

Towards free, fair and safe trade in Africa

Guidance for the setting-up of a  
**NATIONAL TECHNICAL REGULATORY  
FRAMEWORK**  
(NaTReF)

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Final draft  
7 April 2025

Supported by



## **ACKNOWLEDGEMENTS**

One of the requirements of Africa Quality Policy, adopted in 2021, is the creation of an African Continental Technical Regulatory Framework (ACTReF), which is essential for the implementation of the African Free Trade Area. In 2024, the framework document ACTReF has been validated by the AU Member States and finally adopted by the African Union Specialized Technical Committee on Trade, Tourism, Industry and Minerals. The creation of adapted national frameworks remains of course a sovereign task of the Governments of the AfCFTA State Parties and must be implemented through national law.

This present guide for the setting-up of a National Technical Regulatory Framework (NaTReF) supports national Governments in developing their national frameworks in accordance with the ACTReF with the aim of promoting trade within Africa and substantially advancing the economic integration of the continent.

Special thanks go to the author Beer Budoo for his dedicated work. Without his extensive expertise, which has contributed significantly to the quality and relevance of the document, this guidance would not be available.

We would also like to thank the members of the Africa Quality Policy Council, including the continental Quality Infrastructure institutions and the representatives of the Regional Economic Communities, for their dedicated contributions

Furthermore, we express our gratitude to the African Union Commission (AUC) and the Department of Economic Development, Trade, Tourism, Industry and Minerals (ETTİM) in particular, for the vital support in promoting Quality Infrastructure related matters in Africa and in assisting Member States in overcoming technical barriers to trade through the approximation of technical regulations across the whole continent.

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## ACRONYMS AND BBREVIATIONS

<b>AB</b>	Accreditation body	<b>NaTReF</b>	National Technical Regulatory Framework
<b>AfCFTA</b>	African Continental Free Trade Area	<b>NSB</b>	National Standards Body
<b>AFSEC</b>	African Electro-technical Standardisation Commission	<b>OECD</b>	Organisation for Economic Co-operation and Development
<b>AQP</b>	Africa Quality Policy	<b>PAFTRAC</b>	Pan-African Private Sector Trade and Investment Committee
<b>ARS</b>	African regional standard	<b>PAQI</b>	Pan African Quality Infrastructure
<b>ARSO</b>	African Organisation for Standardisation	<b>PTB</b>	Physikalisch Technische Bundesanstalt
<b>AU</b>	African Union	<b>REC</b>	Regional Economic Community
<b>AUC</b>	African Union Commission	<b>RIA</b>	Regulatory impact assessment
<b>CA</b>	Conformity assessment	<b>RMS</b>	Regulatory management system
<b>CEA</b>	Cost-effectiveness analysis	<b>RP</b>	Regulatory policy
<b>EAC</b>	East African Community	<b>STC-</b>	Specialized Technical
<b>EU</b>	European Union	<b>TTIM</b>	Committee for Trade, Tourism, Industry and Minerals
<b>FAO</b>	Food and Agriculture Organization	<b>TBT</b>	Technical Barriers to Trade
<b>FTA</b>	Free trade area	<b>TR</b>	Technical regulation
<b>GIRG</b>	Global Indicators of Regulatory Governance	<b>TRP</b>	Technical regulatory policy
<b>GRP</b>	Good regulatory practice	<b>UNCTAD</b>	United Nations Trade and Development
<b>IEC</b>	International Electrotechnical Commission	<b>UNECA</b>	United Nations Economic Commission for Africa
<b>IRC</b>	International Regulatory Co-operation	<b>UNECE</b>	United Nations Economic Commission for Europe
<b>ISB</b>	International standardizing body	<b>WTO</b>	World Trade Organization
<b>ISO</b>	International Organization for Standardization		
<b>ISR</b>	Industry self-regulation		
<b>MCA</b>	Multi-criteria Analysis		
<b>MR</b>	Mutual recognition		
<b>MRA</b>	Mutual Recognition Arrangement		

## DEFINITIONS AND TERMINOLOGY

For the purpose of this Guidance, the definitions outlined in the African Continental Technical Regulatory Framework (ACTReF) and the following shall apply:

- 1) Compliance means adherence to regulation with direct or statutory application in a given activity (*Source*<sup>1</sup>).
- 2) Co-regulation means that the regulatory role is shared between government and industry. It is usually effected through legislative reference or endorsement of a code of practice. Typically, the industry or a large proportion of industry participants formulate a code of practice in consultation with government, with breaches of the code usually enforceable via sanctions imposed by industry or professional organisations rather than the government directly. This approach allows industry to take the lead in the regulation of its members by setting standards and encouraging greater responsibility for performance. It also exploits the expertise and knowledge held within the industry or professional association (*Source: Regulatory Impact Assessment, OECD 2020*).
- 3) Enforcement means the activities undertaken by a regulator for the purpose of securing compliance (*Source*<sup>1</sup>).
- 4) Harm means injury or damage to the health of people or damage to property, economic damage to consumers, damage to economic operators, damage to the environment, economic damage to the country, etc. (*Source: EU general risk assessment methodology*<sup>2</sup>)
- 5) Hazard means potential source of harm (*Source: EU general risk assessment methodology*).

NOTE: The hazard, or danger, can be intrinsic to the product or to the regulatory process.

- 6) Inspection (in the context of enforcement) means the process carried out by inspectors which involves assessing relevant documents held by the duty holder, interviewing people and/or observing site conditions, standards and practices to verify compliance. It is a type of intervention (*Source*<sup>1</sup>).
- 7) International Regulatory Co-operation (IRC) means any agreement or organisational arrangement, formal or informal, between countries to promote some form of co-operation in the design, monitoring, enforcement, or ex post management of regulation.
- 8) International standard: standard that is adopted by an international standardizing/ standards organization and made available to the public (*Source: ISO/IEC GUIDE 2:2004*).

