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Department:
Trade and Industry
REPUBLIC OF SOUTH AFRICA

GOVERNMENT STRATEGY TOWARDS AN EFFICIENT NATIONAL TECHNICAL REGULATORY FRAMEWORK (NTRF) FOR SOUTH AFRICA

FOREWORD

The Strategy Towards an Efficient National Technical Regulatory Framework (NTRF) for South Africa is published for public comment as well as to invite voluntary implementation of the NTRF by all formulators and implementers of technical regulations in South Africa. Voluntary implementation means utilising this Framework as a guideline for formulating new technical regulations and reviewing existing technical regulations.

The purpose of the NTRF is to establish a common South African approach to the country's technical regulatory responsibilities. In addition the framework ensures that South Africa's technical regulations comply with international requirements and that they are responsive to the changing needs of the economy.

The principles put forward in this document are underpinned by international best practice. These principles include transparency, the use of international standards, necessity, proportionality and the use of the least trade restrictive measures.

The publication of the NTRF follows on a process of consultation of relevant government departments as well as the social partners labour and business through NEDLAC. Further comments are invited and should be sent to NTRF@thedti.gov.za by 31 December 2006. For more information contact: esteyn@thedti.gov.za.

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Date:26/09/2006

GOVERNMENT STRATEGY TOWARDS AN EFFICIENT NATIONAL TECHNICAL REGULATORY FRAMEWORK (NTRF) FOR SOUTH AFRICA

1. Purpose

The purpose of the Strategy Towards an Efficient National Technical Regulatory Framework (NTRF) for South Africa is to improve and establish a common South African approach in terms of its technical regulatory responsibilities. In addition the framework ensures that South Africa's technical regulations comply with international requirements and that they are responsive to the changing needs of the economy.

2. Introduction

The last quarter of the previous century has seen tariff barriers to trade coming down and the volume of cross-border trade and investment growing rapidly. National economies have increasingly been integrated into an interdependent global economic system that requires conformance to rules, norms and standards adopted by the international trade community. Whilst the World Trade Organisation (WTO) succeeded in promoting a decrease in tariff barriers towards increased trade between nations, the world has witnessed a rise in non-tariff trade barriers such as subsidies, quotas, anti–dumping policies and regulations, including technical regulations.

Technical regulations arise firstly because national economies recognise the obligation to protect human and animal health and safety and the environment, and secondly to maintain a balance between divergent interests for example trade interests vs. protecting of domestic industries. Compliance to the technical regulations of some countries and/or regions has become a key challenge to international trade. Inter-country differences and the complex nature of technical regulatory issues have led to various international processes of harmonisation.

The concept of a national technical regulatory framework (NTRF) could be defined as an inter-related constellation of all technical regulations in a particular country. A well-structured and harmonised NTRF is an important condition for sustaining and expanding any economy as a competitive player in the world trading system. A properly functioning technical regulatory system will benefit the economy in terms of balancing regulatory and trade interests, reducing unintended effects, eliminating technical barriers to trade, providing critical market information, improving the quality and consistency of technical regulations and complying with international requirements.

The government regards an efficient national technical regulatory framework to be of crucial importance to economic development. Establishment of such a national framework would impact positively on competitive trade, small

enterprise development, broad based black economic empowerment (BBBEE) and job creation, and attract investment. Consumers, regulatory bodies, producers, manufacturers, processors, importers and exporters will benefit equally from an effective technical regulatory system. The challenge for South Africa is to develop a system that takes account of its legislative and political system and reflects its economic, social and political environment and values. The system should respect the discretion of policy makers in balancing the complexities and trade-offs between market competitiveness and legitimate measures.

Core principles for a national technical regulatory framework (NTRF) would include:

- Transparency;
- The use of the least trade restrictive measures;
- Internationally harmonised measures;
- Necessity;
- Proportionality; and
- Non- discrimination.

South Africa's technical regulatory infrastructure includes the following institutions and legislation:

- National Standards Authority
- National Accreditation System
- National Metrology Laboratory
- A wide range of accredited bodies including laboratories, verification, laboratories, certification and inspection bodies
- Regulators (including government departments that are regulators)
- Legislators

Based on international best practice the main features of an efficient NTRF would include:

- Consultation and participation;
- The use of impact and risk assessment tools;
- Exchange of information;

- The codification of technical regulatory process as well as consultation and research processes;
- The use of performance based standards;
- Strong linkages between technical regulations and internationally harmonised standards;
- The regular review, update and modification of technical regulations to meet changing needs; and
- Co-ordination amongst various institutions that are part of the technical regulatory infrastructure.

The strategic direction these features indicate for South Africa is addressed in par. 9 below. In addition to addressing the issues raised above this strategy presents the variety of actions that would constitute a successful strategy towards an efficient NTRF for South Africa. It also deals with the need to consult with business, labour, consumers, regulators and other key stakeholders. Stakeholder inputs have been used to refine the original policy proposals. This strategy follows on from the Government Discussion document on Modernising Technical Regulatory Infrastructure and will guide legislative processes and inform mandates for the relevant departments and their regulators.

3. What is a Technical Regulation?

Technical regulations lay down compulsory requirements for product or service characteristics or their related processes and production methods and have specific administrative provisions and conformity assessment requirements with which compliance is mandatory with regard to safety, health, environmental control and consumer protection.

