MALAYSIA

BEST PRACTICE REGULATION HANDBOOK

JULY 2013

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Regulatory Review Department
Malaysia Productivity Corporation (MPC)
Lorong Produktiviti, Off Jalan Sultan, 46904 Petaling Jaya
Selangor Darul Ehsan, Malaysia
Tel : 603 - 7955 7266 | Fax : 603 - 7957 8068 | Email : regulatoryreview@mpc.gov.my

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About this Handbook

Regulation is a key instrument used by the Government to achieve various policy objectives and ensure the wellbeing of citizens. It is an important tool for protecting health and safety, the environment as well as for ensuring a balanced and continuous development of the economy.

Recognising the impact that regulations can have on the economy, the Government has issued the *NATIONAL POLICY ON THE DEVELOPMENT AND IMPLEMENTATION OF REGULATIONS* to ensure the adoption of best regulatory practices by all federal government agencies. The process for developing and implementing regulations is complex. Regulations are required to comply with the legal requirements contained in various Acts approved by Parliament and also with policies of the Government.

The Government has established the Special Task Force to Facilitate Business (PEMUDAH) to ensure that Malaysia remains an attractive and competitive investment location and PEMUDAH has been addressing existing service delivery issues that relate directly to investment such as starting a business or establishing a factory. The implementation of this policy is a complementary initiative to PEMUDAH's efforts and will ensure that any new regulation does not result in similar disincentives to business, investment and trade.

This *Best Practice Regulation Handbook* is a tool to facilitate the implementation of this National Policy. It is intended for use by civil service employees and those involved in developing regulations or otherwise implementing the *NATIONAL POLICY ON THE DEVELOPMENT AND IMPLEMENTATION OF REGULATIONS*. The Handbook should be used in conjunction with the National Policy document as it provides detailed guidance for implementing the policy and developing regulations in accordance with the Regulatory Process Management Requirements as specified in the policy document.

The handbook provides guidance for compliance to the policy and process. It is intended that there be flexibility in implementation as long as the principles and key process steps are adhered to. Existing arrangements should be reviewed to ensure that these fulfill the policy and process requirements and changes made to the existing arrangements as necessary.

Additional information and documents on the Malaysian regulatory process can be found at regulatoryreview@mpc.gov.my. The following address, email, and telephone numbers may also be useful:

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1.0 Good Regulatory Practice (GRP)

Regulations are issued by persons or bodies, a Minister of the Government, or an administrative agency, to whom Parliament has delegated its authority in an Act. Regulations are a form of law as they have binding legal effect. The process for developing regulations assumes that officials have evaluated the range of options available to achieve a given policy objective and have determined that regulation is a necessary part of the selected option. The responsibility for assessing the effectiveness and appropriateness of regulatory and non-regulatory instruments for achieving policy objectives lies with the respective departments and agencies.

While regulations are essential for the proper functioning of society and the economy, the challenge for the Government is to deliver effective and efficient regulations; effective in addressing an identified problem and efficient in terms of maximising the benefits to the community, taking into account the costs. Determining whether regulations meet the dual goals of effectiveness and efficiency requires a structured approach to policy development that systematically evaluates costs and benefits.

The identification of the problem to be addressed and the related policy objective should constitute the first step in the policy development process. A range of options for achieving the objective should be considered (including the no action or the status quo option); and an analysis of the likely economic, social and environmental impact should be carried out.

Effective consultation ensures that both the regulator and the affected parties have a good understanding of the problem, of the alternative options to address this problem, of the relevant administrative and compliance mechanisms that will ensue, and the subsequent benefits as well as costs and risks of the proposed regulation.

Transparency in the development of regulations is important for regulatory governance. Transparency improves accountability as well as assists in avoiding regulatory failures, in reducing uncertainty, in facilitating communication with affected parties and finally in assisting with compliance.

The Government's Regulatory Process Management Requirements provide a systematic approach to ensure high quality regulation in line with the *NATIONAL POLICY ON THE DEVELOPMENT AND IMPLEMENTATION OF REGULATIONS (NPDIR).*

2.0 Regulatory Impact Analysis (RIA)

Regulatory Impact Analysis (RIA) is an essential feature of sound regulatory practice. It consists of a process of examining the likely impact of a proposed regulation and a range of alternative options which could meet the Government's policy objectives.

The NPDIR provides a consistent approach to making regulations while ensuring that the policy commitments and legal obligations of the Government are met. The structured process also ensures predictability for citizens, institutions, and businesses affected by regulation.

The Government's RIA requirements are intended to achieve better regulation by supporting:

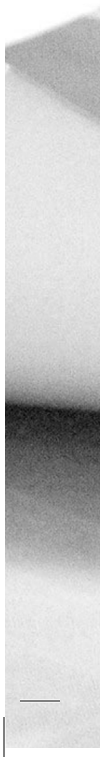
- *Sound analysis.* The case for acting in response to a perceived problem, including addressing the fundamental question of whether regulatory action is required, needs to be demonstrated. The analysis should also outline the desired objective of the response, a range of alternative options to achieve the objective, and an assessment of the impact of each option, and should include effective consultation;

- *Informed decision making.* Decision makers, faced with a range of options for achieving the Government's objectives, must understand the implications and be informed about the likely impact of the available options before deciding; and

- *Transparency.* The information on which government's regulatory decisions are based should be publicly available.

Regulatory Impact Statement (RIS) is a key requirement of the Government's RIA process. RIS is a document prepared by the regulator in support of proposals for new regulations, following consultation with affected parties. It formalises and provides evidence of the key steps taken during the development of the proposal, and includes an assessment of the costs and benefits of each option considered. The RIS must be presented to decision makers so that their decision is based on a balanced assessment of the best available information. After a decision has been officially announced, RIS will be published by MPC in consultation with the regulator. This means that RIS is posted on the publicly accessible RIS register maintained by MPC.

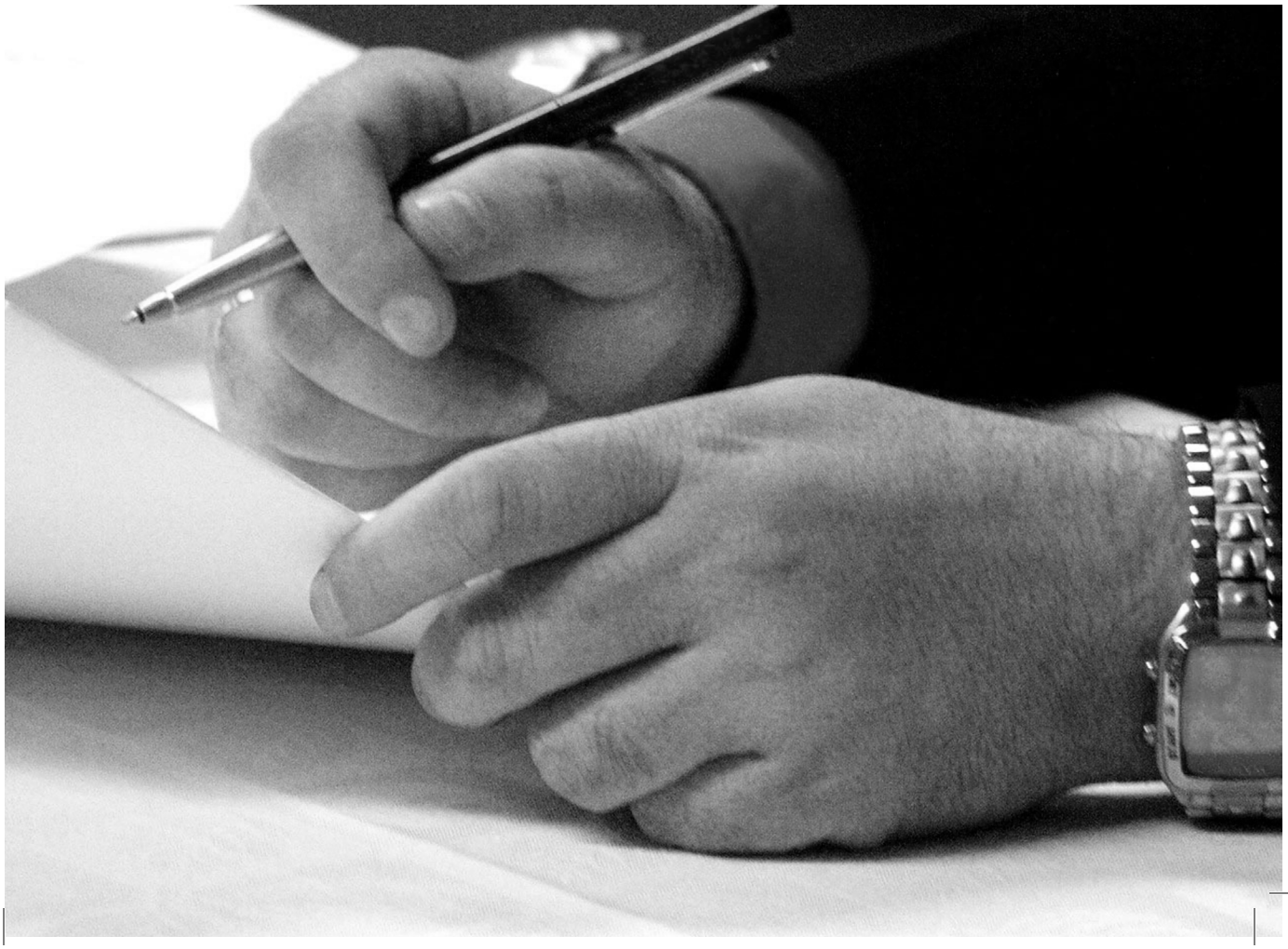
The National Development Planning Committee (NDPC) oversees the regulatory process with the support of MPC and administers the Government's RIA requirements.



