Biosafety Group

ICGEB Biosafety Group Activities

Wendy Craig

Group Leader - Biosafety

craig@icgeb.org

www.icgeb.org/biosafety

ICGEB's Instruments of Action

- Cutting-edge scientific research in its laboratories in Trieste, New Delhi and Cape Town
- Advanced education supported by long- and short-term fellowships for PhD students and post-docs
- Competitive research grants for scientists in Member States, including Early Career Return Grants
- Technology transfer to industry for the production of biotherapeutics and diagnostics
- Organisation of meetings, courses and workshops at the international level
- **Provision of technical assistance and capacity enhancement in the regulation of biotechnology and its products**

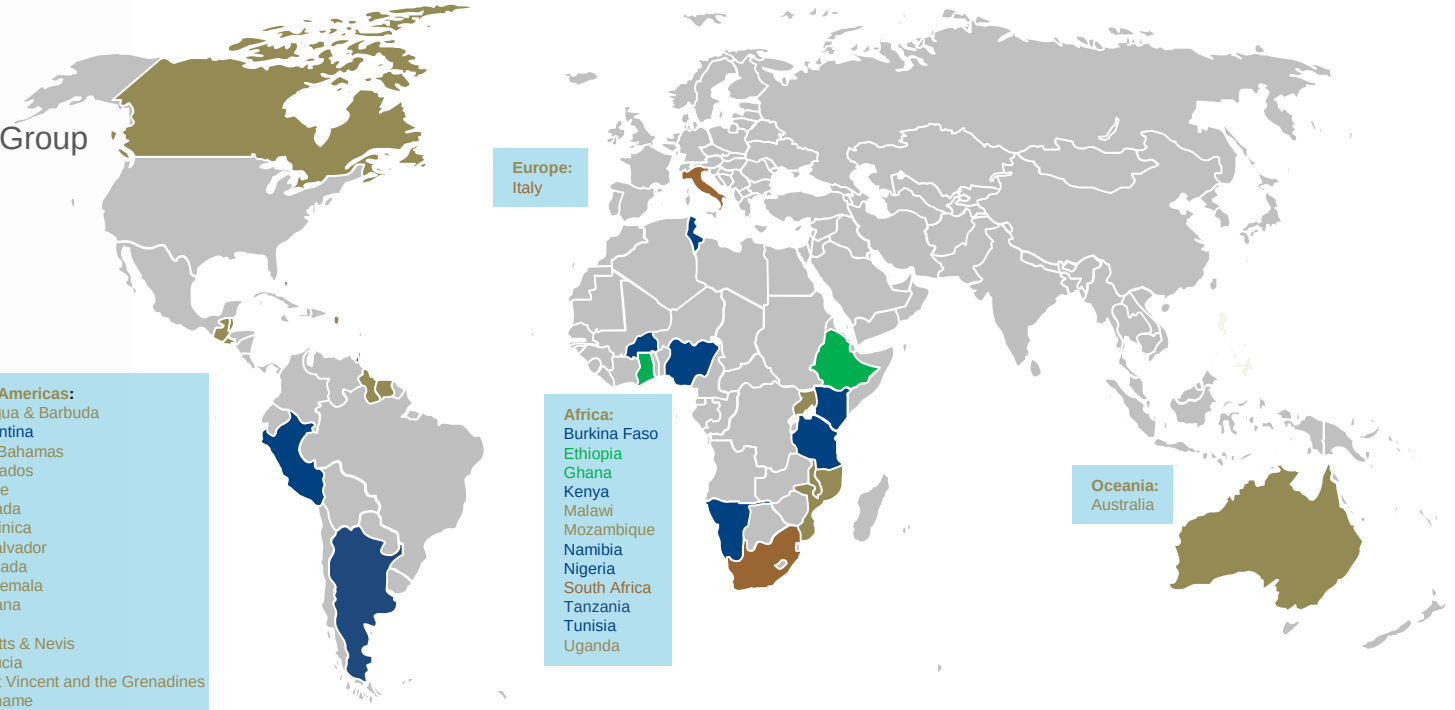
Biosafety Group

The Role of the Biosafety Group

To **assist its Member States in their capacity** to identify, regulate, manage, and monitor those products within their own countries

