African, Caribbean and Pacific Group of States

(ACP)

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Good Regulatory Practice

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The British Standards Institution (BSI)

GOOD REGULATORY PRACTICE GUIDELINES

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ACRONYMS AND ABBREVIATIONS

ACP	African, Caribbean, and Pacific Group of States
BSI	British Standards Institution
CA	Conformity Assessment
CAB	Conformity Assessment Body
CARICOM	Caribbean Community
COTED	Council for Trade and Economic Development
CROSQ	CARICOM Regional Organisation for Standards and Quality
GRP	Good Regulatory Practice
NSBs	National Standards Bodies
NTB	Non- Tariff Barrier
PIA	Preliminary Impact Assessment
RIA	Regulatory Impact Assessment
RIAD	Regulatory Impact Assessment document
MSME	Micro, Small-Medium Enterprises
TBT	Technical Barriers to Trade
TR	Technical Regulations
WTO	World Trade Organisation

DEFINITIONS

Technical regulation

Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

Standard

Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

Conformity assessment procedures

Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled. These can be procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity;

Central government body

Central government, its ministries and departments or any agency subject to the control of the central government in respect of the activity in question.

Risk Assessment

The process of assessing (quantitatively or qualitatively) an adverse effect related to an activity, product or event and its probability;

Risk Management

The legislative response to the identified risk;

Primary laws

Primary laws, which are defined as regulations which must be approved by the parliament or congress. Primary laws are also referred to as “principal legislation” or “primary legislation”.

Regulators

Administrators in government departments and other agencies responsible for making and enforcing regulation.

Regulatory Impact Assessment (RIA)

Systematic process of identification and quantification of benefits and costs likely to flow from regulatory or non-regulatory options for a policy under consideration. May be based on benefit-cost analysis, cost effectiveness analysis, business impact analysis etc.

Regulatory policy

The set of rules, procedures and institutions introduced by government for the express purpose of developing, administering and reviewing regulation.

Secondary legislation

Regulations that can be approved by the head of government, by an individual minister or by the cabinet. That is, by an authority other than the parliament. It should be noted that secondary legislation must be subject to parliament scrutiny on the basis of disallowance.

1. BACKGROUND

Regulation may be generally defined as any government measure or intervention that seeks to change the behaviour of individuals or groups.

Government interventions have an impact on the country as whole, at home and in the workplace. Where regulation is poorly designed or overly complicated it can impose excessive costs and inhibit the economic sector it is trying to regulate. The role of the government is to ensure that the balance is right, providing proper protection and making sure that the impact on those being regulated is proportionate.

The main vision of the Caribbean Community is to develop a Caribbean Community that is integrated, inclusive and resilient; driven by knowledge, excellence, innovation and productivity; a Community where every citizen is secure and has the opportunity to realise his or her potential with guaranteed human rights and social justice; and contributes to, and shares in, its economic, social and cultural prosperity; a Community which is a unified and competitive force in the global arena.

CARICOM Regional Organisation for Standards and Quality (CROSQ) is the regional centre for promoting efficiency and competitive production in goods and services, through the process of standardization and the verification of quality. In this regard, CROSQ aims to support international competitiveness for the enhancement of social and economic development of the region.

Differences in the regulatory requirements and which standards are made mandatory in individual CARICOM Member States are among those that may have the greatest impact on regional trade let alone international trade. In certain situations, regulatory requirements may actually impede any gains from regional trade agreements.

The policy objectives of CROSQ in regards to technical regulations and standards can be said to be the following:

1. Enhance the current framework for the development and adoption of national standards in accordance with established international principles;
2. Implement an efficient Technical Regulations regime;
3. Define clearly the roles and responsibilities of the competent authorities for the adoption of Standards and enactment of Technical Regulations;
4. Develop a framework for Technical Regulations, in a transparent manner that satisfies a legitimate objective in the least trade restrictive manner.

All the above supports the requirements of the WTO TBT agreement. Therefore, this document is intended to be supportive of international good practice based on WTO principles.

One of the key challenges for the Caribbean Region remains regulatory reform. Most CARICOM Member States in the region still retain the system of mandatory standards which are embedded in the Standards law of each country. Thus, there exists a "back-log" of old mandatory standards which may not be appropriate to today's regional economies.

2. OBJECTIVES

This guide is intended to provide similar approaches to regulatory management within the CARICOM in the preparation, compliance to and review of technical regulations. It is intended to assist regulators in CARICOM Member States in the adoption of efficient regulatory arrangements which should improve the consistency and transparency of technical regulations, thereby leading to reduction in regulatory barriers to trade.

To ensure this guide is considered as one of the means for assisting regulators in meeting the requirements of the WTO Agreements, given that the main responsibility of all government are to protect the health and safety of its citizens, the protection of the environment and protection against deceptive/fraudulent practices.

The guide is also to ensure that before deciding to develop and/or implement the regulatory system for a particular economic sector, regulators should consider alternative approaches to fulfil legitimate objectives and the need to minimise the use of mandatory measures.

The guide is also intended to ensure that the regulatory processes and requirements should be as understandable and accessible as practicable and where possible, regulations should enable those affected to better understand the implications of regulatory measures.

