



**INFORMATION NOTES ON
GOOD PRACTICE FOR
TECHNICAL REGULATION**

TABLE OF CONTENTS

INFORMATION NOTES ON GOOD REGULATORY PRACTICE FOR TECHNICAL REGULATION.....	1
1. INTRODUCTION.....	1
2. REGULATION OF PRODUCTS	3
What is Regulation?.....	3
Forms of Regulatory Responses.....	3
Choosing the Appropriate Regulatory Response.....	6
Guidelines on Technical Regulation	7
3. TECHNICAL REGULATION.....	9
Performance Based Technical Regulations	9
Referencing Voluntary Standards	10
Alignment with International Standards	10
Equivalency	11
Minimising the Trade Restrictive Effects of Technical Regulation.....	12
4. CONFORMITY ASSESSMENT	13
Conformity Assessment Regimes.....	13
Types of Conformity Assessment Regimes.....	14
Choosing the Appropriate Conformity Assessment Regime	16
Recognising the Results of Conformity Assessment Activities.....	16
5. REGULATORY SAFETY NETS	18
Types of Regulatory Safety Nets	18
6. POST-MARKET SURVEILLANCE	21
APPENDIX 1 - RISK ASSESSMENT TECHNIQUES	25
APPENDIX 2 - ESTABLISHING A REGULATORY REGIME.....	30

INFORMATION NOTES ON GOOD PRACTICE FOR TECHNICAL REGULATION

These Information Notes provide member economies with resource materials for reference when preparing, adopting or reviewing their regimes for the regulation of products according to the Principles and Features of Good Practice for Technical Regulation compiled by the APEC Sub-Committee on Standards and Conformance (SCSC). The reference material contained in these Information Notes is intended to assist member economies in the adoption of efficient regulatory arrangements, which should lead to reductions in regulatory barriers to trade. Use of these Information Notes should be considered as one of the means for assisting member economies in meeting their international obligations under the WTO TBT Agreement and their commitment under the APEC Bogor Declaration.

These Information Notes will be revised for their improvement and augmented, over time, by a number of case studies and the outcomes of issue specific seminars.

1. INTRODUCTION

With the reduction in tariffs, non-tariff barriers to trade are moving to the forefront as market access issues. Of these, differences in the regulatory requirements of individual economies are among those which have the greatest impact on trade. In certain situations, regulatory requirements may actually impede gains from trade liberalisation.

While economic literature is replete with estimates of the welfare losses from tariffs and the benefits of market liberalisation, studies that identify and quantify the effects of non-tariff barriers are generally lacking. The information that is available tends to be limited to particular markets and industries in which disputes have arisen or in which case studies have been undertaken. Much of this information appears to be subjective and anecdotal. This noted, the information and studies available do agree that regulatory reform in the form of adoption of good regulatory practices can generate gains in terms of trade facilitation.

In an APEC Economic Committee study in November 1997 entitled *The Impact of Trade Liberalisation in APEC* existing trade facilitation programs (such as those relating to standards and conformance) were estimated to generate gains of about 0.26 percent of real GDP to APEC (or about US\$45 billion) whereas gains from trade liberalisation (ie. tariff reductions) would only amount to about 0.14 percent of real GDP, or half that achievable through trade facilitation measures.

The APEC Sub-Committee on Standards and Conformance (SCSC) has already taken significant steps in addressing standards and conformance related barriers to trade by developing and endorsing:

- a Guide for Alignment of APEC Member Economies' Standards with International Standards;
- accelerated alignment of member economies' standards with international standards in agreed priority areas; and
- APEC Guidelines for the Preparation, Adoption and Review of Technical Regulations;

The impact of the work of the SCSC in alignment of standards and the development of mutual recognition arrangements on conformity assessment will be magnified if good regulatory practice is adopted by member economies.

2. REGULATION OF PRODUCTS

What Is Regulation?

Regulation can be defined as any measure or intervention implemented under government authority that acts to control the behaviour of individuals or groups that come within the ambit of that authority. Regulation includes the primary laws and subordinate instruments developed by government and the rules issued by government and non-government agencies under delegated powers.

The Organisation for Economic Cooperation and Development (OECD) identifies three categories of regulation:

- economic regulations which intervene directly in market decisions.
- social regulations which protect public interests such as health and safety, the environment and social cohesion; and
- administrative regulations which are administrative and paperwork requirements through which governments collect information and impact on individual decision making through the requirement for licensing et cetera.

The regulatory environment for governments and regulators is one in which there is an increasing focus on systematic analysis and review of both existing and new regulatory proposals. This focus is emanating from three main drivers - the desire of governments themselves to efficiently and effectively manage their regulatory responsibilities; the desire of those to which the regulation applies for efficient and effective regulatory and compliance regimes; and the increasing recognition of the benefits that can be realised from regulatory cooperation between governments.

Forms of Regulatory Responses

The greatest economic gains occur as governments move towards open and transparent marketplaces where community interests are supported without excessive regulation being imposed on business. Therefore, before implementing mandatory requirements, governments should consider all available regulatory options and should favour the adoption of the minimum effective regulation necessary to achieve the desired outcomes.

While not limiting the forms of regulatory responses available, the most recognised are identified and briefly discussed below.

Status Quo

The status quo should always be considered as an option. Alternatives may not always result in an outcome that is better than the status quo.

Legal Recourse

Governments can take a “hands off” approach to regulation and rely on common law to ensure the appropriate behaviour of individuals and business. By providing access to legal remedies, parties can enforce their rights rather than relying on government action. Legal remedies can, however, be uncertain, slow or too costly to be an efficient method of modifying behaviour.

To belay the costs of legal remedies, some economies have developed product liability insurance schemes which protect certain groups (eg. consumers) against specific risks. Such insurance schemes, which may be developed, promoted or required by government, can contain in-built health and safety considerations. In such cases, the insurance scheme sets the appropriate level of control without the direct intervention of government.

Liability Laws

As governments place an increasing emphasis on preventative measures, the regulatory responses they choose are designed to reduce risks. Yet risk by itself is not sufficient reason for governments to intervene in the market place. Technical regulations may not be necessary if those who are able to reduce the risk of accidents and/or injury face effective incentives to do so. This can be achieved through laws which make the manufacturer/supplier accountable for any damage caused through their actions. Robust, transparent liability laws create strong incentives for manufacturers or suppliers to educate consumers, workers, and others about risks that may be outside the realm of their direct experience.

Economic Instruments

Economic instruments seek to influence market behaviour by altering the relative prices of goods. These instruments can be more efficient than prescriptive regulation because they allow individuals to make their own cost-benefit trade-offs in pursuing certain behaviour. Therefore, they can achieve desired regulatory outcomes in a way that imposes the least cost on them. By using such economic instruments, the costs of enforcing behaviour can be reduced.

Market behaviour can be influenced either directly (for example, through a tax or user charge), or indirectly (for example, through controlling the overall level of supply). The most common use of economic instruments is as a response to externalities. Economic instruments are a means of “internalising” the costs of externalities, so that they will be taken into account in production and consumption decisions.

Education Programs

This option improves the functioning of the market by allowing individuals to make decisions that better match their requirements through improved knowledge. The main advantage of

this option is that it allows individuals to choose what is best for them, given the information available, rather than imposing one solution on all.

This type of approach does not set legally binding rules of behaviour. Instead objectives are reached through education and persuasion.

The provision of information or education may be as effective as coercion for obtaining desired results. Information can be disseminated through government action by requiring companies to disclose information on certain features or attributes of the product to consumers, and through the government collecting and disclosing information to the public.