*Author's note:* The WTO TBT Agreement indicates that international standards are those prepared by international standardizing bodies (ISB). The WTO TBT Agreement, however, does not offer a precise definition of an ISB. In 2000, the Committee adopted a Decision on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the TBT Agreement. This decision essentially specifies that the following principles and procedures should be observed, when international standards, guides and recommendations are elaborated, to ensure: transparency, openness, impartiality and consensus, effectiveness and relevance, coherence, and to address the concerns of developing countries. How these principles are applied is further described in the document referred to in footnote 3.

- 9) Intervention means any activity undertaken by a regulator with respect to a particular business, in order to encourage or require compliance (*Source*<sup>1</sup>).

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<sup>1</sup> PROPOSALS FOR DEVELOPING A COMMON APPROACH TO RISK ASSESSMENT, Better Regulation delivery office, UK, [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/263921/risk-assessment-paper.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/263921/risk-assessment-paper.pdf)

<sup>2</sup> EU general risk assessment methodology (Action 5 of Multi-Annual Action Plan for the surveillance of products in the EU (COM(2013)76)<https://ec.europa.eu/docsroom/documents/17107>

<sup>3</sup> DECISIONS AND RECOMMENDATIONS ADOPTED BY THE WTO COMMITTEE ON TECHNICAL BARRIERS TO TRADE SINCE 1 JANUARY 1995, G/TBT/1/Rev.15 15 November 2022, <https://web.wtocommerce.org.tw/file/PageFile/378062/GTBT1R15.pdf>

- 10) Market surveillance means the measures that authorities take to ensure that products comply with the legislation's operational requirements and comply with high levels of protection and fair competition (*Source: The Basics of Quality Infrastructure for Trade (2023), UNECE*<sup>4</sup>).
- 11) Ministerial agency regulator means an independent regulatory body, at arm's length from the executive branch of government, with its own internal governance structure and some level of management and budgetary autonomy.
- 12) Ministerial department regulator means a regulatory body reporting to a minister and its internal governance is merely the ministry's administrative set-up.
- 13) Performance-based regulation specifies required outcomes or objectives, rather than the means by which they must be achieved. Firms and individuals are able to choose the process by which they will comply with the law. This allows them to identify processes that are more efficient and at lower cost in relation to their circumstances and also promotes innovation and the adoption of new technology on a broader scale (*Source: Regulatory Impact Assessment, OECD 2020*).
- 14) Performance-based standard describes a desired performance level or performance target to be achieved, but do not make specific demands on how that level/target is reached. Instead of prescribing the need in terms of inputs, it is described in terms of outputs. In other words, it centres on user needs instead of focusing on technical parameters (*Source: Performance-Based Specifications: Exploring when they work and why, (2014), The International Institute for Sustainable Development*).
- 15) Policy coherence refers to the efforts of governments at ensuring that increasingly complex and globalised policy objectives can be met, and that the achievement of high-level policy goals are not undermined by a failure to deal with this complexity.
- 16) Regulatory impact assessment (RIA) is a process of systematically identifying and assessing the expected effects of regulatory proposals, using a consistent analytical method, such as cost-effectiveness or cost/benefit (*Source*<sup>5</sup>).
- 17) Regulatory management system (RMS) refers to the way in which regulatory management systems are organised in terms of institutions, tools and policies (*Source: OECD*<sup>6</sup>).
- 18) Risk means combination of the probability of occurrence of a hazard generating harm in a given scenario and the severity/magnitude/impact of that harm (*Source: EU general risk assessment methodology*).
- 19) Self-regulation for a particular industry or entire industry sectors means that firms in those groups agree to act in prescribed ways, according to a set of rules or principles. Participation by firms in the groups is often voluntary but could also be legally required.
- 20) Standard: document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context (*Source: ISO/IEC GUIDE 2:2004*).

NOTE: Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.

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<sup>4</sup> The Basics of Quality Infrastructure for Trade (2023), UNECE, [https://unece.org/sites/default/files/2023-11/ECE\\_TRADE\\_478.pdf](https://unece.org/sites/default/files/2023-11/ECE_TRADE_478.pdf)

<sup>5</sup> OECD (2010) INTRODUCTORY HANDBOOK FOR UNDERTAKING REGULATORY IMPACT ANALYSIS (RIA), <https://regulatoryreform.com/wp-content/uploads/2015/02/OECD-HANDBOOK-FOR-UNDERTAKING-RIA.pdf>

<sup>6</sup> Jacobzone, S., C. Choi and C. Miguët (2007), "Indicators of Regulatory Management Systems", OECD Working Papers on Public Governance, 2007/4, OECD Publishing

21) States refer to African Union Member States and African Continental Free Trade Area (AfCFTA) State Parties.

22) Technical specification: document that prescribes technical requirements to be fulfilled by a product, process or service (*Source: ISO/IEC GUIDE 2:2004*).

NOTE 1: A technical specification should indicate, whenever appropriate, the procedure(s) by means of which it may be determined whether the requirements given are fulfilled.

NOTE 2: A technical specification may be a standard, a part of a standard or independent of a standard.

## FOREWORD

Institutional complexity and diversity within States is a key feature of Africa and the importance of this factor in designing and integrating regulatory tools and processes must be considered. This goes with a growing appreciation of the diversity of legal and cultural contexts in which regulatory policy needs to take root.