3. GOOD REGULATORY PRACTICE GUIDE

3.1. Introduction

All governments should ensure that regulations are necessary, fair, effective, and affordable. Regulations should also enjoy a broad degree of public confidence.

Policy interventions and its enforcement, should meet the following five principles shown below which today are the international basis of good regulatory practice:

- Proportionality
- Accountability
- Consistency
- Transparency
- Targeting

These principles are useful for measuring the value of any regulation and its enforcement; these describe the obligations between stakeholders and government.

These should be used for new domestic legislation or the revision of existing legislation and should also be used for assessment of international agreements in order to measure if the policy objectives are being met. The principles should be applied to all the alternatives as shown in 3.2 of this document.

If technical regulations are not complied with these are neither efficient nor effective which result in not being effectively enforced and if found to be the case should be withdrawn or amended.

Technical regulations that are outdated or poorly designed to achieve their intended policy objectives contribute to inefficient regulatory arrangements. Technical regulations require the principles, procedures, and institutions of government to be in place and working effectively to ensure that any regulation is necessary, cost effective, and in the best interest of society.

Risk-based approach should be a key feature of national legislation for the creation of a fair national, regional and international market and in the areas for the protection of workers, safety and health, and the environment. Risk assessment includes the government authorities in determining what level of risk is deemed unacceptable and, conducting a quantitative and qualitative assessment of the risk as applicable.

3.1.1. Proportionality

Regulations should be only used if necessary, the measures used to address a problem are identified related to acceptability to the level of risk based on established criteria.

- Policy solutions identified in 3.2 must be appropriate to the perceived problem or risk and should be evaluated on its compliance costs;
- All the options in 3.2 to achieve policy objectives must be considered;
- Regulations will have an impact on all the relevant stakeholders, but it may be disproportionate on MSMEs, which account in most economies for about 98% of businesses;
- Enforcers should consider an informative, instead of a penalising approach where possible and should be involved when deciding on implementing policy;
- To prevent the authorities to adopt arbitrary measures, the authority must carry out as comprehensive as possible risk assessment.

3.1.2. Accountability

Regulators should be able to justify decisions and answer to public concerns as applicable.

- Measures or proposals being considered should as standards have to have public consultations with all stakeholders and these should be considered before decision are taken (national notification and internationally if applicable as per WTO Notification procedure);
- Regulators should explain rationale for its decisions (Regulatory Impact Assessment);
- An appeals procedure should be established, it should be considered fair, effective and accessible by the expected end users, so it should be also consulted with the stakeholders;

3.1.3. Consistency

During the development of a RIA the measures taken must be consistent across government e.g. joined up and implementation should be considered.

- Regulators should be consistent and collaborate as appropriate in a joined-up way;
- New regulations should take account of existing or other proposed regulations, whether domestic or of international origin;
- Regulation should be planned and not unexpected so as to provide consistency of outcomes on stakeholders which are being considered for regulation;
- Enforcement agencies should have the ability to apply regulations with a minimal degree of variation throughout the country.

3.1.4. Transparency

Regulations should be as simple as can to prevent confusion and wrong application of the regulation by the regulated stakeholders.

- Objectives should be included in recitals/preambles of regulations which include the rational for the regulation and be clearly defined and effectively conveyed to all stakeholders which may be affected;

- consultation documents should be distributed to all relevant stakeholders before measures are developed, to ensure that all possible knowledge and expertise are taken into account;
- Stakeholders should be given sufficient time and information, to be able to make their comments on the proposed measures (e.g. provide draft regulation, PIA or RIA);
- Regulations should be clear and simple, and guidance, in plain language, should be issued within an appropriate time before the regulations comes into force or an appropriate timeline as agreed with stakeholders, but at all time respecting the WTO Notification process; This will make those being regulated aware of their obligation and how to comply;
- A minimum of 6 month should be allowed as a transitional period by which the stakeholders affected can prepare for compliance with the regulation (WTO guidelines);
- The consequences of non-compliance should be made very clear and be enforceable.

3.1.5. Targeting

Regulations should address the objectives and ensure these are appropriate and that the regulation can effectively fulfil the needs of the objectives and not have unintended effects.

- Objectives should be defined, the measures should focus on the objectives that identify the problem(s);
- How to meet the objectives of the measure should be clear and unable to be misunderstood e.g. explicit, enforcers and the regulated should be able to have alternative means to achieve the targets, whilst still complying;
- Guidance and support should be adapted to the needs of different groups;
- Enforcers should focus on the highest risks;
- Regulations should be reviewed within a timeframe to determine if the objectives are still being met. If not, these should be modified or withdrawn; a sunset clause would be an appropriate method to ensure this aim is implemented.

3.2. Alternatives to investigate and consider

Policy makers have a wide range of options available for implementing policy objectives, and regulators should not make automatic prescriptive decision before considering all options.

