Implementing National Biosafety Frameworks in the Caribbean Sub-Region

RISK COMMUNICATION GUIDELINES

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EXECUTIVE SUMMARY

Risk communication is an integral part of the risk analysis of genetically modified organisms (GMOs) and the products derived from them. Risk communication is an active, two-way process through which governmental regulators: 1) exchange information relevant to the risk analysis process with stakeholders; 2) engage with stakeholders as to the regulation and risk analysis of GMOs, and; 3) build stakeholder trust in the regulatory process. These guidelines present best practices for risk communication, including discussions of stakeholder outreach, considerations of risk perception when drafting stakeholder messages, and the selection of venues and media for specific stakeholder groups.

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1. INTRODUCTION

These Guidelines discuss the main objectives of risk communication and the approach that the Government takes to fulfil these objectives in the context of risks associated with the development and use of organisms derived from modern biotechnology[1], commonly called genetically modified organisms or GMOs. The Government has a duty to undertake rigorous, science-based assessment and management of risks associated with the development, importation, and use of GMOs in an open and transparent manner. At the same time, the Government acknowledges that the general populace holds a wide range of views on modern biotechnology, and it considers all issues and concerns raised that are relevant to the regulation of GMOs. In recognition of these concerns, the Government commits to raise awareness of the Government's regulatory system for modern biotechnology; to communicate the reasoning behind regulatory decisions regarding GMOs in an open, clear, and objective manner; to listen and respond, in a timely manner, to relevant concerns of stakeholders, and; to periodically review communication Government strategies and practices to ensure effective, appropriately targeted, and efficient communication with stakeholders.

2. WHAT IS RISK COMMUNICATION?

Risk communication is a two-way process to provide, share or obtain information and to engage in dialogue with stakeholders regarding the analysis of risk. It is not an attempt to change basic values and beliefs. Risk communication provides the Government with access to relevant factual information and analyses and familiarises the Government with the needs, values, and concerns of stakeholders. The Government also communicates with stakeholders as to decisions regarding regulated activities with GMOs and the reasoning behind those decisions. Effective risk communication requires the Government to determine clear objectives for each communication effort; determine what information will be disseminated or collected; identify key stakeholders with an interest in the information; determine which media will be most appropriate, and; decide when the process will occur. Lastly, the Government should evaluate the effectiveness of each communication effort and determine whether the process needs to be adjusted.

3. THE ROLE OF RISK COMMUNICATION IN THE RISK ANALYSIS PROCESS

Risk communication is integral to the assessment and management of risks associated with the development, importation, and use of GMOs. Risk assessment involves the evaluation of the probability that a particular hazard will cause harm to a valued resource, such as biodiversity or

1 "Modern biotechnology" means the application of:
a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
b. Fusion of cells beyond the taxonomic family, that overcome natural physiological re-productive or recombination barriers and that are not techniques used in traditional breeding and selection.

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human health. During the assessment process, risk communication ensures that the scope and boundaries of the assessment are clearly elaborated, the criteria used to make decisions about risk are clearly defined, stakeholder interests are considered, and feedback is provided.

If significant risks are identified in the assessment process, the Government will develop a risk management plan to mitigate those risks. The risk management plan helps communicate, to the applicant and others, the analysis and rationale for proposed controls or restrictions that are designed to reduce or mitigate risks identified in the risk assessment. Permit conditions should explicitly and clearly describe the permit-holder's obligations to ensure that risk is managed. In addition, consultation with the applicant or subject matter experts may be required during any prescribed monitoring, and the results of such monitoring may be communicated to stakeholders.

4. WHAT IS THE PURPOSE OF RISK COMMUNICATION?

Effective risk communication is central to effective risk analysis. The fundamental goals of risk communication relevant to regulating GMOs are as follows:

- **Engagement** – to involve internal and external stakeholders in the regulation of GMOs through dialogue;
- **Informing** – to exchange data and other information, relevant to the regulation of GMOs amongst different constituencies (e.g., individuals subject to Government regulation, researchers, farmers, food processors, health workers, industry, consumers, special interest groups, and the general populace). The information can relate to the existence, evaluation, significance, management, and monitoring of risks associated with the regulation of GMOs. The exchange of information is bi-directional: depending on the circumstances, the Government may at times be disseminating information, while at other times the Government may be collecting information;
- **Building trust** – to promote trust and credibility in the ability of the Government to effectively regulate GMOs.

4.1 ENGAGEMENT

Merely disseminating information regarding the government's regulatory programme for GMOs is not sufficient to constitute good risk communication. Fischhoff argued that effective risk communication involves presenting the facts, communicating and explaining the facts, demonstrating that similar risks have been accepted in the past, and bringing stakeholders on board as partners. The development and use of GMOs, including their release into the environment, is of interest to a wide spectrum of the populace, including regional and local governments, non-governmental organisations, community groups, businesses, and individuals. Stakeholders' views should be sought as necessary to provide input into the risk assessment and risk management processes. In addition to communicating with stakeholders, the government may also consult with any experts or interest groups having insights useful for decision-making.

