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 Keese (2013). Building an Effective Biosafety Regulatory System: The Nuts and Bolts. *Collection of Biosafety Reviews* 8: 10-39. http://biosafety.icgeb.org/sites/default/files/Keese.pdf.

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ADMINISTRATIVE PROCEDURES

Administrative processes serve to put legal requirements and policies into practice. The primary objective of administration is to ensure that procedures and systems are in place to support sound decision-making. This involves fulfilling all legally-required steps correctly.

Good administration also seeks to establish reliable, efficient processes and to maintain a complete record of relevant actions and decisions. The quality of administration is central to building a trusted regulatory system that demonstrates competence, credibility and integrity.

Important components of administration associated with regulation may include:

- application forms that clearly express the type of information required,
- application lodgement and processing procedures,
- procedures for decision-making and delegation,
- monitoring procedures for approvals,
- operational policies for achieving compliance,
- procedures for accessing, recording and maintaining information,
- access to, and use of, legal advice,
- formal arrangements with advisory bodies,
- structures for processing confidential information,
- arrangements for policy inputs,
- acquisition and maintenance of resources and structures for collection of fees,
- structures and procedures to develop and maintain linkages with other relevant government bodies, and
- procedures for handling queries and consultation.

However, good administration is a balancing act. A more detailed administrative system supports greater certainty, reliability and consistency. For example, legislation may require seeking advice from certain government agencies or advisory bodies, but in the absence of appropriate administrative processes, the advice may be late in coming or could come in a form that does not support decision-making. Nevertheless, an overly detailed system can frustrate decision-making, especially when it includes unnecessary or unclear requirements.

Other important considerations for establishing appropriate administrative processes include access to resources (such as people), costs and supporting structures (e.g. business management, legal services, physical resources, procurement etc.). In addition to the initial establishment of a regulatory system, longer term changes to the resource base may need to be considered.

Administrative costs and requirements associated with regulation also affect applicants. High costs can restrict those who can participate in developing GMOs and the types of products produced. This is of particular relevance to public research efforts and small-scale companies.

RECOMMENDATIONS

Recommendations for streamlining procedures include:

- keep the number of steps/handling processes to a minimum,
- use standard administrative tools to assist with developing effective and efficient processes, e.g. standard operating procedures, checklists, guidance documents, decision trees, concept mapping, structured decision-making, networking ,
- maintain good communication between all persons in the decision-making process,

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- develop collaborations and networks, both nationally and internationally, to share knowledge, experiences and resources, and
- be prepared to change and innovate to achieve continual improvement.

