BEST PRACTICE REGULATION

HANDBOOK 2.0

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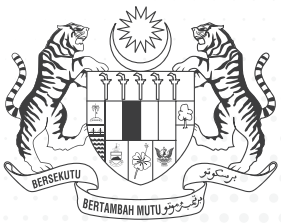

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Acronyms

CBA	Cost-benefit Analysis
CEA	Cost-effectiveness Analysis
DRN	Digital Regulatory Notification
GRP	Good Regulatory Practice
MPC	Malaysia Productivity Corporation
MCA	Multi Criteria Analysis
MyCure	Cutting Red Tape
NPDIR	National Policy on the Development and Implementation of Regulations
NPGRP	National Policy on Good Regulatory Practice
NTM	Non-Tariff Measures
OECD	Organisation for Economic Co-operation and Development
PIR	Post Implementation Review
RC	Regulatory Coordinator
RIA	Regulatory Impact Analysis
RIS	Regulatory Impact Statement
RPMS	Regulatory Process Management System
RURB	Reducing Unnecessary Regulatory Burdens
SCM	Standard Cost Model
SME	Small Medium Enterprises
TBT	Technical Barriers to Trade Agreement
SPS	Agreement on the Application of Sanitary and Phytosanitary Measures
WTO	World Trade Organization

1.0 About this Handbook

Regulations are instruments widely employed by Governments to achieve public policy objectives. Good regulations contribute significantly to increasing the welfare and smooth functioning of society. Regulations should be designed in a manner that ensures they are 'fit for purpose', effective and efficient in achieving intended objectives.

The Malaysian Goverment has formulated the National Policy on Good Regulatory Practice (NPGRP) containing principles, practices and tools to guide regulatory management in Malaysia. The NPGRP replaces the National Policy on the Development and Implementation of Regulations (NPDIR) which as issued in July 2013.

This Best Practice Regulation Handbook 2.0 serves as a reference for regulators in implementing the NPGRP. The handbook is intended for use by regulators and egulatory officials particularly those involved in the process of formulation and implementation of regulations. This handbook should be used in conjunction with the NPGRP and the Regulatory Process Management System (RPMS) as specified in the policy document. It provides step-by-step guidance for the implementation of and compliance with the NPGRP.

This handbook consists of 5 sections. The initial section explains about this handbook while the second section on the definition of terms briefly acquaints the reader with the terms frequently used in GRP. This is followed by the third section which presents an overview of the GRP principles within the RPMS. The next 2 sections outline, from the regulatory cycle amongst others, the key features and the administrative arrangement for the implementation of GRP and describes in greater detail the preparation of RIS, the RIA process and the key requirements as well as explains about ex-post evaluation i.e. the process of reviewing the performance of regulations implemented and how to conduct the evaluation.

Existing arrangements and practices should be reviewed to ensure that they meet with the requirements of the NPGRP. This handbook is a dynamic document and will be improved and updated from time to time.

Additional information and documents on the Malaysian regulatory process can be obtained at grp.mpc.gov.my. For more information, please contact:

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2.0 Definition of Terms

2.1 Good Regulatory Practice

Good Regulatory Practice (GRP) is an approach to rule-making practice comprising principles, methods, processes and tools for improving the quality of regulations. GRP seeks to ensure regulations are 'fit for purpose' and will deliver the public policy outcomes they are set out to achieve in a balanced, equitable and transparent manner.

GRP sets out the various stages in the development of regulations systematically. It calls for a careful analysis of the issues and proposals before addressing them and requires that stakeholders be consulted before proposed solutions are presented to decision-makers for consideration. The principal objective of GRP is to enable decision-makers to make informed decisions based on a robust and transparent rule-making process.

2.2 Regulations

Regulations are measures of general application in various forms that are undertaken by regulators at various levels for which compliance is mandatory. Regulations include primary and subsidiary legislations. Primary legislations include Acts of Parliament, Enactments and Ordinances. Subsidiary legislations include Regulations, Rules, Bylaws, Orders and Guidelines.

Regulations are used by Governments as an instrument, in combination with other instruments, to achieve public policy objectives. Regulations set out principles, rules, and conditions that govern the behaviour of citizens, businesses, and organisations towards achieving the desired public policy objectives.

2.3 Regulator

Regulator refers to a Government agency (Ministry, Department, Statutory Body, Regulatory Commission, etc.) that is responsible for developing, implementing, maintaining and enforcing regulatory functions.

2.4 Regulatory Policy

Regulatory policy concerns the principles, practices and processes by which governments use regulatory instruments to deliver better economic and social outcomes for the welfare of citizens.

2.5 Technical Regulation

Technical regulation is a type of regulation issued by an authority that provides binding technical requirements, either directly or by referencing to or incorporating the contents of an established product or service standard, a technical specification or a code of practice.

Technical regulation may specify the type of a product or a service that is allowable or not allowable or the outcome that is required. By their very nature, they affect the types of products or services available in the market.

2.6 Regulatory Impact Analysis

Regulatory Impact Analysis (RIA) is the process of systematically analysing and communicating the impacts of proposed new regulations or from the review of existing regulations. The essential characteristic of RIA is its informed and evidence-based decision-making for regulatory intervention through analysis of problems and solution options, stakeholder consultation, a cost-benefit analysis, and implementation strategy.

2.7 Full RIA

Full RIA refers to the level of analysis expected to be undertaken for proposals that have significant impact across all or key sectors of the economy. In-depth analysis, a comprehensive cost-benefit study and extensive consultations are required.

2.8 Light RIA

Light RIA is undertaken for proposals which are of minor significance and low impact on the economy or the impact of which is confined to a limited number of economic sectors. Quantification of costs and benefits is required and may be supplemented by qualitative analysis.

2.9 Regulatory Impact Statement

Regulatory Impact Statement (RIS) is a document prepared by the regulator in support of a proposal for a new regulation or an amendment to a regulation following consultation with affected parties. It contains a description of the RIA undertaken and its analysis, recommended option and implementation strategy. The RIS is presented to the decision-maker to enable informed decisions to be made based on a balanced assessment of the best available information.

2.10 'Whole-of-Government' Approach

The 'whole-of-government' approach refers to an arrangement within the public sector to enhance inter-agency coordination and integration in response to the problem of ever-increasing fragmentation of the public sector and public services. The rationale is to reduce the incidences of different policies cutting across and undermining one and other as a result of agencies working in isolation (silos).

3.0 Regulatory Process Management System (RPMS)

Malaysia's regulatory system encompasses institutions, principles, practices and processes through which regulations are formulated, implemented, enforced and reviewed. The development of regulations may follow a top-down or a bottom-up approach with proposals originating from the Cabinet or a regulating Agency. Approval must be obtained from the Cabinet (the Executive) and, where appropriate, from the Parliament (Legislature) with royal assent to be obtained subsequently from His Majesty, the King.

Regulations are issued by a Government Minister or an administrative Agency to whom the legislature (for example, Parliament or state legislative assembly) has delegated its authority via an enabling statute for example, Act of Parliament or Enactment or Regulation. Each Minister is assisted by a Ministry, Departments, Statutory bodies and/or Regulatory Commissions to carry out his portfolio of responsibility. Regulations are used by Governments, when necessary, to achieve public policy objectives as they have binding legal effect.

The process of developing regulations equires regulatory officials to evaluate a range of options in order to achieve a given policy objective including regulation as a part of the solution options. The responsibility for assessing the effectiveness and suitability of regulatory and non-regulatory instruments for achieving policy objectives lies with the respective regulatory authority.

The challenge for the Government is the delivering of regulations that is effective in addressing an identified problem and efficient in terms of the use of resources in maximising benefits while minimising costs to the community. In determining whether regulations meet the dual goals of effectiveness and efficiency, a structured approach to be adopted towards policy development is required.

The RPMS, outlined under the NPGRP, calls for a 'whole-of-government' approach in managing the regulatory regime of the country. It outlines the principles, practices, processes and tools to guide regulators in managing their regulatory responsibilities.

Effective identification of the issue or problem and the related policy objective or intention should constitute the first step in the policy development process. A range of options for achieving the desired policy objective or outcome should be considered. An analysis of the likely economic, social and environmental impacts of each of the options should be carried out. Effective consultation ensures that both the regulator and the affected parties have a good understanding of the problem, the options to address the problem, the benefits, costs and risks of the proposed regulation, and the administrative and compliance mechanisms that will ensue.

Transparency in the development of regulations is of the utmost importance for regulatory governance. Transparency improves accountability and accessibility, reduces regulatory failures and uncertainty, facilitates communication with affected parties, and improves compliance.

3.1 Principles of Good Regulatory Practice

3.1.1 Government Intervention Necessary and Justifiable

Governmental intervention in the economy should be based on clear evidence that such action is necessary and justifiable. Implementing regulations should not be the default option as non-regulatory options should be considered first. Regulator should avoid imposing unnecessary regulatory burden which may stifle economic activities.

3.1.2 Accountability

Regulators must be answerable and responsible for their decisions which should be able to withstand public scrutiny. Regulators must ensure regulatory actions are backed by legal provisions and inter-agency coordination is undertaken to avoid conflict of policies.

3.1.3 Transparency, Accessibility and Effective Stakeholders Consultation

Transparency is of the utmost importance for a credible regulatory process. Regulator are to disclose information on the regulatory process, issues, decisions and their bases unless there is justification for non-disclosure. Regulators must ensure that parties which will be directly or indirectly affected by any proposed regulatory action are duly informed and their views are sought after and considered. Affected parties should have access to the regulations aecting them.

3.1.4 Benefits Outweigh Costs

Ex-ante assessment of costs, benefits and risks is an essential component of regulatory analysis. The costs and benefits to all affected parties must be taken into account. Such analysis should be based on quantitative data whenever possible and qualitative analysis is to be used when necessary. A regulation should be imposed only when it can be shown to offer an overall net benefit to the community as a whole and that any adverse impact is minimised.

3.1.5 Proportionality

Proportionality ensures that regulators' actions do not 'over-reach' or unnecessarily extend beyond addressing the specific problem(s). The scope or nature of governmental action should be commensurate with the magnitude of the problem, its impacts, and the level of risk involved. The principle of proportionality is applicable to the analysis, design and implementation of regulations including the use of appropriate risk assessment and management approaches.