Technical regulations reflect the values of a government and the society it serves. It represents the relevant country's measures to deal with specific economic, social and political issues and values.

4. Multilateral Trade Responses to Technical Regulations

The WTO Agreement on Technical Barriers to Trade (TBT) codifies multilateral responses to technical regulations and defines the rights and obligations of countries in their trading relations in terms of the use of technical regulations.

The following principles have emerged as concepts employed in the multilateral trading system and most of them are included in the WTO TBT agreement. The aim is to provide countries with a uniform set of principles that could be applied to achieve an optimal balance of rights and obligations in their trading relations in terms of the use of technical regulations:

- **Non-discrimination Principle** Under the Most Favoured Nation and National Treatment Provisions. The non-discriminatory principle of the most-favoured nation and national treatment provisions of the TBT agreement (Article 2.1) provides for the equal treatment of products in terms of technical regulations. Technical regulations should not discriminate between products on the basis of their country of origin and should allow for equality of competitive opportunities between like products and services from all trading partners. This principle should be applied through all the different stages of preparing, adopting and applying technical regulations and conformity assessment procedures in order to ensure equal treatment of products in terms of technical regulations

- **The Necessity Principle** implies that governments should be able to justify their interventions. The principle also attempts to address those instances where countries create domestic technical regulations that could discriminate against possible imports. Article 2.2 of the TBT agreement would sanction such regulations if they were considered necessary for the efficient attainment of legitimate domestic policy goals with regard to safety, health, environmental control and

consumer protection. The ultimate test for necessity should be that alternative options would not be able to fulfil the objective. The risk of non-fulfilment should be assessed against factors such as available scientific and technical information, processing technology and end-uses of products. The ideal is an optimal balance of rights and obligations.

- **Prevention of Trade Restrictiveness**: This principle requires legislators to choose technical regulations that cause the least distortion to trade. This approach would prevent technical regulations to become an unnecessary technical barrier to international trade (Article 2.3 of the TBT agreement). Targeting may be a key tool for meeting the 'prevention of trade restrictions' principle. Targeting implies that technical regulations should focus on the core problem and that unintended effects should be prevented.

- **The Proportionality Principle** implies that government only intervenes when it is necessary, that remedies should be appropriate to risk and that cost should be identified and minimised. Cost would refer to both the regulator and regulated and should be in proportion to the benefit that the regulation is expected to bring. It also implies that domestic technical regulations should not be more burdensome to foreign investors and exporters and that sanctions in the event of non-compliance should be proportionate to the benefit.

- **Principle of Harmonised Measures**. The TBT Agreement encourages the use of internationally harmonised technical regulations to improve production efficiency, facilitate free trade and minimize any negative effects of domestic technical regulations on trade (Article 2.4 and 2.5 of the TBT agreement). Appropriate internationally harmonised measures furthermore imply the use of essential parts of international standards in performance based technical regulations.

- **Mutual Recognition of Equivalent Regulatory Measures**. Regulatory objectives of trading partners are often equivalent although their technical regulations may differ. Trade opportunities could be expanded through mutual recognition of the equivalence of each other's technical requirements for products or services and of each other's conformity assessment procedures. The TBT Agreement identifies criteria for mutual recognition. Firstly, trading partners should be confident that their different but equivalent regulations/technical requirements adequately fulfil the same objectives. Secondly, trading partners should be confident that conformity procedures of other countries offer an equivalent assurance of conformity with the applicable regulation. The WTO TBT Agreement recommends that trading partners give positive consideration to accepting 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 (Article 2.7 and 6.1 of the TBT agreement).

- **Maintain Transparency**. This principle implies that the technical regulatory processes and the technical regulatory system should be open, accessible, simple and user friendly. The TBT agreement requires that countries should publish technical regulations prior to their entry into force and that a reasonable time should be allowed for comment and for consideration of those comments prior to the adoption of a final technical regulation. This will promote trade certainty and also make it possible for competitors to adapt their products and methods of production as per the technical regulation (Article 2.9 and 2.12 of the TBT agreement).

5. Regional Trade Responses to Technical Regulations

Over the last few years a growing number of regions recognised that technical regulations can create unnecessary barriers to trade, economic efficiency and investment. The other side of the coin is that improvement of technical regulatory quality would sustain and competitively expand economies as part of the world trading system.

The quality of technical regulatory decisions is a matter of mutual concern to countries that are linked by cross-border trade or agreements for technical regulatory harmonisation, mutual recognition or coordination. Governments responded to the pressure for improvement of regional technical regulatory practices by embarking on joint programmes to improve the quality and cost effectiveness of national regulations. The joint programmes questioned long-standing practices and investigated innovative forms of co-operation.