The options chosen have implications for stakeholders and ultimately for the success of a policy. The unplanned and planned outcomes need to be taken into account where possible. Taking into consideration the above at national and regional level in the Caribbean, by using GRP it should lead to convergence of views on common approaches to policy, and as a result good regulation should consider the following course of action:

3.2.1. Do nothing

This means to maintain the "status quo", having investigated the problem and considered all the impacts it may be appropriate to recommend that nothing should be done and that although there is a public perception that something is required the evidence does not support this view. It may then be necessary to undertake a public campaign to dissuade the citizens from the perception which they have adopted.

3.2.2. Advertising campaigns and education

This approach uses good marketing practices in the development of campaigns that will persuade stakeholders and the public that a measure makes good sense and should be followed by all. All means could be used including social media.

3.2.3. Using the market

This option identifies what is not working in a market, the reasons for not working and provides information to the market or develops a new market such as environmental credits etc. In this case it is the Government who influences the market instead of the market influencing the Government.

3.2.4. Financial incentives

Financial incentives may take many forms such as tax incentives and subsidies; and price caps in non-competitive industries. These measures should create incentives to achieve the outcomes planned for and no unintended outcomes (unplanned ones), officials must take care that these methods do not break the WTO rules especially with regards to equal treatment.

3.2.5. Self-regulation and voluntary codes of practice

Self-regulation and voluntary codes of practice involve stakeholders themselves in the process of self-regulation, and may be more effective and flexible to use than government prescriptive regulations. There are many forms of self-regulation and the government should with the stakeholders (associations, chambers of commerce or others) agree the methodology and level of government intervention according to the risk involved.

3.2.6. Prescriptive regulation

As in its title "prescriptive" this is the ultimate tool of all Government, the authorities will use this methods to change behaviour in a compulsory manner, in this case there are no options other than those provided for in the regulation itself. This method should be used when all other options or combination of options have failed. There are areas where this is the best means of achieving a policy objective. It should be noted that prescriptive regulation, may have unintended consequences, and without enforcing compliance it may have limited effects.

3.3. Check List for development of Technical Regulations

The options mentioned above should be considered once this non comprehensive check list is used as a tool for establishing the necessary information to be able to make rational decisions.

- serve clearly identified policy objectives,
- be effective in achieving the objectives set (means of measuring should be included);
- have a sound legal and risk assessment basis;
- produce benefits that justify costs,
- take economic, environmental and social effects into account;
- minimise costs and market distortions;
- be clear, simple, and practical for users;
- be consistent with other regulations and policies;
- be transparent to both regulators and those affected by regulation;
- be based on international or national standards that are harmonized to international standards, except where legitimate reasons for deviations exist;
- reference only those parts of a standard that represent minimum requirements to fulfil the desired objectives;
- be least trade restrictive to achieve the desired objectives;
- be performance based rather than prescriptive;
- accord equal treatment to products of national origin and like products from elsewhere;

4. PREPARATION OF TECHNICAL REGULATIONS

When deciding to regulate, the regulator needs to consider how the regulation is prepared, adopted and reviewed so that it will be effective over time. Generally, the regulator should align their practices to the WTO obligations when preparing, revising, or applying technical regulations and associated conformance requirements.

4.1. Preparation of technical regulations

In order for a regulation to be useful to the stakeholders, as mentioned in this document, it should be clear in what it demands but also it have the same format to facilitate ease of understanding of the stakeholders so these get used to reading similar type of legal documents, it is suggested that the following titles are included in all technical regulations so these become consistent.

- Recital/Preamble (should include rationale and objectives);
- Definitions;
- Scope;
- What is not included (optional as required);
- Obligations of the Economic Operators;
    - Manufacturer;
    - Manufacturer authorised representative;
    - Importer;
    - Distributor;
    - Seller;
    - Users;
- Obligation of Government Agencies;
- Use of voluntary standards;
- Intervention of conformity assessment bodies (based on product risk assessment);
- What are the conformity assessment procedures required;
- How are conformity assessment bodies approved;
- Obligations of Market Surveillance Authority;
- Complaint procedure and appeals;
- Penalties;
- Requirements for protection of health and safety and environment;
- Transitional date for industry to adapt to the changes;
- Date of Enforcement (when the regulation becomes enforceable);
- Annexes as required.
- be subject to review to maintain flexibility and adaptability to national changes (Review or Sunset clause).

4.2. Compliance to technical regulations

Regulatory measures should contain compliance strategies which ensure the greatest degree of compliance at the most appropriate level of regulator intervention and at the lowest possible cost to all parties and hence provide economic benefits and stability.

For produce and products an approach based on use of voluntary standards and voluntary or compulsory conformity assessment procedures (CAPs) and acceptability criteria for conformity assessment bodies (CABs), should be considered and included in the regulations depending on the risk these pose to citizens and the environment, these should be kept to the minimum necessary to achieve the regulatory objectives.

Costs to stakeholders can be reduced and/or eliminated if the authority unilaterally accepts the results of CA activities undertaken by competent CABs in other countries. Such a move would reduce the amount of retesting, cost and the workload for the regulators.
When deciding on CA, the regulator should ensure that:

(a) CAPs are not prepared, adopted or applied with the effect of creating unnecessary technical barriers to trade;
(b) CAPs compliance is treated the same for products of national origin and for that are products imported;
(c) the implementation of registration, licensing or approval of regulated products prior to placing the goods onto market, where possible, should be limited to high risk products;
(d) results of compliance produced by a CAB should be accepted as applicable to all approved CABs be these national or international.