4.0 Implementing Good Regulatory Practice in Malaysia

4.1 Objective

The objective of the NPGRP is to promote an effective, efficient and accountable regulatory system and a rule-making process that support efforts to achieve the Nation's economic development goals.

4.2 Scope and Exemption

The NPGRP is applicable to all regulatory activities affecting the economic, social and environmental aspects. The preparation of Regulatory Impact Statement (RIS) is not required for:

- Regulations that are implemented for reasons of national security and sovereignty;
- Regulations relating to criminal law, such as the Penal Code; and
- Administrative circulars that are intended for public service administration.

In addition, regulators may proceed to implement regulations without RIS in exceptional circumstances when dealing with urgent matters that require immediate action. In such cases, the regulator must notify MPC and provide to MPC the reasons for the decision. A post-implementation review is required for such regulations.

4.3 Regulatory Process

A regulator seeking to introduce any new regulatory proposal or an amendment to an existing regulation is required to notify MPC early in the decision-making process and provide information for MPC to determine whether an RIS is required.

4.3.1 Digital Regulatory Notification (DRN) assessment

Regulators are to first notify MPC on any proposal to create or amend regulation using the Digital Regulatory Notification (DRN). The information required includes a brief outline of the proposal and likely impact on business and other stakeholders. The system will generate feedback whether Regulatory Impact Statement (RIS) is required for the proposed regulations. RIS is the document that contains the outcome of the Regulatory Impact Analysis (RIA).

If RIS is required, the regulator should then proceed to make a preliminary announcement of the intention for the intended regulatory action on its website, informing the public of the objectives.

Frequently Asked Questions - Requirement for Regulatory Impact Statement (RIS)

Is RIS only required for primary legislation or any legislative instruments?

No. RIS is required for all regulations and also for all other requirements that the Government imposes that do not form part of explicit Government regulation (such as industry codes of practice, guidance notes, industry-Government agreements, administrative circulars and accreditation schemes).

Is RIS required if any other party other than the Cabinet is making the decision?

Yes. RIS is required for all regulations regardless of which entity makes the decision. The purpose of the RIS is to enable the decision-maker to make an informed decision.

Is RIS required only for new regulations and not for amendments to regulations?

No. RIS requirements are applicable to both new and to-be-amended regulations.

Is it true that RIS only has to consider the impact on businesses and not on the not-for-profit organisations?

RIS must consider the impacts on all relevant groups such as consumers, the Government and the community.

Is it true that RIS is only required if the regulation imposes compliance costs?

No. RIS is required if a regulatory decision is likely to impact on businesses. This impact includes items that can be readily quantified in monetary terms (such as compliance costs, service charges or subsidies) as well as items that cannot be readily quantified in monetary terms (for example, the costs of pollution).

Is RIS required even when the regulation will provide a benefit to business?

Yes. A RIS is required for regulatory decisions that are likely to have a positive or a negative impact on businesses unless the impact is of a minor nature.

Is RIS only required as a record?

No. RIS is required to be presented to decision-makers to assist in decision-making.

Does RIS need to examine non-regulatory options?

Yes. If non-regulatory options can feasibly address the Government's objective, they should be included in RIS.

If benefits are difficult to be evaluated, does the RIS still need to have a cost-benefit analysis?

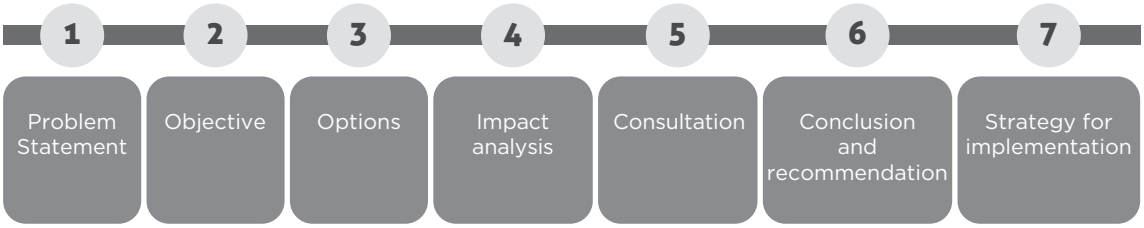
Yes, even though it can be very difficult to determine a monetary value on certain factors including environmental and social impacts. The cost-benefit analysis should recognize this difficulty and include a qualitative discussion of these impacts for comparison with the other impacts that can be quantified. The objective of using cost-benefit analysis is to present a comprehensive analysis of positive and negative impact. If necessary, other impact analysis tool may be used if it achieve the same purpose.

4.3.2 Initial RIS Assessment

The RIA process normally commence after MPC has informed the regulator that RIS is required. RIS is a report that contains contains description of the RIA undertaken and its findings, recommended solution options and implementation strategy. RIS enables informed decision making based on a through and balanced assessment of the best available information.

Elements of RIA are is shown in Figure 1 below:

Figure 1: Elements of RIA



The initial RIS , regulator needs to provide first 4 elements which covered identification of issue(s) or problem(s), objectives of the intended solution, solution options and preliminary assessment of cost-benefit where available. After discussing the Initial RIS with MPC, the regulator proceed to prepare the Final RIS.

4.3.3 Final RIS Assessment

Regulator prepares the Final RIS covering all 7 elements and MPC will comments on the adequacy of the elements. MPC's final assessment will be issued after reviewing the 7 elements of RIS.

4.4 Publication of Annual Regulatory Plan

MPC will publish a report, Modernisation of Regulations, which covers regulatory activities undertaken by governmental regulators. The report will provide an assessment of the progress made in the implementation of the NPGRP.

As part of its role in facilitating the implementation of the NPGRP, MPC will request regulators to prepare a list of all their regulations approved during the previous year. MPC will review these regulations to determine the progress achieved in the adoption of GRP.

Regulators should also communicate their regulatory plans (plans for new regulations and/or for review of regulations in the upcoming year) to MPC in the month of January of each calendar year. The publication of an annual regulatory plan will enhance transparency and predictability as well as encourage stakeholder participation.

4.5 Five-Yearly Implementation Review

All regulations are to be reviewed periodically to ensure that their purposes remain relevant. It is recommended that each regulation should be reviewed once every 5 years unless it is subject to any other statutory review provisions. The review plan should state the original objective of the regulation and its performance to-date in achieving its purpose.

5.0 Preparing Regulatory Impact Statement

5.1 Key Elements

Regulatory Impact Statement (RIS) is a document prepared by a regulator in support of a proposal for a new regulation or an amendment to a regulation. The statement contains a description of the RIA undertaken and its findings, recommended option and implementation strategy. The RIS is presented to the decision-maker to enable informed decisions to be made based on a thorough assessment of the best available information.

RIA utilises a well-established framework for collecting, organising and evaluating data on the anticipated consequences of alternative policy options. It helps to ensure that regulatory actions are necessary and justifiable to achieve the desired objectives and that these actions are implemented in a most efficient, least burdensome and cost-effective manner. (Refer to Annex 1 for Template of RIS)

The 7 elements of the RIA process are as outlined below:

5.1.1 Element 1: Problem Statement

The RIA should clearly identify the issue or problem that needs to be addressed. Care must be taken to distinguish between symptoms and the underlying cause. Identification of the underlying cause helps in resolving the problem.

When identifying the nature and the size of the problem, empirical evidence and the perceptions of the problem must be referred to, wherever available. If the problem involves risk to the public, businesses, workers or the environment, a description of the risk should be included. A discussion should be held of the likelihood that the risk will occur. Answering the questions listed in Box 5.1 may assist in identifying problems or issues. (Refer to Box 5.1)

Box 5.1 Key Questions in Identifying Problem

- What is the problem or issue being addressed? Is it a symptom? What is the root cause?
- How significant is it? What is the magnitude of the problem?
- Has the risk been properly identified and assessed?
- What are the benefits, costs and risks of maintaining the status quo?
- What are the consequences of not taking any actions?
- Why is government action needed to correct the problem?
- Is there any relevant regulation already in place?
- If regulation is in place, why is additional action needed?
- Will the problem self-correct within a reasonable time frame?

The analysis must:

i) Present evidence on the magnitude (scale and scope) of the problem;
ii) Clearly state issues/problems to be addressed;
iii) Identify the affected parties and stakeholders;
iv) Document relevant existing regulations at all levels of the government and demonstrate that they cannot adequately address the problem
v) Identify the relevant risks (risk to safety, health, the environment or businesses), if the problem involves risk and estimate the probability of an adverse outcome, including if no action is taken, and how governmental action will reduce the risk; and
vi) Present a clear case for considering governmental action to be necessary and justifiable, taking into account any existing regulations, any governmental action undertaken previously and risk issues.

5.1.2 Element 2: Objective

Objective refers to the intent or the desired policy outcome of the proposed intervention or regulatory action in relation to the issues or problems identified. The regulator should relate the objective to the broader existing policy or the goals of the agency and the government, if any. The objectives should be specified in a manner that is specific, measurable, achievable, realistic, time-bound, ethical and research-based (SMARTER).

The desired outcome of a proposal should not be confused with the means of obtaining the outcome. For example, an objective of road transport regulation is to reduce injuries and deaths due to traffic accidents. This objective refers to an intended outcome which differs from the introduction of compulsory use of seat belts which refers to one of the means of attaining the desired outcome of reducing injuries and deaths.

The aim of this part of the analysis is not to pre-justify a preferred solution but to specify the policy objective or outcome broadly enough so that all relevant alternative solutions can be considered. However, the specification of objectives and outcomes should not be made so broad or general that the range of alternatives lacks focus and becomes too wide to be assessed and measuring the extent to which the objectives/outcomes have been met becomes difficult to be established.

Information that should be provided includes:

i) A description of the outcomes that the regulation intends to achieve;
ii) Any secondary objective(s) that supplements the primary objective of the proposal;
iii) Whether there are any constraints such as results must be achieved within a certain timeframe;
iv) An explanation of how the proposed regulation fits into the department's broader policy framework and a clarification of how it is within the department's mandate; and
v) Whether there is any enabling legislation or a government directive such as a relevant Cabinet decision or a government policy relating to the implementation of a new regulation.

Answers to some of the key questions as discussed in Box 5.2 below can help to formulate the objectives:

Box 5.2 Key Questions in Establishing Objectives

- Are the objectives presented in a clear and simple language, providing context to help the reader understand the proposed regulation?
- Are the objectives long-term or medium-term in nature?
- Are the objectives in compliance with the SMART criteria?
- Is the performance criteria long-term or medium-term?
- Are essential and relevant links to existing governmental policies stated?
- What are the constraints and barriers to success?