Education programs can improve outcomes while still preserving consumer choice. Even poorly-informed consumers have more information than governments about their preferences, their financial situation, their skills and so on. Governments, on the other hand, can obtain critical information for consumers. It is far easier to provide information to consumers than to try to collect all of the information that would be required for the government to substitute its own judgement about when and how goods should be used. For example, it may be better to label appliances with energy-use information than to set energy-efficiency standards, since the government does not know whether a furnace will be installed in a well- or poorly-insulated house; whether an air conditioner will be used daily, or only on weekends; how many people will be taking showers from a water heater; how many people will be contributing laundry to a washing machine. All these conditions change the cost-benefit analysis of specific energy-use decisions.

It should be noted, however, that the administrative burdens of collecting and maintaining information under mandatory disclosure schemes can be high. Furthermore, disclosed information should be easily understood or interpreted by consumers.

Voluntary Standards

In the context of the social infrastructures that exist, Government endorsement of, or support for, a voluntary standard or compliance regime may be as effective as a mandated regime without the compliance costs to government associated with a mandated conformity assessment regime. Voluntary standards established with the consent of all the stakeholders should be assumed to fulfil the necessary requirements for the products to be placed on the market. Consequently, a compliance regime with voluntary standards should be considered as an effective alternative tool to mandatory regulation. Needless to say, maximum efforts should be given to align these voluntary standards with the international standards.

Industry Self-Regulation

Self-regulation can be defined as an arrangement in which an organised group (such as an industry association) regulates the behaviour of its members. The advantages of self-regulation are that rules may be more likely to be observed if they are made by members of the group, changes and updating can be more rapid, and it is cheaper for the governments because the group bears the costs of regulating.

Government oversight may be needed to ensure that the public is being protected, rather than the private interest of the regulated group.

Codes of Practice

Voluntary schemes may be established by a private body or group of private bodies in the form of codes of practice. These can cover issues such as standards, information requirements, or dispute resolution mechanisms. Codes of practice can be effective tools for building consumer confidence, and providing effective communication between consumers and suppliers. The effectiveness of codes of practice depends on how many members are in the scheme, the sanctions for non-compliance and the degree to which consumers are involved in developing and monitoring the scheme.

Codes of practice are often developed by consensus between those who will be applying them. In addition, codes of practice tend to be developed by those with a good knowledge of market conditions, and so should be better suited to economic and competitive conditions than technical regulations. Care needs to be taken that codes of practice are subject to effective competition laws so that codes of practice will not be used to reduce competition or create de facto cartels.

Technical Regulation

A technical regulation is a document 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 the most stringent form of government control and should ideally be used only in situations where none of the other options for the regulation of product, outlined above, will ensure the adequate protection of health, safety and the environment.

Choosing the Appropriate Regulatory Response

Whilst regulation will continue to be an important tool for preserving and advancing public interests, it is recognised that regulations can become an obstacle to achieving the very economic and social well-being for which they are intended.

The OECD notes that regulatory arrangements can impede innovation and create unnecessary barriers to trade, investment and economic efficiency. They may involve duplication between regulatory authorities and different layers of government, and between governments of different economies. They may also promote the influence of vested interests seeking protection from competition. Similarly, regulations that are outdated or poorly designed to achieve their intended policy objectives contribute to inefficient regulatory arrangements.

In discussing the rationale for reviewing regulation, a recent OECD study stated:

Inappropriate regulations can potentially result in substantial costs or inefficiencies being imposed upon both the sector and the economy as a whole ... the direct results of inappropriate regulation in a particular sector are likely to be higher costs, higher prices, misallocation of resources, a lack of product innovation and poor service quality.

Given this, it is evident that the economy-wide gains that can be captured by pursuing regulatory best practice may be significant. The same OECD study estimated economy-wide effects of regulatory reform in eight economies and found the potential for significant gains in labour and capital productivity and potentially significant economy-wide increases in GDP and real wages.

The challenge for all economies is to achieve the objectives of the government, in terms of protecting the health and safety of the community, while keeping regulatory intervention to a minimum. By keeping regulatory intervention to the minimum necessary to achieve the regulatory objective, member economies will not stifle innovation and competition amongst businesses and thereby ensure benefits to consumers and to the community in general.

This challenge is encapsulated in Article 2.2 of the WTO TBT Agreement which states:

Members shall ensure that technical regulations are not prepared, adopted or applied with the view to or with the effect of creating unnecessary obstacles to international trade. For this purpose technical regulation shall not be more trade restrictive than necessary to fulfil a legitimate objective.

Accordingly, to maximise economic well-being, member economies should adopt the least restrictive regulatory response possible to achieve their legitimate regulatory objectives.

Tools for Regulatory Analysis

Cost-benefit analysis is a useful tool for policy-makers to decide whether a particular regulatory response is the 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 risk¹

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.

Monitoring the Effectiveness of Regulatory Responses

Member economies should be mindful of the fact that the market place is a dynamic environment and that problems are seldom resolved completely in the first instance. Accordingly, member economies should have mechanisms for the ongoing evaluation of the success of the chosen regulatory response.

Guidelines on Technical Regulation

Recognising the potential gains from the pursuit of regulatory good practice, all economies are coming under increasing pressure to adopt good regulatory practice, as applied at both the domestic and international level. Many governments have moved to establish central

¹ A discussion of Risk Analysis Techniques is to be found in Appendix 1.

agencies to oversee the development and review of regulation. Similarly, many governments have moved to adopt standardised, systematic analytical tools to aid their decisions in relation to the review of current regulation and the vetting of new regulatory proposals.

The *APEC Guidelines for the Preparation, Adoption and Review of Technical Regulations*² provides one such analytical framework. It is a simple but effective analytical tool. The checklist developed as part of the Guidelines asks the following questions in relation to a regulatory proposal:

- Has the problem been clearly identified?
- Have all the options to address the problem been considered?
- Has the design and implementation of technical regulations been considered?
- Have performance-based regulations and/or standards been considered?
- Have international standards and obligations been considered?
- Have compliance mechanisms been considered?
- Have provisions for review and monitoring of the technical regulation been considered?
- Has consultation taken place?

In developing this framework, member economies recognise that the development of complementary analytical frameworks for regulatory review will facilitate good regulatory practice.

² These Guidelines have been endorsed by APEC Senior Officials and referred to other APEC fora for consideration and use where appropriate.

3. TECHNICAL REGULATION

Performance-Based Technical Regulations

There are two main types of technical regulations. These are:

- prescriptive - which specify the means for attaining the specified outcome; and
- performance-based - which specify the desired objective in precise terms but allow the regulated entity to determine their own technique for achieving the outcome.

Prescriptive regulations focus attention on only one means of achieving the desired objective. As such, prescriptive regulations can create an obstacle to trade and economic development. Firms are locked into a single solution with no opportunity to utilise alternative, and possibly more cost efficient, compliance solutions. Prescriptive regulations may suppress innovation and create barriers to the uptake of new technology.

Prescriptive regulations do, however, provide certainty for those being regulated and for those whose role it is to determine whether the desired objective has been met. Because of the implications that result from reduced flexibility, prescriptive regulations should only be applied when there are extremely limited ways of achieving a desired objective or when the problem that the regulation addresses is static. In these cases, certainty may be more important than flexibility.

On the other hand, performance-based regulations represent a more flexible approach and allow regulated entities to devise the most efficient and effective method of compliance.

Performance-based technical regulations are generally preferred over prescriptive requirements as they provide flexibility while ensuring that the objective is achieved. Performance-based regulations are a less trade restrictive form of regulation and are endorsed by APEC member economies through their adoption of the *APEC Guidelines on Preparation Adoption and Review of Technical Regulations*, and by members of the WTO, through Article 2.8 of the WTO TBT Agreement which states:

Wherever appropriate Members shall specify technical regulations based on product requirements in terms of performance rather than design or descriptive characteristics.