The Organisation for Economic Cooperation and Development (OECD) and the Asian Pacific Economic Community (APEC) respectively developed programmes that were built onto the WTO TBT agreement in an effort to find innovative solutions for technical regulatory harmonisation, mutual recognition and coordination. The two regional initiatives have the following common approaches:

- That the problem that technical regulations will address has to be clearly defined and supported with evidence, establishing the nature and magnitude of the problem and explaining why the problem arose;
- That alternative mechanisms to technical regulations always have to be considered first;
- That performance based regulations and international standards have to be used;
- That conformity assessment requirements have to be clearly defined and that they should reflect the risk levels that were identified;

- That a transparent and predictable technical regulatory system is important and provision has to be made for participation, consultation, publication and comment periods;
- That intergovernmental and inter regulatory coordination and participation has to be promoted to avoid inconsistency, incompatibility or duplicative technical regulations;
- That impact and risk assessment analysis are important tools that policy makers and regulators can use to choose appropriate technical regulatory responses;
- That technical regulations have to be continuously monitored and reviewed

6. National Trade Responses to Technical Regulations

At a national level countries have shifted their focus from deregulation to regulatory reform with the focus on the improvement of the quality and efficiency of national technical regulatory systems. Some of the commonalities in national technical regulatory approaches are the following:

- The philosophy that technical regulations have to be sensible, reasonable and based on sound science and economics and that there has to be a balance between the benefits and the burdens and costs of technical regulations.
- The provision of guiding principles and guidelines to enhance the quality of technical regulations.
- The requirement that technical regulations have to be developed in a transparent, effective and open manner.
- The use of negotiated mechanisms for the development of technical regulations and the provision of a code of practice for consultation.
- The use of international standards and conformity assessment requirements when technical regulations are developed.
- The use of performance based standards rather than prescriptive standards. (Prescriptive would specify the means for attaining the specified outcome; and performance-based would specify the desired objective in precise terms but allow the regulated enterprise to determine their own technique for achieving the outcome)
- The conducting of technical regulatory impact and risk assessment analysis for each proposed new or amended technical regulation.
- The regular review of technical regulations and the use of sunset clauses.

Technical regulations should contain appropriate but flexible 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 and preventative actions by regulators.

7. Emerging Best Technical Regulatory Practices and Challenges

Best practice patterns in terms of technical regulatory approaches are evident in terms of transparency, the use of least trade restrictive forms of technical regulation and the use of internationally harmonised standards and technical regulations.

Transparency is considered to be one of the most important building blocks of a good technical regulatory system. The key elements of a transparent system are effective access to existing technical regulations and systematic information of technical regulations in the making. A transparent system also facilitates effective and appropriative participation by and consultation with stakeholders. The benefit of a transparent system is that it makes the technical regulatory system predictable and clear, thus providing for certainty. The codification of the technical regulatory process, supplemented with policies relating to the technical regulatory activities and detailed guidance on processes could guide policy makers when they develop, implement and monitor technical regulations.

Regions that have successfully reviewed technical regulations made use of a stakeholder interaction approach.

In order to prevent unnecessary trade restrictiveness, policy makers increasingly use technical regulatory impact and risk analysis to inform their decision-making processes. Tools used to ensure consistent high quality and effective technical regulations include guidelines and checklists on consultation, impact and risk assessment tools, and research. These tools are often supported by training of the technical regulatory officials who are responsible for the preparation of technical regulatory impact assessments. Coordination at interdepartmental level prevents duplication, inconsistency and incompatibility of technical regulations. The use of international performance-based standards as a basis for domestic technical regulations is recognised and accepted as best practise.

It is difficult to identify clear patterns in terms of conformity assessment, as a variety of approaches to streamline conformity assessment processes are in use. Best practice approaches in the area of equivalence are also not forthcoming. The establishment of internationally recognised national accreditation mechanisms and networks are increasingly useful to enhance confidence in the efficiency of conformity assessment activities. These national accreditation institutions are actively establishing an international network that allows the acceptance of results and eliminate duplicative efforts. The aim of these streamlining efforts is to have a test-once, certify-once or inspect-once approach that is accepted by others. It also aims to introduce competition to the conformity assessment market and potentially reduces the cost borne by manufacturers in certifying and testing their products.

8. Current Approaches To Technical Regulations in South Africa

In South Africa various national line function departments are responsible for technical regulations. Due to the absence of a central coordinating system for technical regulations there appears to be some gaps and well as areas of overlap between national departments in respect of coverage. This suggests that the regulatory system is fragmented, that access to information on existing and proposed technical regulations may be problematic and that the system may be unpredictable and unclear.

Although National Departments use stakeholder consultation processes when technical regulations are developed, there is no consistent national approach.

The challenge for line function departments is to provide for balance and uniformity in terms of representation in consultation and to establish mechanisms and structures where gaps exist. Significant variations between the approaches to the notification of technical regulations to the WTO and domestic publication of technical regulations for comment constitute additional causes of concern.

Although a number of mechanisms exist to promote co-ordination amongst government departments, regulators and other technical regulatory organisations like the conclusion of bilateral memorandums of understanding, significant room for improvement exists in this area.

8.1. Gaps to be addressed

Government will prioritise, resource and address the following gaps:

- The technical regulatory process as set out in 5, 6 and 7 above must be codified which would cover checklists, manuals and guidelines on consultation processes. These codes will be developed as a priority to guide policy makers in developing, implementing and monitoring technical regulations.
- The establishment and maintenance of a compendium of technical regulations will be considered.