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The government can establish a dialogue with stakeholders and the populace in a number of ways:

- Consultation with stakeholders and the populace regarding applications for the development, importation, or use of a GMO;
- Communication with permit applicants on data requirements and with permit-holders on the implementation of permit conditions;
- Requests for advice or submissions from experts and interested parties on specific guidance documents.
- Communication with other Government regulators, academics, industry representatives, risk analysts and interest groups at public meetings, workshops, and conferences on risk assessment and regulation of GMOs;
- Communication with Government policy groups;
- Involvement in specific focus group meetings, workshops and collaborations (e.g., Institutional Biosafety Fora, consensus documents produced by the OECD Working Group on Harmonisation of Regulatory Oversight of Biotechnology, and similar groups);
- Exchange of information with Government agencies and experts from other countries on approaches to risk analysis and regulation of GMOs.

Successful engagement depends upon providing suitable opportunities and procedures for dialogue. Processes for engagement range from public fora, which provide the highest level of stakeholder involvement, to short announcements in the Government gazette, which provides simple, one-way communication. Three broad categories of engagement (Passive, Participatory, and Consultative) are described in Table 1.

Table 1. Different levels of stakeholder engagement

Mode of engagement	Examples	Strengths	Weaknesses
Passive	• Public notices • Surveys	• Efficient use of resources • Information can be shared quickly	• One-way processes may frustrate audiences
Participatory	• Written comments on draft documents • Public hearings	• Allow stakeholder input • Enables more informed decisions • Demonstrates transparency	• Conflicts are not resolved directly • High resource costs and time investments
Consultative	• Technical advisory bodies • NGOs, industry groups • Advisory bodies	• Useful for controversial issues needing expert opinions	• Difficult to achieve full representation

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4.2 INFORMING

One of the duties of the Government is to provide information and advice to the public about the regulation of GMOs. However, the Government also has a duty to solicit relevant information from the general public and more focused stakeholder groups when such information is needed to effectively carry out its regulatory responsibilities for GMOs.

Informing serves several purposes, including:

- increasing the awareness in the general populace of the technology and of the regulatory process;
- clarifying the obligations and requirements of stakeholders such as permit applicants and permit-holders;
- assisting the coordination of different Government agencies with a role in the regulation of GMOs or GM products;
- informing the Government of stakeholder perceptions of risks relating to GMOs;
- informing the general populace of decisions and the reasons for those decisions;
- maintaining links with international organisations and agencies associated with the regulation of GMOs.

The standard model of information transmission in risk communication has three components. First, the messages are put in a form that can be transmitted by the Government. Second, the message is transmitted through a communication channel (e.g., newspaper, website, email, telephone, letter, etc.). Third, the message is received by an audience and interpreted. The message should be comprehensible to the audience and consistent with the meaning intended by the Government. In turn, the audience may inform the transmitter in terms of feedback.

Many factors influence the effectiveness of information transmission. Some of these include:

- the degree of concern or controversy;
- the complexity of the technological concepts in the message;
- the appropriateness of the communication channel and its impact on the clarity of the message;
- the social and cultural background of the audience;
- any assumptions made by the Government in creating the message;
- any uncertainty of the meaning of words in the message;
- the timeliness in sending the message;
- the knowledge or understanding of the audience;
- the motivation, readiness and interest of the audience to process the message.

Many of these factors are characteristics of individual people within the audience. The Government should attempt to maximise effective transmission of information by taking a structured, consistent approach to risk communication and using consistent language when communicating about risk.

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Under some circumstances, information may be intentionally omitted from a risk communication message. For example, information may be intentionally restricted for privacy reasons or because it is confidential commercial information. When this happens, the Government should explain its obligations to protect these types of information and emphasise that this information was still taken into consideration, as appropriate, in the risk analysis process.

4.3 BUILDING TRUST

Another important goal of risk communication is building trust. Loss of trust in the Government ultimately diminishes the effectiveness of regulation. It may result in loss of confidence by the general populace, reduced compliance by permit-holders, or reduced numbers of permit applications.

Trust is considered to involve the confident expectation of certain behaviours and has three key components:

- **Competence** – having appropriate expertise, knowledge and experience, and applying sound judgment.
- **Integrity** – operating in a manner that is objective, fair, consistent, and honest, and with goodwill.
- **Respect** – recognising and valuing individuality and differences, and demonstrating listening, compassion, empathy and caring, particularly in a crisis.

Regulators have a duty to explain the workings of the regulatory system, specifically how it works in practice. For any regulatory system, including one for GMOs, building trust involves the demonstration of regulatory rigour, specifically that the regulations are strictly enforced and that a breach of the regulations results in an appropriate penalty. Moreover, risk communication must reinforce the fact that regulators are neither proponents for, nor opponents of, modern biotechnology but impartial decision-makers who are required to communicate to the Government and people on matters relating to the risk assessment and risk management of GMOs. Regulators should also strive to demonstrate openness – that they listen to stakeholders and hold themselves accountable for errors. Lastly, the regulatory system must be as transparent as possible, especially because the technology behind GMOs is difficult for most stakeholders to fully understand.