The major advantage of performance-based regulations is that they can accommodate a range of technical solutions provided the outcomes are the same. Performance-based regulations provide flexibility for manufacturers in terms of demonstrating compliance with outcomes, thus providing scope for firms to innovate and adopt new technology.

However, in its analysis of performance-based regulation, the OECD has highlighted that performance-based regulatory solutions:

- may introduce uncertainty regarding what constitutes acceptable compliance;
- are suitable only in situations where the regulated entity is in a better position than the regulator to understand and address the potential causes of problems which the regulation is designed to address; and
- may pose difficulties for regulators to monitor and enforce compliance.

These concerns go to the level of uncertainty created by allowing flexibility in methods of achieving compliance. It can be argued that performance-based regulations disadvantage some firms, particularly small and medium sized enterprises, which may need or prefer more guidance on how to meet the regulatory requirements of both the domestic and export markets. Small to medium businesses may, therefore, prefer the legal certainty provided by approved or recommended methods of compliance as opposed to the costs of legal advice and liability insurance that are often associated with compliance with performance-based regulations.

One method of addressing this problem is for regulators to provide performance-based regulations that include references to optional prescriptive standards (called ‘deemed-to-comply solutions’). These prescriptive standards can be effectively used as examples with the view to lessening the compliance burden of small-medium sized enterprises. Compliance can be achieved either by using the prescribed deemed-to-comply solutions or by using an alternative solution that can be demonstrated as achieving the regulatory objectives. This approach offers the flexibility and speed to market of performance-based regulations as well as the certainty of prescriptive regulations for those who wish to continue to use that option.

Referencing Voluntary Standards

Having noted the benefits of performance-based technical regulations, and the referencing of standards and sanctioned guidelines as deemed to comply solutions where a greater degree of certainty is desirable, member economies should be cautious as to the manner in which such referencing occurs.

Standards, in particular voluntary standards, developed by both domestic and international standardisation bodies, are not necessarily written with a view to possible endorsement or reference by mandatory requirements. As a result, voluntary standards can contain aspects which are not essential to the legitimate objective of the regulations that reference them.

Accordingly, only those parts of a standard that represent the minimum necessary to fulfil the regulatory objective should be referenced by the regulations.

Alignment with International Standards

The adoption of common standards reduces the trade restrictive effects of regulation. Manufacturers benefit through the removal of the artificial segmentation between markets that differences in standards create. Instead of having to produce numerous small batches for each of the markets they may wish to enter, manufacturers can produce a single version of the

product that is acceptable in all markets. This can lead to significant cost savings through economies of scale.

The WTO TBT Agreement endorses the adoption of international standards as a mechanism for eliminating technical barriers to trade. In particular, the TBT Agreement states that where technical regulations are prepared, adopted or applied in accordance with the relevant international standards, there shall be a presumption that the regulations do not create an unnecessary obstacle to international trade.

International standards, however, should be drafted in a transparent, open and non-discriminatory manner. They should also have relevancy, responding to market and regulatory needs, scientific and technological developments, and should not distort global market competition. Furthermore, International standards should be continuously reviewed to confirm that they are fulfilling those requirements.

Within APEC, member economies have committed to:

- aligning their standards with international standards, wherever possible³, by the year 2010 in the case of industrialised economies and 2020 in the case of developing economies;
- aligning their standards for radios and their parts, televisions, video apparatus, refrigerators, air-conditioners, industrialised robots, rubber surgical and examination gloves, rubber condoms and food labelling by the year 2000 in the case of industrialised economies and the year 2005 in the case of developing economies; and
- aligning their standards for electrical safety and electromagnetic compatibility with the IEC 60335 and CISPR series of standards, respectively, by the year 2004 in the case of industrialised economies and the year 2008 in the case of developing economies.

Equivalency

In the absence of international standards, member economies can still achieve similar benefits through the use or recognition of standards from other economies. Acceptance of the technical regulations or standards of another economy, even where the standards are not exactly identical, can result in significant efficiency gains for industry and regulators. For industry, the practice results in the removal of segmentation effects caused by different standards. The problems faced by regulatory authorities in one economy are often the same as those faced in another economy. The regulatory responses adopted by either economy, while they may be different, generally achieve the same level of protection of health and safety for their respective communities. Accordingly, it should be possible for member economies to reference compliance with the standards of another economy as an acceptable solution provided they are satisfied that these standards adequately fulfil the objectives of their own regulations. This might be achieved by referencing the standards of another economy as a deemed to comply solution (see performance-based technical regulations above).

³ The 'wherever possible' caveat was inserted to allow member economies to deviate from international standards for reasons of national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment (see WTO TBT Article 2 and Annex 3)

This process for reducing the burden to industry and trade is encouraged within the terms of the WTO TBT Agreement, which states:

Members shall give positive consideration to accepting as equivalent technical regulations of other Members. even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations.

In summary, there are a number of steps which can be taken to minimise the trade restrictive effects of technical regulations. These steps include:

- the adoption of performance based, rather than prescriptive, technical regulations;
- ensuring that, when voluntary standards are referenced, only those standards, or parts of standards that are necessary to achieve the legitimate objective are referenced;
- reducing the differences in regulatory requirements through the adoption of, or alignment with, international standards; and
- accepting the standards and/or technical regulations used by other member economies, provided these standards and/or technical regulations adequately fulfill the objectives of the accepting economy's regulations.

4. CONFORMITY ASSESSMENT

Conformity Assessment Regimes

Conformity assessment regimes typically fall into two broad categories. The first category includes regimes that require products to be assessed prior to entry into the market. Such conformity assessment regimes or requirements are often called ‘pre-market’ conformity assessment regimes and often take the form of product approvals, product registrations, licences (import/practice) or inspections.

Pre-market conformity assessment requirements, by their very existence, delay the entry of goods onto the market. In some cases, these delays can constitute a significant barrier to entry and may prevent the uptake of new, innovative and more efficient technologies. This is not to say that pre-market conformity assessment is inherently bad. In high risk areas, for example medical devices and pharmaceuticals, pre-market assessment of a product’s conformity may be essential to give adequate sureties that the products do not pose a risk to the health or safety of the community.

The second category of conformity assessment regimes relies on the manufacturer or supplier, rather than the regulatory agency, taking on the responsibility for ensuring that products entering the market comply with the relevant mandatory technical regulations. Conformity assessment regimes in this category are typically referred to as supplier declaration regimes.

Supplier declarations should not, however, be confused with no conformity assessment at all. A manufacturer or supplier still needs to undertake some form of conformity assessment to show that due diligence has been undertaken prior to placing the good onto the market. This is a necessary step for manufacturers so that they are in a defensible position should the conformity of their products with the required technical regulations ever be questioned by a regulatory body, during the course of a post-market surveillance exercise, or by the courts in the case of a product liability or negligence action.

Supplier declarations provide significant advantages to industry. Suppliers are no longer required to seek approvals from a regulatory agency prior to the placement of goods onto the market. Instead, suppliers can choose from any number of conformity assessment bodies or, in some cases, use their own internal conformity assessment mechanisms to ensure compliance.

However, as recognised by the WTO Committee on Technical Barriers to Trade, reliance on supplier declarations is not appropriate in all cases. As previously discussed, there remain instances where a pre-market conformity assessment requirement is necessary to give adequate confidence that the product conforms with the technical regulations.

Types of Conformity Assessment Regimes

While not limiting the types of conformity assessment regimes available to governments, the most common conformity assessment regimes are described below.

Inspection

Inspection involves the assessment of each individual product. In cases where a product may deteriorate over time (for example: gas cylinders, motor vehicles and marine vessels), inspection may occur a number of times over the product lifecycle.

Inspection is a highly stringent conformity assessment regime and places a significant burden on industry and consumers. Inspection should, therefore, only be used in high risk situations or in instances where the product or device is constructed on-site and does not reach final form until ready to be put into use (for example, lifts, cranes, large boilers and buildings).