4.3. Introduction of voluntary standards in regulations

There are many methods that can be used to introduce national voluntary standards into technical regulations and below is a description of the options. It is for the national authority to decide which method it may wish to adopt.

International Standards and public policy in many cases share similar objectives such as in enhancing economic competitiveness and efficiency, and facilitating international trade. International Standards are useful tools for policy makers for a number of reasons such as;

(a) International Standards is consistent with the obligations of countries that are members of the WTO to reduce technical barriers to trade;
(b) International Standards are instruments of governance because of the effects their use can have on goods, services and on quality of life;
(c) International standards have a number of parallels between good policy-making practice and good standardization practice, which has led to the use and referencing of international standards becoming widely and increasingly considered as forming part of good regulatory practice and good public governance.

4.3.1. General considerations

There is a number of considerations that regulators should take into account, and these are:

(a) Should the International Standard be mandatory or voluntary?
(b) How does the regulator assess that the international standard is suitable for use and addresses the needs?
(c) Will the regulator reference the whole standard or selected parts of it?
(d) How will the regulation be kept up-to-date?

4.3.2. Various approached to referencing

There are a number of ways in which a standards may be quoted in a legal text, these are:

(a) Direct references to specific standards in the legal text, e.g. full identification and title which can be dated or undated.

If the international standards has been adopted identically as a national standard, then this is not considered a TBT, but if it has been modified prior to its adoption, it may fail the WTO TBT criteria based on geographic, climatic or technical reasons, it may still be considered as a TBT therefore the regulator must be careful not to include a TBT in its regulation.

The international standard need not be adopted, and could just be quoted this would preclude issues related to copyright and others matters, but it may be over prescriptive for the objectives intended.

Examples are as follows:

Example 1: The quality management system shall conform to ISO/IEC XXXX: 2013, <TITLE>,

This being dated may require continuous changing as the standard gets amended and changes the date.

Example 2: The quality management system shall conform to ISO/IEC XXXX: 2013 (as amended), <TITLE>.

This allows for continuous amendment of the document from the date as shown, but it means that the regulation in a manner is passive to the changes made by the national or international standardisation body, this may mean that over time, if not checked the standard may divert from the objectives of the regulation.

Example 3 The quality management system shall conform to the latest edition of ISO/IEC XXXX, <TITLE>.

This allows for the latest edition of the standard to become effective as and when these changes are made, but it still means that the regulation in a manner is passive to the changes made by the national or international standardisation body, this may mean that over time, if not checked the standard may divert from the objectives of the regulation.

(b) Indirect references to the use of IEC and ISO International Standards

This is better known as the EU New Approach system, it means that the regional standard bodies (CEN/CENELEC) are requested to develop standard that support the technical regulation, when these are published in the Official Journal of the European Union it is conferred a status harmonised standards that provides for presumption of conformity with the essential requirements of the relevant EU technical legislation.

This means that, if the harmonised standard is used by a manufacturer the onus of proof is for the market surveillance authorities to demonstrate non compliance, but the manufacturer is free to use any other standard or technical specification as long it can prove that it meets with the essential requirements of the legislation to the relevant authorities upon request.

Examples:

Example 1: Where the product complies with the relevant IEC or ISO International Standard whose reference number has been published in [refer to relevant official listing here], the relevant authorities shall presume compliance with the requirements of this law.

Example 2: A product shall be presumed safe, as far as the risks are concerned, when it conforms to voluntary IEC and ISO International Standards, the references of which have been registered on [refer to relevant official listing here].

(c) Adaptation of options a and b

A third option would be for the regulator to work closely with the national standards body and when the regulator describes in its technical regulation the essential requirements the NSB adopts the appropriate number voluntary supporting standard outlining in it which are the clauses that fulfil the law requirements and which the economic operators must comply with e.g. based on protection of health and safety, environment and deceptive practices.

In this manner the manufacturer can choose any voluntary standard but must fulfil the clauses to be used, this would be something like the appendix Z or ZA included in EU standards which provide a listing of the standards clauses compared with the relevant clauses of the essential requirements of the EU legislation to demonstrate compliance.

Depending on the regulation intended to be developed any of the above methods should be considered and included in the RIA and in the option that is recommended if applicable.

4.4. Review Clauses

Review clauses are requirements in regulations for review to be conducted within a certain period. The basic principle of this tool is the following: a rule will continue to be applied unless action is taken to eliminate it. The action means to integrate a clause in the regulation that will lead to its review and possible legal cancellation.

Different types of review clauses are used for the stock of regulations. Automatic review clauses can establish an examination of the efficiency and effectiveness of regulation over

time. Other less restrictive clauses may provide a greater degree of flexibility and extend the validity period for a concrete regulation unless concrete action is taken to eliminate or change it.

By contrast, Sunset Clause is a process in which new regulations are given automatic expiration dates, unless remade through normal rulemaking processes. This ensures continuing review and updating of the stock of regulations. Sunset clauses ensure that review of regulations takes place after a determined period of time. A time period must be set on the technical regulation.