This Guidance is meant to assist States to establish their respective National Technical Regulatory Frameworks (NaTReFs) which serve as a structured approach for developing, applying, and enforcing technical regulations in compliance with international trade agreements. NaTReFs constitute the means for transposing the principles and policies of the African Continental Technical Regulatory Framework (ACTReF) whose main objective is to contribute towards bringing regulatory convergence on technical regulations in Africa. The Guidance has benefited from the enormous amount of work that is going on internationally aimed at achieving better regulatory governance. The lessons and findings from around 41 such publications, all referenced in footnotes, have been assimilated and adapted to the specific domain of technical regulations as needed for the purpose of this Guidance.

While the objective of the Guidance offered is to help African countries align with international best practices, it has been deemed necessary to take account of their special situation, more specifically in terms of resource constraints. Lack of trained personnel and data, for example, would not allow complex cost-benefit analysis to be carried out systematically by all in assessing regulatory impacts. In accordance with advice from organizations which have studied the situations of developing countries, this Guidance suggests a gradual implementation of certain tools instead of a “big bang” approach.

The Guidance should thus be considered as a menu of advice on best practices which African countries may use and apply at their own pace. Constant sharing of experience, knowledge and practices among regulators, stakeholders, businesses and policy-makers in the context of the African Continental Free Trade Area (AfCFTA) Agreement is to be encouraged. The Africa Quality Policy (AQP) Action Plan also provides for training and capacity-building on the application of NaTReFs.

A NaTReF takes the form of public document adopted at the relevant level of Government. Through this formal document, Government demonstrates its over-arching technical regulatory policy and the commitment to apply best practices in developing, applying, enforcing and reviewing technical regulations. Annex A provides an example of a typical structure of the NaTReF document which States may amend in accordance with their respective needs.

Before developing a NaTReF in line with this Guidance, it is recommended that States carry out an initial assessment of the existing technical regulatory framework to identify any gap in good regulatory practices. This Guidance provides a self-assessment checklist at Annex B to help States carry out this task.

Annex I proposes a simplified flowchart to kick-start the development of the NaTReF document at national level. Each country would further detail the flowchart according to their specific needs.

# Guidance for the setting-up of a National Technical Regulatory Framework (NaTReF)

## 1. Introduction

A key challenge for Africa as a region is to move away from an economic growth path built on consumption and commodity exports onto a more sustainable developmental path centred on manufacture-based industrialization and trade of high-quality products as well as the promotion of environmental and social well-being.

Consolidating this continent into one single market through the African Continental Free Trade Area (AfCFTA) provides great opportunities for trading enterprises, businesses and consumers across Africa.

However, widely differing technical regulations can be the source of unnecessary trade barriers between countries as producers and traders struggle to comply with divergent requirements. Cooperation between countries in bringing technical regulation requirements to converge facilitates free trade.

The African Continental Technical Regulatory Framework (ACTReF), adopted by the African Union Ministerial Specialised Technical Committee for Trade, Tourism, Industry and Minerals (STC-TTIM) at their meeting held in Malabo, Equatorial Guinea from 13 to 15 May 2024, aims at bringing regulatory convergence on technical regulations within the African Union (AU).

At the national level, the Africa Quality Policy (AQP) and ACTReF encourage States to implement best practices through the adoption of National Technical Regulatory Frameworks (NaTReFs). These NaTReFs should be aligned with ACTReF and at the same time take into account the specificities of each country. The result of both the ACTReF and NaTReFs operating seamlessly would mean convergence of technical regulations across the whole continent, thus enhancing not only intra-Africa trade but also international trade.

This Guidance is meant to assist States in establishing their respective NaTReFs in line with the principles and policies of ACTReF and the requirements of the WTO TBT and AfCFTA Agreements.

## 2. Concepts

The following concepts as they apply in the national context are defined. The definitions are in line with the current international understanding surrounding each concept and the relevant source is cited as applicable. **It should be noted that while these concepts and definitions relate more to regulations in general, they should be understood to apply mainly to technical regulations in the context of ACTReF and NaTReF.** For a definition of other concepts of law, please refer to the publication in the footnote<sup>7</sup>.

### 2.1. Principles

Principles are fundamental norms, rules or values that represent what is desirable and positive for a person, group, organization, or community. They are fundamental to the formulation of policies and

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<sup>7</sup> SETTING-UP AN AFRICAN CONTINENTAL TECHNICAL REGULATORY FRAMEWORK (ACTReF) – CONCEPT PAPER (Beer Budoo, September 2020) [https://www.paqi.org/wp-content/uploads/2024/02/PAQI\\_ACTReF\\_ConceptPaper.pdf](https://www.paqi.org/wp-content/uploads/2024/02/PAQI_ACTReF_ConceptPaper.pdf)

objectives, because they give a direction to the latter. Principles and policies lead to the formulation of best practices to attain objectives.

Example: The WTO agreements are lengthy and complex because they are legal texts covering a wide range of activities. There are about 60 agreements and decisions totalling 550 pages. But a number of simple, fundamental principles run throughout all of these documents and form the basis of the multilateral trading system. These principles are that the trading system should be

- without discrimination;
- freer;
- predictable;
- more competitive;
- more beneficial for less developed countries.

## 2.2. Regulatory policy

Regulatory policy (RP) may be defined broadly as an explicit, dynamic, and consistent “whole of government” policy to pursue high quality regulation<sup>8</sup>. An effective regulatory policy supports economic development as well as the rule of law, helping policy makers to reach informed decisions about what to regulate, whom to regulate, and how to regulate. It has a social as well as an economic dimension.

Note: While the adoption of a regulatory policy is meant to cover the whole spectrum of regulatory needs of a country, this Guidance focusses on the sub-set of technical regulations. If a national RP exists and is operational, then the NaTReF’s Technical Regulatory Policy (TRP) should be based on the RP and aligned with ACTReF with regard to the area of technical regulations. If not, NaTReF should develop a technical regulatory policy aligned with ACTReF. The adoption of good practices in the development, application and enforcement of technical regulations contained in the NaTReF could also pave the way for wider application of better regulatory practices in all other areas in the country.

