MALAYSIA

QUICK REFERENCE
BEST PRACTICE REGULATION HANDBOOK

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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

Introduction

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 the health and safety, the environment and for ensuring a balanced and continuous development of the economy.

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

This *Best Practice Regulation Handbook* is a tool to facilitate the implementation of the *POLICY ON THE DEVELOPMENT AND IMPLEMENTATION OF REGULATIONS*. It is to be used by agencies who are involved in developing regulations or otherwise implementing this policy. The Handbook, in conjunction with the National Policy document, provides guidance for implementing the policy and developing regulations in accordance with the Regulatory Process Management Requirements. This summarised version contains the essential elements on the prescribed best regulatory practices that are elaborated in the Handbook.

As regulations can have serious impact 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 as regulations are required to comply with existing Acts enacted by Parliament and also with policies of the government.

The handbook provides guidance for compliance to the policy and process. In so far as the principles and key process required are adhered to, there is flexibility to implementation of the policy. Agencies should review their existing arrangement to ensure that they comply to the policy and process requirements.

Additional information and documents on the Malaysian regulatory process can be found at www.mpc.gov.my. Agencies can contact the department below for further guidance.

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1.0 Good Regulatory Practice (GRP)

Regulations are developed and implemented by Government. These are normally based on an Act of Parliament and implemented by the Ministry or the government agency that has been authorised in the Act. Regulations are a form of law that have to be complied with and non compliance will result in penalties including fines and imprisonment.

The development of the most appropriate regulations is dependent on the selection of the best alternative solutions. The selection process should be transparent to include consultation with stakeholders. Problem resolutions should include non regulatory approaches such as provision of tax and financial incentives, educating the public and letting market forces resolve the problems.

The determination of whether regulations are effective and efficient requires a structured approach that systematically evaluates costs and benefits. The best practice regulation requirements in this handbook provide a systematic approach to ensure high quality regulation that is based on the *NATIONAL POLICY ON THE DEVELOPMENT AND IMPLEMENTATION OF REGULATIONS (NPDIR).*

2.0 Regulatory Impact Analysis (RIA)

Regulatory Impact Analysis (RIA) is the process of examining the likely impacts of a proposed regulation and a comparison with a number of alternative options which could meet the government's objectives. It is an essential tool for implementation of Best Practice Regulation.

The RIA process is based on the following:

- ***Sound analysis. The reasons for the introduction need to be clearly identified. The justification of the selected method is based on an analysis of the options available and after making an assessment on the impact of the alternative options;***

- ***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 the government's regulatory decisions are based should be publicly available.***

3.0 Regulatory Impact Statement (RIS)

Regulatory Impact Statement (RIS) is a requirement of the Government's RIA process. RIS is a document prepared by the regulator in support of a regulatory proposal, following consultation with affected parties. It records the key steps taken during the development of the proposal, and includes an assessment of the costs and benefits of each option. RIS is presented to decision makers at the time the decision is to be made. After a decision has been made, RIS is made public and posted on RIS register maintained by MPC.

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 government.

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.

4.0 RIS Process

RIS process and the requirements are defined in the National Policy on the Development and Implementation of Regulations and the handbook provides guidance for implementing the policy and developing regulations. Chart 1 on page 17 provides a summary of the process.

4.1 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 and does not substantially alter existing arrangements. This includes amendment to an existing regulation and for regulatory initiatives implemented by way of administrative circulars[2] that require mandatory compliance.

Note 1:

The implementation of "sanitary and phytosanitary measures" in food and agricultural sector has regulatory impact on business and therefore a 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.

4.2 Exemptions

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

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

b) For administrative circulars that are intended for public service administration do not require RIS; and

c) Where 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 exemption.

4.3 Notifying MPC

The Regulator intending to introduce a new regulation should contact MPC at an early stage in the decision making process and before a final decision on whether or not to regulate. MPC will discuss the proposal with the concerned agency and assist in deciding if it is necessary to conduct a RIA and prepare RIS.

When MPC determines that RIS is required, the level of analysis will have to be commensurate with the likely impact of the proposal. If the proposal is likely to have significant impacts on business and the community, a detailed analysis of those impacts will be required; if the impacts are likely to be less significant, then a less detailed analysis will be sufficient.

4.4 Contents of Regulatory Impact Statement

Regulatory Impact Statement (RIS) should contain seven elements as follows:

i) The problem or issues that give rise to the need for action;

ii) The desired objectives;

iii) A range of options (regulatory and non-regulatory, as applicable) that may constitute feasible means for achieving the desired objectives;

iv) An assessment of the impact (costs, benefits and where relevant, levels of risk) of a range of feasible options for consumers, business, government and the community;

v) A consultation statement;

vi) A conclusion and recommended option; and

vii) A strategy to implement and review the preferred option.