Licensing

Licensing individuals or companies is a conformity assessment regime that assesses the competence of an individual or a company to undertake a specific task. Licensing is applicable in situations where the performance characteristics of the product are not readily discernible and confidence that the product conforms with the applicable technical regulations can only be achieved if the product was manufactured by appropriately qualified individuals or companies. Such individuals or companies would be licensed and, where appropriate, subject to review of their licence to ensure maintenance of competencies. Typically, licensing applies to trade professionals and quality management systems of companies.

Batch testing

Batch testing involves a sample test of each batch or shipment of mass produced product. In terms of the conformity assessment spectrum, batch testing lies somewhere between 'inspection' - which involves the assessment of each product – and 'type approval' - which involves the assessment of only one sample of the product which is applicable to future batches.

Batch testing is declining in popularity as a conformity assessment regime. This is because of the uptake of quality management systems by manufacturers that ensures each product made is of the same quality, and has the same characteristics, as the original batch or sample.

Batch testing should, therefore, only be used where the regulator has little confidence that each individual product will be of the same quality as the original or sample product.

Approvals

Approvals are currently the most common form of pre-market conformity assessment. Approvals typically involve the assessment of a sample of a product. In many economies, the regulatory body undertakes the assessment of the product, whereas in others the conformity assessment is undertaken by competent test facilities or laboratories. However, in both cases the regulatory body retains the final decision, based on the test report, to approve or otherwise the sale and/or use of the product.

Approval systems are usually augmented by a post-market surveillance mechanism (see Chapter 7) to ensure that the goods being placed on the market are the same as those for which the original approval was given.

Certification

Typical certification systems involve initial testing of products and ongoing product surveillance. In some cases, an initial assessment of the manufacturer's premises/manufacturing practices is also undertaken. Manufacturer's quality management system may also be assessed during the course of certification.

Governments in a number of economies are choosing to rely on certification programs delivered by competent third party product certification bodies who operate in a competitive environment. Such regimes have the advantage of delivering a conformity assessment regime whose costs are reduced through competition while maintaining the same, or possibly better, level of control/regulation of the market place as that offered through the approval system.

Listing/registration

Listing/registration is similar to approvals except that there is no direct activity by the regulatory agency before a product is placed onto the market. Manufacturers and suppliers submit the appropriate documentation, together with supporting evidence, such as test reports, to the regulatory body. The regulatory body, following an assessment of the documentation, lists the product on a register or gazette of approved/recognised products.

Listing/registration of products provides the regulatory body with a quick reference for identifying the manufacturer/supplier of any product on the market. Should an instance of non-conformity arise, the regulator can quickly and easily identify the relevant party and take necessary actions. However, for less critical products there are other mechanisms that can be used to facilitate the easy identification of the manufacturer/supplier without the need for a pre-market approval step to be taken.

Supplier Declarations

As outlined previously, supplier declarations do not equate with no conformity assessment at all. Supplier declarations still require the manufacturer or supplier to undertake some form of conformity assessment. This assessment can be undertaken, at the choice of the supplier, by any one of a number of conformity assessment bodies, or by the supplier's own internal test facility in some cases. All the supplier needs to demonstrate is that due diligence has been exercised prior to placing the product onto the market. This will place suppliers in a defensible position should the conformity of their products with the required standards or technical regulations ever be challenged by a regulator or a court.

Supplier declarations provide significant advantages to industry. In particular, they give manufacturers and suppliers the choice of agency used to demonstrate conformity with the mandatory requirements that apply. Suppliers are not required to seek approvals from a regulatory agency prior to the placement of goods onto the market. This can lead to significant time and cost savings to industry and consumers and may represent a significant reduction in regulatory burden.

A mechanism to ensure that the declarations made by suppliers are valid is an essential element of supplier declaration regimes.

Choosing the Appropriate Conformity Assessment Regime

Regulatory measures should contain compliance strategies which ensure the greatest degree of compliance at the lowest level of government intervention. By doing so, member economies encourage the establishment of effective and open markets that will, in turn, provide economic benefits and stability. (see also Chapter 2)

Member economies should, however, be mindful of the risk non-compliance may pose to human health, the safety of animal and plant life, and the environment. Accordingly, the least interventionist conformity assessment regime may not be the most appropriate in all circumstances. As outlined above, there are situations/sectors where the more interventionist conformity assessment regimes, such as inspections, are not only warranted but necessary.

In addition to the type of conformity assessment regimes chosen, member economies should consider the specifics of any conformity assessment regime. For example, the number of licenses, certifications, approvals, authorities et cetera. should be kept to the minimum necessary to achieve regulatory objectives. The regulatory burden for industry can be reduced if the level of interaction between individuals or companies, and the government, is kept to a minimum. This can be achieved through measures such as one-stop shops, better forms and process design.

Recognising the Results of Conformity Assessment Activities

It is accepted that member economies may require assurance that products placed on their market comply with the technical regulations they have determined as essential to ensure the health and safety of their citizens. This need for positive assurance of conformity with technical regulations does, however, place an inherent burden on manufacturers. This burden manifests itself most noticeably for manufacturers who are required to have products re-tested or re-certified even though they have already been tested or certified in another economy. This requirement can substantially increase costs for manufactures to enter the market. As a result; manufacturers may choose not to enter a market; the number of products available in the importing economy can be limited; and the degree of competition faced by domestic manufacturers, and hence the level of innovation and technological advances made in the importing economy, restricted. This has a negative effect on the prosperity and economic stability of the importing economy. This is particularly noticeable for those products with a relatively short market life, for example high technology IT products, where the additional time delays associated with product testing and certification in the importing country can severely impact on their marketability.

Costs to manufacturers and limitations to the importing member economies' economic prosperity, can be reduced and/or eliminated if member economies unilaterally accept the results of conformity assessment activities undertaken by competent bodies in other member economies. Such a move would reduce the amount of re-testing that occurs, and therefore the cost, in addition to reducing the workload for the regulatory agencies.

There are a number of mechanisms that can be used for acceptance of the results of conformity assessment. The key factor, however, governing any recognition arrangement at government level is the **confidence** that regulatory authorities in the importing economy have in the **technical competence** of the conformity assessment bodies in the exporting economy to assess product to the **importing economy's requirements**.

Whichever mechanisms for the acceptance of the results of conformity assessment is used it must, for the purposes of the WTO TBT Agreement, meet the essential WTO TBT principles of transparency and non-discrimination and take into consideration national and most favoured nation treatment.

Mutuality, even though supported by the WTO TBT Agreement⁴, is not necessary for the recognition of overseas test reports and/or certificates. Indeed, it has been said that mutual recognition arrangements are nothing more than a structured set of unilateral arrangements in which each party unilaterally accepts the result of the conformity assessment activity undertaken in the other party(ies).

The concept of unilateral recognition arrangements, sometimes called national treatment of laboratories, is embodied in the WTO TBT Agreement. The WTO TBT Agreement states, at Article 6.1, that:

Without prejudice to the provisions of paragraphs 3 and 4, Members shall ensure, whenever possible, that results of conformity assessment procedures in other Members are accepted... provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures.

These principles are supported by the WTO TBT Agreement, which states that:

Prior consultations may be necessary in order to arrive at a mutually satisfactory understanding regarding, in particular adequate and enduring technical competence of the relevant conformity assessment bodies in the exporting Member, so that confidence in the continued reliability of their conformity assessment results can exist; in this regard, verified compliance, for instance through accreditation, with relevant guides or recommendations issued by international standardising bodies shall be taken into account as an indication of adequate technical competence.

There exist a number of commonly used mechanisms for determining the technical competence of conformity assessment bodies. Such mechanisms include accreditation; peer assessment; and government designation.