The TRP constitutes the foundation on which the technical regulatory framework, i.e. NaTReF, is built. Since the TRP is the overarching policy that engages the whole of Government, it should be adopted by the Cabinet of Ministers or by a lead Ministry designated by the Cabinet. As the TRP is included in the NaTReF document, the adoption of the latter by Government is deemed to be an adoption of the TRP as well.

## 2.3. National Technical Regulatory Framework (NaTReF)

A NaTReF is a country-level system that establishes how technical regulations are developed, applied, enforced and reviewed. The system is documented in a formal NaTReF document. Annex A provides an example of a typical structure of the NaTReF document which States may amend in accordance with their respective needs. ACTReF’s objective of bringing convergence on technical regulations within the African Union can only succeed if NaTReFs operate as the fundamental building blocks for the continental technical regulatory framework. Indeed, aiming at convergence on technical regulations at the continental level is mostly about targeting convergence among States through their respective NaTReFs.

## 2.4. Regulatory harmonization

ACTReF defines regulatory harmonization as the adoption of joint rules across two or more jurisdictions aimed at doing away with regulatory divergence between participating countries at its very root , e.g. development of common Regulations and Directives in the European Union (*Source: OECD (2021)*<sup>9</sup>).

Note: Regulatory harmonization covers in practice different realities and different depths of co-operation, i.e. the adoption of another jurisdiction’s rule, the joint adoption of a common rule through a deliberative process in a joint institution, the joint adoption of common rules without the involvement of a joint institution, or the joint reference to a third rule-maker (typically

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<sup>8</sup> OECD (2011), Regulatory Policy and Governance: Supporting Economic Growth and Serving the Public Interest, OECD Publishing ([https://www.oecd-ilibrary.org/governance/regulatory-policy-and-governance\\_9789264116573-en](https://www.oecd-ilibrary.org/governance/regulatory-policy-and-governance_9789264116573-en))

<sup>9</sup> OECD (2021), International Regulatory Co-operation, OECD Best Practice Principles for Regulatory Policy, OECD Publishing, Paris, <https://doi.org/10.1787/5b28b589-en>.

an international organization). Any form of regulatory harmonization comes with a certain loss of sovereignty and therefore such a process can best be carried out in Africa at the level of regional economic communities where agreements could already be in place for such regulatory harmonization. For instance, the East African Community (EAC) can declare East African Standards as compulsory, which is the same as declaring the compulsory standard as a regional technical regulation.

One of ACTReF's specific objectives is precisely to improve convergence on TRs within RECs and therefore regulatory harmonization efforts can be driven by RECs.

## **2.5. Regulatory coherence**

ACTReF defines regulatory coherence as a focus on reform and discipline of domestic regulatory processes.

Ensuring regulatory coherence within NaTReFs is meant to avoid inconsistency, incompatibility, or duplication among various regulations adopted at the national level by various regulators. In practice, it means performing coordinated reviews of agency rulemakings to ensure that regulatory decisions made by one agency do not conflict with applicable law or the policies or actions taken or planned by another agency. It also drives the setting-up of an institutionalized plan to periodically review existing regulations to determine whether they are still relevant and whether they remain compatible with each other and not duplicative or inappropriately burdensome for the community or economic operators.

## **2.6. Regulatory convergence**

ACTReF defines regulatory convergence as the reduction of unnecessary regulatory differences and is based on common principles and policies which States can apply. The ACTReF policies for regulatory convergence for Africa cover harmonization of regulatory approaches, convergence of technical regulations (TRs) and harmonization of standards. Other policies cover the mutual recognition of TRs, conformity assessment results, standards and accreditation.

ACTReF makes provision for the monitoring of progress in regulatory convergence i.e. whether regulatory dissimilarities among States are being reduced and whether regulatory management systems are improving in terms of more effective institutions, tools and policies.

Thus, when we refer to regulatory convergence in the context of ACTReF and NaTReF, it means that we are looking at convergence of regulatory management systems, i.e. whether the institutions, tools and policies for the development, application and enforcement of TRs are performing according to the principles and policies laid down in ACTReF.

## **3. Structure of the Guidance**

Part I - Scope, objectives, rationale, principles

Part II- Governance and oversight

Part III- Regulatory management system – Best practices

Part IV- Implementation of NaTReF

## **PART I - SCOPE, OBJECTIVES, RATIONALE, PRINCIPLES**

### **4. NaTReF scope**

#### **4.1. At international level**

NaTReF establishes the framework for national technical regulations to be developed, applied, enforced and reviewed so as to comply with the requirements of the WTO TBT and the AfCFTA Agreements. As of January 2025, the database of WTO notifications show that African countries are involved in 48 Regional trade agreements (RTAs), out of which 40 are with partners outside Africa. Thus, NaTReFs can support African countries which are involved in RTAs to benchmark their regulatory systems with international best practices and hence facilitate international trade under the RTA and with other trading partners.

#### **4.2. Continental level**

By being aligned with ACTReF, NaTReFs lay down the foundations for regulatory convergence to be achieved at continental level, hence enhancing intra-African trade under the AfCFTA Agreement.

#### **4.3. Regional level**

NaTReFs also constitute the basis on which regulatory harmonization, in line with ACTReF policies, should be achieved among members of a REC, thus moving towards similar rules. The roles of RECs can also be enhanced as they offer a very good context for the use of mechanisms of regulatory cooperation among member countries to move towards regulatory harmonization.