- Technical regulations have the potential to impact negatively on trade and investment and small businesses. Risk assessment and analysis will be used as tools to ensure effective technical regulations that are reasonable and practical.
- A need has been identified for government support in order to provide training for technical regulatory officials that are responsible for the preparation of technical regulations. In this regard appropriate investment in information and human resources will be made.
- Government intends to introduce a systematically organised technical regulatory reform process and will establish the necessary institutional arrangements in the course of this process.
- The fact that both outcomes-based technical regulations as well as technical regulations containing prescriptive product characteristics are used in South Africa means that some trade restrictive forms of technical regulations may be in place and will be reviewed.
- Stakeholder consultation mechanisms that are in line with international best practice will be introduced.
- A standardised approach to notification to the WTO TBT will be developed.

8.2. Strengths that government should capitalise on

- The principle of using or referencing standards in technical regulations is well established in South Africa. Government understand that the use of international standards facilitates access to national and international markets and eliminates technical barriers to trade.

- The use of performance-based regulations provides for flexibility whilst ensuring that the objectives are achieved. Performance based technical regulations are generally preferred because they represent a more flexible approach and allow those that are regulated to devise the most efficient and effective method of compliance.

- It is encouraging to see that the South African accreditation system has achieved a high level of international recognition. The public sector has also started to take advantage of the benefits of the system.

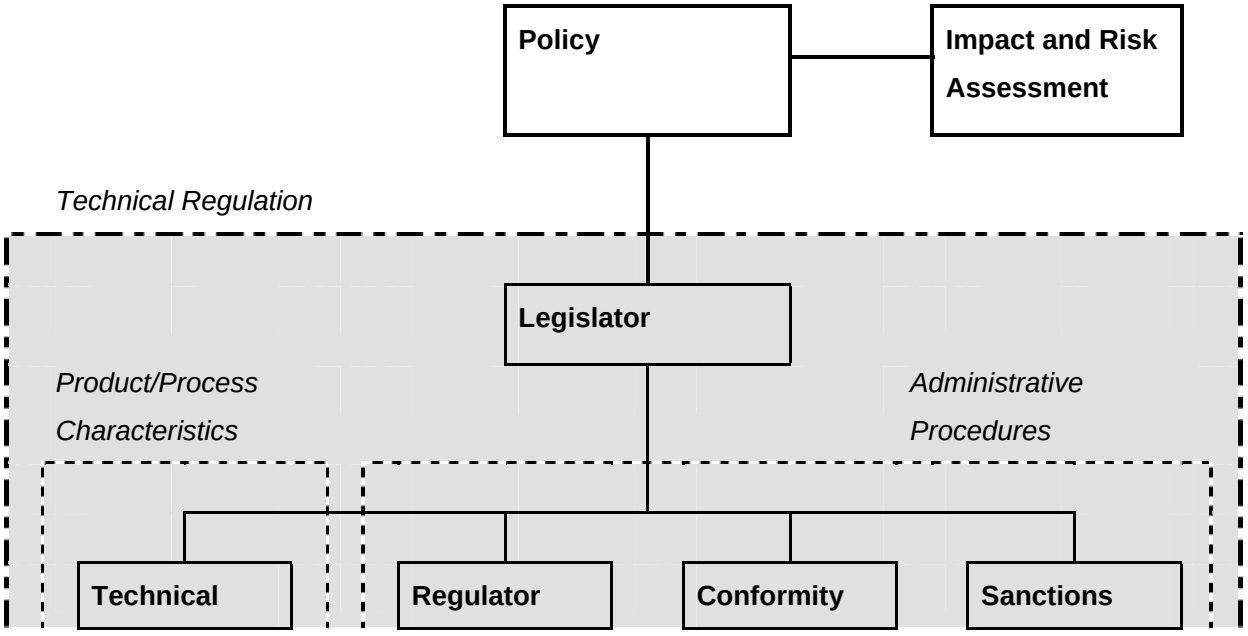
9. Formulation of a National Technical Regulatory Framework (NTRF)

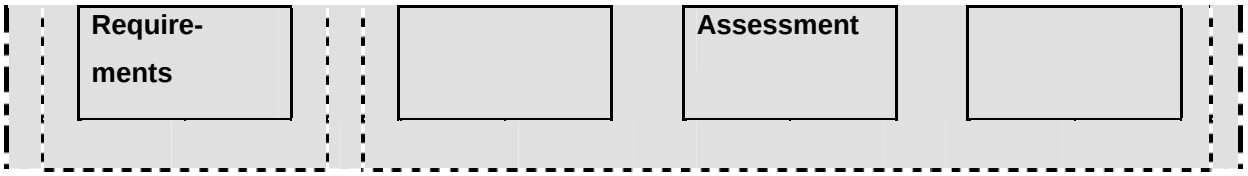
Government will introduce international best practice with respect to national technical regulatory frameworks, which includes the adoption of the principles that have emerged as concepts employed in the multilateral trading system, and alluded to in the WTO TBT agreement, as the principles of the national technical regulatory framework (NTRF). The principles include: non-discrimination, necessity, prevention of trade restrictiveness, proportionality, the use of equivalent and internationally harmonised measures and transparency.

The NTRF would be based on the following internationally accepted elements of technical regulatory infrastructure:

- The legislator;
- Technical requirements;
- The regulator;
- Conformity assessment; and
- Sanctions for non-compliance.