⁴ WTO TBT Agreement – Article 6.3

5. REGULATORY SAFETY NETS

The nature of any general consumer protection or product liability regimes based in either legislation or civil law (referred to as regulatory safety nets in this chapter) plays a significant role in the choices of regulatory responses and conformity assessment regimes.

The strength of the regulatory safety net which applies in an economy will influence the types of regulatory responses taken and conformity assessment regimes implemented by an economy in their consideration of issues relating to the suitability or otherwise of particular goods.

In the absence of a strong regulatory safety net, governments may consider it necessary to adopt a more interventionist approach such as mandatory pre-market conformity assessment regimes with stringent post market surveillance techniques to ensure that there is no possibility of non-compliant product entering their market.

Where regulatory safety nets are strong, however, governments can adopt light handed approaches to product regulation such as listings and supplier's declarations (see Chapter 4). It is only when the non-compliance associated with a particular type of product poses a significantly high risk to health and safety that separate, more stringent regulation may be required.

Strong regulatory safety nets promote both economic efficiency and consumer protection while allowing manufacturer's to carry on their business without being overly burdened by government regulation. An effective regulatory safety net can provide manufacturers and suppliers with an incentive to make their goods safe, consumers with a good level of protection and recourse and governments with a means of dealing with potentially hazardous products in the market.

Types of Regulatory Safety Nets

In general terms, regulatory safety nets are of two basic forms. Firstly, those which are created through statute-based consumer protection or product liability laws that can provide ways to limit and deal with hazardous products without demanding compliance with strict technical specifications. Secondly, those that exist due to the operation of case law arising from instances of negligence actions. Case law systems provide private rights of action to consumers and businesses that enable redress to be sought through the legal system. Both statute-based and case law-based systems are capable of creating a strong regulatory safety net.

Statute-Based Regulatory Safety Nets

Consumer Protection Laws

General consumer protection laws relating to product safety can sometimes be found embedded in laws relating to trade practices, commerce or fair trading legislation. The features of such laws are that:

- they create an obligation on the manufacturer and/or supplier to ensure that the goods they place on the market are safe and/or fit for the purpose for which they are offered for sale or use; and
- suppliers must not engage in conduct or practices that are misleading or deceptive including misrepresenting the safety of a product or that the goods are of a particular standard or quality.

Most of these obligations can be enforced whether or not there has been any personal injury or property damage, as the obligations create a strict liability regime which must be adhered to by suppliers regardless of fault or damage. In some instances enforcement agencies may also be able to take actions against suppliers particularly where there is potential for widespread consumer detriment. Actions of this nature normally do not have criminal consequences and are predominantly of a civil nature resulting in civil remedies such as damages, injunctions or rescission of contracts. Enforcement agencies may also require remedies such as corrective advertising or enforceable undertakings.

Product Liability Laws

These types of laws normally provide an individual with a private statutory right of action to obtain damages for personal injury or property losses caused by defective products. The advantage of this type of regime is that liability on suppliers is strict - in other words there is no need for an individual to prove that the supplier has been negligent in the supply of the goods, merely that the defective goods have caused injury or loss. The defectiveness of goods will normally be judged on an objective basis of commonly accepted community standards. A regime of this type thus provides strong incentive for manufacturers to supply safe products.

The strength and success of a statute-based regulatory safety net is, however, dependent on the methods used to detect unsafe product. If the methods used to detect unsafe product, and remove it from the market place, are poor then the pressure for manufacturers and supplier to take full responsibility for their product is reduced and the strength of the regulatory safety net eroded.

Civil Law Systems

Civil law, or tort, based systems are to be found in the body of case law built up over time within an economy's judicial system. Civil law based regulatory safety nets derive their strength from the cost faced by the manufacturer or supplier should they ever be subject to litigation due to injury or damages caused by the products they place on the market. Where the potential costs of litigation are high, the prudent manufacturer will take all necessary steps, including undertaking conformity assessment activities to substantiate the safety of the

product, to ensure that the products placed on the market are safe and do not pose any threat to health or the environment.

In cases where the costs of litigation become so high as to potentially destroy a manufacturer, the manufacturer may resort to taking out product liability insurance to cover any potential losses. In these situations, the insurer is likely to require the manufacturer to demonstrate the safety of the product through assessment of conformity to relevant voluntary standards. In essence, the requirement for conformity assessment is set by the insurer and, in effect, the insurer acts like a regulator operating in a pre-market approval regime.

The benefits of this type of regulatory safety net are that the government can take a light-handed, non-interventionist approach and that the manufacturers/suppliers have greater levels of choice as to the methods of determining that their products are safe to place on the market.

There are, of course, some disadvantages to a case law system because the very nature of case law is reactive rather than pro-active. In addition, litigation procedures can be long, costly, and are slow to respond. Such systems require actual injury or damage to occur and the litigation procedures tend to be drawn-out such that the final result may not be determined for some time.

That said, both statute law and case law based regulatory safety nets are capable of providing the same level of consumer protection and risk abatement necessary for governments to adopt low interventionist type conformity assessment regimes.

6. POST-MARKET SURVEILLANCE

The assessment of products after they have been placed onto the market is the integral part of many conformity assessment regimes. The assessment is often called post-market surveillance and is undertaken to ensure that products comply, or continue to comply, with the relevant regulatory requirements.

Post-market surveillance is essential to conformity assessment regimes where there is no in-built assurance of continued compliance. For example, it is necessary in approval regimes to ensure that the product being offered for sale in the market place has the same performance characteristics as the sample for which the original approval was given. Post-market surveillance is also necessary in supplier declaration regimes to ensure that the supplier's declarations are valid.

In conformity assessment regimes, such as inspection, licensing or batch testing, post-market surveillance is not as critical. The degree of post market surveillance may also depend on whether the conformity assessment regime requires internal auditing and surveillance. For example, where quality management systems are mandated or encouraged, the level of post-market surveillance could be less than would otherwise occur. Conformity assessment regimes which rely on product certification, where the certification body undertakes some degree of post-market surveillance or auditing as well as quality management system assessment, may also attract a lower level of post-market surveillance by regulatory bodies.

Characteristics of an effective post-market surveillance regime

There are two essential characteristics of any effective post-market surveillance regime:

- significant penalties for non-conformity; and
- an expectation by suppliers that non-compliant products will eventually be detected.

Without these two essential elements, suppliers may be tempted to take risks regarding the compliance of their products with required regulations. As a result the health and safety of the community could be endangered through non-compliant products entering the market.

In the first instance, if the penalties for non-compliance are minimal, suppliers may choose to take risks, even though the possibility of non-compliant products being detected may be high. Attracting a penalty or fine may be viewed by suppliers as an annoyance and not as an incentive for compliance.

In the second instance, where the likelihood of detection is low, suppliers may choose to take risks even though the potential penalties for non-compliance, if detected, are high. The likelihood of detection will be balanced against the costs associated with ensuring compliance.

If the likelihood of non-compliant products being detected, in conjunction with the potential penalty, is less than the costs associated with ensuring compliance, then suppliers will be more likely to accept risks associated with potential non-compliance.

In addition to the essential characteristics of an effective post-market surveillance regime described above, the effectiveness of a post-market surveillance regime can be enhanced if the regime attaches responsibility for non-compliant products to all of those involved in the supply chain (manufacturer/importer, wholesaler and retailer). The advantage of this characteristic is that the retailers are more likely to place pressure on their wholesalers or manufacturers to supply only those products which comply with the mandatory requirements. This involvement of retailers in applying pressure to manufacturers/importers and wholesalers assists in achieving compliance with mandatory requirements, while reducing surveillance costs to government.