4.5 Regulatory Impact Statement Template

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

4.6 Other Associated Requirements

4.6.1 Post Implementation Reviews

Where a proposal proceeds without RIS due to emergency situations (as provided in 4.2 c), the resulting regulation is subject to 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 noted to have been implemented without RIS or by RIS that has been determined to be inadequate. All other regulations require a review every 5 years. Regulators should inform MPC of their review plans at the beginning of each year.

4.6.2 Obligations Arising from Treaties and International Agreements

Malaysia is a party to several international treaties and agreements and several of these are likely to involve domestic regulation that will impact on business. RIS should address the impact of the treaty obligations that impact the proposed domestic regulations.

4.6.3 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.

4.7 Non-compliance with RIS Requirements

All regulatory proposals require RIS except those specified in para 4.2. 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.***

MPC will review all regulations to determine progress in the adoption of NPDIR.

5.0 Preparing Regulatory Impact Statement

5.1 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 scale and scope of the problem;

ii) Identify the affected parties and stakeholders;

iii) 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 that additional government action may be warranted, taking account the existing regulation and any risk issues, and the potential for market development to overcome the problem.

5.2 Objectives

5.2.1 In this section of RIS, the objectives, outcomes, goals or targets that are sought in relation to the identified problem should be clearly identified. The section should state the intent of the proposed regulatory action in concrete terms and relate this to the broader policies of the agency and government.

5.2.2 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, the objective should not be 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.

5.3 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 that have the potential to be efficient or cost-effective.

The selection of alternatives may be based on a preliminary analysis of their characteristics or on experience of other governments that have employed such options. The examination of options should always consider whether the problem that is being addressed could be remedied by using existing powers available to the regulator.

5.3.1 Risk Assessment

The section should explain, and where possible quantify, the problem and the risk that the policy is trying to address. Regulatory proposals are introduced to deal with risks to the environment, consumer or worker safety or health. Risk assessment involves identifying the hazard or situation which, in particular circumstances, leads to harm or dietrimental to health. 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). 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 in a year. It may be difficult, sometimes impossible, to quantify a risk. The risk assessment should include the use of qualitative data as well.

5.3.2 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, it should indicate whether the standards under consideration deviate from the relevant International Standards. If this is the case, provide an explanation for the variation and examination of the implications of this variation should be provided.

Where a mix of regulatory and non-regulatory options have been selected, they should be explained together to demonstrate how they achieve the desired outcome. When there are multiple options or alternatives, a "best practice" is to identify which option is the preferred or recommended one.

5.3.3 Regulatory Instruments

Explicit government regulation comprises primary and subordinate legislation. It is the most commonly used form of regulation. Explicit government regulation should be considered where the problem is high-risk, of high impact or significance and where alternatives are not successful or feasible.

Self-regulation includes industry-formulated rules and codes of conduct, where industry is responsible for the enforcement. Self-regulation is a feasible option when there is no strong public health and safety concerns, the problem is of a relatively low-risk and the problem will be resolved by market forces.

Quasi-regulation includes a wide range of rules or arrangements where government influences businesses to comply, 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.

5.3.4 Alternative Non-regulatory Instruments

Apart from the regulatory options, consideration should be made using a number of alternative instruments. Alternative instruments on options 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, tradeable 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.***

5.4 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 the decision-making.

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 will enable the clear identification and comparison of the costs and benefits that would result from implementing of each option.

Costs and benefits are terms used to describe the positive and negative effects of a proposal. The costs and benefits analysis should cover business, consumers, the community and the government.

5.4.1 Benefits

This part of RIS should identify and describe the benefits of the options to business, consumers, government, other affected groups and the community at large. The benefits may include reduction in costs to business, improvement in safety and health, improvement in the environment, reduction in prices and improvement in quality.

The distributional effects of each option are also important in determining the overall outcomes for the community. For example, while a particular option may generate net benefits in aggregate, significant benefits may go to 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.

Small Businesses: Often, small firms have to divert 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 resources professionals) with detailed knowledge of regulation. It is important that decision makers are aware of such impacts on small business.

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 from competition. 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.

Proposals should be tabulated (see format) with summary of quantitative and qualitative benefits and costs to affected stakeholders. 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	

5.4.2 Enforcement and Compliance

Assessment of the likely impact of different enforcement methods should guide the selection of the appropriate option. There is no general answer to what is the most appropriate option to achieve an acceptable level 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.

Administrative methods on preventative control should also be considered. Examples include licensing, registration and enforcement approaches including warning notices, suspension notices and prohibition notices, bearing in mind the cost of administration and the aim to minimise bureaucracy.

If sanctions and penalties for non-compliance are needed, a proportionate approach to non-compliance should be chosen. 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.