Figure 1: Elements of Technical Infrastructure Underpinning the National Technical Regulatory Framework (NTRF)





9.1 NTRF and the Legislator

Government as legislator is increasingly focusing on systematic analysis and review of both existing and new technical regulatory proposals. Two main drivers give rise to this focus - the desire of government to efficiently and effectively manage their technical regulatory responsibilities and the desire of those to which the technical regulation applies for an efficient and effective regulatory and compliance system. Regular reviews, updating and modification of technical regulations and the use of sunset clauses are key to the relevance of technical regulations within an environment of changing needs.

A significant challenge for the legislator is to keep regulatory intervention in the South African economy to the necessary minimum whilst achieving the objectives of government in terms of protecting the health and safety of society and the environment. The proposed interventions are intended to promote innovation and competition amongst businesses and thereby ensure benefits to consumers and society in general. Gains to South Africa would include an increasingly open, transparent and predictable economic system where environmental and social interests are supported without excessive technical regulations being imposed on business. Therefore, before implementing any technical regulation and/or compulsory requirement, government would consider all available options to achieve the desired objective, for example reliance on general law, educational programmes, voluntary standards, economic instruments, insurance and liability laws, codes of conduct/practice, industry self regulation and co-regulation. Even when choosing the technical regulatory option government will favour the adoption of the minimum effective technical regulation necessary to achieve the desired outcomes.

A formal stakeholder interaction approach to technical regulations is proposed. This approach will increase the transparency of the process and ensure that all perspectives on the issues have been considered. It is a useful means of evaluating the accuracy of assessment of the costs and benefits enhancing awareness and thus encouraging compliance.

Policy-makers and regulators will use impact and risk assessment and other analytical tools to inform decisions. The process will be sensitive to the specific social, economic and political environment in South Africa. It will be aimed at enabling policymakers to choose reasonable and practical technical regulations that are designed to impose the lowest costs and yield the greatest benefits. Accurate problem definition will reduce the risks of inappropriate options for government action and the likelihood of over regulation.

Over-regulation occurs where the extent and/or nature of a regulation exceeds what is needed to address a problem. This would result in un-justified additional costs to the economy, for example through increased production costs, or reduced competition, innovation and customer choice.

Risk assessment would consider the following aspects:

- The objectives of the technical regulation,
- The quantifiable risks that the technical regulation is addressing,
- The options and alternatives to technical regulations,
- The business sectors that will be affected,
- The equity and fairness issues if any,
- The benefits, costs and socio-economic impacts of each option and a comparison of the options. This includes cost and benefits to firms, small and medium enterprises, the public sector, consumers, individuals, the environment, and the economy at large.
- The identification of any potential risks associated with each option, e.g. the ability of regulators to take action, the ability of the injured parties to take action, the probability that enterprises might produce defective products, the probability that enterprises may fail to comply,

reliance of consumers on the technical regulation, rate of technological growth, degree of self regulation internal to an industry and the extent to which the business place importance on trademarks, trade names and commercial goodwill.

- The distributional impacts, if any, e.g. transfer of income, redistribution of opportunities, etc.
- The sectors (society or industry) that will bear the costs and benefits of each option and
- The unintended consequences and indirect costs, if any, and how they will be addressed.
- A recommendation for the preferred option, with a motivation in terms of the impact assessment analysis and in particular with a focus on the costs and benefits of the option.

Risk assessment would make provision for:

- Conformity assessment and compliance requirements;
- Enforcement arrangements; and
- Consultation with relevant stakeholders and the establishment of appropriate forums for consultation. These forums will be representative of relevant government departments: both national and provincial; business and industry associations: large, medium and small; labour unions; consumer bodies; academia and technical experts.

Beyond consultation with domestic parties and the publication of technical regulations in the government gazette, notification to the WTO through the WTO TBT Secretariat, of the products to be covered by the proposed technical regulation, will be done at an appropriate stage, when comments can still be taken into account and amendments introduced.

Continuous monitoring and review of technical regulations are important as this ensures that technical regulations remain current, do not become outdated or over-burdensome and are corrected if justified.

9.2 NTRF and the Regulator

For the purposes of these policy proposals the regulator includes national and provincial government departments, local authorities and regulatory agencies established by legislation.

The regulator carries out the mandate of the legislator to oversee implementation and administration of technical regulations. The regulator is assigned the appropriate regulatory powers through legislation to enable it to oversee the implementation of technical regulations, identify and recognise competent conformity assessment service providers and enforce sanctions. Coherence to the principles and guidelines in this policy will require the regulator to administer the technical regulations in an open, transparent and predictable way.

In all cases the cost of pre-market conformity assessment is borne by the supplier.

Depending on the objective and risk assessment, a technical regulation may require the regulator to approve a commodity prior to the supplier distributing it. The regulator would issue such approval based on conformity assessment evidence submitted by a third party service provider such as an accredited laboratory.

Where accreditation of the third party conformity assessment service provider is available, the regulator will prescribe the use of accredited service providers. The South African National Accreditation System (SANAS) accredits bodies against international criteria. Regulators may supplement these criteria depending on the specific conformity assessment required for the regulator. These criteria will then be assessed as part of the scope of assessment. Regulators will be encouraged to participate in the Specialist Technical Committees of SANAS established to establish accreditation criteria for specific purposes.

Approval of any conformity assessment body required in terms of a regulation rests with the regulator. The regulator is responsible for taking all necessary actions for infringement of the criteria for approval. SANAS would take all necessary actions for those facilities not complying with the accreditation criteria, as is normal practice. The regulator retains the responsibility for enforcing punitive actions.