5. MANAGING RISK

Risks are identified starting with the most crucial ones. Regulators cooperate effectively with other stakeholders in identifying risks, as it increases the resilience of the framework by reducing the chances that certain risks might be overlooked. All stakeholders in the system are allowed to participate in identifying risks for the following reasons:

(a) Not only regulations but also voluntary standards help business and society deal with risk. National Standards development organizations can provide important input for risk identification;
(b) For market-surveillance authorities, properly identifying the risks that products placed on the market may cause is a prerequisite for developing timely and appropriate measures and ensuring marketplace safety;
(c) Conformity-assessment procedures act as risk mitigation tools by reducing the risk of placing dangerous products on the market.
(d) Conformity-assessment bodies see the risks that the regulator may not be able to identify;
(e) Business operators may also inform the regulator about risks that in their view require regulatory intervention.

5.1. Risk analyses and risk evaluation

No matter from which source the regulator or other stakeholder learns about a risk, a risk analyses and evaluation must follow, ranking the risk according to its seriousness. This step ensures that critical risks are dealt with in a timely manner.

If the regulator is not willing or is unable to take measures to reduce the probability of the expected impact of a risk, it should consider if and how this information should be communicated to relevant parties. It should also become an input into the contingency planning function;

5.2. Determining a risk treatment strategy

On the basis of the results of the risk assessment, and acting in consultation with the systems' stakeholders, the regulator chooses an appropriate risk management treatment.

This can be:

(a) Avoiding the risk by banning activities or processes where it has occurred;
(b) Sharing the responsibility for managing the risk, including bearing responsibility if it occurs, to economic or social actors (families, firms);
(c) Mitigating the risk: developing a regulatory or non-regulatory response to reduce the probability and the expected impact of a risk:
    i. A regulatory action implies not only developing a new or reforming an existing regulation, but also choosing appropriate conformity-assessment procedures and market-surveillance measures;

ii. Non-regulatory action, on the other hand, includes options such as educational or information campaigns, and subsidies or incentives to economic operators' activities.

5.3. Implementing the risk treatment strategy

Implementing risk-management treatment within a regulatory framework, regardless of the strategy chosen, requires monitoring compliance, evaluating the effect of a risk management treatment on other regulatory processes, other stakeholders and areas of activities.

This involves:

(a) Integrating regulatory and other measures with existing ones;
(b) Performing regulatory impact assessment;
(c) Establishing coordinating mechanisms among competent authorities and stakeholders;
(d) Giving guidance and establishing and appropriate budget for the institutions responsible for monitoring compliance (conformity assessment and/or market surveillance authorities);
(e) Deciding on penalties for non-compliance.

Some risks are unavoidable or impossible to forecast, the regulator should prepare a plan setting out if harm associated with the risk occurs; what is to be done, who should do it and how.

The need for developing contingency plans is widely recognized; however, these will be only be efficient if they are prepared within a framework where contingency planning is an integral part of risk management treatment.

5.4. Monitoring and reviewing the system

Regulators or other interested parties should run processes necessary for continual improvement for the development and implementation of regulations. These may include performing regular internal audits, analysis and review of processes and methodologies that function within the whole system. Its purpose is to improve the effectiveness of regulatory process and to provide common understanding of the regulatory system policy among all regulatory stakeholders.

5.5. General implementation principles

Regulatory authorities and other regulatory stakeholders should use the concept of "risk" to evaluate how balanced regulations are against two extremes:

(a) Excessive regulation (gold plating), e.g. regulations that are too stringent with respect to the objectives and the risk they set out to address;

(b) Insufficient regulations that fail to address the objectives and the risk and unnecessarily expose citizens and economic operators to threats.

Taking into account the level of risk tolerance of stakeholders, regulatory authorities should establish, implement and maintain, a process for determining, analysing, reviewing and monitoring an acceptable level of risk within a regulatory framework.

Regulatory stakeholders, as well as international organizations and other interested parties, should apply the following criteria when evaluating regulatory systems:

(a) Risks are timely identified and identification covers as many risks as possible;
(b) Taking into account the different risk perceptions of the involved stakeholders, risks are analysed and evaluated and the most critical risks are given the highest priority;
(c) Balanced risk treatment is chosen;
(d) Risk treatment is efficiently implemented;
(e) Ongoing monitoring of risk treatment strategies through regulatory activities is carried out and is effective;
(f) Contingency plans are developed, tested and remain relevant; resources are available to implement them.

5.6. International Standards for risk assessment

i. ISO 26000:2010 Guidance on social responsibility; outlines international recommendations for social responsibility. It covers organisational governance, human rights, working practices, environmental policies, sustainable development and community involvement. It provides a framework for companies to build a robust and long-term corporate responsibility strategy. Social responsibility is a critical part of measuring business performance and in all industries, and ISO 26000:2010 can be adapted to different legal, cultural, political and sector environments.
ii. ISO 31000:2009, Risk management – Principles and guidelines. Provides principles, framework and a process for managing risk. It can be used by any organization regardless of its size, activity or sector. Using ISO 31000 can help organizations increase the likelihood of achieving objectives, improve the identification of opportunities and threats and effectively allocate and use resources for risk treatment. ISO 31000 cannot be used for certification purposes, but does provide guidance for internal or external audit programmes. Organizations using it can compare their risk management practices with an internationally recognised benchmark, providing sound principles for effective management and corporate governance.
iii. ISO/IEC 31010:2009, Risk management – Risk assessment techniques focuses on risk assessment. Risk assessment helps decision makers understand the risks that could affect the achievement of objectives as well as the adequacy of the controls already in place. ISO/IEC 31010:2009 focuses on risk assessment concepts, processes and the selection of risk assessment techniques.
iv. ISO Guide 73:2009, Risk management - Vocabulary complements ISO 31000 by providing a collection of terms and definitions relating to the management of risk.