#### **4.4. National level**

NaTReF adopts the principles and policies of ACTReF, adapted to the specific needs and regulatory objectives of the country, and translates these into an operational regulatory management system that complies with international best practices.

### **5. NaTReF objectives**

#### **5.1. Overall objective**

To contribute towards bringing convergence on technical regulations within the African Union by ensuring that the National Technical Regulatory Framework (NaTReF) integrates best practices in managing the national technical regulatory system.

#### **5.2. Specific objectives**

- To develop, consolidate and publish a national technical regulatory policy in matters of technical regulations.
- To improve convergence on TRs within States and RECs by adopting and implementing the ACTReF policies for regulatory convergence.
- To ensure regulatory coherence is a key driver of the national regulatory policy.
- To adopt and apply good regulatory practice (GRP) in developing, applying, enforcing and reviewing technical regulations in line with the principles and policies of ACTReF.
- Monitor presence of sub-standard and dangerous goods within national boundaries through market surveillance and notify States about such goods.

- To develop and deploy a training and capacity building programme for regulators to apply best practices in managing the national technical regulatory system.
- To apply relevant mechanisms of International Regulatory Co-operation (IRC) for the purpose achieving regulatory convergence when dealing with other AU Member States.

## 6. Justification for a NaTReF

### 6.1. Enhancement of trade

Since technical regulations are mostly developed, applied and enforced at the national level in accordance with regulatory practices that may be widely different among African countries, they could become technical barriers to intra-African as well as international trade since compliance with TRs is mandatory among trading partners.

The United Nations Economic Commission for Africa (UNECA) estimates that the AfCFTA Agreement has the potential to double intra-African trade if non-tariff barriers are reduced<sup>10</sup>. On the other hand, the Pan-African Private Sector Trade and Investment Committee (PAFTRAC) released a survey of African CEOs in 2021<sup>11</sup>, where the vast majority of respondents (87 %) from 44 African countries believe that the AfCFTA Agreement will increase intra-African trade, at least moderately. Besides, 85 % of the respondents believe that the AfCFTA will have a positive impact on the regulatory environment for doing business while 82 % think of the same for achieving standards compliance. Around 28 % of respondents also see the availability (or non-availability) of technical facilities for assuring compliance with standards as a main constraint when trading within the region.

The PAFTRAC survey reflects the vital concerns facing African businesses and calls for intervention both in the regulatory domain as well as the in the Quality Infrastructure domain. The adoption of the Africa Quality Policy (AQP) in 2022 and the African Continental Technical Regulatory Framework (ACTReF) in 2024 by the African Union essentially responds to these concerns.

### 6.2. NaTReFs implement ACTReF policies

Since TRs are not developed, applied and enforced by any continental entity at the level of the AU, it follows that ACTReF policies are executable essentially at the national level as it is the sovereign responsibility of States to develop, apply, enforce and review TRs.

Thus, regulatory convergence at the African continental level relies mostly on convergence among States which should implement the principles and policies contained in ACTReF. Implementing NaTReFs is the pathway for implementing ACTReF.

### 6.3. NaTReFs facilitate regulatory harmonization at REC level

Some level of regulatory cooperation *de facto* exists in Regional Trade Agreement (RTAs). Meyer et al<sup>12</sup> showed that there is scope for going even further in terms of regulatory harmonization. Thus, REC management bodies could drive regulatory convergence at the regional level and the whole process could be facilitated if there is a prior degree of similarity between regulatory approaches among their member States. By adopting NaTReFs based on the ACTReF, REC members ensure that there is similarity

<sup>10</sup> African Continental Free Trade Area - Questions & Answers (Compiled by the African Trade Policy Centre (ATPC) of the Economic Commission for Africa (ECA) in association with the African Union Commission)

<sup>11</sup> [https://mcusercontent.com/82a1c769b4c9e47f2566f4d40/files/f062d4ef-84cd-6d1c-c251-3c2eacc433a0/Africa\\_CEO\\_Trade\\_Survey\\_Report\\_Pre\\_Release.pdf](https://mcusercontent.com/82a1c769b4c9e47f2566f4d40/files/f062d4ef-84cd-6d1c-c251-3c2eacc433a0/Africa_CEO_Trade_Survey_Report_Pre_Release.pdf)

<sup>12</sup> Meyer, N. et al. (2010-06-02), "Bilateral and Regional Trade Agreements and Technical Barriers to Trade: An African Perspective", OECD Trade Policy Papers, No. 96, OECD Publishing, Paris

in their regulatory approaches and therefore they can more easily build/consolidate regulatory harmonization among themselves.

#### **6.4. Regulatory convergence enhances economic welfare**

In a study undertaken by UNCTAD, commissioned by the AUC/PAQI/AfCFTA Secretariat and funded by PTB under its project “Upgrading of Quality Infrastructure in Africa/Africa”, the report titled “*Non-tariff measures and deep regulatory integration in the African Continental Free Trade Area - Technical and statistical report*”<sup>13</sup> estimates, in a scenario 1, that elimination of non-tariff barriers in intra-African trade under the AfCFTA Agreement increases economic welfare in Africa by about USD 1.6 billion. However, if the element of regulatory convergence in Africa for intra-African trade is included in a scenario 2, the economic welfare increases to USD 3.4 billion. Finally, if regulatory convergence goes one step further towards complying with international standards for the sake of extra-Africa trade, the increase of economic welfare in Africa reaches the figure of USD 7.1 billion.

#### **6.5. NaTReFs improve business environment predictability**

Regulatory differences across jurisdictions increase the transaction costs for traders and producers of goods in both the importing and exporting countries. Regulatory divergence may be considered as a trade barrier if it increases transaction costs, such as

- specification costs (labour and capital costs to adjust product or service to divergent technical regulations in target market),
- conformity assessment costs (costs of demonstrating conformity with dissimilar technical regulations in target market) or
- information costs (costs of obtaining and monitoring regulatory environment in target market).