Location of Biosafety Group activities (2012-2018)

- Member State
- Signatory Country
- Non-Member State



The Americas:
Antigua & Barbuda
Argentina
The Bahamas
Barbados
Belize
Canada
Dominica
El Salvador
Grenada
Guatemala
Guyana
Peru
St Kitts & Nevis
St Lucia
Saint Vincent and the Grenadines
Suriname
Trinidad & Tobago

Europe:
Italy

Africa:
Burkina Faso
Ethiopia
Ghana
Kenya
Malawi
Mozambique
Namibia
Nigeria
South Africa
Tanzania
Tunisia
Uganda

Oceania:
Australia

Biosafety Group

Capacity Enhancement Activities

Assisting the development of effective safety and regulatory systems for the products of modern biotechnology

- **Biosafety legislation and administrative systems**

  In-country working partnerships, mentored fora

- **Communication strategy and tools**

  Devising tailored public education and outreach strategies and technical content, e.g. radio spots, brochures, videos

- **Training, both academic and vocational, in all aspects of GMO regulation**

  Regulatory experience exchange opportunities, In-country working partnerships, Masters in Biosafety fellowships, eLearning modules, mentored fora

Institutional capacity enhancement

- In-country working partnerships (IWPs)
- Regulatory experience exchange opportunities
- Masters fellowships in biosafety & eLearning
- Re-integration of academically-trained personnel into national regulatory systems
- Biosafety training workshops and mentored fora

Biosafety Group

Biosafety Project for sub-Saharan Africa

Assisting the development of effective safety and regulatory systems for the products of modern biotechnology in selected countries of sub-Saharan Africa (SSA)

Burkina Faso

Nigeria

Ethiopia

Tanzania

Ghana

Uganda

BILL & MELINDA GATES foundation

Biosafety Group

Masters Fellowships in Plant Biotechnology, with a special focus on GM Crop Regulation

THE UNIVERSITY OF ADELAIDE AUSTRALIA

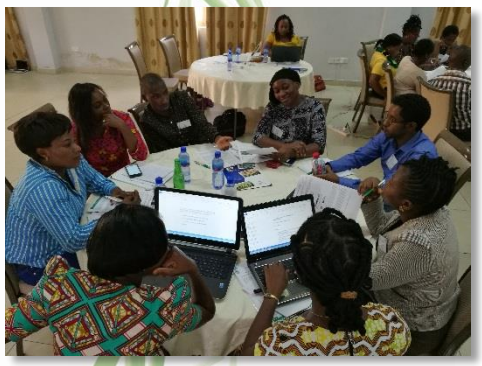
- **17 regulatory officials/scientists** from African Project countries (4 ETH, 4 GHA, 3 NGA, 3 TZA and 3 UGA) completed the programme
- Research conducted under the Master Programme resulted in the generation of **locally-relevant biosafety regulatory baseline information and data**

- Majority of **graduates now playing significant roles** in national GMO regulatory decision-making processes
- **eLearning modules** developed to enable offering of a similar programme in **African HEIs**, as well as directly to **GMO regulatory offices** for *in house* training (later)

https://showcase-icgeb.elearning.it/index.html

Biosafety Group

Biosafety Training Workshops and Mentored Fora



- **25+ workshops and fora delivered to date to over 500 biosafety regulatory officials and technical experts**
- Meetings designed to address **locally-relevant needs**
- Follow-up to determine the extent to which the **training and assistance improved approaches used in their day-to-day duties**

The training activities include:

- *Legal drafting*
- *Development of tools to enhance GMO regulation (forms, checklists, etc.)*
- *Devising regulatory administrative processes*
- *GMO risk analysis*
- *GMO containment & confinement (inspection & monitoring)*
- *Risk communication*