ROLES OF NDPC AND MPC

The National Development Planning Committee (NDPC) oversees the implementation of the National Policy on the Development and Implementation of Regulations. It monitors RIS process, examines and endorses the adequacy of all RIS prior to submission for decision by the decision maker.

The Malaysia Productivity Corporation (MPC) is responsible for assessing the need for RIS and for performing a review of RIS for adequacy prior to submission to the NDPC. It also provides guidance to regulators in facilitating RIA and developing RIS.



3.0 Regulatory Impact Statement (RIS) Process

RIS process and the requirements are defined in the **National Policy on the Development and Implementation of Regulations** and this handbook provides detailed guidance for implementing the policy and developing regulations in accordance with the Regulatory Process Management Requirements as specified in the policy document.

3.1 When is RIS required?

RIS is applicable to all decisions made by the Government and its agencies that are likely to have a regulatory impact[1] on businesses, unless that impact is minor in nature and does not substantially alter existing arrangements. This includes amendments to existing regulation and regulatory initiatives implemented by way of administrative circulars[2] by any part of the Government that requires mandatory compliance.

Minor changes are changes that do not substantially alter the existing regulatory arrangements for businesses or for the non-government sector, such as where there would be a very small initial one-off cost to businesses with no ongoing costs. MPC should however be notified when the regulation is issued even in cases where no RIS is required.

In the case of an exemption for the preparation of RIS due to the minor or routine nature of the regulation, the regulator may proceed to develop and implement the regulation after approval by the relevant authorities in accordance with the law.

Note 1:

The implementation of "sanitary and phytosanitary measures" in food and agricultural sector has a similar impact and requires RIS.

RIS is required for the parts of primary legislation that contain regulatory provisions; other parts that do not have regulatory provisions however do not require RIS.

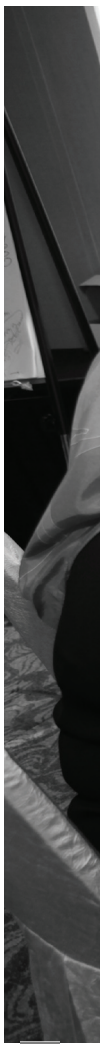
Note 2:

Administrative circulars that are intended for internal Government implementation are not covered by these requirements.

EXAMPLES OF REGULATORY ACTIONS REQUIRING RIS

In an initiative to improve the air quality, the Government is considering reducing environmental pollution from vehicles' exhausts. It is considering raising the quality of diesel fuel resulting in exhaust emissions that are cleaner and correspondingly require advanced engines that have lower emissions. A preliminary investigation indicates significant potential impacts on the vehicle industry and fuel suppliers.

In order to collect more information on diseases, the Government plans to implement a new and more comprehensive medical reporting system for hospitals and doctors. The new system is expected to significantly increase paperwork and data processing by the authorities.



3.2 Exemptions

In addition to regulations with no significant impact and those of a routine nature, regulators may directly proceed to implement regulations in the following situations:

a) RIS is not required for regulations that are implemented for reasons of national security and sovereignty.

b) Administrative circulars that are intended for public service administration are not included in the scope of this handbook and do not require RIS.

c) Regulators may proceed to implement regulations without RIS in exceptional circumstances when dealing with urgent matters which require immediate action. In such cases, MPC should be informed by the regulator and be provided with reasons for the decision. MPC will notify NDPC of regulations which are being developed without RIS.

A post-implementation review (see 3.7.1) is however required for all such regulations. This review is required to commence within one to two years from the date the regulation is implemented.

3.3 Notifying MPC

It is the regulator's responsibility to contact MPC early in the decision making process. This should occur once an administrative decision has been made that regulation may be necessary, but **before** a final decision on whether or not to regulate is made by the Government. The notification should be made on the form in Annex 1. MPC will determine the necessity of the preparation of RIS and inform the submitter.

The final decision on whether to implement a new regulation is only made after the preparation of RIS. Initial discussions about a regulatory proposal may be undertaken without the need for RIS as long as no decision to adopt a specific regulatory approach is made. Ministries and Regulatory agencies may however submit preliminary proposals to the Cabinet, a committee of the Cabinet or Minister, seeking policy guidance without the requirement for RIS. This allows for discussion without RIS when no final decisions are made with regard to a specific regulation.

Upon receiving a notification, MPC will make a preliminary announcement of the intention for the development of a new regulation on its website, informing the public of the objectives of the regulation.

Determining if RIS is required

MPC will require information about the proposal before it can assess whether or not RIS will be required. The notification form includes a request for relevant information as the need for RIS depends on the level of impact of the proposal. At this stage, the information provided to MPC does not need to be particularly detailed; it just needs to allow MPC to make an assessment of what the likely impact of the proposal might be.

Once MPC has this information, it is able to make an assessment of whether the proposed regulation is likely to have a significant impact (and therefore will require RIS); or whether the impact is likely to be of a minor nature (and therefore will not require RIS). MPC will base its assessment largely on the information provided and a prompt response depends very much on how quick and how accurate the information provided is.

MPC will notify the regulator of its assessment as well as the contact officer for the proposal. MPC will also advise the regulator that it needs to be informed if the proposal changes before the final decision is made. This could affect whether RIS may be required when an initial assessment has suggested otherwise.

3.4 Assessing the Need for RIS

When MPC determines that RIS will be required, the level of analysis to be provided in RIS will have to be proportional to the likely impact of the proposal. Proposals likely to have significant impacts on businesses and the community at large require a detailed analysis of those impacts. If the impacts are likely to be less significant, then a less detailed analysis will be sufficient. This requires a judgement about the likely impact of the proposal. For each proposal MPC examines the nature and magnitude of the proposal (and the problem it is addressing), and the scope of its impact to assess the adequacy of the analysis.

Requirement for Regulation Impact Statements- Frequently Asked Questions

Q *Are RIS only required for primary legislation or legislative instruments?*

A *No – RISs are also required for all regulations and also for other requirements that government imposes on businesses but 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).*

Q *Is RIS required if someone other than the Cabinet is making the decision?*

A *Yes – RISs are required for all decision makers, including committees of the Cabinet, ministers, delegated officials or heads/boards of Government departments and statutory bodies.*

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

A *No – RIS requirements apply to both new and amended regulations, as long as they have a significant impact.*

Q *Is it true that RISs only have to consider the impact on businesses or the not-for-profit sector?*

A *RIS must consider the impacts on all relevant groups, including consumers, governments and the broader community.*

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

A *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).*

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

A ***Yes – RIS is required for regulatory decisions likely to have any impact (whether positive or negative) on businesses unless the impact is of a minor nature.***

Q ***Is RIS only required as a record?***

A ***No – RIS is required to be presented to decision makers as they make their decision.***

Q ***Does RIS need to examine non-regulatory options?***

A ***Yes – if non-regulatory options can feasibly address the Government's objectives they should be included in RIS.***

Q ***If the benefits are difficult to value does RIS still need to have a cost-benefit analysis?***

A ***Yes-even though it can be very difficult to place a monetary value on some factors, including environmental and social impacts. The cost-benefit analysis should recognise this and include a qualitative discussion of these impacts so that they can be compared with other impacts that can be more easily quantified.***

3.5 Regulatory Impact Statement Template

RIS format is provided in a template that reflects the requirements of the *National Policy for the Development and Implementation of Regulations.* This RIS format is a requirement for all regulatory proposals. The template is in Annex 2 of this handbook.

3.6 RIS Overview

The Government has implemented the Regulatory Process Management Requirements to ensure a process of examining the likely impacts of a proposed regulation and a range of alternative options which could meet the Government's policy objectives is in place for all new regulations. Preparing RIS ensures that information relevant to the decision making process is documented. RIS process ensures the **principles and policy of regulations** are implemented.

Seven Elements of Regulatory Impact Statement (RIS):

1. The problem or issues that give rise to the need for action.
2. The desired objectives.
3. A range of options (regulatory and non-regulatory, as applicable) that may constitute feasible means for achieving the desired objectives.
4. An assessment of the impact (costs, benefits and, where relevant, levels of risk) of a range of feasible options for consumers, businesses, the Government and the community.
5. A consultation statement.
6. A conclusion and recommended option.
7. A strategy to implement and review the preferred option.

3.7 Other Associated Requirements

3.7.1 Post Implementation Reviews

Where a proposal proceeds without RIS as provided in 3.2(c), the resulting regulation must be the subject of a post implementation review. The review must commence within one to two years of the regulation being implemented. A review will also be required when a regulation has been implemented with RIS that has been determined to be inadequate. 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 would have been prepared for the decision making stage. Issues that should be examined include:

- the problem that the regulation intended to address;
- the objective of Government action;
- the impacts of the regulation (whether the regulation is meeting its objectives); and
- whether the Government's objectives could 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 4.5). The level of consultation should be proportional to the significance of the measure under review. Ideally, where appropriate and required, agencies should establish consultative arrangements well before the review is due in order to gather relevant data in preparation for the review. Regulators should refer to section 6 of this handbook with regard to requirements to conduct periodic reviews of all existing regulations.

3.7.2 Obligations Arising from Treaties and International Agreements

Malaysia is party to a number of international treaties and agreements and some of these are likely to involve domestic regulation and will impact businesses. RIS should address the impact of the proposed domestic regulations on treaty obligations. Annex 3 - *International and Intergovernmental Agreements: Obligations for Regulators*, provides guidance on addressing these issues in the context of technical regulations.

3.7.3 Trade Impact Assessment

Where a proposed regulation has a direct bearing on export 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 assess the overall impact on Malaysia's international trade, including the impact on competitiveness.