6. REGULATORY IMPACT ASSESSMENT (RIA)

6.1. Introduction

In the preparation of technical regulations, the principles as defined in Section 3 should be considered prior to beginning any new regulation or revising existing regulation. In order to implement GRP it would be advantageous to use a Regulatory Impact Assessment (RIA).

RIA is an aid to political decision-making. It is a policy document. It provides transparency on the risk management related to a proposal to establish a national measure. Risk assessment and risk management are a part of RIA.

RIA applies to all regulatory proposals introducing regulatory instruments including primary legislation approved by the Cabinet and enacted through the Parliament (and other regulatory policy proposals approved by the Cabinet), subordinate legislation enacted through the responsible Ministry or Department, remaining forms of subordinate legislation and quasi regulation and international agreements.

The RIA requirements are to be satisfied prior to the initial policy decision to regulate and certainly before the approval to draft stage. This requirement will ensure that the decision maker is provided with a complete analysis of the proposed regulatory policy prior to a decision being made.

RIA is a two-tiered process for assessing regulatory proposals, to determine their impacts on business (including Government businesses), consumers or the economy.

A Preliminary Impact Assessment (PIA) must first be undertaken on each regulatory proposal to determine its impact on business, consumers and/or the economy.

If the PIA identifies a significant negative impact associated with the regulatory proposal, then this should be communicated to the decision maker. The decision maker would advice after considerations whether to continue and request a full RIA or the decision is not to continue and close the PIA.

If no major impact is identified on business, consumers or the economy and the PIA has been completed, the responsible official continues to develop the RIA. In reality this would be a single documents with two phases included e.g. PIA would be part 1 to determine any major impacts and if no major impacts are evident it continues as a RIA.

Proposals that are non-regulatory fall outside the RIA process and assessment under the RIA process is not required. There should be an exceptions mechanism set up for the case were emergency regulations must be enacted, these should be notified to the WTO and the

regulation must then be assessed using a RIA under a post implementation review, when this review is undertaken is the decision of government.

The RIA requirements have been developed as a means to set up a systematic approach to ensure as comprehensive as possible information is available for Regulators to make decisions on proposed measure(s) to manage a perceived national risk to health, safety, the environment or consumers and the net impact on society before it is put forward to regulators to determine the policy outcome; be these prescriptive or other means.

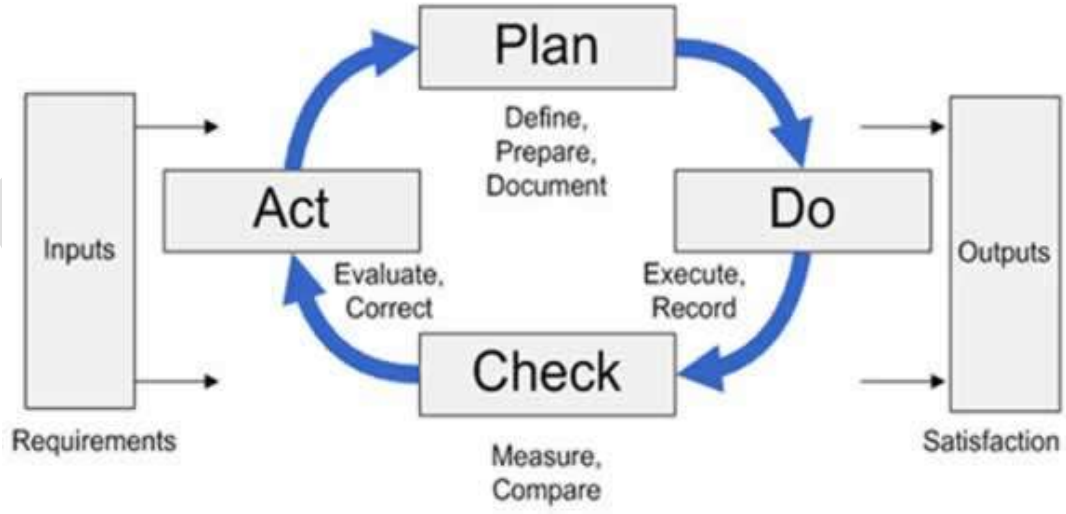
The results of this analysis are detailed in the Regulatory Impact Assessment Document (RIAD).

RIAD is based on a set of steps that structure the preparation of proposals and has the following key elements:

- setting policy and desired objectives;
- analysis of the problem;
- analysis of the likely economic, social and environmental impacts;
- assessing all feasible options;
- consultation with stakeholders;
- review of the regulation and the RIA.