ICGEB
Biosafety Group

Regulatory Working Experience

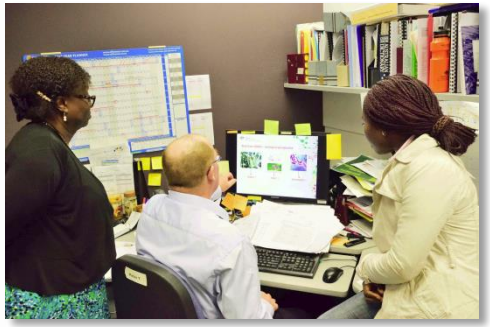
- Visits by **African regulators** and/or their scientific experts to **established regulatory offices**
- These visits provide opportunities for African regulatory officials **to learn from established offices**
- **15+ visits organised**, for periods ranging from 2 – 6 weeks

Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

Ministerio de Agroindustria
Presidencia de la Nación

CANADIAN FOOD INSPECTION AGENCY

UNCST
UGANDA NATIONAL COUNCIL FOR SCIENCE & TECHNOLOGY



Biosafety Group

In-country Working Partnerships

- **Direct in-country technical assistance** to Project countries – BFA, ETH, GHA, NGA,TZA & UGA
- By focusing on pressing and relevant needs, these IWPs have led to **immediate enhancements of national biosafety regulatory capacity**

Documents developed during these visits include:

- *Inter-ministerial MOUs outlining roles and responsibilities*
- *Guidelines on dealing with the unintended presence of GMOs and GM products*
- *Environmental risk assessment guidelines*
- *Forms for Confined Field Trial and general release applications*
- *Checklists for handling CFT applications*

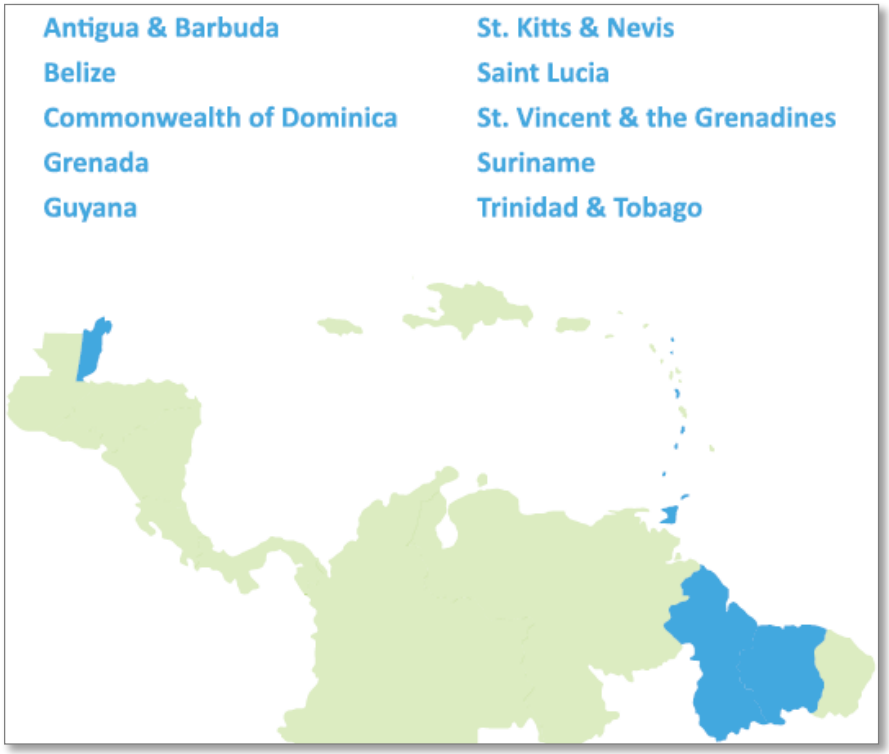
Capacity Enhancement Activities

Biosafety Group

Assisted the UNEP-GEF "*Regional Project for Implementing National Biosafety Frameworks in the Caribbean Sub-region*"

- Enhanced capacities of the small Caribbean Islands to develop their own biosafety legislation and administrative systems
- Developed the key elements for the elaboration of a regional as well as country-relevant communication strategy on the safe use of GMOs
- Provided relevant training in risk analysis