5.1.3 Element 3: Options

The regulator should consider a range of regulatory and non-regulatory options in addressing the issue or risk identified. The RIS should describe each alternative option considered and their associated risks and explain how the options, if implemented, will achieve the desired outcome. Each of the options formulated for consideration should be feasible and able to achieve the policy objective. The feasibility of options is determined by factors such as timeframe, resource availability, the extent and impact of the problem, etc. The regulator should consider at least 3 feasible options including an option of not instituting government intervention.

The examination of options should always consider whether the problem that is being addressed could be remedied by using existing regulations rather than by introducing new measures. For example, if a problem clearly arises from a lack of coordination, improving coordination mechanisms or improving the effectiveness of implementation may then resolve the problem without the need for a new regulation.

a. Risk Assessment

In evaluating options, risk is an important factor for consideration. Risk is the probability of an undesirable event occurring in an option and the consequences that may arise if it occurs. An integral part of the risk assessment process is to determine what action may be necessary to reduce or eliminate the risk and/or its consequences. Most policy proposals are introduced to deal with risks posed to consumers' or workers' safety and health or for the protection of the environment. For example, the risk of persons being harmed by them engaging in a particular activity at the workplace. The notion of harm encompasses fatality, injury or illness while hazard refers to the potential to cause harm. (Refer to Annex 2 for Guide on Risk Analysis).

b. Identifying Options

RIA involves evaluating the effectiveness and suitability of alternative options for achieving the stated objectives. The solution options can be sourced from a choice of regulatory instruments or non-regulatory measures. Regulatory instruments, if adopted, should be the minimum required to achieve the desired outcomes. Where a decision is made to consider regulatory options, the factors that should be considered are as discussed in Box 5.3.

Box 5.3: Key Points When Considering Regulatory Measures

- What is the nature of the problem? Does it concern public health, safety, harm to the environment or unfair competition?
- Are the risks for harm or hazard high or low?
- Is there a case for Government intervention? Is regulation the best solution? Can the problem be resolved through self-regulation?
- Is the problem significant? Are the costs of intervention greater than the potential gain?
- What is the likelihood of the proposed intervention achieving the intended outcome?
- Should the regulator step back and let market forces deal with the problem? What risk is involved?
- Is the proposed measure consistent with the country's international obligations and internationally-accepted standards and practices?
- Have compliance and enforcement issues been considered?

c. Status Quo

The first option is always to maintain the status quo (do nothing) or not do any changes. Status quo is used to describe any existing legislation/regulations, or other relevant government interventions or programmes that are in place and what are the impact on the stakeholders should no action is taken. Maintaining the status quo should also be considered to identify if it is relevant and can be the best option in addressing the problem.

d. Types of Regulatory Options

When Government intervention is warranted, policy-makers may consider a range of policy levers available. Maintaining the status quo or 'doing nothing' can also be a valid policy solution.

i) Self-Regulation

Self-regulation is generally characterised by industry-formulated rules and codes of conduct of a particular industry where the industry concerned is solely responsible for enforcement. Self- regulation is a feasible option if:

- If there is no strong public interest concern particularly if there is no major public health and safety issue.
- The problem is a low-risk event and of low impact or significance.
- The problem can be resolved by market forces.

Self-regulation is not likely to be effective if an industry has a vested interest for not complying with the rules or the codes of conduct.

ii) Quasi-Regulation

Quasi-regulation includes a wide range of rules or arrangements and are used when the risk of harm is low. The Government influences businesses to comply with the rules which do not form part of explicit Government regulation. Quasi-regulation could be industry codes of practice developed together with Government's involvement, voluntary guidelines issued by government agencies and accreditation schemes.

iii) Co-Regulation

Co-regulation refers to the situation where industry develops and administers its own arrangements but the Government provides legislative backing to enable the arrangements to be enforced. Sometimes, regulation sets out mandatory standards but also acknowledges that compliance with an industry code can be deemed as an equivalent.

iv) Explicit Governmental Regulation

Explicit governmental regulation comprises primary and subsidiary legislations. It is the most commonly used form of regulation. Explicit governmental regulation should be considered where:

- The problem is of high risk, high impact or significance (for example, a major publichealth and safety issue).
- The public or business community requires certainty to be provided through legal sanction.
- Universal application is required (or at least where the coverage of an entire industry sector or more than one industry sector is adjudged as necessary).
- There is a systemic compliance problem with a history of repeated or flagrant breaches and no alternative option for effective sanctions has been otherwise applied.

e. Non-Regulatory Options

Non-regulatory options to address a problem or issue should also be considered, either on their own or in concert with regulatory measures. Non-regulatory options include:

- Information and education campaigns including product labelling or media campaigns.
- Standards which may be voluntary or performance-based.
- Other mechanisms such as public information registers, mandatory audits and quality assurance schemes.

Examples of Alternative to Regulation

1. The Communications and Multimedia Commission Act 1998 (Act 588) under Section 185 empowers the Multimedia Commission to designate an industry as a "Technical Standards Forum". This body prepares technical codes for the industry for regulatory issues such as interoperability, safety of networks, approval of customer equipment and devices. The Commission is further empowered to register certification agencies which certify compliance with codes developed by the industry body.

2. The Occupational Safety and Health Act 1994 (Act 514) under Section 37 empowers the Minister to approve industry codes of practice that are developed by any entity and require mandatory compliance with the codes.

3. When bottled LPG gas was introduced to Malaysia, each supplier installed their unique valve on their gas cylinders. This meant that once a consumer bought a particular connecting regulator for his burner or oven, the consumer was only able to use gas supplied by that particular supplier and not any other supplier. This was inconvenient. Consumers were unhappy. The authorities negotiated with the suppliers and arrived at a decision to have a common regulator design. A standard was developed for a common design and all the suppliers adopted this design voluntarily. A regulation was not necessary.

Examples of Non-Regulatory Actions

1. Emissions trading is a market-based approach used to control pollution by providing economic incentives for achieving reductions in the emissions of pollutants. A central authority sets a limit or cap on the amount of a pollutant that can be emitted. The limit or cap is allocated or sold to firms in the form of emissions permits which represent the right to emit or discharge a specific volume of the specified pollutant. Firms are required to hold a number of permits (or carbon credits) equivalent to their emissions. The combined emissions of the total number of permits cannot exceed the cap, thereby limiting total emissions to that level. Firms that need to increase their emissions must buy permits from other firms which require fewer permits.

2. The high tax levied for certain products, for example, tobacco products, is an example of reducing the use of tobacco for improving health objectives.

3. A most commonly used alternative approach to regulation in many countries is through information and education campaigns. These campaigns educate and motivate citizens and consumers to adopt actions or make informed choices, for example, campaigns aimed at reducing speeding when driving, or mustering anti-smoking or anti-littering behaviours. While many information campaigns simply seek to inform citizens and enhance consumer choice, some information campaigns are more explicit in seeking to change behaviour to achieve specific objectives.

4. Voluntary certification schemes for product safety, quality or energy efficiency are some other examples of non-regulatory approaches to achieve objectives. Governments provide support to this action by way of accrediting certification organisations.

5.1.4 Element 4: Impact Analysis

The next step in RIA is to undertake a thorough analysis of the costs and benefits of the options identified. The main objective is to alert decision-makers to the likely consequences of available options.

In general, the depth of the impact analysis should be commensurate with the significance of the overall impact. In the case of a major proposal with significant impact, a greater level of quantification or 'full' RIA and a formal cost-benefit analysis with extensive data collection and consultation will be required. 'Light' RIA is adequate for proposals that are not expected to have significant or major impact. Annex 3 provides examples of RIS categories, their characteristics and the level of analysis required, as used by the Australian Government.

The regulator should:

- Identify the groups in the community likely to be affected by each option and specify the likely economic, social and environmental impacts on them.
- Assess the costs and benefits of all the options over a reasonable timeframe (e.g. 5 years), supported by an acceptable level of evidence, where appropriate, through a detailed cost-benefit analysis.
- Assess the impacts on business, particularly small businesses, and quantify the effect of each option on business compliance costs.
- Analyse the extent to which each option will reduce the risk as well as the costs and benefits involved, if an objective of a regulation is to reduce risk.
- Document any relevant international standards and, if the proposed regulation is not in line with them, identify the implications and justify the variances.
- Demonstrate that the governmental objectives can be achieved only by restricting competition, if the proposed regulation maintains or establishes restrictions on competition
- Provide evidence to support the key assumptions made and clearly identify any gaps in the data available.

a. Identifying Affected Stakeholders

The RIA must clearly identify all the groups affected, whether directly or indirectly, by the problem and its proposed solution. Groups should generally be distinguished as consumers, workers, business and the government. These groups may be further sub-categorised, for instance:

- Within the consumer group, it may be necessary to classify by income, geographical location, age, family unit, cultural background or educational level.
- Within businesses, a distinction can be made along industry or sectoral lines, by the type of activity undertaken or by the size of the business.
- Within the government, a classification can be made as to whether impacts are felt at the federal, state or local government levels.

b. Analysing Options

The RIA should determine feasible options and analyse each of the options for its positive and negative impacts on a cost and benefit analysis. The aim is to identify the option that generates the greatest net benefit and the least cost to the community as a whole. There are a number of different approaches or techniques of quantitative analysis to help establish the option with the best fit as discussed below:

i) Risk Assessment

The risks associated with each option should be clearly identified and assessed. Any weighting of risks should be made explicit, for example, the trade-offs between a high-cost/low-risk option and a low-cost/high-risk option. It may be relevant to assess the probability of a particular risk occurring against the likely magnitude of its impact if it occurs. It may not be possible to estimate this probability with a high degree of reliability but a best-endeavour effort is expected. In certain situations, it may be appropriate that the risk analysis assesses 'the worst-case' and 'the best-case' scenarios and make a comment on the likelihood of either one of these 2 extreme events occurring.

ii) Analysing Costs and Benefits

Costs and benefits are the terms which describe the positive and negative effects of proposals. Costs refer to any item that makes the affected parties, community or sub-groups worse off or reduces their welfare. Cost items may also include 'opportunity foregone' if the proposal is implemented. Benefits include any item that makes the affected parties, community or sub-groups better off.

