Biosafety South Africa
105 Wentworth, Somerset Links Office Park
De Beers Avenue, Somerset West, 7130
E-mail: biosafety@biosafety.org.za
Phone: +27 21 850 0530

GMO RISK ANALYSIS SHORT COURSE

General Objective

To capacitate the wide spectrum of risk assessors and researchers that play a role in national biosafety regulatory systems with the necessary knowledge and skills that will allow them to contribute pertinent information relevant to risk analysis and effectively assess the potential risks of GMOs and make accurate and confident regulatory decisions.

Specific Goals

1. To accurately contextualise GM technology, its regulation and the risk analysis of GMOs.
2. To impart the necessary GMO and risk analysis theory and decision making tools to participants to enable them to structure their own thinking and further self-develop their skills after the engagement.
3. To develop critical thinkers and confident decision makers who can add value to national biosafety systems through their direct role in the system and/or the subsequent teaching of future decision makers.

Proposed structure and content of the short course

General principles:

1. The structure, content and nature of any risk analysis capacity building initiative should always be developed and presented around the principled risk analysis framework as explained below.
2. Ensure a highly interactive and practice-focused engagement to ensure participants really engage with the content and to ensure knowledge and skills are effectively transferred.

Structure and content:

Risk analysis, in principle, is the contextualised integration of risk assessment, risk management and risk communication and can in its most basic form be represented as a simple, three element framework (Figure 1). This approach allows for decision making on GMOs to take into consideration the unique context such as local and international policies and obligations and development objectives. Moreover, all three the aspects of GM products that are regulated to ensure their sustainability, i.e. food/feed safety, environmental safety and socio-economic impact, can be evaluated and managed using such a general, conceptual risk analysis framework.

The contextualised overview and integration of these various elements of risk analysis is important to ensure an appreciation of the conceptual overlaps between the various assessments, how they all contribute towards the sustainability of GMOs, as well as how activities such as risk management and communication relate to each of these assessments.

© Biosafety South Africa, 2019

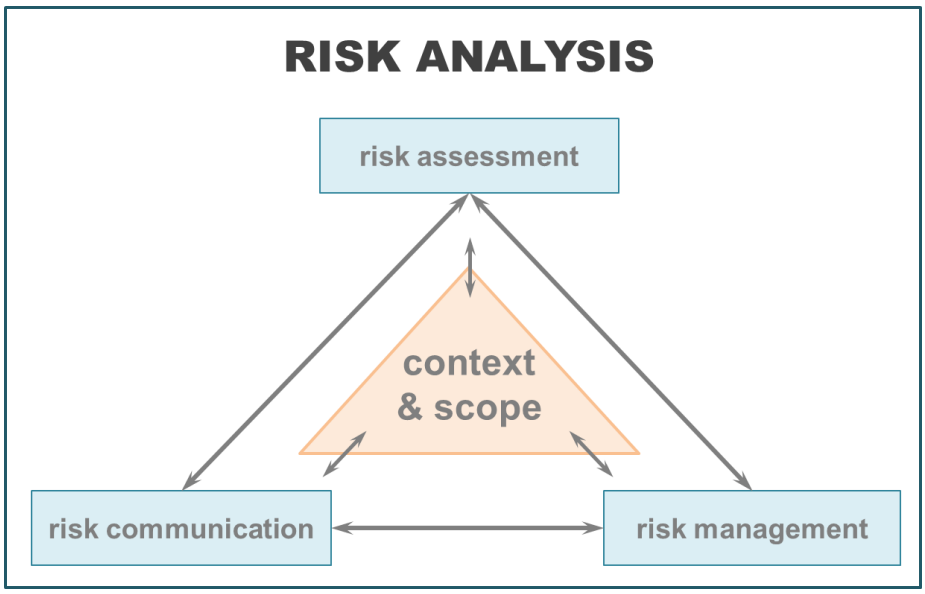

Figure 1. Principled framework for risk analysis.

The structure of the short course will therefore be based on this integrated conceptual risk analysis framework, resulting in six clearly defined teaching modules (Figure 2).