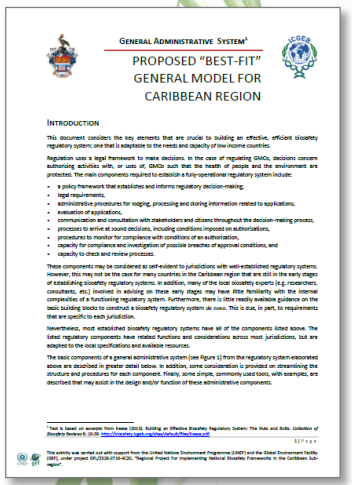
UN environment
United Nations Environment Programme



gef

Biosafety Legislation and Administrative Systems

Biosafety Group



GENERAL ADMINISTRATIVE SYSTEM[1]

PROPOSED "BEST-FIT" GENERAL MODEL FOR CARIBBEAN REGION

INTRODUCTION

This document considers the key elements that are crucial to building an effective, efficient biosafety regulatory system; one that is adaptable to the needs and capacity of low income countries.

Regulation uses a legal framework to make decisions. In the case of regulating GMOs, decisions concern authorising activities with, or uses of, GMOs such that the health of people and the environment are protected. The main components required to establish a fully-operational regulatory system include:

- a policy framework that establishes and informs regulatory decision-making,
- legal requirements,
- administrative procedures for lodging, processing and storing information related to applications,
- evaluation of applications,
- communication and consultation with stakeholders and citizens throughout the decision-making process,
- processes to arrive at sound decisions, including conditions imposed on authorisations,
- procedures to monitor for compliance with conditions of an authorisation,
- capacity for compliance and investigation of possible breaches of approval conditions, and
- capacity to check and review processes.

These components may be considered as self-evident to jurisdictions with well-established regulatory systems. However, this may not be the case for many countries in the Caribbean region that are still in the early stages of establishing biosafety regulatory systems. In addition, many of the local biosafety experts (e.g. researchers, consultants, etc.) involved in advising on these early stages may have little familiarity with the internal complexities of a functioning regulatory system. Furthermore, there is little readily available guidance on the basic building blocks to construct a biosafety regulatory system *de novo*. This is due, in part, to requirements that are specific to each jurisdiction.

Nevertheless, most established biosafety regulatory systems have all of the components listed above. The listed regulatory components have related functions and considerations across most jurisdictions, but are adapted to the local specifications and available resources.

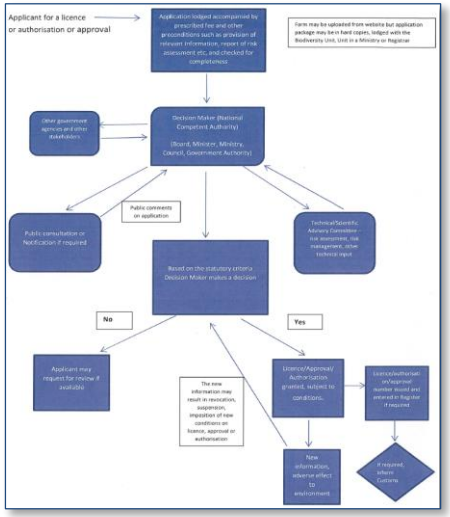
The basic components of a general administrative system (see Figure 1) from the regulatory system elaborated above are described in greater detail below. In addition, some consideration is provided on streamlining the structure and procedures for each component. Finally, some simple, commonly used tools, with examples, are described that may assist in the design and/or function of these administrative components.

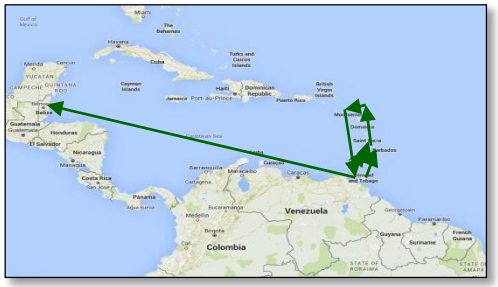
[1] Text is based on excerpts from Kwesi (2013). Building an Effective Biosafety Regulatory System: The Nuts and Bolts. Collection of Biosafety Reviews 8: 33-90. http://biosafety.icgeb.org/sites/default/files/Kwesi.pdf

1 | Page

This activity was carried out with support from the United Nations Environment Programme (UNEP) and the Global Environment Facility (GEF), under project GFL/2328-2710-4C20, "Regional Project for Implementing National Biosafety Frameworks in the Caribbean Sub-region".

