biosafety SOUTH AFRICA

RISK ANALYSIS FOR CONTAINED USE R&D ACTIVITIES WITH GM AQUATIC ORGANISMS

James Rhodes & Hennie Groenewald

Virtual Workshop Series on Regulatory Approaches for Agricultural Applications of Animal Biotechnology

7 OCTOBER 2020

science & innovation
Department:
Science and Innovation
REPUBLIC OF SOUTH AFRICA

technology innovation AGENCY

SERVICE OFFERING

Sustainability researchers & practitioners

Policy developers & regulators

biosafety SOUTH AFRICA

Technology developers

The public & media

biosafety SOUTH AFRICA

THE GMO PERMIT APPLICATION PROCESS

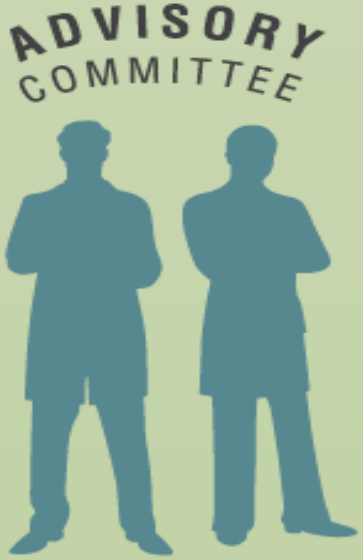
PERMIT ISSUED FOR:

– Contained use –
– Field trials –
– Commercial commodities –
– General release –

DEPARTMENT OF AGRICULTURE, FORESTRY AND FISHERIES

Applications sent to GMO Registrar

SCIENTIFIC EVALUATION BY THE ADVISORY COMMITTEE



THE EXECUTIVE COUNCIL

The Executive Council, consisting of several government departments, makes final decision, taking public input into consideration.

BACKGROUND

- Biosafety SA assisted applicants with regulatory approval for R&D facilities
- Not a lot of experience with GM aquatic organisms- no specific guidance
- Developed a guidance document for the contained R&D of GM aquatic organisms
- Incorporated learnings from published research and standards
  - ABRAC 1995 - Performance standards for safely conducting research with genetically modified fish and shellfish.
  - NRC 2002- Animal Biotechnology: Science-Based Concerns
  - NRC 2004- Biological confinement of genetically engineered organisms

biosafety SOUTH AFRICA

GUIDELINE

- Proposes a number of measures for the design, registration and management of R&D facilities
- Explicitly introduced a few concepts
  - Risk analysis
  - Using plausible pathways to harm to focus risk assessment

biosafety SOUTH AFRICA

GUIDELINE

- Unintentional escape of GM aquatic organisms is a crucial step in the majority of plausible harms – focus is on containment

- Discusses to the use of tools which have been developed to assist with appropriate mitigation and containment measures in a contained use aquaculture facility
  - ABRAC 1995
  - Scientists Working Group on Biosafety 1998

GUIDELINE – RISK ASSESSMENT
Hazard Identification

- Incorporates problem formulation and risk scenarios into the hazard identification step

- Information needed to do this
  - characteristics of the organism
  - the genetic insert
  - the receiving environment e.g. the presence of native populations

GUIDELINE – RISK ASSESSMENT
Risk characterisation

- Risk is a product of the likelihood and consequence of harm
- The risk associated with each identified hazard must be assessed in order to establish appropriate containment measures for the activities
- Tools such as risk assessment matrix and definitions for assessing likelihood and consequence and are introduced
- The focus is on appropriate risk management to ensure possible pathways to harm are disrupted- sufficient containment measures should be put in place to ensure that the overall level of risk is low

GUIDELINE – RISK ASSESSMENT
Risk characterisation

		RISK ESTIMATE			
LIKELIHOOD ASSESSMENT	**Highly likely**	Low	Moderate	High	High
	Likely	Low	Low	Moderate	High
	Unlikely	Negligible	Low	Moderate	Moderate
	Highly unlikely	Negligible	Negligible	Low	Moderate
		Marginal	**Minor**	**Intermediate**	**Major**
		CONSEQUENCE ASSESSMENT			

Risk assessment matrix (modified from OGTR 2009)

biosafety SOUTH AFRICA

GUIDELINE – RISK ASSESSMENT

Risk characterisation

Risk estimate	Risk estimate definitions
Negligible	Risk is insubstantial and there is no present need to invoke actions for mitigation.
Low	Risk is minimal, but may invoke actions for mitigation beyond normal practices.
Moderate	Risk is of marked concern that will necessitate actions for mitigation that need to be demonstrated as effective.
High	Risk is unacceptable unless actions for mitigation are highly feasible and effective.

Likelihood[1]	Likelihood assessment definition[1]
Highly unlikely	May only occur in very rare circumstances
Unlikely	Could occur in some circumstances
Likely	Could occur in many circumstances
Highly likely	Is expected to occur in most circumstances
Consequence[2]	**Consequence assessment definition (related to human health and environment)**
Marginal	No or minimal adverse health effects or damage/disruption to the environment
Minor	Adverse but limited and reversible health effects or damage/disruption to the environment that is reversible and limited in time, space and numbers affected
Intermediate	Adverse, widespread and not readily reversible health effects or widespread damage/disruption to the environment that is of limited severity and reversible
Major	Adverse, severe, widespread and irreversible health effects or extensive damage/disruption to whole natural ecosystems, communities or species that persists over time and is not readily reversible

Scale for level of risk and for assessing likelihood and consequence (adapted from OGTR 2009)

GUIDELINE – RISK MANAGEMENT
Containment of GM aquatic organisms

- Risk management strategies must be adopted to ensure risks are appropriately managed

- Physical containment, biological containment and geographical containment

- Physical containment includes
  - mechanical barriers to block one or more life stages such as filters screens, radiation, biocidal agents, changes in temperature or pH
  - must be effective in containing the smallest form in the lifecycle of the organism

GUIDELINE – RISK MANAGEMENT
Containment of GM aquatic organisms

- Biological containment to block reproduction and contain gene flow e.g. triploidy, single sex populations, GURTs
- Geographic containment – facility in a site where the environmental parameters are not suitable for the survival of the organism or away from closely related populations
- Learning through R&D when stepping up to commercial production- recommended that efficacy of containment should be tested during the R&D phase

GUIDELINE – RISK MANAGEMENT
Containment of GM aquatic organisms

- Increasing difficulty in containment
  - Decreasing size
  - Increasing fitness and physical tolerance
  - Increasing dispersal ability
  - Increase in scale
  - Proximity to receiving environment

- Two different facility categories are proposed for contained R&D activities based of scale
  - R&D laboratory – fully enclosed and small volumes
  - R&D small and medium facilities- not necessarily fully enclosed

GUIDELINE – RISK MANAGEMENT
Containment of GM aquatic organisms

- Redundancy should be employed to reduce the likelihood of escape and reduce uncertainty
    - Failure of one barrier should not result in the failure of another barrier
    - Multiple containment simultaneous methods recommended
- Monitoring of effective containment

GUIDELINE – RISK COMMUNICATION

- Promote clear understanding of different aspects of risk
- Communicate basis of decisions made

GUIDELINE – APPLICATION FORM

- Facility details
- Risk assessment
- Facility management

biosafety
SOUTH AFRICA

THANK YOU

James Rhodes | james@biosafety.org.za
www.biosafety.org.za