There are various approaches to undertake analysis of costs and benefits and the choice of approach depends on the availability of information, especially quantitative data. Among more commonly used approaches are Cost-Benefit Analysis (CBA), Cost-Effectiveness Analysis (CEA) (Annex 4: Guide to CEA) and Multi-criteria Analysis (MCA) (Annex 5: Guide to MCA) .CBA is most effective in instances where there is reliable quantitative data on which to base the analysis. However, it should also be noted that cost-benefit analysis should also involve consideration of the distribution of benefits and costs, as well as taking account of impacts which are difficult to be quantify. CEA can be employed when quantitative cost data is available and information on outcome can be translated into unit of measure, such as lives saved, reduction of accidents, etc. MCA is an approach that compares outcomes of options based on a set of criteria (objectives) using a system of rating and ranking.

Key points with regards to cost and benefit analysis is shown in Box 5.4 below:

Box 5.4 : Key Points of Cost-Benefit Analysis

1. **Costs**
   Costs to businesses may include:

- 'Paper burden' or administrative costs to be borne by businesses that are associated with complying with or reporting on regulatory requirements.
- License fees or other charges levied by the government.
- Changes likely to be required in production, transportation and marketing procedures.
- Shifts to alternative sources of input supply.
- Higher input prices.
- Restricted access to markets.

Costs to consumers may include:

- Higher prices of goods and services resulting from restrictions on competition.
- Reduced utility (quality, choice, etc.) of goods and services.
- Delay in the introduction of goods to the marketplace and/or restriction in product availability.

Costs to the community and/or the environment may include :

- Environmental degradation or pollution.
- Reduction in public health and safety.
- Undesirable redistribution of income and wealth.
- Lower employment levels or economic growth.

Costs to the government may include:

- Costs of developing regulations.
- Conducting an education campaign/providing information.
- Administration of licensing/inspection services.
- Collection and collation of business information.
- Enforcement costs including the costs of litigation.

2. Benefits

Identify and describe the benefits of the options to consumers,businesses, the government, other affected groups and thecommunity at large. Certain benefits may not be quantifiable. Examples of benefits include:

- Improvements in product and service quality.
- Availability of a wider range of products and services.
- Reduction in the costs or prices of products and services.
- Reduction in accidents and improvements in public health and safety.
- Improvement in the environment.
- Reduction in compliance costs for businesses and administrative costs for the government.
- Improvements in the information available to businesses, the workforce, consumers or the government.

3. Distribution of Costs and Benefits

To the extent that distributive and equity values are affected by government intervention, regulators should make transparent the distribution of regulatory costs and benefits across various social groups.

A cost-benefit summary proposal should also be included in RIA. The format for Cost-Benefit Summary Statement is shown in Table 1 below. The table summarises quantitative and qualitative benefits and costs for affected stakeholders.

Table 1: Cost-Benefit Summary Statement

IMPACT	COST/UNIT
A. Quantified impact (RM/year) Benefits (by stakeholder group) Costs (by stakeholder group) Net Benefits	
B. Quantified impact non-monetary (unit/year) Positive and negative impact (by stakeholder group)	
C. Qualitative or Intangible Impact Positive and negative impact (by stakeholder group)	

Explanatory Notes

1. **Section A: Quantified and monetised impact.**
As some of the benefits generated from regulatory policies are difficult to quantify, attempts should be made to use alternative methods for quantification. Only benefits and costs that are monetised can be aggregated to arrive at net benefits.

2. Section B: Quantified but not monetised impact.
For items where the benefits or cost cannot be monetised but can be quantified, list out these items in terms of physical units. Include both positive and negative impacts that have been quantified and indicate clearly the unit of measure (e.g. the number of deaths or injuries avoided).

3. Section C: Qualitative or intangible impacts that are neither monetised nor quantifiable.
Intangible or qualitative items that are likely to have a significant impact on decision-making should be listed out and their importance briefly stated. These items are the elements of analysis that matter but cannot be estimated. List both their positive and negative impacts by stakeholder group. These qualitative impacts can be very important to a decision-maker.

iii) Business Compliance Costs

Regulations impose various costs on businesses such as financial costs, opportunity costs, indirect costs and compliance costs. Regulatory costs on businesses tend to be passed through to end-consumers. In evaluating regulatory costs, the focus has been placed on compliance costs as this provides the opportunity for a significant reduction of regulatory burdens. Compliance costs include substantive costs and costs of administrative burdens. Regulatory options are more cost-effective when only the least burden possible is imposed while bringing the greatest possible net benefit to the community. All compliance costs should be quantified. The regulator's main task is to provide the decision-maker with a fair and balanced assessment of these costs. Detailed guidance on compliance cost is included in Annex 6: Guide to Business Compliance Costs.

The common method to measure costs of administrative burden is the Standard Cost Model (SCM). SCM makes it possible to quantify the administrative burden of regulations through measurement which focuses on the administrative activities that must be undertaken in order to comply with regulations.

iv) Impact on Small Businesses

Regulation may have a disproportionate impact on small businesses as they have to allocate a relatively greater portion of their limited resources to meet regulatory requirements. In addition, small businesses are less likely to have specialist staff such as lawyers, accountants or human resource professionals with detailed knowledge of regulation and, hence, additional costs may have to be incurred to procure their services.

Regulators should consider the degree of the impact on small businesses, the number of small businesses affected and whether the overall impact on small businesses is disproportionate to the ability of these businesses to absorb costs.

v) Restriction on Competition

Certain regulations restrict competition. Restriction on competition ranges from monopolies that block competition in entire sectors to a host of less-visible restrictions on starting-up and operating businesses such as business licensing quotas and restrictions on shop-opening hours.

For instance, licensing requirements to promote health and safety objectives may limit the number of firms engaged in an industry or occupation, thereby allowing opportunity to existing operators to raise their charges. Similarly, restricting producers from freely labelling products can restrict competition, thereby limiting supply and resulting in for the raising of prices.

Where a proposal restricts competition, RIA must demonstrate that it will deliver benefits to the community that outweigh costs, and that there is no alternative means of achieving the same objective without restricting competition.

If a proposal is likely to restrict competition, RIA should examine its impact on the following:

- **Incumbent businesses.**
  Will the proposed regulation affect incumbent firms differently and altering the competitive relationships between them in a way that will reduce the intensity of competition in the market as a whole?
- **Entry of new businesses.**
  Will the proposed regulation restrict entry for all, or only particular types of, new businesses? What is the likely degree of this restriction occurring and is it likely to significantly reduce competitive pressures in the longer term?
- **Prices and production.**
  Will the proposed regulation cause a rise in prices by imposing new costs on producers? Will the regulation lead to the closure of some incumbent firms, thereby reducing supply and increasing prices? Will the regulation increase the prospect of collusion among firms to increase prices?
- **Quality and variety of goods and services.**
  Does the proposed regulation include minimum standards that will reduce the range of price/quality combinations available in the market? Is it likely to reduce product variety by restricting the entry of new firms?
- **Market growth.**
  Does the proposed regulation likely to limit market growth either by increasing costs to all producers or by limiting the possibility of entry by new firms?
- **Related markets.**
  Does the proposed regulation in a market also have anti-competitive effects in upstream markets (those that supply inputs to the market in question) or in downstream markets (those to which the market in question supplies inputs)?

vi) Enforcement and Compliance

In evaluating options, it is also important to ensure that proposed measures are enforceable. A careful assessment of how affected parties will comply with the proposal must be done. It is equally important to examine the reasons for current non-compliance and to consider other options of improving the situation without introducing more regulation. For example, targeted action on businesses or individuals who are not complying should be considered first. Some key issues on enforcement and compliance are discussed in Box 5.5.

Box 5.5: Key Points on Considering Enforcement and Compliance

1. Assessment of the likely impact of different enforcement methods and associated risks should be considered.

2. Alternative methods of enforcement and their likely costs should be compared. Where risks are low, the use of a light approach will be appropriate and should be considered.

3. Levels of scrutiny can be varied according to the risks of non-compliance, the characteristics of the firm, firms' sizes, etc.

4. Self-assessment may be a viable option instead of requiring enforcement officers to routinely check whether businesses are complying with a regulation.

5. Preventive controls such as licensing, registration and enforcement should be considered including warning, suspension and prohibition notices. The main objective is to reduce administrative costs and minimise bureaucracy.

6. If active enforcement is required, all relevant enforcement authorities should be involved at an early stage to agree on procedures and to estimate resource implications.

7. If the proposal requires a new enforcement body to be created, its activities are to be integrated with the activities of existing agencies. Governmental approval and sufficient time allocated for its preparation have to be ensured to be available.

8. Where enforcement responsibilities of agencies overlap, co-ordination among the agencies has to be ensured.

Regulations are intended to direct or modify public behaviour to achieve desired outcomes. Sanctions may be necessary to encourage compliance. If sanction for non-compliance is needed, choose a fair and effective regime which is proportionate to the non-compliance. The decision on sanctions should be determined based on the provisions of the law. Expert advice on such matters should be sought as required.

5.1.5 Element 5: Consultation

In general, any proposed new regulation or change to regulation must involve consultation with relevant stakeholders particularly the parties affected by the proposal such as the community, businesses and non-governmental organisations (NGOs). Consultation helps to ensure that the full range of impacts is discussed and feedback is heard and considered.

Consultation must be held for a minimum of 30 days. Consultation must be conducted in a timely manner that reflects a genuine effort to hear and consider the views of stakeholders and must not be conducted as a 'box-ticking' exercise after the policy decision has effectively been made.

The benefits of consultation include:

- Transparency and accessibility.
- Better regulatory proposals through more comprehensive information, allowing potential problems to be identified early.
- Accountability through increased scrutiny of officials' analyses and advice.
- Greater public acceptance as stakeholders are more likely to accept a proposal which they have been consulted with.
- Improved understanding and compliance.

It is incumbent on the regulator to identify affected and interested parties and provide them with opportunities to participate in open and meaningful consultations. The process should also include an inter-agency consultation through which other affected Ministries and regulatory agencies are included and given an opportunity to express their views. Consultation documents summarising the issues, objectives, options and analysis should be circulated in advance to consultative session participants to facilitate effective consultation. Nonetheless, the extent of consultations undertaken should be influenced by the significance and anticipated impact of the proposed regulation.

The RIS must demonstrate that the consultation process was credible, balanced and fair. Draft regulations should be made available to interested parties for them to be informed in greater detail on the government's proposed course of action.