- UWI/ICGEB **mentored fora** on:
  - Biosafety Legislation
  - Biosafety Regulations & Administrative Systems
  - Application of technical guidelines and support to the administrative systems
  - Food and feed risk assessment
  - Risk communication
  - Mock exercise in the analysis of a dossier
- A "best-fit" **general model of an administrative system** developed for managing LMOs, LMO-FFPs and contained use
- **IWPs** and Skype sessions, as well as **1-week visits to ICGEB HQ premises**, provided technical support and coaching to project countries in the process of developing their own administrative systems
- Production of **guidelines** to enable the project countries to operationalise their administrative systems



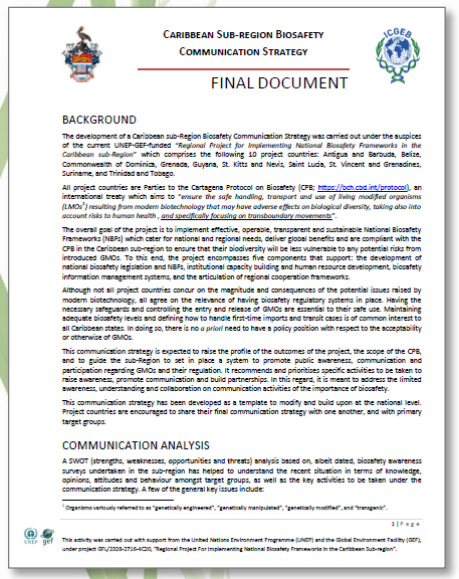


skype

Biosafety Group

Communication Strategy and Tools

- Developed a **public education and outreach strategy** for the project to guide the development and sharing of public awareness material regarding biotechnology and biosafety.
- Developed **technical content** on biotechnology and biosafety for outreach materials such as: texts for radio spots (2), short video clips (10), video (1), newsletter, banners and brochures


CARIBBEAN SUB-REGION BIOSAFETY COMMUNICATION STRATEGY

FINAL DOCUMENT

BACKGROUND

The development of a Caribbean sub-Region Biosafety Communication Strategy was carried out under the auspices of the current UNEP-GEF-funded *"Regional Project for Implementing National Biosafety Frameworks in the Caribbean sub-Region"* which comprises the following 10 project countries: Antigua and Barbuda, Belize, Commonwealth of Dominica, Grenada, Guyana, St. Kitts and Nevis, Saint Lucia, St. Vincent and Grenadines, Suriname, and Trinidad and Tobago.

All project countries are Parties to the Cartagena Protocol on Biosafety (CPB; https://bch.cbd.int/protocol), an international treaty which aims to *"ensure the safe handling, transport and use of living modified organisms (LMOs[1]) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health , and specifically focusing on transboundary movements"*.

The overall goal of the project is to implement effective, operable, transparent and sustainable National Biosafety Frameworks (NBFs) which cater for national and regional needs, deliver global benefits and are compliant with the CPB in the Caribbean sub-region to ensure that their biodiversity will be less vulnerable to any potential risks from introduced GMOs. To this end, the project encompasses five components that support: the development of national biosafety legislation and NBFs, institutional capacity building and human resource development, biosafety information management systems, and the articulation of regional cooperation frameworks.

Although not all project countries concur on the magnitude and consequences of the potential issues raised by modern biotechnology, all agree on the relevance of having biosafety regulatory systems in place. Having the necessary safeguards and controlling the entry and release of GMOs are essential to their safe use. Maintaining adequate biosafety levels and defining how to handle first-time imports and transit cases is of common interest to all Caribbean states. In doing so, there is no *a priori* need to have a policy position with respect to the acceptability or otherwise of GMOs.

This communication strategy is expected to raise the profile of the outcomes of the project, the scope of the CPB, and to guide the sub-Region to set in place a system to promote public awareness, communication and participation regarding GMOs and their regulation. It recommends and prioritises specific activities to be taken to raise awareness, promote communication and build partnerships. In this regard, it is meant to address the limited awareness, understanding and collaboration on communication activities of the importance of biosafety.