The above methodology could be considered that it fulfils the requirements of the quality management system ISO 9000 that are used in all walks of life based on common sense.

Figure 1 Standard Process Map relevant to regulatory approach[1]



The methodology of the process for the development of regulatory outcomes based on a systematic approach is shown below.

[1] Source: https://www.google.com/search?q=quality+management+system&biw=1280&bih=563&tbm=isch&tbo=u&source=univ&sa=X&sqi=2&ved=0ahUKEwiF1Jfk4LTPAhUSBh4KHUdyAT4QsAQIdA#tbm=isch&q=iso+9001+quality+management+system&imgrc=7C9jjlkG4kI15M%3A

6.2. The PIA

The main criteria to follow for a PIA would be as follows:

a) Identify the objective and the policy (see 5.2);
b) Seek consultations with all relevant stakeholders on economic or environmental impact issues (see 5.6);
c) Seek information relating to any international/regional agreements which may be impacted by the regulation;
d) Determine if any WTO rules are affected;
e) Determine if any major economic, social or environmental impact will arise due to the regulation intended (see 5.5);
f) Attempt to identify if there would be any unintended outcomes.

The above would use the same methodology as described in the sections below for a RIA but the intent is to discover rapidly if there is a major impact which would create a major problem so that decision makers can take appropriate measures.

6.3. Setting policy and desired objectives (Targeting)

This element is a clear statement of the objectives that the regulator is pursuing with the request for developing proposed measures to manage the problem. This part is usually determined by government in response to perceived issues or problems (national or international) or external pressures and lobbying from interested groupings, that consider that a government regulation is necessary.

The objective must be concise, clear and targeted to the relevant problem which is attempting to manage. It should not attempt to resolve too many issues that appear to be connected but in reality would only add to confusion in the preparation of the RIAD or could be better addressed in a horizontal regulation.

The system is based on the regulatory objectives identified by the regulator. Regulatory and societal objectives are used for setting the criteria against which the risk is evaluated.

This part of the document is so important that the official responsible for the RIAD should ensure that it is clear not only to s/he but also be clear to any other stakeholder and this should be tested by wide preliminary consultations, e.g. does the objective addresses the perceived problem.

Government objectives in many cases are set to reduce the risk associated with a particular problem which has been identified.

Absolute safety is not regarded as a regulatory goal. Appropriate criteria are selected to decide which risks are tolerable, and risk tolerance is used as a method for achieving a regulatory balance. The regulatory objectives are drawn up in consultation with all relevant stakeholders.

Any reduction in risk involves costs, there is a need to determine how much risk is acceptable, what is the value of the risk cost trade-off, and the goal should be the minimum effective regulation to meet the objectives.

6.4. Analysis of the problem (Consistency)

In order to ensure proportionality of any regulatory approach it is necessary in defining the problem, some basic questions are required to be addressed, such as:

(a) What has led to considering regulatory action?
(b) What data is available concerning the problem either national or international?
(c) What is the reaction of government, business or public concerning the problem?
(d) Do self regulating approaches exist, and how effective are these?
(e) Other than regulation are there other approaches being used?
(f) Why such regulatory action is necessary?
(g) How a regulatory scheme could improve the situation?
(h) What are likely outcomes if nothing is done;
(i) What is the probability that the outcome will occur?
(j) How serious is the harm or injury that could occur?
(k) How widespread will it be and who will be affected?
(l) What is the level of uncertainty?

Defining the problem reduces the risk of choosing inappropriate options for regulator action or ignoring more effective solutions, and reduces the likelihood of over regulation which may have adverse consequences such increase in costs, reduce customer choice or others.

6.5. Analysis of economic, social and environmental impacts (Consistency)

This is an assessment of the impact of a range of viable options (both regulatory and non-regulatory) on all groups affected. Each option should be considered carefully in terms of costs and benefits. The option preferred should be the option which either provides the maximum net benefit or the least net cost to society.

An assessment of the impact (costs and benefits) on consumers, business, government and the community of each option, including the impact on MSMEs and compliance costs should be carried out. This should be carried out for macroeconomic and microeconomic conditions.

It is suggested that the responsible authority captures trade impacts by assessing the following macroeconomic domains:

(a) general macroeconomic impacts;
(b) more specifically effects on exports, imports, investment, openness, attractiveness and competitiveness of the national economy;
(c) interaction between proposed measures and the international regulatory environment;
(d) effects on third countries.

Following on the above it should assess in detail:

(a) In investment (public, private, infrastructure, real estate, etc.);
(b) In consumption (public, private), and what imports and exports are likely to be affected by a proposed measure;
(c) Actual impact of a proposed measure on demand side by category.
(d) It must identify predicted impacts per category in order to reflect indirect effects on other parts of the economy. An increase or reduction in demand in one economic sector should trickle down into other economic sectors;
(e) It must econometrically evaluate the impact on labour markets and in particular effective gender equality;
(f) It must present its findings in standardised tables, which highlight whether the proposed law or regulation may alter the official GDP prognosis for the coming years.