The RIS should provide a summary of the consultation process, the main substantive comments received and how they were taken into account. This summary should address the following:

- Which parties were consulted.
- The main views of the stakeholders indicating areas of agreement as well as areas of differences.
- Information on inter-agency consultation conducted.
- What consultation mechanisms were used.
- When and how long the consultations were conducted.
- Results of the consultations held and whether the regulation was changed as a result.
- How the proposed regulation was prepared to reflect and respond to comments received during the pre-publication process.
- How the proposal has been modified to take into account stakeholders' views. If the proposal has not been modified, the RIS should explain why dissenting views have not been accepted.
- Name any groups still opposed to the regulation.

Notifications that are required to be submitted to the World Trade Organisation (WTO) should be included for proposals that fall within the scope of the notification obligations of the Agreement on Technical Barriers to Trade (TBT) and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) The WTO TBT[1] and SPS[2] enquiry points should be consulted for advice and assistance in making the notifications.

The regulator should take the necessary action to ensure that the draft regulations are not subject to the confidentiality requirements of the Official Secrets Act 1972 (Act 88) at the appropriate stage.

1. Further information and guidance is available from the WTO/TBT Enquiry point at SIRIM Berhad. e-mail: smd@sirim.my, URL: http://sirim.my/WTO/main.htm

2. Further information and guidance is available from the WTO/SPS Enquiry points at :Ministry of Agriculture and Agro-based Industry, email: tnfoo@agri.moa.my, URL: http://www.agrolink.moa.my and Ministry of Health, email: fqc-ebmaster@dph.gov.my and URL: http://www.moh.gov.my/fqc/Index.htm

Consultation Documents

1. Preparation for consultation should include the preparation of consultation documents that are clear, concise and focussed.

2. A list of questions for affected parties can be included to:
   - Check if the benefits and costs are comprehensive.
   - Confirm if the assessment of competition effects is appropriate.
   - Seek a response on the enforcement methods proposed.
   - Check for unintended consequences.

3. Ensure that submissions received on potential costs are supported by evidence. This will prevent respondents from overstating costs in orderto deter the department or agency from pursuing a particular course of action.

4. Seek responses on:
   - The validity of key assumptions.
   - The options that are available (regulation and alternatives to regulation).
   - Implementation issues (including guidance and timing).
   - The preliminary findings on the issue.

Unified Public Consultation

The Government has established the online Unified Public Consultation (UPC) portal which is a website where all proposed new regulations or changes to regulations can be published for review and comment by stakeholders and other regulators. All regulators are required to utilise UPC for the purpose of public consultation on proposed new regulations or changes to regulation. Further information on UPC can be found on the UPC website upc.mpc.gov.my.

5.1.6 Element 6: Conclusion and Recommendation

This section involves preparing a clear statement recommending the preferred option based on the impact analysis conducted. The recommendation for the selected option must be supported by a preceding analysis and a comparison of the costs and benefits among the other options provided. It must be demonstrated that the selected option adequately meets the objectives of the proposed action in the best overall manner and is consistent with the requirements of the GRP Policy.

5.1.7 Element 7: Strategy for Implementation

Having identified the preferred option to achieve the objectives stated at the beginning of RIS, it is necessary to outline how the option will be implemented, monitored and reviewed. Implementation Strategy should address the following issues:

- The communication plan is to ensure that affected parties are informed of the regulation and implementation plans.
- Explain the mechanism adopted to ensure compliance (including prohibition, offences, inspection, licensing, registration, or other governmental approval requirements).
- Describe the penalties for non-compliance (for example, fines, imprisonment and taxes).
- Describe the means and resources that will be used to detect non-compliance (for example, inspection or testing).
- Consider the capacity of regulated parties to take required actions such as completing forms and retaining personnel with expertise or educational qualifications.
- Minimise the impact on stakeholders. For example, this can be achieved through a gradual or phased introduction of new requirements and the provision of information, training and other assistance to affected businesses.
- If joint enforcement is required or enforcements overlap, all relevant enforcement authorities should be involved at an early stage to agree on procedures and to estimate resource implications.
- If a new enforcement body is created due to a proposal, its activities have to be integrated with the activities of existing agencies. Governmental approval and sufficient time allocated for its preparation are to be ensured to be available.

It is important that new policies including regulations are monitored and reviewed to determine if they deliver the expected outcomes i.e. delivering the anticipated benefits at expected costs, whether the policies pose any unforeseen consequences and whether they remain relevant.

There should be an indication on how and when the regulations will be monitored and reviewed. The review plan should consider the following:

- Outline the proposal for monitoring and evaluating the effectiveness of the preferred option including the performance indicators and on how the necessary data will be collected.
- Explain how the regulations will be monitored and reviewed and what the review process will involve.

5.2 Assessing Adequacy of RIS

After MPC has determined that RIS is required, the level of analysis to be provided in RIS will have to be proportionate to the significance of the likely impact of the proposal.
Proposals likely to have significant impacts on businesses and citizens at large require greater in-depth analysis of the impacts i.e. a full RIA. If an impact is likely to be less significant, a less-detailed analysis will be sufficient i.e. a light RIA. MPC will examine the nature and the magnitude of the proposal as well as the scope of its impact to assess the adequacy of the analysis.

The criteria for the adequacy of RIS is as listed in Annex 7: Criteria for Assessing the Adequacy of RIS.

5.3 One-Page Summary of RIS

A one-page summary of RIS must be prepared for decision-makers and a copy of it is to be submitted to MPC together with RIS. The summary will include a brief description of the main points of RIS including the impact of the preferred option, the affected stakeholders and the alternative options.
The template for the preparation of the summary is given in Annex 8: Template for One-Page Summary of RIS.

5.4 RIS Process Sign-Off

RIS must be certified by the Secretary-General of a Ministry or the Director General of an Agency or the Chief Executive of an Organisation prior to its submission to MPC for final assessment.

5.5 Post Implementation Review (PIR)

Where a proposal is proceeded with or without an RIS as provided in paragraph 4.2 (Scope and Exemption), the resulting regulation must be the subject of a post implementation review. The review must be commenced within 2 years from the implementation of the regulation. While the terms of reference for each review will depend on the individual circumstances, a review should generally be similar in scale and scope to what would have been prepared at the decision-making stage. Issues that should be examined include:

- The problem that the regulation intends to address.
- The objective of the governmental action.
- The impact of the regulation i.e. whether the regulation is meeting its objectives.
- Whether the Government's objectives can be achieved in a more efficient and effective way.

The regulator should report accurately on the implementation of the regulation and its actual impact in the post-implementation review. Agencies should gather data from businesses and other stakeholders on the actual impact of the regulation including compliance costs.

The review should incorporate consultation in line with the consultation requirements in this handbook (Section 5, Element 5). The level of consultation should be proportional to the significance of the measure under review.

The template for the preparation of PIR is in Annex 9: Template for PIR.

5.6 Obligations Arising from International Treaties and Agreements

Malaysia is party to international treaties and agreements of which some are likely to contain obligations that impact on domestic regulations. RIS should state the impact of the proposed regulation on such obligations and how the impact has been taken into account. Guidance on how to address these issues is provided in Annex 10 International Agreements: Obligations of Regulators on Technical Regulations and SPS Regulations.

5.7 Trade Impact Assessment

Where a proposed regulation has a direct bearing on trade, a trade impact assessment should be incorporated into RIS. The assessment should summarise the impact of regulatory options and proposals on exporters and importers and also gauge the overall impact on Malaysia's international trade including any impact on competitiveness.

5.8 Ex-Post Evaluation

The ex-post evaluation of existing regulations is necessary to ensure that regulations are effective and efficient. Consideration should be given early in the policy cycle to the performance criteria that will be used for the evaluation of performance as well as the allocation of institutional resources. It is necessary to programme the review of regulations to ensure that ex-post evaluation is undertaken.

As part of the RPMS, there is a requirement for regulations to be reviewed every 5 years. Such reviews will include consultation with stakeholders who will be able to provide valuable feedback on the effectiveness and efficiency of the regulation and its implementation approach.

Regulators are also encouraged to conduct ad-hoc review of regulations whenever the need arises such as at the urgent requests of stakeholders. Regulators may seek the assistance of MPC to activate its regulatory review programmes to undertake such reviews. MPC has the necessary resources to undertake regulatory review programmes such as Reducing Unnecessary Regulatory Burden (RURB), Non Tariff Measures (NTM) and Cutting Red Tape (MyCURE).

5.9 References

In the preparation of the NPGRP, reference was made to the OECD Guiding Principles for Regulatory Quality & Performance and the OECD Recommendation of the Council on Regulatory Policy & Governance.

Annex 1

Template for Regulatory Impact Statement (RIS)

Title of Proposal

Full title
Reference to relevant statute (Act of Parliament, Enactment, Regulation, Rules, By-laws) indicating relevant provisions.

1. **Problem Statement**

Provide a brief description of the issue/problem that gives rise for the need for action.

Identify and explain the current policy objective(s) if related.

Identify the affected parties and stakeholders. Explain how each party is affected.

State why the current situation, including the legislative framework is inadequate and why changes and or new regulation is required.

Risk assessment: What risk is the regulation addressing? Can it be quantified, for example how many people are affected and how?

2. **Purpose and Intended Effect of Measure**

Desired Objectives

State clearly the intention of the proposal or proposed regulation. Describe the intended effects or outcomes and identify the parties the regulation will have an impact on.

3. **Options**

List and describe the options (status quo, regulatory and non-regulatory) that may provide a feasible means for achieving the desired objectives. Examples:
Option 1: Do nothing or maintaining the status quo.
Option 2: For example, get the industry to impose a voluntary code of practice/self-regulation.
Option 3: ...

Highlight any potential risks and limitations associated with the options, describing the likelihood of them occurring and their effect if they were to occur.

4. Assessment of Impact

a) Assess the Impact:
Costs, benefits and risks of each of the identified options to consumers, businesses, government and any other parties identified. Ideally assessment of impact should be over a 5 year period.

Impact of Option 1:
Impact of Option 2:
Impact of Option 3: ...

Identify full range of benefits (to people, the economy, firms, environment...) and quantify these whenever possible. As far as possible benefits should be calculated on a per annum basis. Use ballpark figures and ranges where there is uncertainty about the impact.

Business Sectors Affected:
Identify who might be affected both directly and indirectly – which sectors, how many firms, what size the firms are?