3.8 Non-compliance with RIS Requirements

All regulatory proposals require RIS except those specified in para 3.2 (a) and (b). When a regulation may have been introduced or amended without RIS, MPC will contact the agency to obtain additional information. Following consultation with the agency, MPC will recommend that either:

- best practice regulation requirements have been met and no further action is required; or that
- the requirement to prepare RIS has not been met and the agency is required to undertake a post-implementation review.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4.0 Preparing Regulatory Impact Statement

4.1 Problem/Issue Statement

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

i. Present evidence on the magnitude (scale and scope) of the problem;

ii. Identify the affected parties and stakeholders;

iii. State issues and policy objectives that are to be addressed;

iv. Document relevant existing regulation at all levels of Government and demonstrate that it is not adequately addressing the problem or achieving policy objectives;

v. Identify the relevant risks, if the problem involves risk, and explain why it may be appropriate for the Government to act to reduce them; and

vi. Present a clear case for considering that additional Government action may be warranted, taking into account existing regulations and any risk issues, and the potential for market developments to overcome the problem.

This section should clearly specify the problem or issue. It should describe the policy issue(s), including a description of any risk assessment, and demonstrate why Government intervention is needed. A clear summary of the risk assessment should be provided.

The issue should be described in concrete terms. The underlying causes of the problem, and groups likely to be most affected, should also be identified. To show it has appropriately addressed a policy issue, the nature and magnitude of the problem should be provided. Any Government actions that may have been taken in the past to address the issue have to be reviewed as well. In the event that the proposal is to address specific policy objectives, identify the objectives and the issues arising. This section should also provide a summary description of the expected future evolution of problem.

Checklist

- **Has the issue or risk been properly identified and assessed (how it may change over time)?**
- **Have policy objectives been clearly stated in terms of tangible outcomes?**
- **Has the need for government intervention been demonstrated?**
- **Has it been demonstrated that the problem will not self-correct within a reasonable timeframe?**
- **Have the consequences of not taking any action been identified?**
- **Has a quantitative risk assessment been performed if appropriate?**
- **Have scientific and empirical evidence, uncertainties, ethical considerations, and public views of the issue been summarised?**

4.2 Objectives

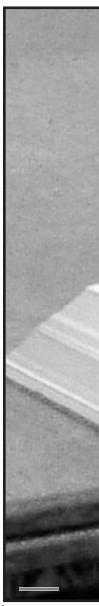
4.2.1 The "objectives" section should state the intent of the proposed regulatory action in concrete terms and relate this to the broader policy of the agency and Government. There may be more than one goal. In this section of RIS, the objectives, outcomes, goals or targets that are sought should be clearly identified in relation to the identified problem.

The desired final outcome of a proposal with the outputs should not be confused with the means of obtaining the outcome. For example, a broad objective of road transport regulations is 'to reduce injuries and deaths due to traffic accidents'. This objective differs from 'compulsory use of seatbelts', which is one of many means of attaining the broader objective of reducing injuries and deaths.

4.2.2 The aim of this part of RIS is not to pre-justify a preferred solution, but to specify the objective broadly enough so that all relevant alternative solutions can be considered. However, avoid making it so broad or general that the range of alternatives becomes too large to assess, or the extent to which the objective has been met becomes too hard to establish.

4.2.3 Other information that should be provided includes, as applicable:

- Any additional secondary objectives that supplement the primary objective of the proposal;
- Whether there are any constraints; for example, if results must be achieved within a certain timeframe;
- Description of the outcomes that the regulation is intended to provide and explain why Government intervention is justified;
- An explanation of how the proposed regulation fits into the department's policy framework and to clarify that it is within the department's mandate; and
- Whether there is any enabling legislation, Government directive such as a relevant Cabinet decision or Government policy to the implement new regulation.



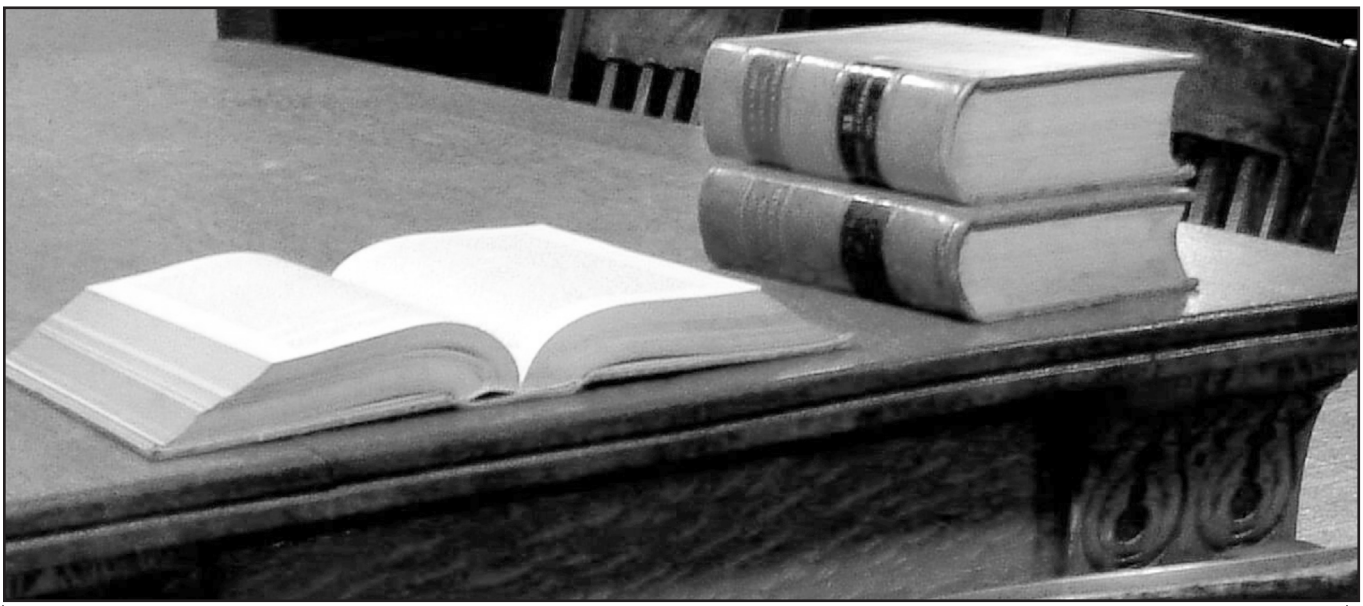
Checklist

- **Is the objective presented in clear and simple language, providing context to help the reader understand the regulation?**
- **Does it describe who will be affected by the regulation and how?**
- **Have essential and relevant links to enabling legislation and Government policies been stated?**

4.3 Instrument Options

This section describes the range of regulatory and non-regulatory options considered in addressing the issue or risk identified, including the proposed regulatory action and the key differences between the options. It should describe each alternative option and explain how the option, if implemented, would achieve the desired result. Ideally, RIS will report on all legitimate options considered. The basis of selection of the option should be explained.

The examination of options should always consider whether the problem that is being addressed could be remedied by using existing powers, rather than by introducing new measures. For example, if the problem clearly arises out of a lack of coordination, it should be considered whether a remedy might be available through improving coordination mechanisms by responsible regulators or by improving effectiveness of implementation.



4.3.1 Risk Assessment

This section should explain, and where possible quantify, the problem or the risk that the policy is trying to address. Many proposals are introduced to deal with risks to the environment, consumers or workers' safety or health. Risk assessment involves identifying the hazard or situation which, in particular circumstances, leads to harm or detriment. It then involves estimating the incidence of that harm (i.e., how often it occurs in a given period) or the probability it will occur (e.g. 1 in 1,000 chance per year). Thus the risk assessment might, for example, consider people dying from electrocution (the harm) as the result of the sale of a dangerous consumer product (the hazard). If in the last 10 years, there have been 20 reported deaths resulting from the use of this product; the risk may be estimated to be two deaths a year. It may be difficult, sometimes impossible, to quantify a risk. The risk assessment should include the use of qualitative data as well.

4.3.2 Identifying Feasible Options

RIS should test the effectiveness and appropriateness of alternative (regulatory and non-regulatory) options for achieving the stated objectives. If any of the options involve establishing or amending standards in areas where international standards apply, indicate whether the standards under consideration deviate from the relevant international standards. If this is the case, provide an explanation for the variation and examine the implications of this variation. Where a mix of regulatory and non-regulatory options have been selected, they should be explained together to demonstrate how they achieve the outcome. When there are multiple options or alternatives, a "best practice" is to identify which option is the preferred or recommended one.

4.3.3 Regulatory Instruments

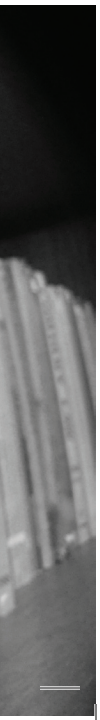
Self-regulation is generally characterised by industry-formulated rules and codes of conduct, with industry solely responsible for enforcement. Assess self-regulation as a feasible option if:

- There is no strong public interest concern, in particular no major public health and safety concern;
- The problem is a low-risk event, of low impact or significance; and
- The problem can be fixed by the market itself. For example, there may be an incentive for individuals and groups to develop and comply with self- regulatory arrangements (industry survival, market advantage).

Self-regulation is not likely to be effective if industry has an incentive not to comply with the rules or codes of conduct.

Quasi-regulation includes a wide range of rules or arrangements where Government influences businesses to comply with, but which do not form part of explicit Government regulation. Some examples of quasi-regulation include industry codes of practice developed with Government involvement, voluntary guidelines issued by Government agencies and accreditation schemes.