All accredited bodies will be eligible for approval by the regulator to undertake the conformity assessment in terms of regulation. Regulators may, where they so choose, require supplementary criteria in addition to the normal accreditation competency criteria.

This will enable a level playing field and also open the field up for other competent accredited facilities to participate.

In those areas where no accredited facilities exist, regulators will insist on accreditation of those facilities that wish to participate, within a fixed time period. Further discussion required. In this instance the regulators should identify interim basic criteria that such facilities should meet as an interim measure. This would also allow for other organisations to apply and not be discriminated against in favour of others based on no written criteria, except preference.

Regulators will conduct market surveillance in order to identify products that do not meet the technical requirements. Sanctions will be applied to distributors of non-compliant products. Inspection bodies responsible for market surveillance will require to be accredited by SANAS.

9.3 NTRF Approach to Performance Based Technical Regulations

There are two main types of technical regulations:

Prescriptive technical regulations which specify the means for attaining the specified outcome; and

Performance based technical regulations, which specify the desired objective in precise terms but allow the regulated entity to determine their own technique for achieving the outcome.

Prescriptive technical 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 technical 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 will 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.

Performance based technical regulations on the other hand represent a more flexible approach and allow regulated enterprises 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.

In order to minimise possible trade barriers technical regulations will be performance based rather than prescriptive in nature, except in cases where this is not possible due to the specific nature of the regulatory control required. One way to achieve this is that technical regulations would include references to optional prescriptive standards (also called deemed-to-comply solutions). Thus compliance can be achieved by using the prescribed deemed-to-comply solutions or by using an alternative solution that can be demonstrated as achieving the technical regulatory objectives.

Applicable international standards will be reviewed for adoption as the basis for technical regulations as the first option. In the event of this approach imposing unnecessary costs on business, only those parts that represent the minimum necessary to fulfil the objective should be used.

A decision to call up international standards in technical regulations should only be taken after the problem that needs to be addressed has been accurately defined and various regulatory options have been considered. The decision should be based on appropriate cost benefit analysis. This approach will ensure that the benefits of regulations are achieved and the costs to business of technical regulations are minimised.

In many sectors voluntary standards provide an important foundation for technical regulations. Voluntary standards however reflect a wide range of perspectives and needs, resulting in requirements, which, while desirable, may not be essential to fulfil legitimate regulatory objectives. It is the regulator‘s responsibility to determine the minimum requirement necessary to fulfil the objective of the technical regulations.

Regulators will participate in the voluntary activities for consensus standards development where a possibility exists that these will be used as the basis of technical regulations. Regulator participation in the technical committees responsible for development of voluntary standards is recognized as an integral part of the technical regulatory process.

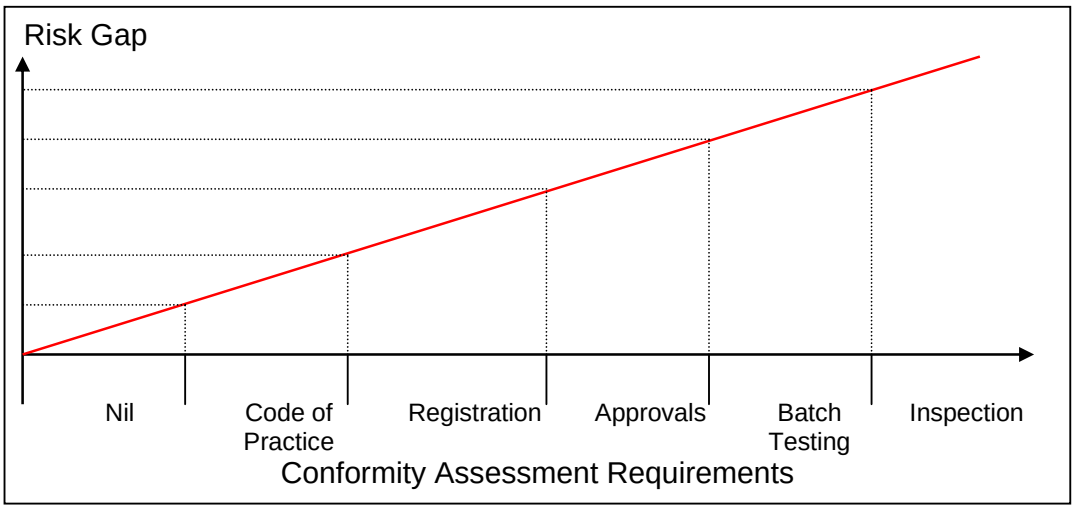
9.4 NTRF Approach to Conformity Assessment Requirements

Conformity assessment is the comprehensive term used for measures taken or required by manufacturers, their customers, regulatory authorities and independent third parties to assess conformity to technical regulations. When deciding on the level of conformity assessment required, consideration must be given to the following issues: the incentives on producers to comply, the level of risk, the costs and the effects on trade.