Issues of Equity and Fairness:
Consider whether the proposal is correcting a current inequality, introducing an inequality that might be justified or will it be neutral in effect. Will some be more affected than others? Will the benefits be gained by a different group from those that bear the costs?

b) Costs

(i) Compliance costs

Option 1:
Option 2:
Option 3: ...

Identify what businesses need to do to comply- for example the need to buy new equipment, to train staff, to provide revised guidance material or to spend more time filling in new forms or to undertake checks.

Identify both initial (one off) and recurring costs. As far as possible costs should be calculated on a per annum basis. Use estimates and ranges where there is uncertainty. The cost analysis should reflect all costs, as well costs due to any unintended consequences.

(ii) Other costs

Identify and quantify costs imposed on persons or organizations other than businesses. Include costs that will be imposed on society or on the environment if relevant.

Summarise the impact of the options –with respect to administrative burdens, permits and licences, compliance costs, SMEs, competition, international trade, market and socio economic factors.

5. Consultation

(i) Within Government
List those departments and agencies in the consultation plan and those that you have consulted in the finalization of the proposal and RIS.

(ii) Public Consultation
Describe plan to consult and indicate which groups are targeted.
Parties consulted can often help you by providing detailed information about costs and benefits.
Provide a brief of process, the number and nature of the responses and analysis.

6. Conclusion and Recommendation

May be summarized in a table:

Options	Total Benefits in RM (per annum)	Total Costs in RM (per annum)	Other Benefits	Unintended Impacts
			(List with Brief Descriptions)	
1				
2				
3				
4				

Explain briefly which option is recommended and why.

The proposal selected should offer the best balance between costs and benefits.

7. Strategy for Implementation

Briefly explain the strategy to implement the proposed action. Identify the parties responsible and their roles. Estimate the implementation costs to the parties responsible.

Communication Plan.
Explain the efficient way in ensuring the affected parties are informed of the regulation

Enforcement Plan.
Identify enforcement body for any regulation and describe the enforcement method. Sanctions imposed for non-compliance of regulation should be identified.

Monitoring and Evaluation Plan.
Detail how the effectiveness of the regulation is to be measured and when.

Declaration

I agree with the recommended option in this RIS and I am satisfied that the benefits justify the costs for the recommended option.

Signed :

Name :

Title :

department :

Date :

Contact point.
Insert name, address and phone number of an officer who can answer any query on the assessment or proposed legislation.

Annex 2

Guide to Risk Analysis

What is risk?

Risk is the probability of an undesirable event occurring. Much regulatory activity, for example in the areas of health and safety, is concerned with the risk of persons being harmed by engaging in a particular activity (for example, by consuming a product or by working in a factory). The notion of harm encompasses fatality, injury or illness.

Risks can be viewed in several ways. It is possible to look at societal risk or individual risk. The former averages out individual risk and measures the risk to society as a whole or to a large group of people. Individual risk, on the other hand, varies from person to person. In addition, voluntary risk can be distinguished from involuntary risk. Voluntary risk occurs where an individual can choose to undertake or avoid the risk-causing activity and is fully aware of the consequences.

Conversely, involuntary risk occurs where there is no choice or inadequate information about the consequences. Incomplete information is one of the main forms of market failure. An analysis should also make a distinction between perceived risks and actual risks. Perceived risks occur where individuals overstate the importance of relatively improbable events or discount the importance of highly probable events.

An important distinction to make when conducting risk analysis is that between risk and uncertainty. Risk involves a situation where the probabilities of the various outcomes are reasonably well known. In statistical terms, a probability distribution can be attached to the cost or benefit in question. Uncertainty involves a situation where, while the values the costs or benefits may be known, the probabilities of the outcomes are not known.

Source: Best Practice Regulation- A Guide for Ministerial Councils and National Standard Setting Bodies. Council of Australian Governments, Oct 2007

What is risk analysis?

Risk analysis is a means of analysing the risk of an undesirable event occurring and the consequences that are liable to arise if does occur. An integral part of the assessment process, following on from these first two steps, is determining what action may be necessary to reduce or eliminate the risk and/or its consequences.

Risk analysis is commonly used by policy analysts as a means of assessing individual and societal risks and proposing possible regulatory and non-regulatory solutions to an identified problem. It is most commonly used to analyse regulatory interventions in the health and safety field. However it can also be applied in other public policy fields.

Risk analysis can serve a number of functions. By comparing the risk associated with the status quo with that after government intervention, it can be used to determine more accurately whether intervention is appropriate and/or worthwhile. Risk analysis can also be used as an input into other assessment techniques like cost-benefit analysis.

Risk analysis, in its most basic form, involves quantitative assessment of the magnitudes of the risk affected by the proposal. The contents of a risk analysis can easily be extended by the assessment of additional information, such as benefits or associated risks.

Risk analysis is a valuable tool in further addressing the threshold issue of whether or not to regulate. Furthermore, risk analysis is of use in answering two important questions. First, whether the risks that regulation is intended to address are of significant magnitude compared with other risks. Second, the extent to which regulation reduces the initial risk problem.

Source: Best Practice Regulation- A Guide for Ministerial Councils and National Standard Setting Bodies. Council of Australian Governments, Oct 2007

Content of a risk analysis

The following issues can be addressed in the risk assessment of regulation:

- An appraisal of the current level of risk to the exposed population from an identifiable source;
- The reduction in risk which will result from the introduction of the proposed measures;
- Consideration of whether the proposed measures are the most effective available to deal with the risk; and
- Whether there is an alternative use of available resources which will result in greateroverall benefit to the community.

The risk analysis process

Risk analysis involves three distinct but inter-linked steps:

- Defining the risk;
- Selecting the appropriate response; and
- Monitoring the situation and reviewing the effectiveness of the response that was selected and implemented.

Defining the risk

The following questions should be answered to ensure that the risk is defined as accurately as possible:

1. What is the hazard? It is necessary to define exactly what the hazard is;
2. What is the risk? It is important to distinguish between commercial risks and physical risks. Commercial risks can, and probably should, be borne by the company or industry involved and resolved at that level. On the other hand, a physical risk (and this ranges from a direct personal threat to life to environmental pollution) is a problem that is likely to affect individuals and society as a whole and therefore is best addressed at the appropriate government level;
3. How widespread is the risk? Is the risk local only, is it state-wide, national or international?

   Obviously, the extent of measures to be considered to combat the risk will depend on this assessment, and may include the need for international co-operation;
4. Is the risk transmittable? In the case of medical risks, for example (such as a contagious disease), the transmittability of the risk is crucial to this assessment, as is the means of transmission and its avoidability. This will also involve identification of the source of the risk and whether transmission occurs across boundaries, for example, from plants to insects to animals to humans, or between different geographical locations;
5. Is chemical used? In what circumstances will the risk arise? Is the risk continuous, or will it arise only in particular circumstances (for example, if a product is used only in a specific way, or only if a particular chemical is used);

Source: Best Practice Regulation- A Guide for Ministerial Councils and National Standard Setting Bodies. Council of Australian Governments, Oct 2007

6. Who or what is most at risk? Identification of the at-risk groups is crucial. It is necessary to determine for instance whether children of certain ages are most at risk, whether it is the population as a whole, whether the risk is confined to a particular group (for example, only plants, or male children below the age of 10, or women over 45); and
7. Is harm or injury liable to occur? Having gone through the above steps, it is important to determine whether any actual harm (for example, to the environment) or injury is liable to occur. This necessarily involves assessing not only the immediate effects but also the longer term effects. If no actual harm or injury is liable to occur, then any question of intervention probably becomes almost superfluous.

Selecting the response

This step is dependent on the accuracy and completeness of having defined the hazard. The first question to be asked is whether there is any realistic, viable action that the government can take to correct or ameliorate the situation. If the answer is no, or if the costs of any action are likely to outweigh the benefits, then serious consideration should be given to not taking any action at all. An explanation must be given as to what actions were considered, why they are impractical and the consequence (if any) of no action being taken.

Monitor the situation and review the effectiveness of the response

Whether the selected response is no action, introduction of a tax or subsidy, or a voluntary code of practice or a mandatory regulation, it is essential that both the situation and the effectiveness of the response be closely monitored. Monitoring will determine whether:

- The risk was under- or over-estimated and the response is adequate in the circumstances;
- The risk has changed and the response no longer applies to new circumstances; and
- Those at which the action was directed are responding.

The monitoring and assessment process requires determination of:

- Whether the risk has been eliminated. In which case, can the response be removed altogether or should it be retained in place to prevent a recurrence of the risk?
- Whether the risk has been reduced but not eliminated. It may be unrealistic to expect complete elimination of the risk to occur. In that case, what level of reduction in the risk leaves a situation which, while not necessarily ideal, is acceptable? and
- How much longer the response should be left in place. If any reduction in the level of risk is not sufficient to justify considering the situation to be acceptable, how much longer should the response stay in place to reach an acceptable level of reduction?

Source: Best Practice Regulation- A Guide for Ministerial Councils and National Standard Setting Bodies. Council of Australian Governments, Oct 2007

Annex 3

Characteristics of RIS Categories

RIS Category	Characteristics	Level of Analysis Required
A	• Major impact on the economy. • Change likely to impact across the entire economy or a significant proportion • New regulations will involve significant change and have high costs. • The regulatory changes are a matter of debate and fundamental disagreement • The issues are highly sensitive and controversial.	• In-depth analysis. • Formal cost–benefit analysis. • Evidence of extensive consultation.
B	• A measurable impact on the economy. • Change likely to impact across a number of sectors or a single sector in a very significant manner. • New regulations will involve significant change and have high costs. • The regulatory changes are a matter of debate and disagreement. • The issues are highly sensitive.	• In-depth impact analysis, including quantifying impacts

RIS Category	Characteristics	Level of Analysis Required
C	• Limited impact on the economy. • Change likely to impact a single sector. • New regulations will involve change and costs but these would not be considered significant in the sector they are to apply to. • The regulatory changes are a matter of some disagreement but not fundamental disagreement • The issues are sensitive.	• Quantification preferred.
D	• Relatively minor significance in the economy. • Likely to impact a single sector. • The regulatory change is well accepted, or even requested by key stakeholders. • The issues have little sensitivity.	• Quantification preferred but qualitative analysis only may be acceptable.