Co-regulation typically refers to the situation where industry develops and administers its own arrangements, but Government provides legislative backing to enable the arrangements to be enforced. This is often referred to as the 'underpinning' of codes, standards and so on. Sometimes legislation sets out mandatory Government standards, but provides that compliance with an industry code can be deemed as an equivalent. Legislation may also provide for Government-imposed arrangements in the event that industry does not meet its own arrangements.



Examples of Alternative to Regulation

1. The Communications and Multimedia Commission Act 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 who certify compliance with codes developed by the industry body.

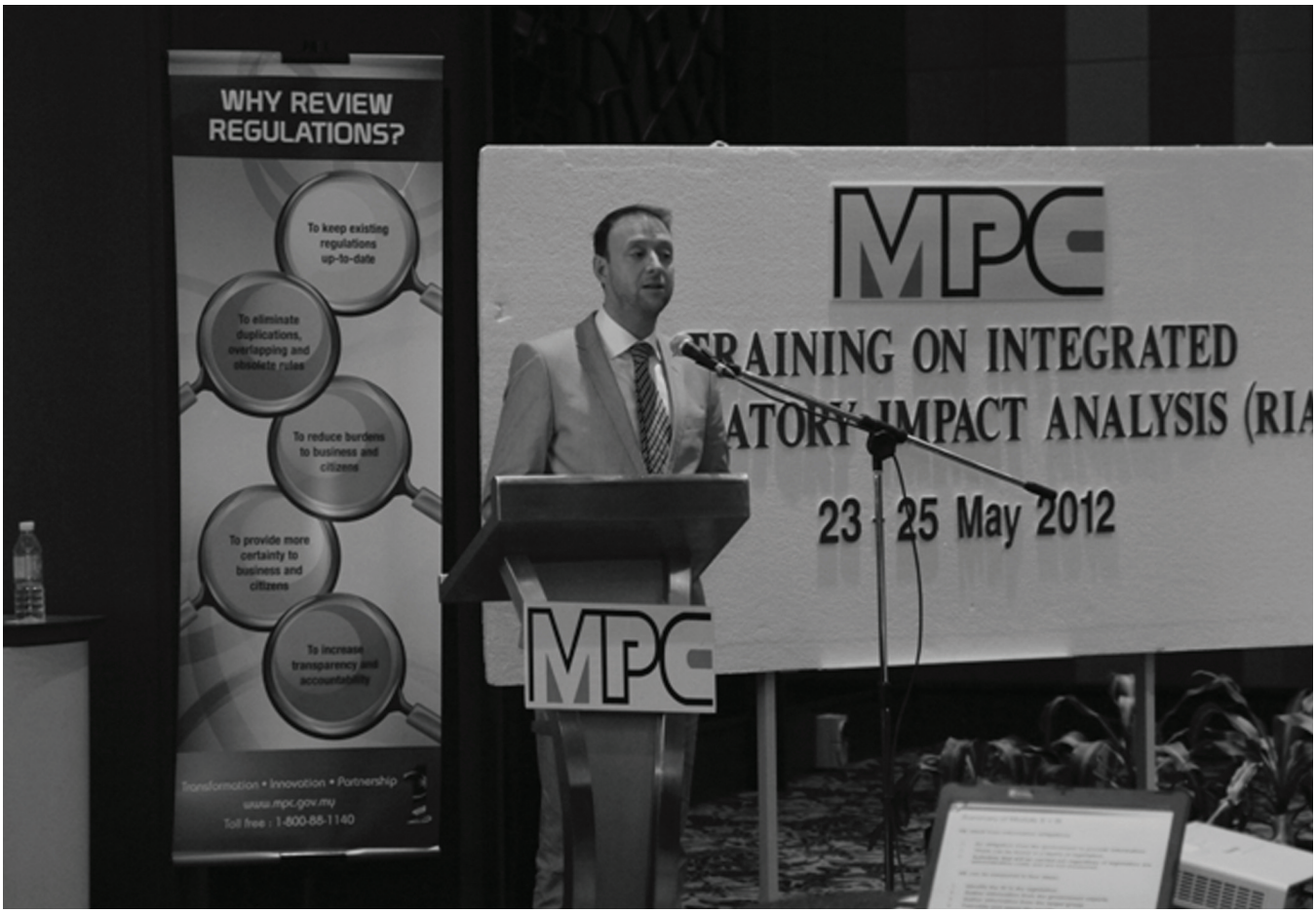
2. The Occupational Safety and Health Act (Act 514) under Section 37 empowers the Minister to approve industry codes of practice that are developed by any body and require mandatory compliance to the code.

3. When bottled LPG gas was first introduced in Malaysia, each supplier had a unique valve on the gas cylinder. This meant that once a consumer bought a particular connecting regulator for his burner or oven, the consumer was only able to use the gas supplied by the same supplier. This was inconvenient and consumers were unhappy. The authorities responsible negotiated with the suppliers and arrived at a decision to have a common design. A standard was developed for a common design and all the suppliers adopted this design voluntarily. Thus the need for a regulation was avoided.

Explicit Government regulation comprises primary and subordinate legislation. It is the most commonly used form of regulation.

One should consider explicit Government regulation where:

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



4.3.4 Non-regulatory Instruments

Within each form of regulation, consider alternative instruments. Alternative instruments may include:

- Taking no specific action (that is, relying on the market in conjunction with existing general laws such as those for liability);
- Relying on information and education campaigns;
- Market-based instruments (including taxes, subsidies, tradable permits);
- Voluntary quality assurance schemes (such as listing, certification and licensing);
- Development and promotion of voluntary standards; and
- Other mechanisms, such as public information registers.

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 total number of permits cannot exceed the cap, limiting total emissions to that level. Firms that need to increase their emission permits must buy permits from those who require fewer permits.

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

3. The most commonly used alternative approach to regulation in many countries is information and education campaigns. These campaigns educate and motivate citizens and consumers to adopt actions or make informed choices, as in, for example, campaigns aimed at reducing speeding when driving, or mustering anti-smoking or anti-litter 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 other examples of non-regulatory approaches to achieve objectives. Governments provide support

Checklist

- **Have regulatory and non-regulatory options that were considered been summarised, including the proposed regulatory action?**
- **Have the key differences between the options been summarised and assessed?**
- **Has a summary description been provided with the essential details of the proposed regulation?**

4.4 Impact Analysis

The next step in drafting RIS is to conduct a comprehensive assessment of the expected impact (costs and benefits) of each feasible option. The objective here is to inform decision makers on the likely merits of available options, and thereby assist in decision-making.

When analysing each option, it is necessary to consider who would be affected if the option were implemented, what costs, benefits and, where relevant, levels of risk would result, and how significant they would be.

Where possible, quantify the impacts; at a minimum, the analysis should attempt to quantify all highly significant costs and benefits. All assessments of costs and benefits, whether quantitative or qualitative, should be based on evidence, with data sources and assumptions clearly identified. RIS should use the existing situation as the baseline for assessing the impact of each option. The baseline should have a strong factual basis and, as far as possible, be expressed in quantitative terms. This approach will allow a clear identification and comparison of the costs and benefits that would result from implementation of each option.

In general, the depth of the impact analysis should commensurate with the overall effects. For example, a comprehensive and detailed qualitative analysis, supported by quantitative evidence where it is available or can be readily obtained, may be adequate if the impacts of the proposal are not likely to be highly significant. However, for major proposals a greater level of quantification in RIS will be required, and a full cost-benefit analysis may be appropriate.

RIS must clearly identify all groups affected by the problem and its proposed solution, whether directly or indirectly. In addition, one should assess the effects on the community as a whole, such as environmental and social impacts. Groups should generally be distinguished as consumers, businesses and Government. Depending on the nature of the proposal, these groups may be further subdivided, for instance:

- Within the consumer group it may be necessary to classify groups according to income, geographical location (regional and rural), age, family unit, cultural background or levels of information held;
- Within businesses, distinctions can be made along industry or sectoral lines, by type of activity or by size of business; and
- Within Government, whether impacts are at the federal, state/ and/or local government level.

The extent to which groups need to be separately identified in RIS will vary according to the problem and option being assessed.

This section should report on the impact of the proposed regulation on the economy, including the administrative burden imposed, the impact on businesses, consumers, competition, and on domestic and international trade (exports and imports). This section should also describe how the recommended option has been developed to minimise the negative impact on health and safety, the environment, society and culture, public security, and the economy.

4.4.1 Estimating Costs and Benefits of the Options

Costs and benefits are terms used to describe the positive and negative effects of a proposal. A cost is any item that makes someone worse off, or reduces a person's wellbeing. Cost items may include 'opportunities forgone' because a particular proposal has been adopted.

A benefit includes any item that makes any person better off, regardless of whether it can be easily measured or quantified.

Once the costs and benefits to each of the affected parties have been identified, one should assess the net impact of each option on the community as a whole.

4.4.2 Costs

Costs to businesses, including small businesses, may include:

- `Paper burden' or administrative costs to businesses associated with complying with and/or reporting on particular 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 supply of inputs;
- Higher input prices; and
- Restricted access to markets.

Costs to consumers may include:

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

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

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

Costs to Government may include:

- The costs of developing the regulation;
- Running education campaigns/providing information;
- Administration of licensing/inspection services;
- Collection and collation of business information; and
- Enforcement costs, including the costs of litigation.

4.4.3 Benefits

Identify and describe the benefits of the options to business, consumers, Government, other affected groups and the community at large. Some benefits may not be readily quantifiable. Examples of benefits include:

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

4.4.4 Distribution of Costs and Benefits

The distributional effect of each option is also important in determining the overall outcome for the community. For example, while a particular option may generate net benefits in aggregate terms, significant benefits may go to only a small number of people who bear no costs, with the costs being borne by a large number or by those who can least afford it.