Penalties for Non-Compliance

Mandatory regulatory instruments should contain appropriate sanctions or remedies to enforce compliance and penalise non-compliance.

Remedies may include:

- Fines
- Injunctions
- Corrective advertising
- Damages (private actions)
- Withdrawal of products
- Product recalls
- Court enforceable undertakings
- Negotiated settlements
- Representative actions by regulators

Some of these remedies may require those suppliers detected as supplying non-compliant products to incur substantial costs which may exceed any fines levied against them.

For example, costs of withdrawing or recalling goods typically include:

- corrective advertising;
- loss of profits on withdrawn or recalled products;
- freight charges;
- repair costs; and
- company downtime.

Other costs include legal fees and additional loss of sales due to loss of reputation through bad publicity.

These potential detection costs act as an incentive to suppliers to do the right thing and produce products which are safe and comply with mandatory requirements.

Choice in Penalties for Non-Compliance

Enforcement options should differentiate between the good corporate citizen and the renegade, to ensure that 'last resort' penalties are used most effectively and model behaviour encouraged. Enforcement measures should not have the effect of encouraging otherwise good corporate citizens to subvert compliance measures.

To maximise flexibility in the penalties, member economies should consider a wide variety of remedial actions and sanctions. A regulator can then apply differing levels of penalties dependent on:

- the seriousness of the safety hazard;
- the quantities that the product is supplied in;
- whether the supplier's conduct is blatant; and
- the level of cooperation from the supplier.

Flexibility of response has advantages for the regulator, business and consumers alike as it allows for the implementation of remedies that can not only differentiate between varying levels of risk but also take into account the conduct of suppliers. For example, minor breaches of a standard by a supplier with a good compliance record may result in a regulator applying a low-level administrative solution. However at the other end of the scale, suppliers may be prosecuted and fined where their conduct has been blatant and resulted in serious breaches. By using flexible remedies in this way, a regulator can encourage good corporate behaviour by suppliers, and help prevent non-compliant products from entering the market.

It is also recognised that flexibility of response is important as it allows regulators to take into account the effect of non-compliance and penalties on all affected parties in an industry as a whole. For instance, certain remedies may be undesirable because of their effect on the availability of certain products to consumers.

A further advantage of having flexible remedial actions or sanctions is that enforcement options can be chosen, such as corrective advertising, which may facilitate public awareness of non-complying products thus leading to an increased likelihood of non-compliance being detected.

Detecting Non-Compliance

As outlined above, post-market surveillance regimes must be sufficient to convey to suppliers that there is a likelihood that non-compliant behaviour will be detected, appropriate actions taken and penalties imposed.

Detection of non-compliant behaviour is normally achieved through two main detection strategies:

- a pro-active program based on risk management principles; and
- a re-active program based on complaints from various sources.

The Risk Management Approach

This approach involves the use of risk assessment criteria relating to potential injury severity, the probability of the hazard occurring and the level of product availability. Risk assessment

based on these criteria is used to decide on priorities for market surveys and further investigation of non-compliant products.

Essentially market surveys need to be planned around maximising opportunities, particularly where a regulator's resources are limited. The use of risk assessment criteria is crucial in identifying those products most appropriate to be surveyed either because of priorities or their availability.

The complaints-based approach

Specific complaints may be received from numerous sources – consumers, competitors of suppliers, other regulatory agencies, and organisations such as accreditation or consumer organisations.

Non-compliant products may also be detected by checking media sources such as newspapers, press clippings and radio or television broadcasts.

Methods for detecting non-compliance

The most commonly used methods to detect non-compliance are:

- Random audits of documentation used by suppliers to substantiate their self-declaration of conformity with the relevant regulations. Regulatory bodies may require copies of test reports from competent laboratories or product certification bodies. Alternatively, regulators may be satisfied with test reports undertaken by the manufacturer where those tests are undertaken in an appropriate manner.
- Audits of documentation following a complaint relating to a regulated product. In such cases, the regulator should first substantiate the complaint to eliminate any nuisance or unfounded complaints before conducting an audit of the supplier.
- Visual examinations of regulated products which are the subject of market surveys or complaints. In many cases, particularly where mandatory regulations apply to labelling or packaging requirements, a simple visual check is sufficient to establish whether a product is compliant.
- Mandatory re-testing of products either on a random basis during a survey or as a result of a complaint. This method generally involves the regulator requiring the supplier to seek, at their own expense, an independent test report, or certificate, to demonstrate compliance of the product. Such a method minimises costs to the regulator. However, where the choice of the sample to be re-tested is left up to the supplier, there may be a tendency for the supplier to provide a 'rolls-royce' for testing.
- Independent sampling of product by the regulator. This method avoids the problem associated with 'rolls-royce' samples but leads to higher costs for the regulator. The independent sampling technique usually involves the regulator purchasing a sample from the market place, without the knowledge of the supplier, and subjecting it to the appropriate assessments of conformity. Depending on the results of the tests, the regulator can then take the appropriate action and levy the relevant penalties.

Appendix 1 RISK ASSESSMENT TECHNIQUES

Operating in a dynamic and volatile environment, regulatory bodies are increasingly presented with the need to identify and respond to the multitude of risks that prevail in the marketplace.

It is through the systematic assessment of risk that regulators seek to ensure effective allocation and utilisation of resources in the face of competing obligations.

The term 'risk' refers to the probability that a particular hazard will cause harm, or that it may lead to the occurrence of an undesirable event. The process by which risk is analysed is to identify the specific hazards, the mechanisms that cause its existence, and the probability that the repercussions of the risk will be felt. The analysis of risk is comprised of well-defined steps designed to enhance decision-making by contributing to a greater insight into risks and their potential consequences. The differing needs of governments dictate that the design and implementation of regulatory regimes will be specific to the environment where it is administered.

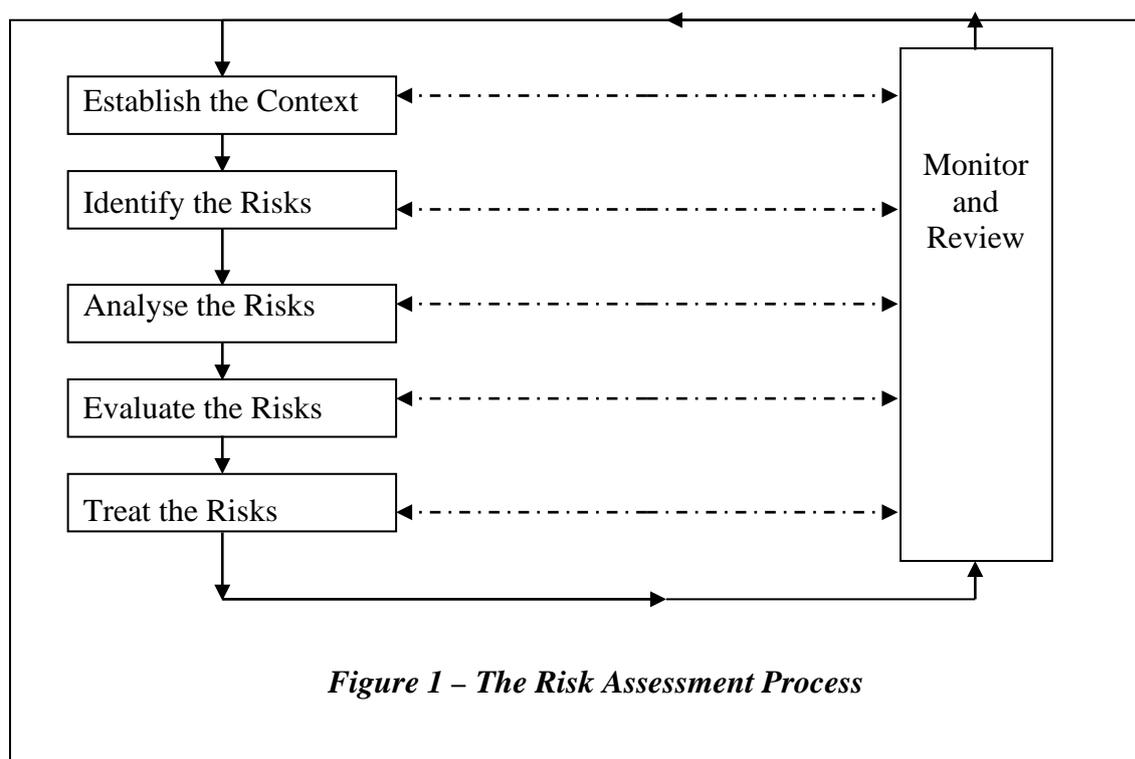
Beyond analysis of conceivable events, decision makers are concerned with the degree of risk associated with following a particular course of action and the response required to control the impact of the hazard. Comprehensive analysis of activities will identify those risks where government intervention will produce the greatest gains or where the directing of government resources will generate only marginal gains.