The level of conformity assessment required also depends on the particular country's regulatory framework. In South Africa product safety is embedded in laws relating to fair trade practices and commerce. South Africa does not have product liability laws. Conformity assessment requirements for South African technical regulations therefore often require that products be assessed prior to entry into the market. Such 'pre-market' conformity assessment regimes often take the form of product approvals, product registrations, licences (import/practice) or inspections. The extent to which pre market assessment is complemented by post market surveillance will be determined on the basis of risk of non-compliance. Post market surveillance is for example required to ensure that the product being offered for sale in the market place has the same performance characteristics as the sample to which approval has originally been granted. Post-market surveillance is also necessary to ensure that supplier declarations are valid.

A technical regulatory system which relies on product certification, where the certification body undertakes some degree of post-market surveillance or auditing as well as quality management system assessment, may require a lower level of post-market surveillance by regulatory bodies. The following model outlines the steps proposed in selecting the appropriate conformity assessment requirements.

Figure 2: Proposed conformity assessment requirements



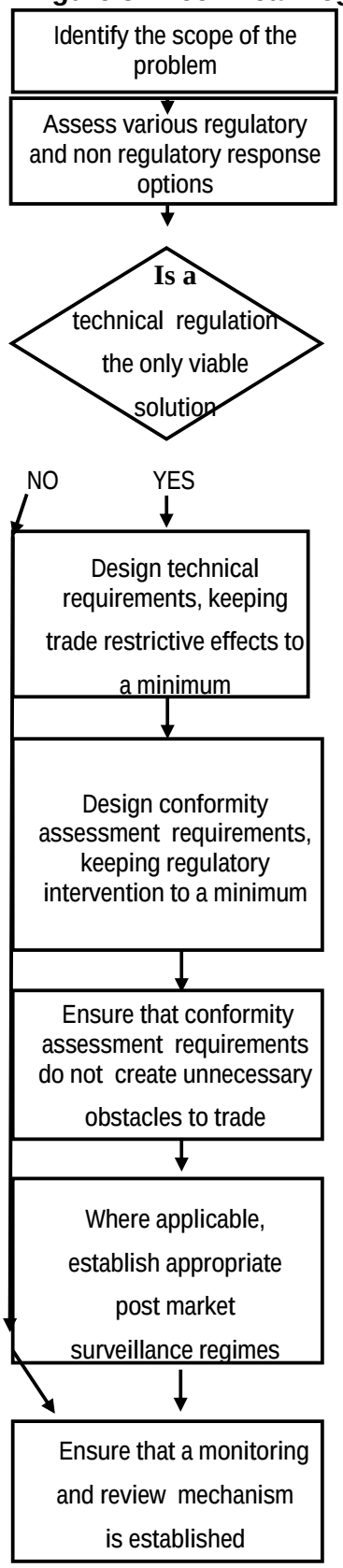
9.5 NTRF Approach to Sanctions for Non-compliance

Technical regulations should contain appropriate but flexible 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 and preventative actions by regulators. Some of these remedies may require that those suppliers detected as supplying non-compliant products incur substantial costs that 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 that are safe and comply with technical regulations. Mechanisms will be introduced to ensure a consistent and balanced approach to the imposition of sanctions.

9.6 Technical Regulatory Flowchart

The flowchart will be applied within the technical regulatory framework, supplemented by a check-list.

Figure 3: Technical Regulatory Flowchart



A clear definition of the problem to be addressed is essential. Problems described to generally may lead to unnecessarily restrictive regulatory responses. Provide clear evidence of its nature and magnitude.

Assess the relative merits of a range of possible responses.

The response chosen, non –regulatory or regulatory should be the one with the greatest net benefit and that is not more restrictive than necessary to fulfil the objective. Consider likely benefits and costs, administrative requirements. Ensure effective and timely input from interested parties such as affected business, trade unions, and other government departments, national and provincial and local. Ensure WTO TBT notification.

Technical regulations should not be prepared, adopted or applied with the effect of creating unnecessary barriers to trade. Departments should therefore, determine the minimum necessary to meet the desired objective and consider:

- the use of performance based regulations;
- the appropriateness of referencing voluntary standards or parts of a voluntary standard;
- the use of international standards or parts thereof

Assess the relative merits of a range of conformity assessment regimes. Select conformity assessment requirements:

- with the least level of interaction between government and business; and
- requiring as little intervention as possible taking into account the risk posed by potential non-compliance.

Accreditation should be used as part of the approval process and as evidence that the conformity assessment service provider is competent for that specific part of the approval process.

Departments should give consideration streamlining of conformity assessment requirements with a view to have a test-once, certify-once or inspect-once approach that will reduce the cost of compliance

Where departments have chosen low interventionist conformity assessment requirements (e.g. type approvals and suppliers declaration) post-market surveillance activities may be necessary to ensure that products comply, or continue to comply, with the relevant technical regulations.

Departments should have in place formalised mechanisms for review of the chosen regulatory response and conformity assessment requirements to ensure that they take into account technological and other changes.

9.7 Proposed Procedure for Operationalisation of the National Technical Regulatory Framework

The National Technical Regulatory Framework set out in this policy will be operationalised over the next three years as follows:

- 2007: Roll-out of the Technical Regulatory Framework Strategy
- 2008: Draft and consult on National Technical Regulatory Framework Bill

9.8 Technical Regulatory Framework Bill

The Bill will provide for inclusion of the elements of the strategy in legislation. In addition the Bill will establish the Interdepartmental Technical Regulatory Committee (ITRC) as a statutory entity. The Bill will bind all organs of state.