4.4.5 Small Businesses

Regulation may have a disproportionate impact on small businesses. Often, small firms have to allocate a greater proportion of their 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. While additional impacts may be unavoidable or may be desirable, it is important that decision makers are aware of the various impacts on small businesses.

One should consider the degree of impact on individual small businesses, the number of small businesses affected, and whether the overall impact on small businesses is in proportion to the impact on other businesses or groups. It is important that particular attention is given to the compliance cost impact on small businesses, and the ability (or inability) of these businesses to absorb such costs.

4.4.6 Restrictions on Competition

Some regulations restrict competition. Such regulations can restrict consumer choice, raise prices and reduce overall economic productivity by denying the economy the efficiency gains competition provides. Significant restrictions on competition range from monopolies that block competition in entire sectors, to a host of less visible restrictions on starting up and operating businesses, such as quotas on business licences and restrictions on shop opening hours.

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

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

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

- *Incumbent businesses.* Will the proposed regulation affect incumbent firms differently, altering competitive relations between them in a way that would reduce the intensity of competition in the market as a whole?

- *Entry of new businesses.* Will the proposed regulation restrict entry for all (or particular types of) new businesses? What is the likely degree of this restriction and is it likely to significantly reduce competitive pressures in the longer term?

- *Prices and production.* Will the regulation raise prices by imposing new costs on producers? Will the regulation lead to exit of some incumbent firms, 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 regulation include minimum standards requirements 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.* Is the 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 regulation in one 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)?

4.4.7 Cost-benefit Summary Statement

Proposals should include the following table that summarises quantitative and qualitative benefits and costs to affected stakeholders. Please note that the format of this table should be followed to ensure consistency of presentation across regulatory proposals.

Format for Tabulating a Summary of Costs and Benefits

IMPACT	COST/UNIT
A. Quantified Impacts (RM per year)	
Benefits (by stakeholder group)	
Costs (by stakeholder group)	
Net Benefits	
B. Quantified Impacts (Non-monetary, per year)	
Positive Impacts (by stakeholder group)	
Negative Impacts (by stakeholder group)	
C. Qualitative Impacts	
List of qualitative impacts (positive and negative) by stakeholder	

Explanatory Notes

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

2. ***Section B: Quantified but not monetised impacts.*** *For items where the benefits or costs cannot be monetised but can be quantified, list these in physical units. Include both positive and negative impacts that have been quantified, and indicate clearly the unit of measure (e.g., 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 and their importance briefly stated. These are the elements of analysis that matter but cannot be estimated. List both positive and negative impacts by stakeholder. These qualitative impacts can be very important to decision makers.*

4.4.8 Enforcement and Compliance

Proposed measures must be enforceable. Obtain a clear view of how those affected will comply with the proposal. It can be tempting to try to resolve current compliance problems by proposing more regulation. Before proposing to do this, look carefully at the reasons for current non-compliance, and improving this situation without more regulation should be considered, for example, by targeted action to those businesses or individuals who are not complying.

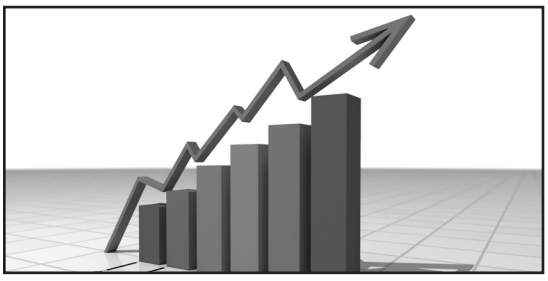
Assessment of the likely impact of different enforcement methods should be considered. There is no general answer to what is the most appropriate option to achieve an acceptable level of compliance but the nature of the risks involved should give some indication. For example, safety in the petroleum industry is clearly of more concern than whether employers keep records of names and addresses of temporary workers. Alternative methods of enforcement and the likely costs should be compared. If risks are low the use of a light approach would be appropriate and must be considered.

Levels of scrutiny can be varied according to risks of non-compliance and according to the characteristics of the firm, by size etc.

Another option is self-assessment. Instead of requiring enforcement officers to check whether businesses are complying with a regulation on a routine basis, rely on complaints from individuals if they believe it is not complying with a regulation and conduct less frequent inspections.

Administrative methods of preventive control should also be considered. Examples include licensing, registration and enforcement approaches including warning notices, suspension notices and prohibition notices. Bear in mind the cost of administrative methods, and aim to minimise any bureaucracy.

If it is decided that active enforcement is required, involve the potential, enforcement authorities at an early stage to agree on procedures and estimate resource implications. Where enforcement responsibilities overlap, ensure there is co-ordination among authorities. If the proposal creates a new enforcement body, ensure that its activities are integrated properly with those of existing agencies, that Government approval is available and that sufficient time is allocated for preparation.

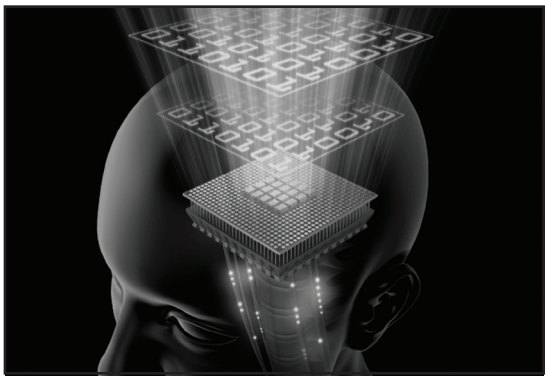


4.4.9 Sanctions for Non-compliance to Proposed Regulations

If sanctions for non-compliance are needed, choose a fair and effective regime which is proportionate to the non-compliance. The decision on sanctions should be determined on the basis of the provisions of the existing laws. Expert advice on such matters should be sought as required.

Checklist

- **Is the depth of the analysis commensurate with the level of significance of the impacts?**
- **Have both the costs and benefits of regulatory and non-regulatory measures been described?**
- **Have both quantitative and qualitative measures been included?**
- **Is there a summary of potential positive and negative economic, environmental, and social impacts of the proposed regulation and its feasible alternatives**
- **Have positive and negative impacts distributed across various affected parties, sectors of the economy, and regions of Malaysia been identified?**
- **Has a cost-benefit summary statement of the quantifiable and non-quantifiable costs and benefits been presented?**



4.5 Consultation

In general, any proposed new regulation or change to regulation, will involve consultation with relevant stakeholders, including the main parties affected by the proposal: businesses, non-governmental organisations (NGOs), the community, regulators and other Government agencies. Consultation helps to ensure that the full range of impacts is taken into account when assessing how best to solve a problem and the transparency it fosters helps to build trust in the policy process.

It is important that consultation be conducted with the attitude that the stakeholders' views will be heard and taken seriously, rather than conducted as a 'box-ticking' exercise after the policy decision has effectively been made.

Consultation Documents

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

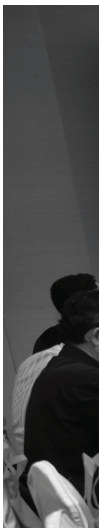
2. **A list of questions for affected parties at the beginning could be included to:**

   - **Check if the benefits and costs are complete;**
   - **Confirm if the assessment of competition effects is appropriate;**
   - **Seek a response on enforcement methods proposed; and**
   - **Check for unintended consequences.**

3. **Ensure that submissions on potential costs are supported by evidence. This will prevent respondents from overstating costs in order to deter the department or agency from pursuing a particular line.**

4. **Seek responses on:**

   - **Validity of key assumptions;**
   - **Options that are available (regulatory and alternatives to legislation);**
   - **Implementation issues (including guidance and timing); and**
   - **The preliminary findings on the issue.**



The regulatory agency should identify interested and affected parties and to provide them with opportunities to take part in open, meaningful, and balanced consultations at all stages of the regulatory process. The "Consultation" section of the RIS should demonstrate that this requirement has been met. The regulatory agency should take necessary action to ensure that the draft regulations are not subject to confidentiality requirements of the Official Secrets Act 1972 (Act 88), at the appropriate stage.

As is the case with other issues addressed in RIS, the extent of consultations undertaken should be influenced by the significance and anticipated impact of the proposed regulation. RIS should demonstrate that the consultation process was balanced and not unduly influenced by the views of one particular group. It is important to remember when writing the RIS that consultations are not a legitimate substitute for analysis of an issue.

The process should include an inter agency consultation through which all affected ministries and agencies are included and given an opportunity to comment.

Notification to The World Trade Organization (WTO) should be included for proposals that come within the scope of the notification obligations of WTO Technical Barriers to Trade (TBT) and Sanitary and Phytosanitary (SPS) Agreements. The WTO TBT[1] and SPS[2] enquiry points should be consulted for advice and assistance in making the notifications.

Draft regulations should be made available to interested parties to provide an opportunity to be informed on the Government's proposed course of action. The Pre-publication of drafts should be accompanied by an invitation for submission of comments, there by providing an additional channel for any stakeholder to comment on the draft regulation. Pre-publication of draft regulations is also not sufficient for consultation. The groups that are most affected by the regulation should be consulted before pre-publication.

Reference should be made to the Government circular on online public engagement issued on 25 April 2012 (Surat Pekeliling Am Bilangan 2 Tahun 2012, Reference PM(T) 10766/7) issued by the Chief Secretary to the Government of Malaysia with regard to online publication of draft regulations.

[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

Key Elements of a Consultation Exercise

Plan : Decide on who is being consulted, about what questions, in what timescale and for what purpose.

Use the most **appropriate** approach. Written consultation is not always sufficient to canvas views on a new regulation, but must always be included alongside other methods. Other methods include:

- Meetings with interested parties;
- Seminars;
- Web forums;
- Public surveys; and
- Focus groups.