The World Bank’s Global Indicators of Regulatory Governance (GIRG)<sup>14</sup> project explores how policymakers interact with stakeholders when shaping regulations affecting business communities. GIRG data from 2017-2018 for the 52 African countries surveyed, shows that out of a maximum score of 5, there are 42 African countries which score 2 or less while only 4 countries score more than 3. This shows a significant lack of business involvement in the processes that States use to implement basic regulatory practices, hence a lack of business predictability.

Since NaTReF is designed to include a public technical regulatory policy, detailed under section 8.4, it follows that it will offer a clear and consistent overall approach to rulemaking and intervention that is understood by regulated entities and stakeholders.

## **7. NaTReF guiding principles**

The totality of ACTReF principles, listed in Annex C, apply to NaTReF.

Since the above principles are in line with recommendations from various international and regional organizations, they are deemed to benchmark NaTReFs as applying internationally-recognized principles of “good regulation”.

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<sup>13</sup> <https://unctad.org/publication/non-tariff-measures-and-deep-regulatory-integration-african-continental-free-trade-area>

<sup>14</sup> <https://rulemaking.worldbank.org/en/methodology>

## **PART II – GOVERNANCE AND OVERSIGHT**

### **8. NaTReF elements**

#### **8.1. Policies leading to regulatory convergence in Africa**

NaTReFs should provide the framework for implementing ACTReF policies (as detailed in section 2.6) to achieve an efficient and effective regulatory management system at the national level in order to meet the objectives of regulatory convergence across Africa. This Guidance provides the elements to develop NaTReFs, which should be formal public documents and adopted at the relevant level of Government in each country. Annex A provides an example of a typical structure of the NaTReF document which States may amend in accordance with their respective needs. As mentioned elsewhere in this Guidance, NaTReFs are expected to be different for each country but since they have all to be aligned with ACTReF principles and policies, it is assumed that technical regulations adopted under well-performing NaTReFs would enable regulatory convergence in Africa. Figure 1 provides a schematic illustration of the elements that constitute NaTReF. These are the main elements on which guidance will be elaborated in this document. The various element boxes in Figure 1 are hyperlinked to the corresponding part of the text in this guidance (Just CTRL+click inside each hyperlinked box to access the section concerned).

Figure 1- NaTReF elements

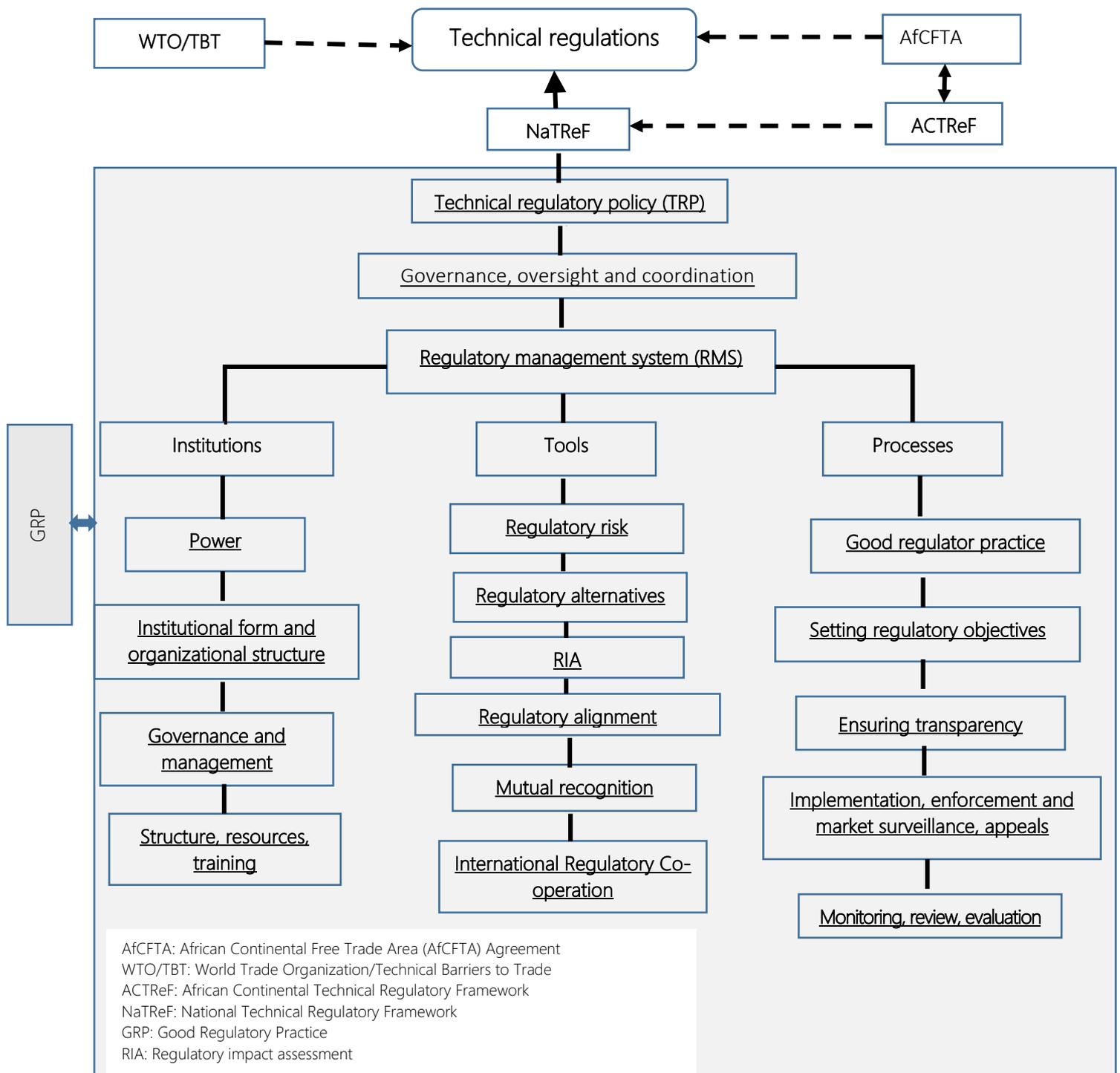


Figure 1 reflects the fact that TRs have to meet requirements imposed by both the WTO TBT and AfCFTA Agreements. However, the AfCFTA Agreement is totally in line with the WTO TBT Agreement since it urges State Parties to promote compliance with the latter.