The following seeks to provide a generic framework to facilitate the identification, analysis, evaluation, treatment and monitoring of risk for regulatory bodies.

The Risk Assessment Process

It is through strategic analysis of the environment in which the regulatory body operates that those elements that may generate future risks will be identified and assessed. The objective of risk analysis is to develop efficient and effective risk management strategies through the analysis of data to assist in the identification, assessment and management of risk.

Figure 1 is a graphical depiction of the risk assessment process.



Establishing the context

The strategic and organisational context within which the processes for risk assessment are to take place must be established by the regulator. Part of this process is to prioritise risks according to their significance to the regulatory body. The structure of regulatory compliance regimes should therefore reflect risk assessment processes whereby risks are identified, assessed and strategically managed. A well structured systematic risk assessment process provides the basis for engaging in best regulatory practice. Monitoring and reviewing the performance of the regulatory regime in managing the risk is essential to ensure the strategies employed continue to reflect the priorities of government.

Considering the multitude of risks faced on a daily basis it is necessary to distinguish between these risks in terms of the probability of the hazard occurring and their potential to cause harm. Not only must the regulator understand why the hazard came into existence and what the potential consequences are, but they must also comprehend the magnitude of the risk involved. It is advisable for the regulatory body to have identified certain criteria against which they can assess the probability of the risk causing harm.

Inherent in developing an understanding of the potential risk factors is an acknowledgment of the existing control barriers in place to guard against potential hazards. Analysis of the existing regulatory infrastructure, coupled with an understanding of the environment in which the regulatory body operates, will combine to produce an estimated level of risk.

The identified risks are then placed in perspective against those risks previously regarded as government priorities. Certain hazards for example, may be particularly inauspicious but have a low risk or likelihood of occurring. Other hazards however, may have a smaller detrimental effect but have a high risk or probability of occurring. The perceived level of risk

will direct government resources where they will produce the greatest gains. Low priority risks may be accepted and monitored accordingly, while higher priority hazards may require the development and implementation of risk management strategies.

Risk identification

Identifying sources of risk and areas of impact provides a framework for risk analysis. The following sources of risk are generally identified as generic in nature:

- Legal environment - the ability of regulators to take action and the ability of injured parties to take action;
- Size of manufacturers - the likelihood that small opportunistic organisations might produce defective products, or that large organisations will systematically undermine the regulatory regime based on their own risk strategies;
- Reliance of citizens on the regulatory regime - the degree to which consumers do not make individual separate assessment of a product's safety;
- Political and international factors - relationships between economies which may impede or assist direct action against imports from another economy;
- Technological growth - the degree to which the rate of technological growth can introduce new products on to the market place;
- Self regulation - the degree of controls internal to an industry and the manner in which the behaviour of business in that industry is regulated; and
- Business culture - the extent to which businesses place importance on trade names, trade marks and commercial goodwill.

Analysis of the likelihood and consequences of a risk occurring is a subjective task, founded on judgements and assumptions where information may be incomplete. To minimise subjective biases, the analysis should be based on information gathered from past records; relevant experience; industry practice and experience; relevant published literature; test marketing and market research; experiments and prototypes; economic, engineering or other models; and specialist and expert judgements.

A well structured systematic process is critical to identifying those risks that will require government attention. Risk identification therefore involves the use of both prospective and retrospective intelligence to develop an appreciation of existing and developing risks.

A preliminary screening of the identified risks provides for an efficient allocation of resources between low consequence risks and those requiring a more detailed review. Identification of risks at this stage is critical to ensure they are not excluded from analysis at a later stage. Following identification of the risks, it is necessary to generate a comprehensive list of events to consider the causes and scenarios that may eventuate. The specific nature of the risk can then be assessed against a standard list of events.

Approaches to risk identification may range from basic management practices to scientific engineering techniques. Standard checklists, records, flow charts, brainstorming, systems analysis, scenario analysis and systems engineering techniques can all be employed to assist in the identification of risks.

Risk analysis

In addition to ensuring accurate information from which to conduct risk analysis, it is essential that the techniques employed to gather the information are reliable and authoritative. Recognised practices include: structured interviews with experts in the area of interest; the use of multi-disciplinary groups of experts; individual evaluations using questionnaires; the use of computer and other modelling; and the use of fault trees and event trees.

Depending on the information and the data available on the risks identified, risk analysis can be undertaken to varying degrees of refinement. The complexity and costs of these analyses increase in range from qualitative, semi-quantitative to quantitative analysis. In practice, qualitative analysis is preferred as an initial screening activity to identify risks that require more detailed analysis. Qualitative analysis utilises the word form or descriptive scales to describe the probability of an event arising and its consequences. Such analysis is often conducted where the level of risk does not justify the time and effort required for a more detailed study.

Semi-quantitative analysis produces a more substantial account of the relationship between the probability and the consequence of an event occurring. Semi-quantitative analysis attributes values to the scales identified in qualitative analysis, seeking to reflect relativities in the data under analysis. The number allocated to each description is not required to reflect an accurate relationship between the magnitude of the likelihood or consequence of the event. The numbers can thus be combined by any one of a range of formulae provided that the system used for prioritisation matches the system chosen for assigning numbers and combining them. Inconsistent outcomes may result, however, if the numbers chosen do not reflect existing relativities.

The likelihood and consequences of a risk occurring can also be assessed on the basis of quantitative analysis. Quantitative analysis provides for consequences to be estimated by modelling the outcomes of an event or set of events. The consequence, or impact, of risk may be quantified in terms of dollars, technical, human, or other criteria. As such, the quality of the analysis will depend on the accuracy and completeness of the numerical values assigned. Considering the nature of quantitative analysis and the capacity for imprecise measures of estimates, a sensitivity analysis should be conducted to test the effect of changes in assumptions and data. Sensitivity analysis is designed to establish the capacity for the results of the risk assessment process to change in accordance with variations in the assumptions upon which the research was based.

Risk evaluation

Risk evaluation is concerned with the comparison of the level of risk identified during the analysis process with previously established risk criteria. Risk evaluation produces a prioritised list of risks upon which further action to manage the events can be based. In order to ensure meaningful comparisons, it is necessary to ensure risk evaluation employs the method of research utilised in the preceding stages of risk analysis. Qualitative evaluation thus involves comparison of a qualitative level of risk against qualitative criteria, while quantitative evaluation estimates level of risk against criteria which may be expressed as a specific number or value.

Risk evaluation should be performed with the view of acquiring a broad perspective of the context of the risk, including detailed consideration of the tolerability of the risks borne by elements within the broader community. While minimal treatment may be required if a risk is deemed to be of low or acceptable proportions, such risks should be subject to additional monitoring and review on a periodical basis to ensure they remain at acceptable levels.