Accessibility: Consultation should be easy to respond to, for example by using electronic means or a separate questionnaire. Put all consultation documents and their accompanying RIS on the department or agency website in a clear and accessible form. Include details of where to send responses when you put a consultation document on the website. Make sure that consultation documents are easy to access from the website – for example, via a link on the home page.

Proactive Approach: Send emails to affected parties with a hyperlink to the consultation document. Placing a consultation document on the website and leaving it up to people to find out about it for themselves is inadequate.

Publish a summary of the consultation document, containing an overview of the proposals, as well as the full length version. This will help affected parties decide whether they need to read and digest the full version, saving them time. Make sure your overview contains details of all the proposals, so that the overall effect or impact is not diluted.

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

- **Who was consulted;**
- **Main views of the stakeholders indicating areas of agreement as well as areas of difference;**
- **Information on inter agency consultation;**
- **What consultation mechanisms were used;**
- **When and how long the consultations were conducted;**
- **Results of the consultation and whether the regulation 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 account of stakeholders' views. If the proposal has not been modified, RIS should explain why dissenting views have not been accepted; and**
- **Name any groups still opposed to the regulation.**

Checklist

- Does this section explain how affected parties were consulted?
- Does the section clarify which groups of stakeholders were consulted? Have their views been summarised?
- If required, does RIS ensure that the confidentiality of specific stakeholder comments has been protected?
- Have outstanding issues been addressed? If not, why?
- If comments were received, does this section detail what measures were taken to address them?

4.6 Conclusion and Recommendation

This section should include a clear statement identifying the preferred option based on the impact analysis. The recommendation for the selection of this option must be supported by the preceding analysis and a comparison with other options provided. The costs and benefits of this option for all affected groups should be identified. 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 National Policy on the Development and Implementation of Regulations.

4.7 Strategy for Implementation

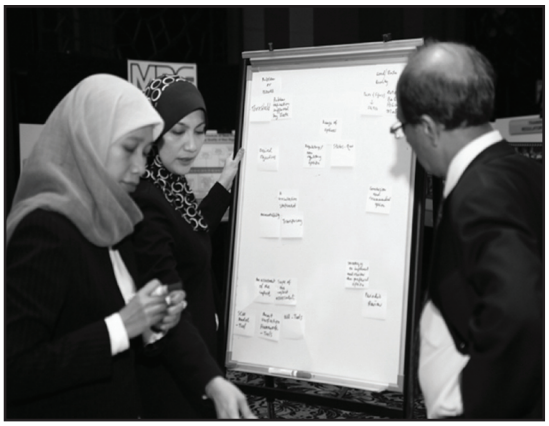
Having identified the preferred option to meet the objectives stated at the beginning of RIS, it is necessary to consider how the option will be implemented and enforced, and to establish a review strategy that will allow the option to be evaluated after it has been in place for some time.

This section describes the implementation plan for a regulatory action, including any communication or outreach activities, dates for coming into force, partner institutions, or cooperation and coordination activities that will be necessary to ensure effective and efficient implementation.

Regulations are usually intended to modify the behaviour of individuals to protect or enhance the public interest. It cannot, however, be assumed that all individuals will voluntarily comply, and sanctions may be necessary to encourage compliance. Departments and agencies establish compliance and enforcement policies as part of the regulatory development. RIS should describe these policies.

This section of RIS should address the following :

- The communication plan for ensuring that affected parties are informed of the regulation and implementation plans.
- Explain the mechanism adopted to ensure compliance (including criminal law sanctions, ticketing, prohibition and corrective action orders, inspection, licensing, registration, or other Government approval requirements);
- Describe means that will be used to detect non-compliance (for example inspection or testing); and
- Describe the penalties for non-compliance (for example fines, imprisonment and taxes).



Practical implementation issues need to be considered before the option is adopted. These include:

- Administrative issues, for instance, which authority will implement and enforce the proposed option;
- Availability of resources, costs involved and budgets;
- Capacity of regulated parties to take the required actions, such as maintaining extra information, completing forms, retaining personnel with expertise or educational qualifications; and
- Consider transitional arrangements to minimise the impact on stakeholders, for example delayed or gradual introduction of new requirements, and provision of information, training and other assistance to affected businesses.

4.7.1 Review

RIS needs to outline how the regulation will be reviewed. This part should set out when the review is to be carried out, and information on how the review will be conducted; for example, if special data is required to be collected.

Checklist

- **Has the authority (ies) responsible been clearly identified and their roles defined?**
- **Has a compliance and enforcement strategy been developed and explained?**
- **Have any issues and possible barriers to compliance been clearly assessed?**
- **If constraints with compliance exist, are mechanisms to overcome them described?**
- **Has the methodology that will be used to review and evaluate the regulatory activity been summarised?**

4.8 One Page Summary

A one-page summary of RIS must be prepared for decision makers and submitted to MPC together with RIS. The summary for proposals will be examined by the NDPC for adequacy.

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. It will also assess the extent to which the preferred option reduces business compliance costs and improves productivity growth. A template for the preparation of the summary is in Annex 4.

5.0 Assessing RIS for Adequacy

RIS must be certified by the Chief Executive of the Regulator or by the Secretary-General of the Ministry prior to submission to MPC for final assessment. If MPC formally assesses RIS as not adequate, the office will provide advice to the agency on the reasons for the decision.

To be assessed as adequate, RIS must have a degree of detail and depth of analysis that is commensurate with the magnitude of the problem and the size of the potential impact of the proposal.

Annex 5 lists the criteria which will be used to assess whether RIS contains an adequate level of information and analysis.

6.0 Publication and Review

6.1 Publication of Regulatory Annual Report

MPC will publish regulatory annual report on regulatory activities undertaken by federal Government regulators. It will provide an assessment of the progress made in the implementation of the NPDIR.

As part of its role in implementing the Government's requirements under the *National Policy on the Development and Implementation of Regulations*, MPC will request each agency to prepare a list of all regulations made during the previous year. The office will review all regulations to determine progress in the adoption of NPDIR.

Regulators should communicate their review schedule (all regulation subject to review in the upcoming year) and strategies to MPC in January of each year.

6.2 Five Yearly Implementation Review

All regulations that have an impact on businesses and are not minor in nature, are to be reviewed periodically unless it is subject to other statutory review provisions and each regulation should be reviewed once every 5 years. The review plan should take into account the nature of the regulation and its perceived performance. Five-yearly reviews will also be published on MPC's online RIS repository.

7.0 Explanation of Terminology Used in the Handbook

7.1 Regulations

Regulations include measures of general application in various forms that are undertaken by Ministries/Department/Agencies for which compliance is mandatory. These include measures may alternatively be termed as regulations, rules, by-laws, orders and guidelines.

A regulation sets out principles, rules, or conditions that govern the behaviour of citizens and organisations. Governments use regulations in combination with other instruments to achieve public policy objectives.

The authority to make regulations must be expressly provided for in the enabling legislation. Regulations must be consistent with all provisions of the enabling act.

Notes:

1. Regulations as referred to in this handbook is inclusive of all "technical regulations" as defined in the WTO/TBT agreement and the term "sanitary and phytosanitary measures" as defined in the WTO/SPS agreement.

2. Regulations are also introduced for security, and other social purposes such as regulating civil society organisations. Such regulations are excluded from RIS requirements in the current plan.

7.1.1 Technical Regulations

Technical regulations are a type of regulation adopted by an authority that provides binding technical requirements, either directly or by referencing or incorporating the content of a standard, technical specification or code of practice. Technical regulations may specify the type of product that is not allowable, the type of product that is allowable, or the outcome that is required. By their very nature, technical regulations have an effect on the type of products that can be manufactured.

Technical regulations are a stringent form of Government control and should ideally be used in situations where the other options for the regulation of the product, outlined above, do not ensure adequate protection of health, safety and the environment.

7.1.2 Sanitary and Phytosanitary Measure (adapted from WTO/SPS Agreement)

Any measure 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 thereof, 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.

7.2 Impact

An impact is either a positive or negative effect, and covers items that can be readily quantified in monetary terms (for example service charges, subsidies, compliance costs) as well as items that cannot be readily quantified in monetary terms (for example, restrictions on competition).

7.3 Risk and Risk Assessment

Risk is the probability of an undesirable event occurring. This can be distinguished from a situation of uncertainty, where the probabilities of particular outcomes are unknown.

Risk assessment is a means of analysing the risk and consequences of an undesirable event. Risk assessment is a useful tool for determining the significance of the risks associated with a particular problem, and for comparing the effectiveness of various options for addressing that problem.

Risk assessment is commonly used in the areas of health and safety or environmental regulation. It also includes assessing the relative impact of the available options on the level of risk and/or its consequences.

Risk can be managed, but may not always be eliminated. In some cases, risks either cannot be eliminated, or the cost of doing so is prohibitive. An appropriate goal is to manage risk, taking into account the costs and expected benefits of reducing that risk.

7.4 Cost-benefit Analysis

Cost-benefit analysis is a useful tool for policy-makers to decide whether a particular regulatory response is most appropriate in a given situation. It enables decision-makers to make judgements about the reasonableness of a regulation and the practicalities for those who will be required to comply. It also allows regulations to be designed so that they impose the lowest costs and yield the greatest benefits. A major consideration when undertaking a cost-benefit analysis is the assessment of risk.

By quantifying and comparing the total benefits and costs of a proposal, it is possible to determine whether a proposal has a net benefit, that is, whether the benefits outweigh the costs. Those proposals with a net benefit result are potentially attractive and the proposal with the greatest net benefit should be selected and implemented.

7.5 Regulator

A regulator is any organisation or person authorised by the Government to enforce regulations. The authority is usually a department within a Ministry or a Statutory Body established by an Act of Parliament. The regulator usually has the additional responsibility for the development, review and maintenance of the regulations that it enforces.