5. RISK PERCEPTION

The effectiveness of risk communication is often affected by how people understand or perceive risks. As mentioned earlier, risk is expressed as a probability – specifically the probability that something bad will happen to an entity that we value. This includes the regulation of GMOs, which uses highly technical information about a specific GMO to assign probabilities to future potentially adverse outcomes. Many factors influence the perception of risk, and the perception

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of risk varies considerably between individuals, depending upon each person's understanding of, and proximity to, any given risk. The 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 the effective transmission and receipt of risk communication messages. Public meetings and other types of two-way communication may provide risk assessors and decision-makers with insights into psychological and social factors that may affect the perception of risk, and these insights should be incorporated into the formulation of subsequent risk communication messages.

6. RISK COMMUNICATION IN PRACTICE

6.1 CONSULTATION ON APPLICATIONS

Openness and transparency in decision-making is important to citizens, and the Government should undertake public outreach and provide appropriate opportunities for public input as part of the decision-making process. The evaluation of applications regarding proposed activities with GMOs provides several such opportunities when risk communication efforts may be appropriate and useful, such as when the application is first received, during the preparation of the draft risk assessment, and during the preparation of the risk management plan.

The resolution of specific concerns and issues relating to risks to human health and safety and to the environment may involve highly technical questions and may lead the Government to seek further information from the applicant.

In addition, depending on the GMO and the proposed activities in the application, some risk communication efforts may be directed at specific audiences:

- Subject matter experts on technical issues relevant to the risk assessment or risk management plan;
- Stakeholders living in the geographic area where the activity is proposed to occur;
- Non-governmental organisations and trade groups with specific interests in the proposed activity.

Due to the complexity of issues associated with the development, importation, and use of GMOs (such as economic, food labelling, or marketing), the Government may find that some feedback from stakeholders is outside the scope of the risk assessment process. In such situations, the Government response may be to acknowledge the feedback, but indicate that the risk assessment, risk management plan, and any subsequent decisions made were based on relevant information as defined by the regulations.

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6.2 MEDIA CHOICES FOR RISK COMMUNICATION

In addition to forms of communication that are prescribed by law, such as gazetting, a primary mechanism for providing information about the regulatory process to interested people should be the Government website. Documents that provide essential background information for the regulators, such as the biology of plant species that have been modified by modern biotechnology, and other similar resources should also be made available on the website. The website should provide information on the operation of the regulatory programme, including various application forms, guidelines, and links to the legislation. A "What's New?" webpage may provide quick access to new publications, upcoming events, and advice on opportunities to comment on draft risk assessments and risk management plans. A toll-free telephone number or email address can also be provided for anyone wishing to make enquiries, request hard copies of documents, or express particular concerns. In addition to the website, the Government may also provide information in a variety of appropriate formats to interested parties on its regulatory activities regarding GMOs (for examples, see Table 2).

Table 2. Forms of communication with stakeholders

Stakeholders	Form of communication
Applicant	• Application form - Informal/formal discussion • Confidential Commercial Information - application • Risk assessment – draft and final version • Risk management plan – draft and final version • Permit – reporting requirements, ongoing monitoring and compliance
Institutional Biosafety Committees	• Informal/formal discussion • Letter/email requesting advice or notification • National IBC Fora
Experts	• Meeting, informal discussion • Letter requesting advice
Prescribed agencies	• Memoranda of understanding • Informal/formal discussion • Letter/email requesting advice or notification
Local governments	• Letter/email requesting advice
National Government	• Memoranda of understanding • Informal/formal discussion • Letter/email requesting advice
Public	• Website • Advertisements • Toll-free telephone number • Email/letter

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6.3 ADAPTING RISK COMMUNICATION TO CHANGING CONDITIONS

In an environment of rapidly changing forms of communication, the Government should attempt to continually improve its risk communication processes. This involves monitoring submissions on consultation documents, reviewing the type and form of information made available to stakeholders and interested parties, and improving collaboration and coordination with other Government agencies on risk communication.

Initiatives to adapt risk communication to changing circumstances include:

- using graphics or other media to communicate risk-based decisions and consultation processes (including making better use of existing tools, i.e., the Government website);
- using modern Internet-based tools, such as social media, to enhance engagement with a broader range of people in the general populace;
- increasing the use of clear language, including minimising scientific/technical jargon and complex bureaucratic language.

7. CONCLUSION

The Government should undertake a wide range of risk communication activities, exchanging information with stakeholders and the general populace about potential risks from modern biotechnology.

To summarise:

- Risk communication is crucial to all aspects of risk analysis.
- Risk communication seeks to engage, inform, and build trust with stakeholders and the populace.
- Consultation with stakeholders, interest groups and the populace is an important component for establishing engagement.
- The general populace varies considerably in their attitudes, interests, beliefs and risk biases, which requires accommodation with different types, amounts, and channels of communication.

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