Source: Best Practice Regulation Handbook, Australian Government, July 2013

Annex 4

Cost-Effectiveness Analysis

Cost-effectiveness analysis (CEA) is an alternative to Cost-benefit Analysis (CBA). The technique compares the relative costs to the outcomes (effects) of two or more options (courses of action).

CEA is most useful when analysts face constraints which prevent them from conducting cost-benefit analysis. The most common constraint is the inability of analysts to monetise benefits. CEA is commonly used in comparing social or environmental outcomes such as reduction of illnesses, accidents or pollutants, where it is difficult to put a value on outcomes, but where outcomes themselves can be counted and compared, e.g. 'the number of lives saved' or 'the number of complaints reduced'.

CEA measures costs in a common monetary value (RM) and the effectiveness of an option in terms of physical units. Because the two are incommensurable, they cannot be added or subtracted to obtain a single criterion measure. One can only compute the ratio of costs to effectiveness in the following ways:

Cost Effectiveness (CE) ratio = C1/E1

Effectiveness Cost (EC) ratio = E1/C1

where: C1 = the cost of option 1 (in RM); and E1 = the effectiveness of option 1 (in physical units).

The first equation above represents the cost per unit of effectiveness (e.g. RM spent per life saved). Options can be rank ordered by CE ratio from lowest to highest. The most cost-effective option has the lowest CE ratio. The second equation is the effectiveness per unit of cost (e.g. lives saved per RM spent). Options should be ranked from highest to lowest EC ratios.

Often, it may be difficult to quantify the final intended outcome of a policy such as improved quality of healthcare or improvement in road safety. This can be addressed by quantifying and measuring intermediate outputs (proxy indicators) from the policy (e.g. reduction in medical expenses, incidents of illness, road accidents, etc.) or comparing cost with published research data on effectiveness a product (vehicle safety belt).

The example below presents the results from a cost-effectiveness analysis of a hypothetical proposal to regulate to improve the quality of repair and maintenance at automotive repair workshops. This cost-effectiveness ratio can be compared to another intervention to determine which is more cost-effective.

Example: Regulation to improve service of automotive repair and maintenance workshops.

This proposal is to address frequent complaints by consumers on poor service and fraud at automotive repair and maintenance workshops. The objective of the proposed solution is to reduce the number of complaints. In this case, the number of complaints from owners of car aged 10 years or less is a proxy indicator. Car age of '10 years or less' is used to reduce variations of car conditions and repairs and maintenance required.

The 3 options are:

1. Status quo
2. Introduce regulation on automotive repair and maintenance workshops. This would require regulations on pricing and qualification of mechanics.
3. Industry to self-regulate through a rating system. This would require industry to introduce a voluntary rating system among members for quality service with input from customers. Consumers will be able to make better choice.

	Activity	Option 1	Option 2	Option 3
1	Determine measurable proxy indicator for objective: •To measure reduction of customer complaints for vehicles aged 10 years or less.			
2	Costs of compliance by industry (per annum): • Increased cost for equipment. • Increased cost for staff.	RM0	RM10,000,000 RM500,000	RM4,000,000 RM200,000
3	Regulator's costs of implementation (cost of monitoring and enforcement).	RM0	RM200,000	RM50,000
4	Total cost per annum		RM10,700.00	RM4,250,000
5	Identify change in outcomes expected.		Reduce complaints by 1500 per annum	Reduce complaints by 5000 over 5 years (or ave. 1000 pa)
6	Calculate cost-effectiveness (cost per unit of complaint reduced)		RM7,133	RM4,250

The indicative cost for the reduction of 1 compliant in option 2 is RM7,133 while from option 3 is RM4,250. Under option 3, the rate of reduction of complaints will be gradual as workshop operators and car owners will take time to adjust to the system. Eventually, a reliable rating system will help consumers to make better choices and reduce the number of compliant.

Annex 5

Multi-Criteria Analysis (MCA)

MCA is a qualitative approach to evaluate costs and benefits that are unable to be monetized or converted into numerical values. It should be used when there are multiple policy objectives that cannot be practically quantified. There may be several approaches or options to achieve these objectives. The aim of this method is to identify the best option to be considered for recommendation to decision makers.

MCA establishes preference between options by evaluating the options to set of objectives that the decision-making body has identified, and for which it has established measurable criteria to assess the extent to which the objectives can be achieved. A key feature of MCA is its emphasis on the judgement of the decision-making body, in establishing objectives and criteria, estimating relative importance (weights) and, to some extent, in judging the contribution of each option to each performance criterion. A certain degree of subjectivity is inherent in this method and this can be moderated by using a decision-making body with representative from various key stakeholders to participate in the identification of objectives, criteria, weights and assessment of achieving the objectives. MCA brings a degree of structure, analysis and openness to decision-making when it is not practical to use CBA.

Steps in MCA

1. Establish the decision context – what is the aim or purpose of the evaluation
2. Conduct workshop among key decision-makers and stakeholders to establish the objectives and criteria for evaluation.
3. Establish the options (alternative solutions).
4. Construct the evaluation matrix using the established options and evaluation criteria.
5. Assign weight to each of the evaluation criteria to reflect their importance in achieving the objectives.
6. Score the expected performance of each option to each of the criteria.
7. Tabulate the weighted score of each option.
8. Examine the result, conducted sensitivity analysis and discuss outcome.

Example: Case of E-hailing Taxi

The regulator in considering possible solution to the issues relating to the emergence of unregulated e-hailing taxis posing unfair competition to regular taxi operators, established a study team that comprises representatives from key stakeholders. The study team identified 4 objectives in tackling the issue relating to E-hailing Taxis. These are:

- Efficient & convenient public transport
- Public safety
- Maintaining fair competition; and
- Impact on Government revenue

Three options (possible solutions) were also identified. They were:

- To maintain the status quo
- To regulate E-hailing Taxis
- To ban E-hailing Taxis

Options Criteria	Wt	1 Status Quo	2 Regulate e-hailing taxi	3 Ban e-hailing taxi
Efficient & convenient public transport.	40	5 (200)	8 (320)	3 (120)
Public safety	30	5 (150)	5 (150)	4 (120)
Fair competition	20	5 (100)	7 (140)	5 (100)
Government Revenue	10	5 (50)	6 (60)	3 (30)
Total weighted score	**100**	**(500)**	**(670)**	**(370)**

Total weight of 100 divided among the criteria. Assign score 1-10 in terms of ability to achieve the criteria in each cell.

Option 2 to regulate E-hailing Taxi attained the highest score and should be the recommended solution.

Annex 6

GUIDE TO BUSINESS COMPLIANCE COSTS

1. Introduction

Business compliance costs is an important component in assessing cost-benefit of regulatory actions. They are the costs arising from compliance with the regulatory requirements imposed by the government that must be borne by business, government and the broader community.

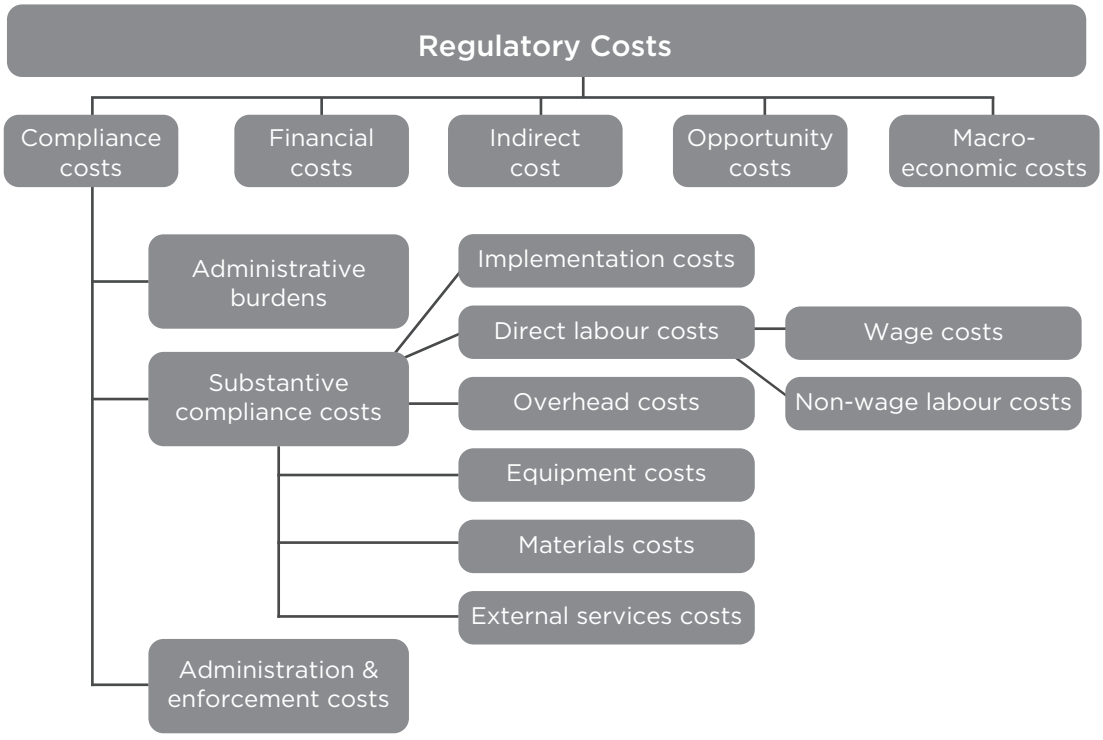
While compliance costs are inevitable as a result of regulatory measures, it is crucial to identify and eliminate unnecessary regulatory cost in the form of excessive or unnecessary requirements of the regulation. These costs, which are above the costs necessary for compliance, add burden to the parties being regulated and cause inefficiency that results in poor economic outcomes and reduced welfare. Regulatory costs on businesses tend to be passed through to end consumers.

This Annex provides a description of regulatory costs focusing specifically on the compliance costs component and their measurement, and the use of the Standard Cost Model (SCM) as the tool for measuring administrative costs.

2. Overview of Regulatory Costs

The total costs of a regulation are made up of the compliance costs and all other regulatory costs that fall outside the definition of compliance costs, such as financial costs, indirect costs, opportunity costs and macroeconomic costs. Figure 2 sets out a taxonomy of regulatory costs.

Figure 2 : Taxonomy of Regulatory Costs



Source: OECD Regulatory Compliance Cost Assessment Guidance, 2014

3. Compliance Costs

The compliance costs are costs borne by business being regulated in undertaking actions necessary to comply with the regulatory requirements and the direct costs to government in administrating and enforcing the regulation.