## 8.2. From principles to practices

Work on defining Good Regulatory Practice (GRP) was led by the WTO TBT Committee since entry into force of the TBT Agreement. GRP is not referred to in the TBT Agreement and it is not defined in clear

terms by the WTO TBT Committee. However, in 2012, it identified a non-exhaustive list of voluntary mechanisms and related principles of GRP<sup>15</sup> to guide WTO Members in the efficient and effective implementation of the TBT Agreement across the regulatory lifecycle. All these TBT Committee’s mechanisms and principles are part of the ACTReF principles but ACTReF also includes additional principles from other organizations as well, such as the EU<sup>16</sup> and the OECD<sup>17</sup>.

Furthermore, where applicable, ACTReF principles have been expanded to cover not only national but regional and the African continental dimensions as well. For example, the TBT GRP principle of assuring “internal (domestic) coordination mechanisms” addressed to WTO members has been expanded under ACTReF to cover “national, regional and continental regulatory coordination mechanisms”, such as International Regulatory Co-operation practices.

NaTReFs now have to translate these comprehensive ACTReF principles into good regulatory practices. In the context of this Guidance, GRP in NaTReFs covers all the elements depicted in the shaded box in Figure 1, i.e. the over-arching national technical regulatory policy, the governance, oversight and coordination arrangements as well as the institutions, tools and processes. The system working as a whole-of-government approach ensures that good regulatory practices pervade in each State to ensure that technical regulations are developed, applied, enforced and reviewed in a manner that is equivalent among States.

### 8.3. Life cycle of a technical regulation as understood by the WTO

Figure 2 is an illustration from the WTO<sup>18</sup> representing the regulatory lifecycle of a technical regulation. The core inner circle anchors the central importance of a “whole-of-government” approach to the regulatory process while the next level shows the procedural obligations contained in the TBT Agreement that lead to transparency and coordination; finally, the outer circle comprises elements of regulatory process across the regulatory lifecycle, starting with an analysis of the need to regulate, an assessment of alternatives (including through regulatory impact assessment (RIA)), publication, implementation and enforcement, and review.

This Guidance lays down practices for NaTReFs to follow the “whole-of-government” approach to the regulatory process across the regulatory lifecycle. Coordination at the national, regional and continental levels is also the pivotal consideration around which the regulatory system hinges and is amply covered in this Guidance. This document however does not provide guidance on the procedural obligations on transparency as these are well laid out in the WTO TBT and AfCFTA Agreements, e.g. publication of an “early notice” of anticipated regulatory activity.

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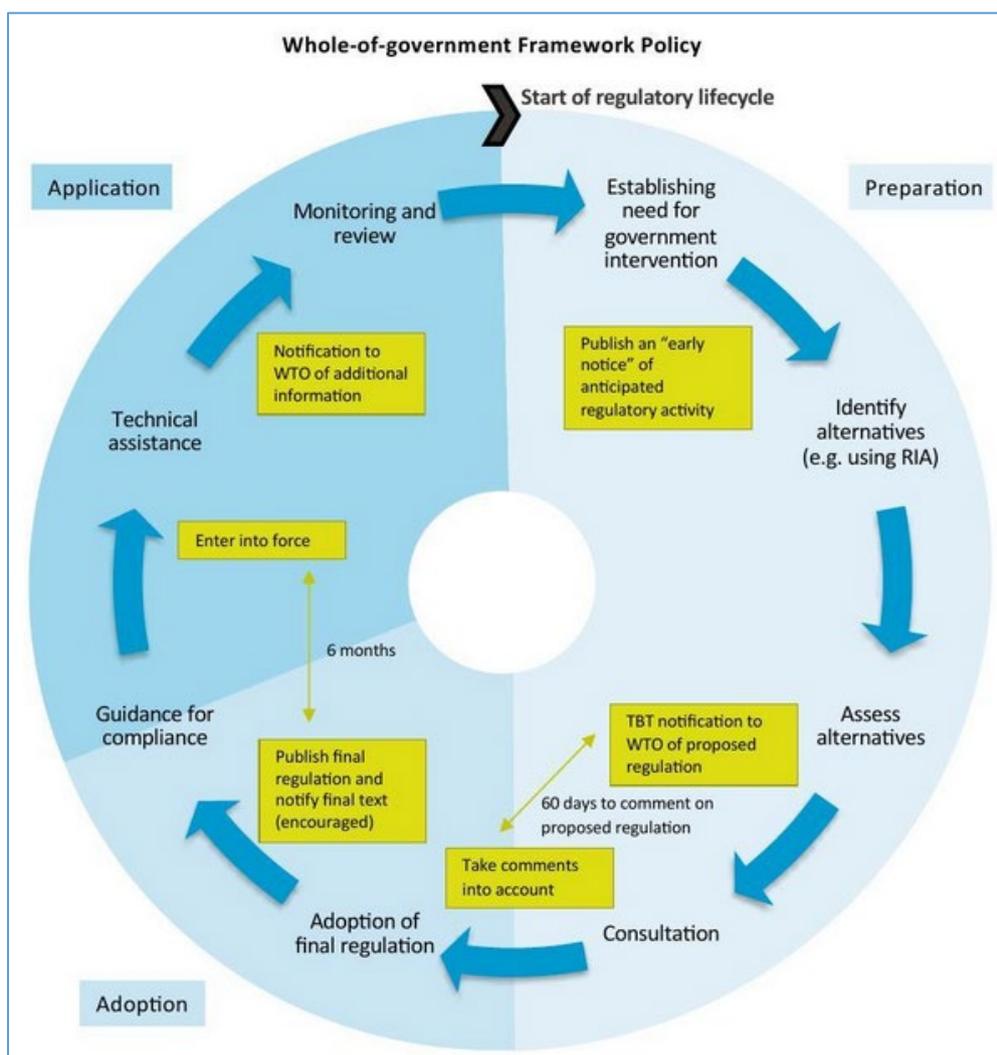
<sup>15</sup> The WTO TBT Committee’s principles of Good Regulatory Practice (GRP) adopted at the Sixth triennial review of the operation and implementation of the agreement on technical barriers to trade <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/G/TBT/32.pdf&Open=True>