This communication strategy has been developed as a template to modify and build upon at the national level. Project countries are encouraged to share their final communication strategy with one another, and with primary target groups.

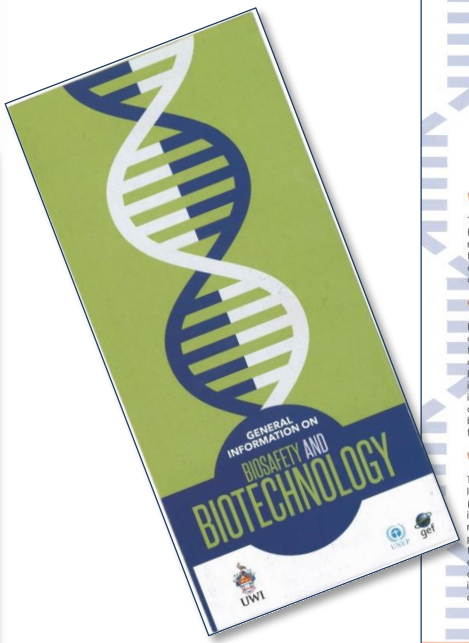
COMMUNICATION ANALYSIS

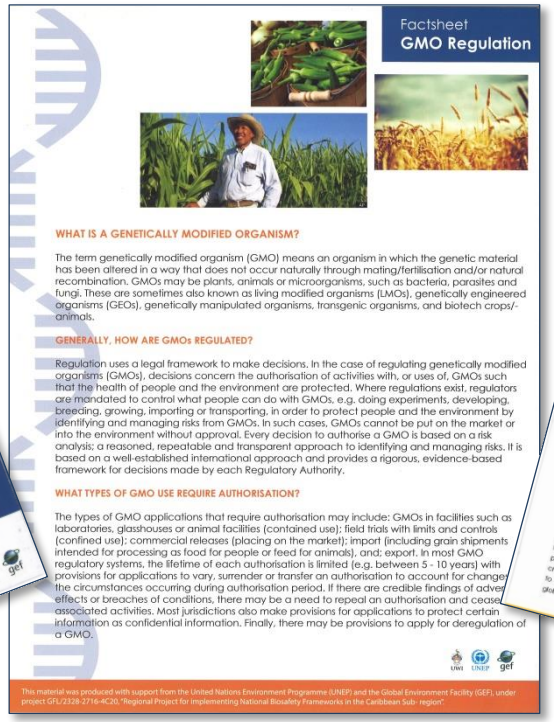
A SWOT (strengths, weaknesses, opportunities and threats) analysis based on, albeit dated, biosafety awareness surveys undertaken in the sub-region has helped to understand the recent situation in terms of knowledge, opinions, attitudes and behaviour amongst target groups, as well as the key activities to be taken under the communication strategy. A few of the general key issues include:

[1] Organisms variously referred to as "genetically engineered", "genetically manipulated", "genetically modified", and "transgenic".

1 | P a g e

This activity was carried out with support from the United Nations Environment Programme (UNEP) and the Global Environment Facility (GEF), under project GFL/2328-2716-4C20, "Regional Project For Implementing National Biosafety Frameworks in the Caribbean Sub-region".




Factsheet
GMO Regulation

WHAT IS A GENETICALLY MODIFIED ORGANISM?

The term genetically modified organism (GMO) means an organism in which the genetic material has been altered in a way that does not occur naturally through mating/fertilisation and/or natural recombination. GMOs may be plants, animals or microorganisms, such as bacteria, parasites and fungi. These are sometimes also known as living modified organisms (LMOs), genetically engineered organisms (GEOs), genetically manipulated organisms, transgenic organisms, and biotech crops/-animals.

GENERALLY, HOW ARE GMOs REGULATED?

Regulation uses a legal framework to make decisions. In the case of regulating genetically modified organisms (GMOs), decisions concern the authorisation of activities with, or uses of, GMOs such that the health of people and the environment are protected. Where regulations exist, regulators are mandated to control what people can do with GMOs, e.g. doing experiments, developing, breeding, growing, importing or transporting, in order to protect people and the environment by identifying and managing risks from GMOs. In such cases, GMOs cannot be put on the market or into the environment without approval. Every decision to authorise a GMO is based on a risk analysis; a reasoned, repeatable and transparent approach to identifying and managing risks. It is based on a well-established international approach and provides a rigorous, evidence-based framework for decisions made by each Regulatory Authority.