The supply-side analysis should seek to evaluate the mid- and long-term impacts of proposed measures on the availability of labour, capital and effects on productivity and thereby exports.

6.6. Assessing feasible options (Accountability and Proportionality)

These options, regulatory and non-regulatory, may constitute viable means for achieving the desired objectives.

This element sets out a range of viable options for addressing the proposed regulation. It is here that non-regulatory solutions (such as information and education campaigns, the use of codes of practice and voluntary standards) must be described, as well as possible regulatory options.

Alternative options may be based on risk avoidance e.g. to prohibit the activity or alternatively to transfer the risk e.g. cause another party to accept the risk (contracts, compulsory insurance, privatisation etc.)

The option of risk retention can be based in accepting the loss from the risk event (in this case it means accept the status quo), another option would be risk reduction, this method reduces the probability of the risk event by various methods such as licensing, using codes and standards developing enforcement strategies and others.

6.7. Consultation with all stakeholders (transparency and accountability)

This element sets out what consultation (see 3.4) is undertaken and summarises the views of the main affected groups. This is an important aspect of the transparency of the regulation-making process and provides those most affected with adequate lead-in-time before the regulations take effect.

The regulation making process should be transparent to both regulators and those affected by regulation. The process should ensure the issuance of notice of a proposed regulation with a sufficient consultation period to allow:

(a) all stakeholders, including consumers and business to have access to the draft proposals and to submit comments;
(b) adequate consideration and analysis of those comments; and
(c) responses to significant points and explanations of the rationale for revisions when adopting the final regulation.

Openness, transparency, proportionality and accountability in the preparation and application of regulations are fundamental to ensuring public confidence in the approach taken to address a particular problem that has been identified.

Consultation with all parties affected by the technical regulation is an essential element in the preparation and implementation of technical regulations. A well-designed and implemented consultation:

(a) increases the transparency of the process;
(b) ensures that all perspectives on the issues have been considered;
(c) highlights alternative approaches to achieve objectives;
(d) can be a useful means of evaluating the accuracy of regulators' assessment of the costs and benefits; and
(e) enhances awareness and therefore encourages compliance.

It is suggested that regulatory cooperation between regulators from different Member States of the CARICOM could also be viewed as an element of GRP. This voluntary and "informal" activity, where regulators from different Member States exchanged information on regulations and conformity assessment procedures, could help to achieve a better understanding of different regulatory needs and avoid unnecessary regulatory differences (through means such as achieving harmonized, equivalent or compatible solutions).

If stakeholders' consultations are inadequately carried out, stakeholder engagement may ultimately only provide access to policy-makers from specific groups.

6.8. Propose a recommended option

This element is a statement of the recommended option. It can be expressed as a separate document to that of the RIA, but it includes the RIA, or alternatively the design of the RIA document contains on its second page the recommended statement.

6.9. An implementation strategy

The RIA should contain a plan for the implementation of the measures proposed in it, the implementation should take into account the following:

If the measure is going to be a compulsory technical regulation

(a) Was the measure notified to the WTO, if not it should included in the implementation strategy, e.g. when to notify;
(b) Provide sufficient time for the measure to be adopted in the statutes of the country;
(c) Provide sufficient time after the consultations for the stakeholders affected to make the necessary changes to ensure compliance;
(d) Will there be a need for publishing the measure to consumers, how will this be done?
(e) Will there be a need for training on the measure to be provided by the national authorities, if so type and how many and often over which period of time will this take place;
(f) Have national agencies such as market surveillance and others been provided with the necessary resources to enforce the regulations;
(g) Enforcers approach to regulation implementation must be considered e.g. immediate enforcement, a transitional period, education of the regulation of stakeholder by the enforcers?

If the measure is NOT going to be a compulsory technical regulation:

(a) Codes of practice set by the NSB;
(b) Codes of practice set up by the sector association;
(c) How will members of an association be encouraged to follow the code of practice;
(d) What information to provide to Consumers which will trigger a reaction and encourage consumer militancy with respect to a particular issue;
(e) What publicity would government carry out in order to change market perspective or consumer attitudes?
(f) How would NSBs encourage the use of standards or voluntary certification to demonstrate the safety of a product;
(g) Other mechanism which ensure that the market self regulates effectively
(h) The regular measurement that it continues to self regulate effectively.

The overall strategy and implementation should be properly planned so that the measure proposed will succeed in its objectives by being accepted at all levels, internationally, regionally and nationally by all stakeholders.

6.10.Review of technical regulation

To ensure that technical regulations continue to meet their intended objectives efficiently and effectively, it is important that provisions exist for the review of current regulation and the vetting of new regulatory proposals.

RIA is applicable not only to new regulatory proposals but also when reviewing the existing regulations. Monitoring is essential to assess whether the circumstances or objectives giving rise to their adoption have changed. It is also essential to assess whether the regulation is achieving the desired objectives in a proportionate way.

The RIA itself does not have a comprehensive part for the reviewing of existing or new technical regulations, therefore a more integrated use of RIA, stakeholder engagement and post evaluation provides for the determination if the technical regulation has met its objectives and if not what would be required to do in order to achieve the objectives e.g. amend, change or withdraw the regulation.

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