5.5 Consultation

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

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 RIS should demonstrate that this requirement has been met. The regulatory agency should take necessary actions to ensure that the draft regulations not subject to confidentiality requirements of the Official Secrets Act 1972 (Act 88).

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.

Notification to World Trade Organization (WTO) should be included for proposals that come within the scope of the notification obligations 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.

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

5.6 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. It must be demonstrated that the selected option adequately meets the objectives for the proposed action in the best overall manner and is consistent with National Policy on the Development and Implementation of Regulations.

The costs and benefits of this option for the range of groups that are affected should be identified.

[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*

5.7 Strategy for Implementation

This section describes the implementation plan for a regulatory action, including any communications 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.

Practical implementation issues that need to be considered for implementation include identification of the authority that will implement and enforce the proposed option and the resources, costs involved and availability of budgets.

5.7.1 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.

5.8 One Page Summary

A one page summary of RIS must be prepared for decision makers and submitted to MPC together with RIA. The summary for proposals will be considered by the NDPC and Cabinet. The summary will need to be approved by MPC as a fair, balanced and accurate summary of an adequate RIS.

The summary will include a brief description of the main points of RIS, including the impacts 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 available on the MPC website.

5.9 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 RIS is assessed to be in adequate, MPC will advise agency on the reasons for the inadequacy.

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.

6.0 Publication of annual reports

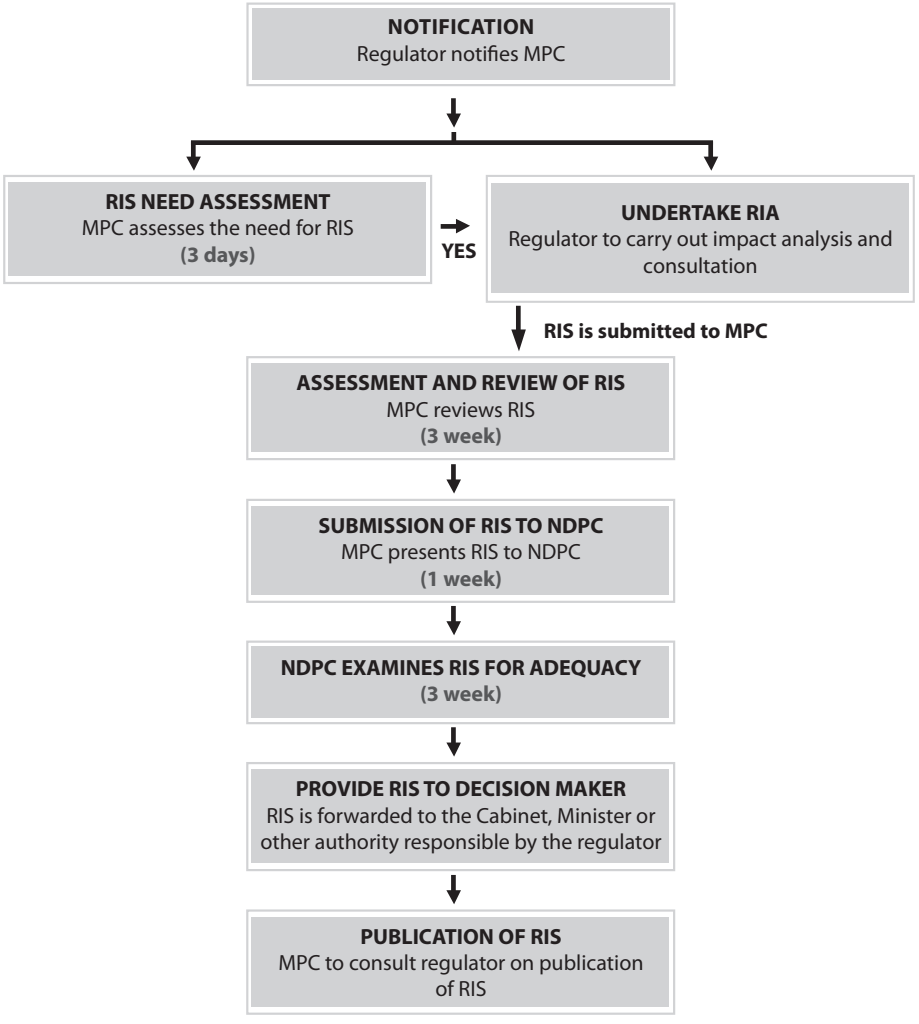
MPC will publish annual reports on regulatory activities undertaken by federal government regulators. It will provide an assessment of the progress made in the implementation of the NDPIR.

7.0 Five Yearly Implementation Review

All regulations that have an impact on business and is 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.

Regulatory Agencies should submit their review schedule (all regulation subject to review in the upcoming year) and strategies to MPC in January of each year. The five-year reviews will also be published on MPC's online RIS repository.

Chart 1: RIS Process



Transformation • Innovation • Partnership

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