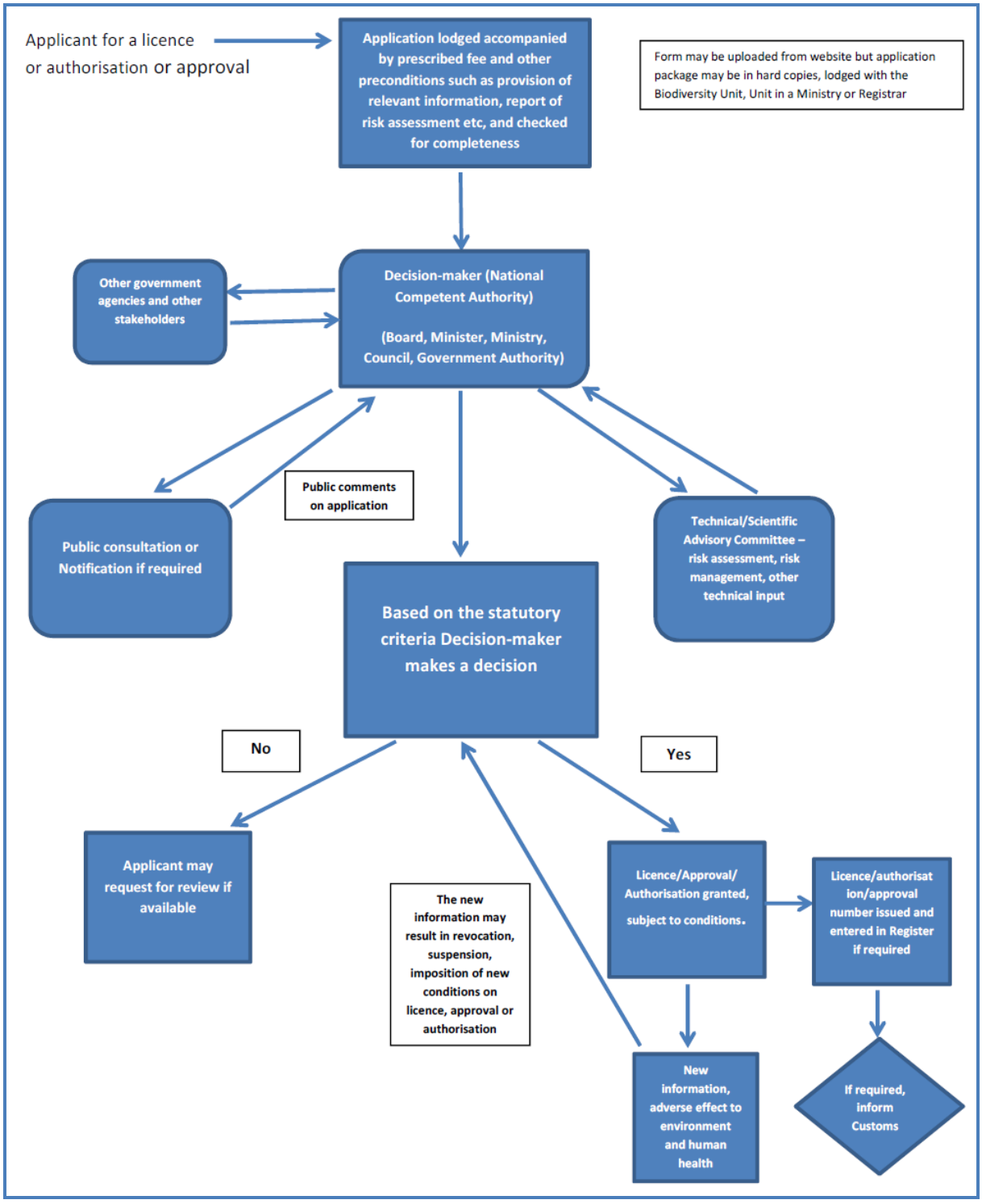

Figure 1. General application and decision-making administrative arrangements

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EVALUATION OF APPLICATIONS

Evaluation of applications for activities with GMOs, in particular the release of a GMO into the environment, typically requires risk assessment and a risk management plan to address significant risks.

Risk, the potential for harm from an activity, can be viewed as the relationship between: 1) a source of risk; 2) harm to an object of value, and; 3) a causal linkage between 1) and 2) (Figure 2).

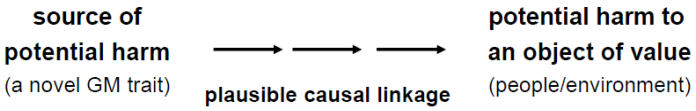

Figure 2. Structure of risk.

Risk assessment is a structured reasoned approach to consider the potential for harm that could arise out of certain dealings with a GMO. The following questions generally guide the risk assessment process (e.g. Gray, 2012): What could go wrong? How serious could the harm be? How likely is the harm to occur? What is the level of concern? Typically therefore, risk assessment includes the following four key components (OGTR, 2013):

1. **Establishing the context (planning/scoping)** - which defines those things that should be considered in the risk assessment and how they should be considered. This includes national and international legal requirements, as well as protection goals.
2. **Risk identification** - which describes scenarios (risk hypotheses/conceptual models) whereby plausible causal pathways to harm are postulated. This will take into account the biology of the parent organism, the properties of the novel trait and the type of environment where the GMO is expected to occur.
3. **Risk characterisation** - which considers the consequences and likelihood of potential harm.
4. **Risk evaluation** - which judges the significance of risk and the overall risk. For example, a risk matrix can be used to estimate the level of risk (Figure 3).

		LEVEL OF RISK			
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			

Figure 3. Risk matrix to estimate the level of risk (OGTR, 2013).

Where possible, a comparative risk assessment approach is used, such that risk from a GMO is considered relative to the parent organism within the environment where the GMO is expected to be present. The focus of the assessment is whether traits modified by gene technology increase the level of risk, or give rise to additional risks.

Most approaches to risk assessment are based on the methodology described in Annex III of the Cartagena Protocol on Biosafety (CPB; Secretariat of the Convention on Biological Diversity, 2000).

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Often there are calls for risk assessment to acknowledge and consider uncertainty. However, it should be recognised that uncertainty is an inherent part of risk. The risk assessment is a structured, reasoned approach to address uncertainty. Therefore, the risk assessment methodology and points to consider in Annex III of the CPB is one such approach.