7.6 Regulatory Coordinator

The Regulatory Coordinator is an officer appointed by a Ministry or a Regulator under the requirements of the *National Policy on the Development and Implementation of Regulations* and has the responsibility to act as the focal point for the Ministry or Regulator for communications with MPC. The name of the Regulatory Coordinator shall be notified to MPC.

The Regulatory Coordinator shall be a senior officer of the organisation who is additionally assigned to oversee the implementation of the *National Policy on the Development and Implementation of Regulations* in the Ministry or agency concerned.

Annex 1

Template for RIS Notification Form

The Malaysia Productivity Corporation (MPC) assesses all regulatory proposals to determine whether Regulation Impact Statement (RIS) is required. This form will help you identify the key features of your regulatory proposal, which, in turn, will allow MPC to assess whether RIS is required.

Name of Ministry/Department/Agency

Title of Proposal

Please provide a brief outline of the proposal. This could include the following information:

- The problem that the regulation is attempting to solve, and the government's objectives;
- Any preliminary options that are being considered; and
- Information on whether it is a proposal for a new regulation, or to amend an existing regulation.

Brief Outline of the Proposal

Likely impact on the business and other stakeholders.

RIS is required for all proposals that are expected to have a significant impact – whether positive or negative – on businesses or non-governmental organisations, unless these costs are of a minor nature.

Impacts may include:

Changes to the number or type of products and services that businesses can offer, such as :

- **Banning products or industry practices; and**
- **Changing the way in which products and services can be offered for sale.**

Impact on consumer demand for certain products and services, such as :

- **Increasing prices brought about by the regulation's requirements;**
- **Changing the information available to consumers;**
- **Requiring a self-regulatory regime for an industry sector;**
- **Changing the requirements for a licence, permit or other authorisation;**
- **Influencing the price or quantity of goods which are sold;**
- **Requiring conformance to mandatory standards for product/service quality; and**
- **Changing the price or restricting the types of inputs available to businesses.**

Is your proposal likely to have any regulatory impacts? If so, please specify.

Compliance costs **are those costs that businesses face as a result of dealing with the government. Compliance costs include:**

- **Requiring the collection and reporting of certain information;**
- **Keeping abreast of certain requirements and re-training staff;**
- **Changing operating procedures or purchasing patterns;**
- **Cooperating with audits or inspections; and**
- **Engaging lawyers, accountants or other advisors.**

Is your proposal likely to affect compliance costs? If so, how?

Timing

Key dates, as well as an indicative timeline, should both be clearly outlined in the box below.

Key dates and timeline:

Stage	Event

Contact Information

Please enter your contact information below.

Name :

Email :

Phone :

Date :

Please forward the completed form to MPC, Regulatory Review Department (regulatoryreview@mpc.gov.my) or call 03-79557266 to discuss your proposal with an MPC officer.

Annex 2

Template for Regulatory Impact Statement (RIS)

0. Title of Proposal

Full title
Reference to relevant Acts of Parliament indicating relevant provisions.

1. Policy Objective / Problem Statement

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

Identify and explain the relevant policy objective(s)
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 and identify the parties the regulation will have an impact on.
State if the regulation applies to the whole country, Peninsula Malaysia only or also Sabah and Sarawak or if any territory is exempted.

3. Options

List and describe the options (both regulatory and non-regulatory) that may provide a feasible means for achieving the desired objectives. Examples:

Option 1: Do nothing

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.

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 organisations 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, 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 finalisation 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 Recommended Option

May be summarised in a table:

Option	Total benefits in RM (per annum)	Total costs (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. Implementation of the Preferred Option

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

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

Monitoring and review. Detail how the effectiveness of the legislation is to be measured and when.

Declaration
I agree with the recommended option in this Regulatory Impact Statement 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 3

International and Intergovernmental Agreements: Obligations for Regulators with Regard to Technical 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 to.

Specific Requirements

When developing or changing technical regulations, regulators must :

1. Ensure that regulatory officials are aware and take account of obligations agreed to by the Government of Malaysia, for example the provisions of the World Trade Organization (WTO) Agreement, the ASEAN Free Trade Agreement (AFTA) and other multilateral, regional and bilateral Agreements such as the Safety of Life At Sea Convention of the International Maritime Organisation;

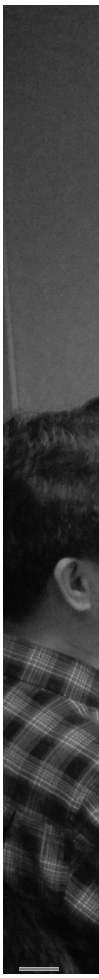
2. Ensure that regulatory officials are aware and take account of their general obligations as laid out in the WTO Technical Barriers to Trade Agreement (TBT) and the Sanitary and Phytosanitary Agreement (SPS); AFTA and other multilateral, regional and bilateral Agreements referring to regulations and standards; and

3. 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.

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.

Annex 4

Template for One-Page Summary of RIS

Title of Proposal

1. Policy Objective / 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. Purpose and Intended Effect of Regulation.

State clearly the intention of the proposal or proposed regulation.

Describe the intended effects and identify the parties the regulation will have an impact on.

3. Options

List the options (both regulatory and non-regulatory) considered.

Summarise the basis for the option selected.

4. Impact

List (both regulatory and non regulatory) that may provide feasible means for achieving the desired objectives.

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.

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. Implementation of the Preferred Option

Briefly summarise strategy for implementation of the proposed action.

Annex 5

Criteria for Assessing the Adequacy of RIS

1. Problem/Issue

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 considering 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

RIS should explain the objectives, outcomes, goals or targets of government 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

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

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 Recommended Option

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 RIS.

7. Implementation and Review

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.

References

1. Australian Government 2010, Best Practice Regulation Handbook, Canberra

2. Better Policy Making: A Guide to Regulatory Impact Assessment - Regulatory Impact Unit Cabinet Office, UK

3. RIAS Writer's Guide, 2009 Treasury Board of Canada Secretariat

4. OECD Publications on Regulatory Practice:

   - The 1995 Recommendation of the Council on Improving the Quality of Government Regulation [C(95)21/FINAL]

   - The 1997 OECD Report to Ministers, which set up a comprehensive plan for action on Regulatory Reform.

   - The 2005 OECD Guiding Principles for Regulatory Quality and Performance

   - The 2005 APEC-OECD Integrated Checklist on Regulatory Reform

   - Regulatory Impact Analysis: A Tool for Policy Coherence (2009)

   - Introductory Handbook for Undertaking Regulatory Impact Analysis (2008)

   - Building an Institutional Framework for Regulatory Impact Analysis: Guidance for Policy Makers (2008)

   - Regulatory Impact Analysis – Best Practices in OECD Countries (1997)

   - OECD REPORT, Alternatives to Traditional Regulation

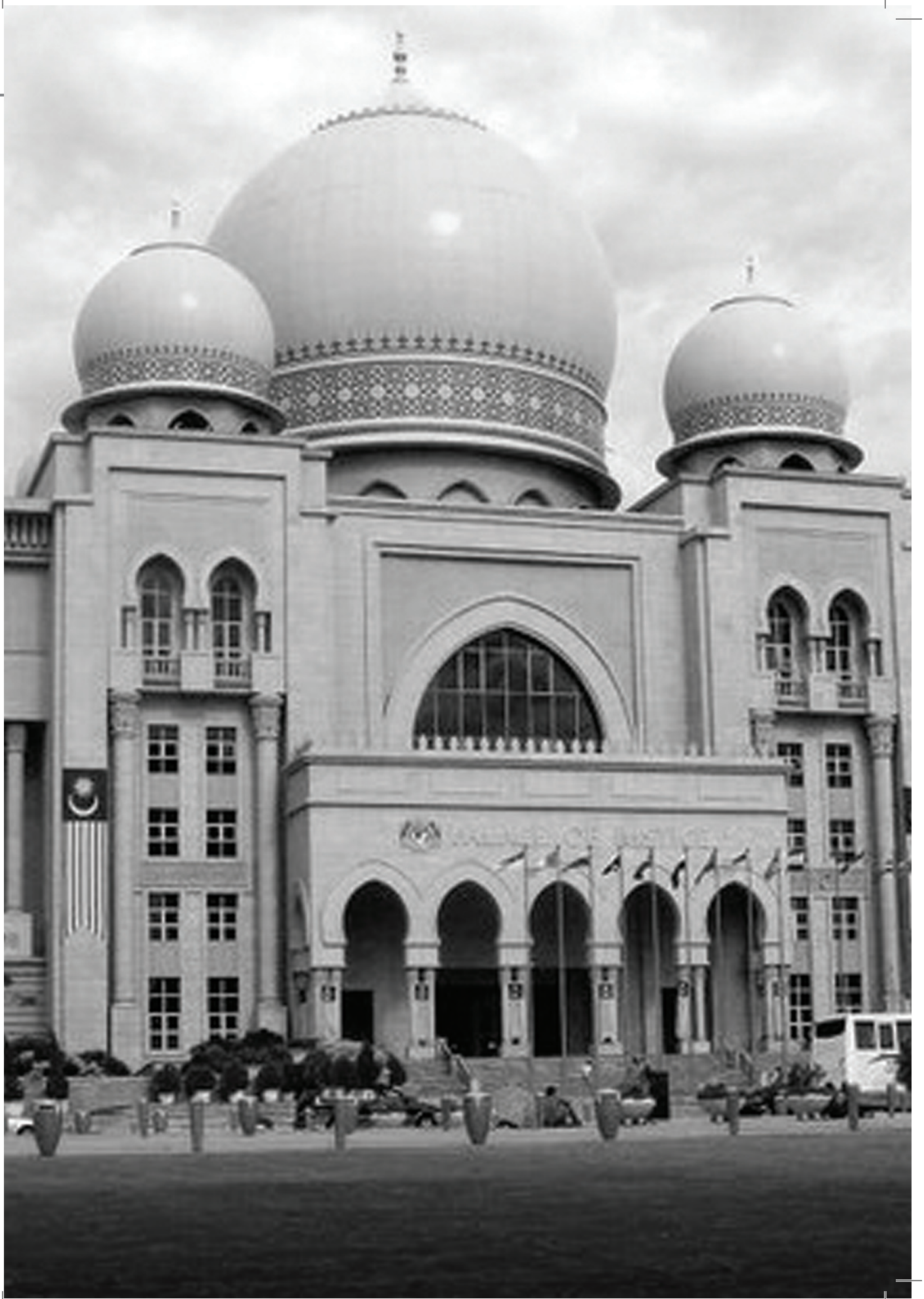
Supplementary information on good regulatory practice is available from the following publications :