WHAT TYPES OF GMO USE REQUIRE AUTHORISATION?

The types of GMO applications that require authorisation may include: GMOs in facilities such as laboratories, glasshouses or animal facilities (contained use); field trials with limits and controls (confined use); commercial releases (placing on the market); import (including grain shipments intended for processing as food for people or feed for animals), and; export. In most GMO regulatory systems, the lifetime of each authorisation is limited (e.g. between 5 - 10 years) with provisions for applications to vary, surrender or transfer an authorisation to account for changes in the circumstances occurring during authorisation period. If there are credible findings of adverse effects or breaches of conditions, there may be a need to repeal an authorisation and cease associated activities. Most jurisdictions also make provisions for applications to protect certain information as confidential information. Finally, there may be provisions to apply for deregulation of a GMO.

This material was produced with support from the United Nations Environment Programme (UNEP) and the Global Environment Facility (GEF), under project GFL/2328-2716-4C20, "Regional Project for Implementing National Biosafety Frameworks in the Caribbean Sub- region".

Biosafety Group

Training in Risk Analysis

- UWI/ICGEB Biosafety Training Workshop held in Bridgetown, Barbados, in collaboration with the Government of Barbados
- UWI/ICGEB Regional Biosafety Workshop held in Castries, Saint Lucia
- UWI/ICGEB Biosafety Training Workshop held in Nassau, The Bahamas, in collaboration with the Bahamas Environment, Science & Technology (BEST) Commission