Following the outcomes of the risk assessment, risk management is then used to consider measures that mitigate or reduce the level of significant risks in such a way as to protect aspects such as the health of people and the environment. Therefore there is a focus on preventing risk from being realised rather than on reducing or repairing the resultant harm. Nevertheless, contingency plans are usually incorporated as part of any conditions imposed on the authorisation.

The risk management plan may consider a number of general questions (OGTR, 2013), such as:

- What measures are available for managing risk?
- How effective are the risk management measures?
- How feasible, practical or compatible are the risk management measures?
- Which treatment measure(s) provides the optimum and/or desired level of control?
- Do the risk management measures themselves introduce new risks or exacerbate existing ones?

The risk management plan may also consider advice received during consultation with stakeholders.

RECOMMENDATIONS

Recommendations for streamlining procedures include:

- use information from risk assessments of the same or similar GMOs approved in other jurisdictions,
- adopt existing national and international standards (e.g. Codex Alimentarius, 2009, ISO 31000:2009 [ISO, 2009], ISO 15189:2012 [ISO, 2012], OECD, 2015),
- develop collaborations and networks, both nationally and internationally including with other regulatory agencies, to enhance knowledge and understanding of risk analysis as it is applied to GMOs and other organisms,
- establish clear criteria for harm, including the rationale, types and degree of harm,
- apply a proportionate response to analysing risks such that attention is focussed on risks that are significant,
- Where possible, consider the use of tried and tested systems e.g. that have been used to assess 'problematic plants', namely weeds,
- Distinguish 'need to know' information from 'nice to know'.

COMMUNICATION AND CONSULTATION

Release of GMOs onto the market or into the environment is of interest to a wide spectrum of the community, including various government bodies, non-government organisations, community groups, businesses and individuals. Therefore, communication is an integral component of every step and process in regulatory decision-making. This includes internal communication with staff in the regulatory agency.

Communication is a continual and iterative process to provide, share or obtain information and to engage in dialogue with stakeholders. Communication provides the decision-making authority with access to the relevant factual information and analyses, as well as awareness of the needs, values and concerns of stakeholders. It is also important to communicate the reasons underpinning decisions.

Effective communication is central to effective decision-making. It relies on good governance, openness and transparency. The goals of communication relevant to regulation can be categorised as follows (OGTR, 2013):

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- **Informing** – to foster understanding with different constituencies (e.g. licence/permit holders and others from the regulated community, as well as researchers, farmers, health workers, industry, consumers, interest groups and the general community). This could include providing information about regulatory processes relating to risk assessment and risk management.
- **Engagement** – to involve internal and external stakeholders in the regulation process through dialogue.
- **Building trust** – to promote trust and credibility in the ability of the decision-making authority to effectively regulate GMOs. This includes demonstrating competence, integrity and respect.

Communication processes consider the following questions (Standards Australia, 2012):

- What are the objectives of the specific communication?
- Who will be involved?
- What is to be communicated?
- How will the information be communicated?
- How will consultation be conducted?

However, communication is affected by how people understand or perceive the information that they receive, including what is regarded as risk. Perception and understanding of risk can also be influenced by personal experiences, knowledge, beliefs, values and attitudes.

Understanding how risks may be perceived can be important in ensuring effective transmission and receipt of risk communication messages. It also provides risk evaluators and decision-makers insights into psychological and social factors that may affect their perception of risk as well as that of different stakeholders, thereby influencing the communication process. This includes the type of communication channel that is considered to be appropriate and effective (e.g. forms, internet, letters, telephone, meetings, public forums, newspapers, social media etc.).

RECOMMENDATIONS

Recommendations for streamlining procedures include:

- use stakeholder mapping to identify key stakeholders, and
- use social/electronic media as a means to communicate rapidly, broadly and cost effectively.

Informing and engaging with applicants, other stakeholders and the public is crucial to building trust in regulatory decisions and ultimately acceptance of the technology. Therefore, restrictions in communication and consultation may not be cost-effective.

DECISION-MAKING

Decision-making is tailored to each jurisdictions needs and requirements. Decision-making may be informed by considering a number of general questions listed below.

WHAT TYPES OF APPLICATION REQUIRE AUTHORISATION?

The types of applications 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 addition there may be provisions for applications to vary, surrender or transfer an authorisation to account for changes in the circumstances during the lifetime of the authorisation. Most jurisdictions also make

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provisions for applications to protect certain information as confidential information. Finally, there may be provisions to apply for deregulation of a GMO.