1) Guide for the referencing of standards in technical regulations
   (available from Department of Standards Malaysia URL: standardsmalaysia.gov.my)

2) Guide for the selection of Conformity Assessment Procedure
   (available from Department of Standards Malaysia URL: standardsmalaysia.gov.my)

3) ASEAN Good Regulatory Practice Guide
   (available from Department of Standards Malaysia URL: standardsmalaysia.gov.my)

The OECD publications are available for reference from OECD website:
http://www.oecd.org/document/



Heralding good regulatory practice

The Malaysia Productivity Corporation (MPC) recently held a seminar on good regulatory practice (GRP), which was attended by each ministry and other bodies within the federal government. The GRP seminar provided momentum to ministries and agencies to prepare themselves before the upcoming Best Practice Regulation system implementation.

By Stephanie Augustin

State Civil Service ups efforts in business regulation modernisation

KUCHING: The State Civil Service has embarked on a number of new initiatives to improve further its services in order to support the effort in modernising business regulations.

Modernizing Business Regulation", Morshidi pointed out "today our customers demand faster, more efficient and high quality service and this requires us to continue to innovate and transform more of our work

"Among the initiatives that led to this improvement were in the area of registering property, where Malaysia improved by 25 places, from 85th position to 60th position. This was possible because Malaysia

reformed or removed totally."

He added: "In the Report, Malaysia maintained its top position in Getting Credit and its 4th position in Protecting Investors. It is our target now to be among the top ten countries for ease of doing

and various focus groups

Streamlining the licensing process

MITI deputy minister Datuk Mukhriz Tun Mahathir weighs in on how his ministry is working to ease business licensing process

By Zul Izwan Hamzah

In a recent cover story (MALAYSIA SME ™, March 24) MALAYSIA SME ™ recently talked to Malaysia Productivity Corporation (MPC) deputy director general Abdul Latif Abu Seman on the issue of licences. MPC commented that in ease of doing business, the Malaysia is ranked hi... on par...

our progress thus far," commented Mukhriz.

He said that it is a far cry from where MITI was even five years ago. "However, we cannot rest on our laurels just yet - other government ministries are fast catching up," he said.

"For example I'm told that now that we have SPAD (Land Public Transport Commission) looking into transport licences, and only transport licences; it turns out that the tourism ministry was handling buses, which is a bit of an anomaly, as it is not their core busine... So it was natural for the... try to hand...

BUSINESS › NEWS

Mpc Wins Plaudits From OECD On Regulatory Impact Statement Application

KUALA LUMPUR, April 24 (Bernama) - The Malays... has won plaudits from the Organisation of Econom... (OECD), for the work done in terms of adaptin... ...mpact Statement (RIS) into the policy m...

...Naru said man...

Kurangkan bebanan peraturan dalam urusan perniagaan

CHRISTINA ULAU

KUCHING, Jumaat – Mengurangkan bebanan peraturan dalam urusan perniagaan dapat membantu meningkatkan kadar pera... ...Keluaran Dalam Negara Kasar (GDP) di...

...RAHATI ... Datuk Abang Haji Abdul Karim menyampaikan cenderahat ... Datuk Amar Haji Mohamad Morshidi pada majlis perasmian 'Forun ...dernising Business Regulation' di Kuching semalam.

...taran yang cekap bagi membantu ...ahawan meningkatkan produktivit... ...ya saing mereka dalam pasaran," ...si yang berpandukan program pembangunan yang dikenali sebagai Key Focus Activities (KFA)," katanya sambil memberitahu semu...

Good regulatory policy needed to fulfill nation's interest

PUTRAJAYA (Dec 12, 2012): Better governance and sound institutions would lower transaction costs, reduce uncertainty and level the playing field in society, said Malaysia Productivity Corporation (MPC) director-general Datuk Mohd Razali Hussain.

Therefore, he said, it was very important to have a good regulatory policy to ensure the government regulatory machinery worked effectively, beside the...

Kelulusan dapatkan permit pembinaan kini lebih pantas

MPC

Model baru pemberian permit pembinaan akan diperkenalkan

MOHD. Sidek Hassan (kiri) mendengar penerangan Abdul Latif Abu Seman ketika melawat pameran pada majlis Konsultasi Awam Model Baru Penambahbaikan Kecekapan dalam Pengendalian Permit Pembinaan di Kuala Lumpur...

SME News | MALAYSIA

Advertorial

14 FEBRUARY 25 - MARCH 9, 2012

A whole new way of doing business

MPC dapat pujian OECD

RIA garis panduan tingkat daya saing

MPC kaji kurang kos kawal selia RM1b

Easing licensing, easing business

With the focus moving towards domestic investors for economic growth, examining the Malaysian business climate has never been more important than now. *MALAYSIA SME™* spoke to usually-reticent local SME owners, foreign investors and a government agency which is busy slashing licenses - to get a feel of how well this translates to the number of licenses, processing times, different authorities and automation used in starting a business.

By Stephanie Augustin

Improving Efficiency in Dealing with Construction Permits in Kuala Lumpur

Good regulatory policy needed to fulfill nation's interest – director-general

PUTRAJAYA: Better governance and sound institutions would lower transaction costs, reduce uncertainty and level the playing field in society, said Malaysia Productivity Corporation (MPC) director-general Datuk Mohd Razali Hussain.

Therefore, he said, it was very important to have a good regulatory policy to ensure the government regulatory machinery worked effectively, besides the regulatory framework and regulations being of optimal quality to meet policy objectives and fulfill public interest.

Mohd Razali said it was also important to strengthen the country's economic performance and competitiveness at international level, towards promoting good regulatory practice (GRP).

"In order for ministries to ensure the quality of new regulations, we must have a standardised and systematic process of Regulatory Impact Analysis (RIA) application. RIA is an evidence-based process of informing policy decision and based on clear definition

organisations attended the half-day seminar organised by MPC.

According to Mohd Razali, to standardise the systematic process of RIA, there should be links between openness and innovation in public sector and social inclusion and growth.

Mohd Razali stressed that some countries such as Mexico, had striven to improve its regulatory policy to support business activity and discourage informality.

He said Malaysia was always optimistic in learning good regulatory systems from countries like Australia and New Zealand, which had a mature regulatory quality management system (RQMS), a standard comparable to the best in the world.

"Therefore, we are here to strengthen this initiative and must boldly and promptly seek for reform of outdated regulations which can hinder innovation and economic growth at the same time, not to neglect that the creation of new regulations also needs to ensure

State Civil Service ups efforts in business regulation modernisation

PUTRAJAYA: The State Civil Service is embarked on a number of new initiatives to improve further its services in order to support the effort in modernising business regulations, said State Secretary Datuk Amar Mohamad Morshidi bin Abdul Ghani, yesterday.

"We initiated agency-based improvement program known as Key Focus Activities or KFAs. All state agencies are required to undertake major process improvement that will create impact in their service delivery and to date we have a total of 125 KFAs in place," he stated.

Officiating at the opening of an inaugural forum entitled "Forum on Modernizing Business Regulation", Morshidi pointed out "today our customers demand faster, more efficient and high quality service and this requires us to continue to innovate and transform more of our work especially into ICT (Information and Communication Technology). In this context, the State Civil Service will continuously develop more e-government initiatives so that the concept of paperless government will become a norm to our way of working life one day."

He said the World Bank Doing Business Report 2011 that was released last November showed that Malaysia had moved up 2 ranks to 21st position from 23rd in 2010.

"Among the initiatives that led to this improvement were in the area of registering property, where Malaysia improved by 25 places, from 85th position to 60th position. This was possible because Malaysia digitised property registration, saving more than two months in the process and introduced online procedures to assess and pay stamp duties, cutting six days from the process.

"The Report also noted that Malaysia taxes can be paid online. All these reforms are part and parcel of regulatory review, whereby redundant or obsolete regulations that stand in the way of business efficiency and productivity are either reformed or removed totally."

He added: "In the Report, Malaysia maintained its top position in Getting Credit and its 4th position in Protecting Investors. It is our target now to be among the top ten countries for ease of doing business and various focus groups represented by both the public and private sectors have been established to ensure improvements in terms of time, processes and costs. With this close collaboration between the public and private sectors, I am confident that the target of achieving top tenth position in terms of ease of doing business in the near future is attainable," said Morshidi.

Notes

Transformation • Innovation • Partnership

Regulatory Review Department
Malaysia Productivity Corporation (MPC)

Lorong Produktiviti, Off Jalan Sultan, 46904 Petaling Jaya,
Selangor Darul Ehsan, Malaysia
Tel: 603 - 7955 7266 | Fax: 603 - 7957 8068 | Email : regulatoryreview@mpc.gov.my