The breakdown of compliance costs is shown in Table 2.

The components of the costs borne by business are:
- administrative costs, and
- substantive costs.

Administrative costs are further elaborated in Section 4.
Substantive costs are the direct costs borne by those being regulated to fulfil compliance obligations. They include implementation costs, direct labour costs, overheads, equipment costs, materials costs and the costs of external services.

The direct costs to the government are the administration and enforcement costs. These are the costs incurred and borne by the government in administering and enforcing the regulatory requirements. They fall into the category of compliance costs since they are directly related to the achievement of the underlying regulatory objective and are an unavoidable part of the cost of regulation.
In principle, regulatory fees paid by businesses are imposed in order to recover the costs of government administration and enforcement of the regulations, thus are not considered as costs borne by business. Its inclusion into costs borne by business would result in double counting, if cost of government administration and enforcement are taken into account.

Table 2 : Compliance Costs of a Regulation

Category	Activity	Cost Component	
Administrative costs (Business)	Paperwork activities for information obligations (IO)	Costs of making, keeping and providing records	
		Costs of notifying the Government of certain activities	
		Costs of conducting tests	
		Costs of making an application, completing forms	
		Compliance costs associated with financial costs, for example, the time taken to pay a licence fee.	
Substantive costs (Business)	Direct compliance obligation activities	Implementation costs	Costs in acquiring sufficient knowledge about new or amended regulatory compliance obligations, developing compliance strategies and allocating responsibilities for completing compliance-related tasks
		Direct labour costs	Staff time devoted to completing the activities required to achieve regulatory compliance
		Overhead costs	Costs of rent, office equipment, utilities and other inputs used by staff engaged in regulatory compliance activities, as well as corporate overheads, such as management inputs, that are attributable to compliance activities
		Equipment cost	Costs of acquiring items of capital equipment to comply with many kinds of regulations which include both machinery and software.
		Material costs	Incremental costs incurred in changing some of the material inputs used in the production process in order to ensure regulatory compliance

Category	Activity	Cost Component	
		External services costs.	Cash cost of payments made to external consultants in the course of achieving regulatory compliance.
Administration and enforcement costs (Government)	Administrating and enforcing regulatory requirements	Costs of publicising the existence of the new regulations	
		Costs of developing and implementing new licensing or registration systems	
		Costs of assessing and approving applications and processing renewals	
		Costs of devising and implementing inspection and/or auditing systems	
		Costs of developing and implementing systems of regulatory sanctions to respond to non-compliance.	

Annex 7

Criteria for Assessing the Adequacy of RIS

1. Problem Statement

The RIS should clearly identify the problem(s) that need to be addressed. This part of the analysis must:

- Present evidence on the magnitude (scale and scope) of the problem;
- Document relevant existing regulation at all levels of government and demonstrate that it is not adequately addressing the problem;
- Identify the relevant risks, if the problem involves risk, and explain why it may be appropriate for the government to act to minimise them; and
- Present a clear case for consideration that additional government action may be warranted, taking into account existing regulation and any risk issues, and the potential for market developments to overcome the problem.

2. Objectives

The RIS should explain the objectives, outcomes, goals or targets of the government's proposed action.

3. Options

The RIS should identify a range of alternative options including, as appropriate, non-regulatory, self-regulatory and co-regulatory options. If only one option (apart from the option of non intervention) is considered feasible, the RIS should provide sound justification for considering only two options. If the Cabinet directs that a limited set of options be considered, or options are limited because of other specific reasons, this must be clearly stated.

4. Impact Analysis

The RIS should provide an adequate analysis of the costs and benefits of the feasible options, and should:

- Identify the groups in the community likely to be affected by each option and specify significant economic, social and environmental impacts on them;
- Assess the costs and benefits of all the options supported by an acceptable level of evidence, where appropriate through a formal cost-benefit analysis, using the status quo as a baseline;
- Assess the net impact of each option on the community as a whole, taking into account all costs and benefits;
- Assess the impact on businesses and the not-for-profit sector, including distributional issues such as the impact on small businesses, and quantify the effect of each option on business compliance costs;
- Recognise the effect of the options on individuals and the cumulative burden on businesses;
- Quantify other significant costs and benefits to an appropriate extent, taking into account the significance of the proposal and its impact on stakeholders;

- Analyse the extent to which each option would reduce the relevant risk if an objective of regulation is to reduce risk, and the costs and benefits involved;
- Document any relevant international standards and, if the proposed regulation differs from them, identify the implications and justify the variations;
- If the proposed regulation maintains or establishes restrictions on competition, demonstrate that the regulation results in a net benefit and that the government's objective/s can be achieved only by restricting competition; and
- Provide evidence in support of key assumptions and clearly identify any gaps in data.

5. Consultation

The RIS should:

- Outline the plan adopted for consultation;
- Include results of the inter agency consultation;
- Describe how consultation was conducted (when consultation was undertaken, the timeframes and the methods used);
- Summarise the views of those consulted, including substantial disagreements;
- Outline how those views were taken into consideration; and
- If full consultation was not undertaken, provide a reasonable explanation as to why it was not.

6. Conclusion and Recommendation

The RIS should clearly state the preferred option, why it is preferred, and indicate the costs and benefits of this option. This statement needs to be supported by the analysis contained in the RIS.

7. Strategy for Implementation

The RIS should provide information on how the preferred option would be implemented, monitored and reviewed. Interactions between the preferred option and existing regulation of the sector should be clearly identified.

Annex 8

Template for One-Page Summary of RIS

Title of Proposal

1. Problem Statement

Provide a brief description of the policy objective/problem that gives rise for the need for action.

Identify the affected parties and stakeholders. Explain how each party is affected.

State why the current situation, including the legislative framework is inadequate and why changes and or new regulation is required.

2. Objectives

State clearly the objectives of the proposal or proposed regulation using SMARTER approach.

3. Options

List the options (status quo, regulatory and non-regulatory) considered .

Summarise the basis for the option selected.

4. Impact Analysis

Summarise the impact of the options –with respect to administrative burdens, permits and licences, compliance costs, SMEs, competition, international trade, market, socio economic factors.

Summarise benefits and cost to affected parties and government; and

5. Consultation

Summary of results of public and industry consultation.

Identify parties disagreeing and state reasons.

6. Conclusion and recommendation

Explain which option is recommended and why.

7. Strategy for Implementation

Briefly summarise strategy for implementation of the proposed action.

Annex 9

Template for Post Implementation Review (PIR)

(Note: While the terms of reference for each review will depend on individual circumstances, the review should generally be similar in scale and scope to what should have been prepared for the decision-making stage.)

Title: (State title of regulation)

Regulator: (State organisation name)

Implementation Date:

Section 1: What problem was the regulation meant to solve?

Provide a brief description of the issue/problem that gave rise to the need for regulatory action.

State why existing regulation(s), if any, was inadequate and why changes and/or new regulation was required.

Identify the affected parties and stakeholders. Explain how each party was affected

Risk assessment: What risk was the regulation addressing? Can it be quantified, for example how many people were affected and how?

Section 2: Why was government action needed?

State clearly why government action was needed and the objective of the regulatory action. Describe the intended effects or outcomes including using 'SMART objective' approach to facilitate monitoring and review.

Section 3: What policy options were considered?

Describe options considered for achieving the desired objectives. State anticipated impact of each of the identified options in terms of costs, benefits and risks to businesses, consumers and community, government and any other parties. Ideally assessment of impact should be over a 5-year period.

State the reasons for choosing the implemented option.

Section 4: Which stakeholders were consulted?

List those government departments and agencies, and stakeholder groups that were consulted in the finalization of the proposal and RIS.

Section 5: How was the regulation implemented and evaluated?

Briefly explain the implementation strategy for the regulatory action. Identify the parties responsible and their roles. State the implementation costs to the parties responsible.

Identify enforcement body for the regulation and describe the enforcement method.

Section 6: Has the regulation delivered a net benefit?

Describe the impact of the regulation to date. Has the impact been positive, negative or within expectation?

Annex 10

International Agreements: Obligations of Regulators on Technical Regulations and SPS Regulations

General

When developing or changing regulations, regulators must ensure that regulatory officials are aware and adhere to obligations set out in international and intergovernmental agreements and accords to which Malaysia is a party such as the provisions of the World Trade Organization (WTO) Agreement, the ASEAN Free Trade Agreement (AFTA) and other multilateral, regional and bilateral Agreements including the Safety of Life At Sea Convention of the International Maritime Organization.

Technical Regulations

When developing or changing technical regulations, regulators must

1. Ensure that regulatory officials are aware and take account of their general obligations as laid out in the WTO Technical Barriers to Trade Agreement (TBT) and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and other multilateral, regional and bilateral Agreements referring to regulations and standards; and
2. In particular, for technical regulations that affect trade, regulators must comply with notification obligations, except in urgent circumstances, and take into account comments received. Additionally,
   - for TBT Agreement, ensure technical regulations treat products from one jurisdiction no less favourably than like products from another;
   - for SPS Agreement, ensure measures do not arbitrarily or unjustifiably discriminate where identical or similar conditions prevail;
   - ensure technical regulations are no more restrictive of entry into markets than is necessary;

   With regard to international standards
   - use available international standards, guidelines and recommendations where those standards achieve the regulatory objectives;

   With regard to enforcement
   - treat products from one jurisdiction no less favourably than those from other jurisdictions when assessing conformity to technical regulatory requirements, provided they are in comparable situations;

   With regard to resolution of complaints
   - have in place a process to review complaints concerning conformity assessment procedures and corrective action must be taken when justified.

3. Sanitary and phytosanitary regulations
   SPS regulations refer to measures applied by the regulator:

   a) To protect animal or plant life or health from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;

   b) To protect human or animal life or health risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;

   c) To protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products there of, or from the entry, establishment or spread of pests; or

   d) To prevent or limit other damage from the entry, establishment or spread of pests

Sanitary or phytosanitary measures include all relevant laws, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

The relevant Ministries and Agencies may be consulted for specific guidance. For WTO and trade agreements the main responsibility is with the Ministry of International Trade and Industry. Additional assistance is available from the Department of Standards Malaysia for the WTO/TBT agreement, and from the Ministry of Agriculture and Ministry of Health for the WTO/SPS agreement.

Notes

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