WHAT PROVISIONS OR PROCEDURES ARE THERE FOR CEASING OR CANCELLING AN AUTHORISATION?

If there are credible findings of adverse effects or breaches of conditions, there may be a need to repeal an authorisation and cease the associated activities.

WHO IS THE DELEGATED DECISION-MAKER?

There is considerable variation in the types of decision-maker, including a Board, a Minister, an Administrator, an independent statutory office holder etc. In addition, legislation may allow the decision-maker to delegate some decisions to others.

WHO SHOULD BE CONSULTED BEFORE REACHING A DECISION?

Often there is a need to consult widely on applications, including advisory bodies, other government departments and agencies, and the public.

WHAT MATTERS MUST BE TAKEN INTO ACCOUNT IN REACHING A DECISION?

In addition to the risk assessment and risk management plan, there are typically several other considerations required before reaching a decision. Some examples of other matters that may need to be considered include socio-economic considerations and comments submitted during the consultation. In addition, decision-making requires developing processes and procedures to ensure that valid decisions are reached, including meeting certain legislated timelines.

WHAT CONDITIONS MAY BE PRESCRIBED OR IMPOSED ON AN AUTHORISATION?

When an authorisation is issued there are certain conditions imposed. This is particularly the case for applications for contained or confined use of a GMO. The types of conditions may include: controls to limit the spread and persistence of the GMO; the types of activities that are permitted; documentation and record keeping requirements; the level of containment required; storage, transport and disposal requirements; data collection, including studies to be conducted; measures to manage risk; adverse effects reporting; and contingency planning.

RECOMMENDATIONS

Recommendations for streamlining procedures include:

- where available in legislation, develop criteria to implement clauses for exemption clauses from certain requirements such as risk assessment,
- where appropriate and allowable, delegate minor decisions to lower levels within the regulatory authority,
- minimise the number of steps in the decision-making process,
- use checklists and decision trees to ensure that all steps are completed, and
- be prepared to accept some level of uncertainty.

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MONITORING FOR COMPLIANCE

Monitoring is conducted by inspectors that often have powers conferred by legislation. This may include powers to: search premises; examine or take samples from the premises; make audio or visual records; require answers to questions and to produce any book, document or record required by the inspector; inspect and take extracts or copies of any book, document or record, or; secure a thing prior to seizure by a warrant. Inspectors are usually required to be trained and certified. Nevertheless, greater trust in the regulatory authority may be gained through co-operative compliance, by informing, training and notifications.

RECOMMENDATIONS

Recommendations for streamlining procedures include:

- establish clear criteria for inspections, including breaches of conditions to an authorisation,
- specify the number of monitoring visits that are considered acceptable,
- cluster monitoring visits where possible, and
- establish procedures that foster compliance amongst the regulated community.

COMPLIANCE AND INVESTIGATIONS

Regulation is mandatory when there are enforcement powers and penalties made available through legislation. When there is evidence of a possible breach of conditions imposed by the authorisation, then an investigation is carried out. Investigations may look at authorised activities, facilities/sites and equipment, organisation and governance, document agreements in the case of partnerships and shared services, goods and services, people and institutions, or matters such as procedures for storage, transport and disposal.

Findings of breaches from an investigation may result in directions to rectify matters, orders to cease activities, suspension or cancellation of an authorisation, or injunctions that may lead to prosecution.

RECOMMENDATIONS

Recommendations for streamlining procedures include:

- use clear guidelines for investigation that are derived from existing sources (e.g. criminal codes),
- maintain careful records, and
- apply a proportionate response to incidents.

CHECK AND REVIEW

The purpose of checking and reviewing all steps in the decision-making process is to ensure the right things are done, each step is done correctly, and the outcomes remain valid subject to new information. A number of feedback mechanisms may be applied both within the regulatory authority and externally through stakeholders.

Internal feedback may occur through checklists and standard operating policies, reviewing guidelines and forms, or through peer review procedures. External feedback is provided through consultation, accountability during audits, and through appeals to decisions.

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RECOMMENDATIONS

Recommendations for streamlining procedures include:

- integrate checking and review as part of all processes. Typically the decision-making process involves more than one person to view each step and procedure; this offers the opportunity to check and review each of the steps and procedures.
- use difficult queries and applications as part of the checking and review process. More difficult queries usually offer the opportunity to reassess the rationale and approach that is applied to certain parts of the decision-making process,
- use external reviewers through established networks and partnerships, and
- be prepared to change and innovate to achieve continual improvement.

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