Risk treatment

Risk treatment defines the process of identifying the range of options available for treating risk, assessing those options, and the preparation of plans for risk treatment and its implementation. The decision to follow a particular course of action, such as the institution of pre-market conformity assessment processes, will require analysis of the various contributors to the overall risk and evaluation of how to effectively manage that risk.

The allocation of resources for the purpose of risk assessment should be considered according to the ability of the regulatory body to manage the effects of the risk and/or the potential to benefit from opportunities that may flow from the risk. The allocation of resources should take account of the need to carefully consider the cost of providing additional funding against the benefits that can be derived from doing so. Rare but consequential risks for example, may require significant resource allocations that are not justifiable on strictly economic grounds.

A plan for risk treatment should identify in detail the responsibilities, schedules, the expected outcome of treatments, budgeting, performance measures and the review processes that are to be set in place. Within this plan it is essential that a mechanism for assessing the implementation of the options against performance criteria and objectives be established to monitor critical stages within the implementation process.

Monitoring and review

The systematic review of risk strategies is an integral part of the risk management process. In addition to assessing risks, the effectiveness of risk treatment plans and strategies should be evaluated as a means of reviewing the implementation process. Risks and effectiveness of control measures need to be monitored to ensure they reflect the risk priorities and strategic plans of management. The risk assessment process must be regularly reviewed to ensure the likelihood and consequences of an event remain current, and the suitability or cost of the treatment remains unchanged.

Appendix 2 ESTABLISHING A REGULATORY REGIME

This annex is to provide guidance to member economies in implementing good regulatory practices. It works through the elements of good regulatory practices with respect to the electrical and electronic equipment sector.

While this annex focuses on electrical and electronic equipment, it will serve as a guide to the implementation of good regulatory practices in other sectors.

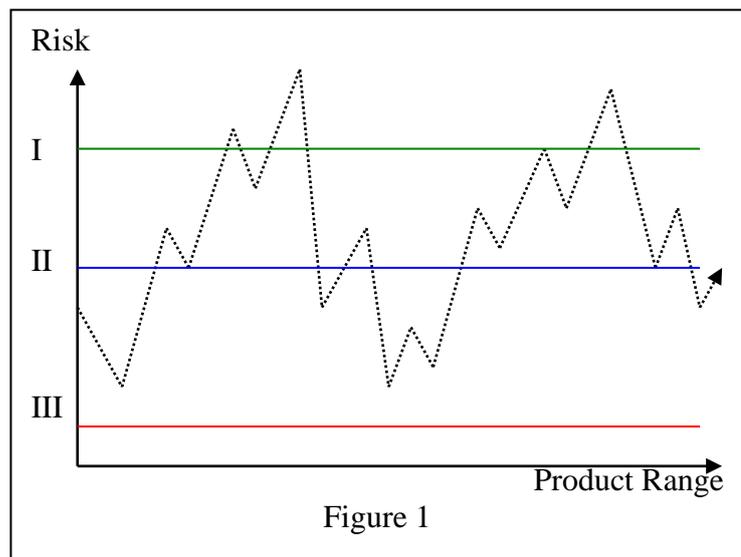
Risks

All products pose an inherent risk to health and safety. Some products pose high risks (for example: pharmaceuticals, medical devices and foods) while others pose low risks (for example: mechanical hand tools). Even within a sector, such as electrical and electronic equipment, products have varying degrees of risk. Electrical and electronic products in which there is the potential for direct and/or indirect contact with 'live' elements (for example: toasters, room heaters, water heaters and track lighting) have a higher risk than other electrical and electronic equipment.

Regulatory Safety Net

As indicated in Chapter 5, the nature of any regulatory safety net plays a significant role in the choice of alternatives to regulation and in any risk assessment in relation to the setting of technical regulations and the choice of conformity assessment regimes.

The variance in the risk posed by electrical and electronic equipment is graphically represented by the dotted line in Figure 1. The strength of different regulatory safety nets is depicted in Figure 1 by the horizontal lines I, II and III.



Where the regulatory safety net is strong (as depicted by Line I), member economies can adopt more flexible and efficient standards and conformity assessment regimes which

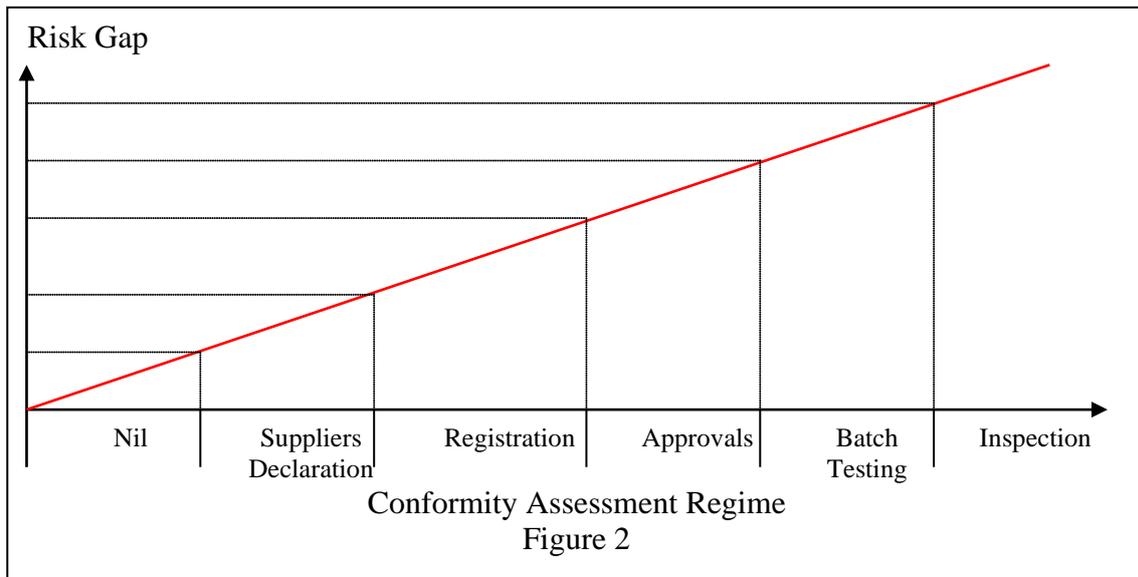
promote technical and economic development. As the strength of the regulatory safety net reduces, the level of risk which the regulatory safety net can account for decreases. That is, the gap between the risk which can be accommodated by the regulatory safety net and the risk posed by the product increases.

In Figure 1, this is shown by an increase in the area under the dotted ‘risk’ line as the ‘regulatory safety net’ lines (I, II and II) drop. Regulation is the means often used by governments to mitigate or regulate this risk gap.

Regulating the Risk Gap

Before looking at the regulatory solutions to mitigating the risk gap, it should be remembered that there are mechanisms, other than the development of technical regulations and mandatory conformity assessment regimes, that can be used. These alternative mechanisms are outlined in Chapter 2 of the *Information Notes on Good Regulatory Practice*.

However, should none of these alternative methods achieve the objective of government, and regulatory intervention become necessary, the following discussion outlines the steps to be taken in selecting the appropriate conformity assessment regime.



As outlined in Chapter 2 of the *Information Notes on Good Regulatory Practice*, the choice of appropriate conformity assessment regime is dependant on the level of risk, or risk gap, that needs to be regulated and controlled. As depicted in Figure 2, for low level risk less invasive and more efficient conformity assessment regimes such as suppliers’ declarations can be used. As the level of risk increases, then more invasive conformity assessment regimes such as approvals and inspections may need to be employed.

It should be remembered, however, that the conformity assessment regime chosen need only apply to those electrical and electronic equipment products for which there is a higher level of risk. The chosen conformity assessment regime need not apply to all products within this sector.