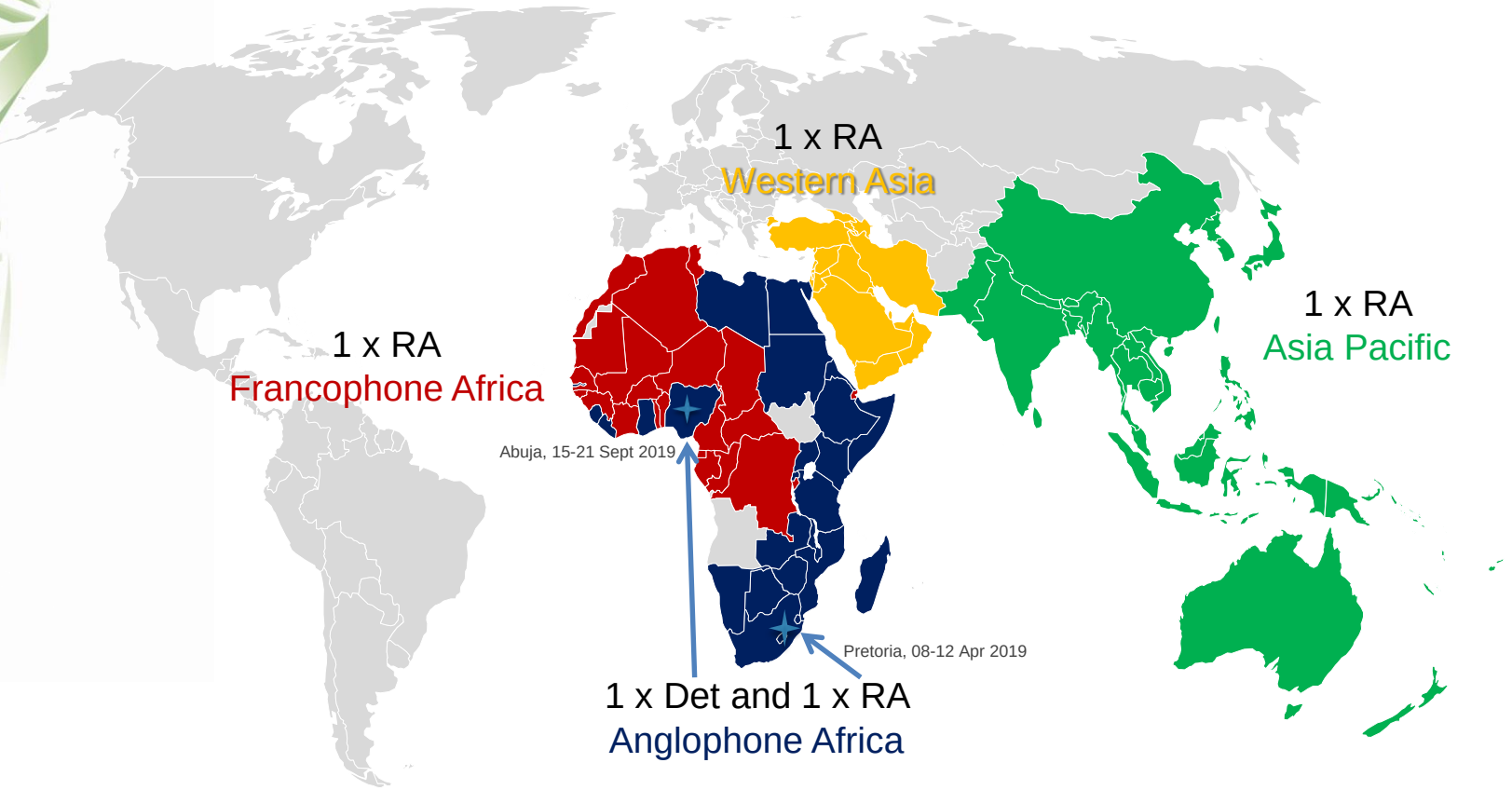





Collaboration with Secretariat of CBD

Biosafety Group is providing 5 Regional training workshops:

- Risk assessment (RA)
- GMO detection & identification (Det)



Biosafety Group

25 YEARS Convention on Biological Diversity
SAFEGUARDING LIFE ON EARTH

Biosafety Group

Collaboration with UN Environment

Supporting the Republic of Panamá, particularly the National Biosafety Commission (NBC) and its sectorial committees, to:

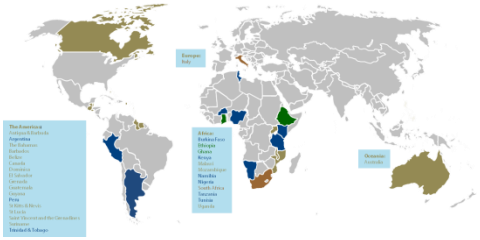
- complete the development and implementation of an updated regulatory and legal framework regarding GMOs, Norms/Regulations/Procedures, and
- analysis of border control (customs)

UN environment
United Nations Environment Programme

Biosafety Group

Institutional capacity enhancement

- Immediate and mid-term
- Consultative approach
- Processes and personnel (experts/staff) – integrated activities to develop and enhance systems
- Legacy - empowerment and self-reliance



eLearning portfolio


RISK ANALYSIS


CONTAINMENT AND CONFINEMENT


BIOSAFETY REGULATORY FRAMEWORKS


GMO FOOD SAFETY


BIOSAFETY & BIOSECURITY


SOCIOECONOMIC CONSIDERATIONS

ENVIRONMENTAL RISK ASSESSMENT

Currently – 7 modules

https://showcase-icgeb.elearning.it/index.html

- Developed with funds from Bill & Melinda Gates Foundation
- Adopted by 6 African Regulatory Offices
- Transferring administration in SSA to AUDA
- Can be offering in other projects

Biosafety Group

Why collaborate with the ICGEB?

- *Dedicated staff serving needs of Member States and project beneficiaries in unbiased, transparent and professional manner*
- *Highly-regarded by international community for providing high quality scientific and technical training in biosafety*
- *Strong associations with established GMO regulatory offices and staff, forming the basis of training and consultancy resources*
- *Complementary and close collaborations with like-minded technical assistance providers around the world*
- *Effective technical and finance administration in ensuring successful project implementation*

ICGEB - Trieste

Biosafety Group

Biosafety Group

Wendy CRAIG
Group Leader - Biosafety

Francesca FAROLFI
Felix MORONTA
Andrè ROSADO