposure to, or the deliberate or inadvertent development or release of, living organisms or biological material that may harm humans or the environment.

In general, *biosecurity* refers to management systems designed to protect society and the environment against potentially harmful organisms and biological materials, but it too has divergent meanings depending on the context in which it is used. In an agricultural context, i.e. veterinary and plant health disciplines, the term has come

[1] WHO Laboratory Biosafety Manual, 2004.

to represent the protection of valued biological resources from foreign, harmful or invasive organisms.[2] In contrast, in a public health context it is used to refer to systems that establish and maintain the security and oversight of potentially hazardous organisms and biological materials – especially those that could be misused to cause deliberate harm. Again, this consensus study will focus only on the latter.

This consensus study report presents the findings of a systematic assessment of the state of laboratory biosafety and biosecurity in a public health context in South Africa. It includes an overview and evaluation of the national legislative framework as well as institutional implementation and practices. The findings report on strengths, weaknesses and gaps in the legal framework and in its implementation at laboratory level. Recommendations are made to address the weaknesses and gaps identified. The study was completed at the time of the Ebola outbreak in West Africa (September 2014), underscoring the importance of recommendations aimed at ensuring the safe, secure and ethical conduct of research in South Africa.

1.2 Goal of the study

The overall goal of the study was to:
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 the 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.

1.3 Approach and methodology

The Academy of Science of South Africa (ASSAf) constituted a Biosafety and Biosecurity panel comprising ten national experts to assess the state of biosafety and biosecurity in South Africa. Brief biographies of the panel members are presented in Appendix 1.

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

i) Convening a series of Biosafety and Biosecurity panel meetings.
ii) Conducting a survey of life scientists' experience and perceptions of biosafety and biosecurity measures in laboratories in South Africa.
iii) Assessing existing legislation and regulations in relation to biosafety and biosecurity to identify strengths, weaknesses and gaps in laws and in their implementation.

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[2] FAO Biosecurity Toolkit, 2007.

iv) Evaluating existing measures and capacity to detect, identify, control, and prevent the natural, accidental, or deliberate spread of infectious agents.
v) Consultation with experts from a variety of disciplines (including experts with proven security expertise).

The research conducted for this consensus study included:
i) An investigation into the applicability and balance of relevant ethical principles through a review of literature.
ii) 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.
iii) 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.
iv) An evaluation of existing measures and capacity to detect, identify, control and prevent the natural, accidental or deliberate spread of infectious agents.

A number of studies were commissioned and contributed to the evidence available to the panel when compiling their recommendations. Commissioned studies included:
1. 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. This study took the form of a survey, based on the application of a self-assessment tool developed by WHO[3] adapted for local circumstances.
2. An evaluation of existing measures and capacity (nationally and regionally) to detect, identify, control, and prevent the natural, accidental, or deliberate spread of infectious agents, using a list of selected agents and toxins as a guideline. This evaluation included the engagement of scientists to discuss the strengths and weaknesses in their own facilities.
3. An overview of the existing relevant legislation and regulations in relation to biosafety and biosecurity and the identification of strengths, weaknesses and gaps in laws and implementation.

In addition to the tasks undertaken as part of the scope of work, the panel investigated the applicability and balance of relevant ethical principles through a review of literature, and developed measures to raise awareness about existing measures (including practices and legislation) to reduce the risks associated with dual-use research and engage the life science community in a dialogue about biosafety and biosecurity.

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[3] WHO, Responsible life sciences research for global health security, 2010.