Institutional arrangements

9.8.1 Interdepartmental Technical Regulatory Co-ordination Committee (ITRC)

An Interdepartmental Technical Regulatory Committee (ITRC) will be established to ensure effective operationalisation of the strategy, with high-level representatives from relevant national departments and regulators that are responsible for technical regulations. The role of the ITRC will be to ensure co-ordination of technical regulations and to prevent duplication and over-regulation.

9.8.2 Technical Regulatory Office (TRO)

A Technical Regulatory Office (TRO) will be established at the Department of Trade and Industry (**the dti)** and will *inter alia* be responsible for the following functions:

- To offer secretarial services to the Interdepartmental Technical Regulatory Committee (ITRC).
- To initiate a process to develop a technical regulatory checklist, guidelines for technical regulatory impact and risk assessment, and codes of practice for:

(a) Consultation,

(b) The technical regulatory process,

(c) Enforcement; and

(d) The publication and notification of technical regulations.

- To work with all relevant government departments and regulators to promote the technical regulatory principles and provide training for officials responsible for technical regulations on checklists and guidelines.
- To manage the WTO TBT notification point, which will be transferred from its current address to the Technical Regulatory Office
- To facilitate South Africa's participation in the WTO TBT Committee.
- To establish a link between the South African WTO TBT notification point and the enquiry point.
- To establish and maintain a close relationship with the technical infrastructure institutions, i.e. the SABS Standards Division, the South African National Accreditation Body and the National Metrology Laboratory of South Africa, in order to facilitate the use of standards and accreditation in support of technical regulatory activities.
- To establish and maintain of a compendium of national technical regulations
- To facilitate the use of the technical regulatory checklist, guidelines for technical regulatory impact and risk assessment, and codes of practice
- To establish and maintain of case studies of best practice technical regulations
- To provide information that would assist South African companies to overcome technical barriers to trade.

APPENDIX 1

LIST OF FIGURES

APPENDIX 2

BIBLIOGRAPHY

APEC. November 1997 *The Impact of Trade Liberalisation in APEC*

APEC. September 2000. *Information Notes on Good Regulatory Practice for Technical Regulations*

CATEORA, PR & GRAHAM, JL. 2002. *International Marketing*, 11th ed. New York: McGraw Hill

HELD, D & MCGREW, A & GOLDBLATT, D & PERRATON J *Global Transformations, Politics, Economics and Culture,* Polity Press

HILL, CWL. 2002. *International Business, 3rd ed.* New York: McGraw-Hill/Irwin

KOTLER, P & ARMSTRONG, G. 1993. *Marketing An Introduction, 3rd ed.* New Jersey: Prentice-Hall.

MCKINLAY, R. *From Isolation to Integration? The South African Economy in the 1990s.* Chapter 3 *Globalisation: Integration and Control in the World Economy.* Ed.Handley A & Mills G

MILLS, G. 2000. *The Wired Model: South Africa, Foreign Policy and Globalisation.* Cape Town: Tafelberg.

MSF/DND WORKING GROUP. March 2002. *The Globalisation of Regulatory Requirements and the Development and Availability of Medicinal Products in Developing Countries: Quality, Efficacy and Safety Issues*

NATIONAL FOREIGN TRADE COUNCIL. May 2003. *Looking Behind the Curtain: The Growth of Trade Barriers that Ignore Sound Science.* www.nftc.org.

NEDLAC. April 2001. *South African Standards, Quality Assurance, Accreditation and Metrology Review*

O'BRIEN, P 2003. *Technical regulations in SADC: Towards a realistic approach in a changing world.*

OECD. 1993. Occasional Papers in Public Management, Regulatory Management and Reform Series No. 4

OECD. 1995. *Recommendation of the Council of the OECD on Improving the Quality of Government Regulation.*

OECD. 1997. *Report on Regulatory Reform*

OECD. 2002. OECD Reviews of Regulatory Reform.*Regulatory Reform in the United Kingdom.*

OECD. 2003. *Integrating Market Openness into the Regulatory Process: Emerging Patterns in OECD Countries*

Oxfam International. 2002. *Rigged rules and Double Standards: Trade, globalisation and the fight against poverty.*

The dti. 2004. ***dti*** *Technical Regulatory Framework Study.*

The dti. 2004*. Modernising of the South African Technical Infrastructure.*

WTO. 1998. *International Trade Trends and Statistics*

WTO. 1999. Trading into the Future. Revised, April 1999

World Bank. 2002. *World Bank research in Progress on Standards. Chapter 3 The multilateral and regional trade responses to technical barriers.*

United States Mission to the European Union. 2002*. An Overview of the US Regulatory System.* 15 January 2002 www.useu.be

United Nations (Economic and Social Council). 2003. *Overview of the US Legislative Process*. Document no Trade/WP.6/2003/2/Add.1- 22 October 2003

Business Day, Johannesburg, 26 July 1999, *Demystifying the globalisation hype"*

APPENDIX 3

GLOSSARY OF TERMS

CSIR	Council for Scientific and Industrial Research
the dti	Department of Trade and Industry
ISO	International Standards Organisation
NML	National Metrology Laboratory
SABS	South African Bureau of Standards
SADC	Southern African Development Community
TBT	WTO Agreement on Technical Barriers to Trade
WTO	World Trade Organisation