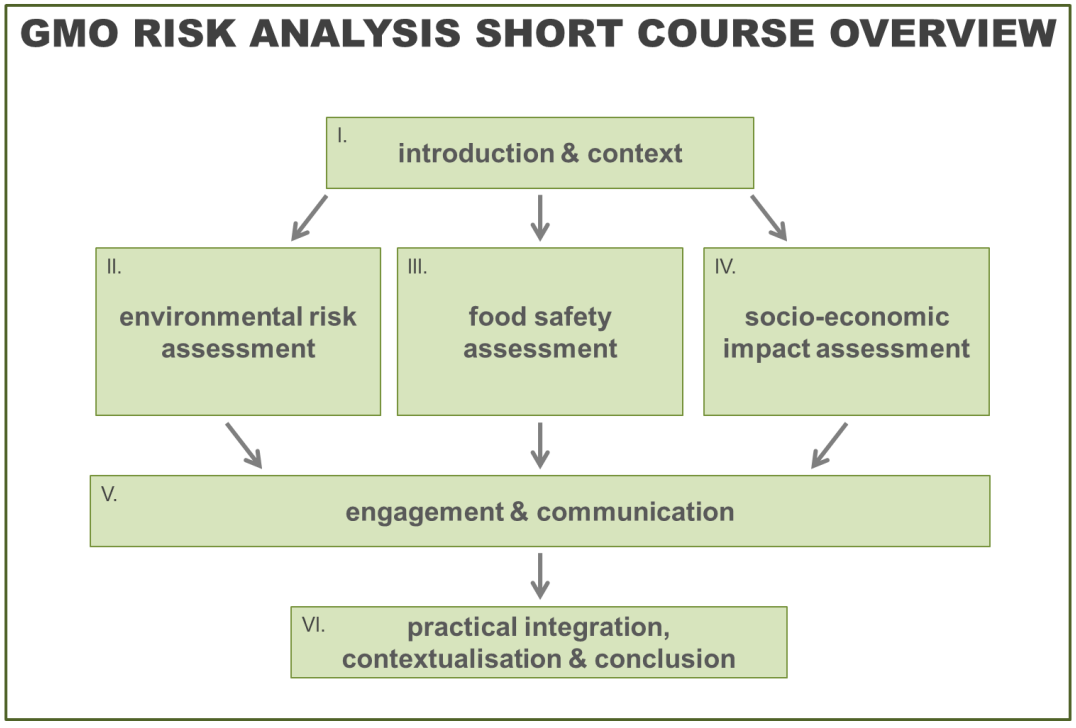

Figure 2. Proposed structure of the GMO risk analysis capacity building course, highlighting both the shared and separate risk analysis elements of a GMO sustainability analysis.

Each module will be structured to offer:

(i) An explanation of the theoretical and/or regulatory basis of the subject matter.
(ii) Relevant assessment- and/or strategic frameworks and/or guidelines.
(iii) Practical examples which illustrate and reinforce the theory.
(iv) Course-specific resources as well as additional, external resources that will facilitate self-learning.

© Biosafety South Africa, 2019

Module content overview:

Module I: Introduction & context		
Topics	**~Time**	**Instructor**
GMO science, why regulate, international regulatory context, approaches to & impact of regulation, hazard-risk-harm, general risk analysis introduction & framework, context & comparators, transportability of data, etc.	45 min 09:00-09:45	H Groenewald
Module II: Environmental risk assessment		
Setting the context for ERA, defining management and protection goals, deriving assessment endpoints & identifying potential harms, likelihood & consequence assessment and identifying plausible pathways to harm, risk management & decision making, tiered approach to ERA, monitoring, preparing an ERA report, etc.	90 min 09:45-11:15	J Rhodes
- TEA BREAK -		
Module III: Food & feed safety assessment		
Food safety basics, international guidance, including Codex Alimentarius, OECD, EFSA, etc., f/f safety framework/elements, comparators, substantial equivalence, transportability of data, resources, e.g. biology documents, preparing a safety assessment report, etc.	40 min 11:40-12:20	J Rhodes
Module IV: Socio-economic impact assessment		
National & international context and regulatory frameworks, CPB, potential SEIA frameworks – problem formulation & value chain based approaches, preparing an impact assessment report, etc.	40 min 12:20-13:00	H Groenewald
- LUNCH BREAK -		
Module V: Engagement & communication		
Different types of engagement and communication, need & value, cultural cognition, differences in audiences, messages, communication exercises, etc.	40 min 14:00-14:40	H Groenewald
Module VI: Practical integration, contextualisation, conclusion & discussion		
Integrate various assessments to come to a relevant overall conclusion, contextualise all the above theory in terms of relevant legislation, discuss examples, case studies, impact of new breeding techniques, etc.	60 min 14:40-15:40	J Rhodes H Groenewald

Course presenters

Biosafety South Africa (www.biosafety.org.za) is a non-profit technology platform in service of South Africa's and the region's biotechnology regulators, researchers, technology developers and public. Its mandate is to enable safe, sustainable and compliant research, development, production, use and application of biotechnology - in particular GMOs. It is an initiative of the South African Department of Science and Technology and funded entirely from public sources.

One of the platform's primary functions is to help develop national and regional capacity in risk analysis to ensure these biosafety systems are able to effectively manage the potential risks associated with biotechnologies.

© Biosafety South Africa, 2019

Instructors:

Individuals that will be involved in the development of resources and presentation of this training course are:

1. Dr Hennie Groenewald*
   Hennie Groenewald has a PhD in plant biotechnology and more than 22 years' experience in research and development, risk analysis, the governance of bio-products, teaching and innovation management in both private and public environments. Hennie is a member of and has served on various international, national and institutional organisations, boards and committees tasked with biosafety, risk analysis, risk governance, biotechnology and agricultural innovation and capacity building.

2. Mr James Rhodes*
   James Rhodes is a Biosafety Analyst at Biosafety South Africa with extensive research and policy analysis experience. James has over 10 years' experience in various aspects of the environmental risk analysis of GMOs at the different stages of research, development and deployment. This includes supporting and advising stakeholders across the whole spectrum on risk analysis theory and practice and providing them with evidence-based biosafety information. James is currently enrolled for a PhD investigating how the regulation of GMOs can be improved to better enable their use in addressing South Africa's sustainable development goals.

   **Note: Comprehensive CVs of the above persons are available on request.*

© Biosafety South Africa, 2019