<sup>16</sup> Better regulation guidelines, EU, 2021, [https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox\\_en](https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox_en)

<sup>17</sup> OECD Guiding Principles for Regulatory Quality and Performance (2005), [https://www.oecd.org/en/publications/oecd-guiding-principles-for-regulatory-quality-and-performance\\_9789264056381-en.html](https://www.oecd.org/en/publications/oecd-guiding-principles-for-regulatory-quality-and-performance_9789264056381-en.html)

<sup>18</sup> The WTO Agreements Series-Technical Barriers to Trade (3rd Edition)

Figure 2- Regulatory lifecycle of a technical regulation



Source: WTO

#### 8.4. Technical regulatory policy (TRP)

Regulatory policy (RP) is defined in section 2.2 as an explicit, dynamic, and consistent “whole of government” policy to pursue high quality regulation.

Since NaTReF is concerned solely with technical regulations, it should state the country’s technical regulatory policy clearly for all interested parties to understand how the regulatory process is designed and implemented in line with the principles indicated in section 7.

The need for such a technical regulatory policy also arises from the necessity for Government to ensure policy coherence in the pursuit of all its goals, taking into consideration the inter-connectedness that is inherent among its various high-level policies. For example, the national industrial policy or the agricultural policy or the trade policy are all connected to the manner in which TRs are developed, applied and enforced.

The NaTReF document should thus include a Technical regulatory policy, in the form of a statement, which commits to a certain number of measures that Government proposes to adopt and apply. All these measures then constitute the foundation on which the technical regulatory framework, i.e. NaTReF, will be built. Box 1 below details these measures.

## **Box 1 - Technical regulatory policy**

### **Policymakers should**

- Declare a statement at the highest political level to an explicit whole-of-government policy for technical regulatory quality.
- Commit to adhere to principles of open government, including transparency and participation in the regulatory process to ensure that technical regulations serve the public interest and is informed by the legitimate needs of those interested in and affected by technical regulations.
- Establish mechanisms and institutions to actively provide oversight of technical regulatory policy procedures and goals.
- Apply, as appropriate, risk assessment, risk management, and risk communication strategies, firstly, to identify problems and determine if Government intervention is warranted and, secondly, to the design and implementation of technical regulations.
- Integrate regulatory impact assessment (RIA) into the early stages of the policy process for the formulation of new technical regulation proposals.
- Conduct systematic programme reviews of the stock of technical regulations to ensure that they remain up to date.
- Regularly publish reports on the performance of regulators.
- Develop a consistent policy covering the roles and functions of regulators.
- Promote, where appropriate, regulatory coherence through co-ordination mechanisms between all levels of government.
- Ensure the effectiveness of systems for the review of the legality and procedural fairness of technical regulations and of decisions made by bodies empowered to issue regulatory sanctions.

### **Regulators should**

- Give consideration, in developing technical regulations, to the requirements of the WTO TBT and AfCFTA Agreements, the principles and policies of ACTReF.
- Assess how technical regulations will be given effect and should design responsive implementation and enforcement strategies.
- Clearly identify policy goals, and evaluate if regulation is necessary and how it can be most effective and efficient in achieving those goals. Consider means other than regulation and identify the trade-offs of the different approaches analysed to identify the best approach.
- Foster the development of technical regulatory management capacity and performance at all levels of government through awareness, training and other capacity-building programmes.

## 8.5. Governance, oversight and coordination of the regulatory system

In this Guidance, it is understood that there is a hierarchy among the 3 functions of governance, oversight and coordination. These functions are not mutually exclusive, rather they are all interlinked and operate synergistically.

### 8.5.1. Governance

With respect to governance of regulators, it is important to distinguish between external governance (above the regulator) and internal governance (within the regulator).

**Regulatory (external) governance** is at the highest level as it leads the formulation of the technical regulatory policy and is meant to ensure that technical regulations will have a positive impact on the economy, the environment and society, and meet underlying public policy objectives. Basically, governance is responsible for closing the loop of the whole process starting from regulatory design, through implementation and up to evaluation of outcomes. This is why it is sometimes described as a regulatory governance cycle<sup>8</sup>. Governance covers the issues of leadership and oversight, of engaging all government players, of setting the role and functions of regulators and of the international dimension. Governance will thus be expected to lead the national effort under NaTReF to apply ACTReF policies and principles to move towards regulatory convergence in Africa.

Regulatory (internal) governance deals with the institutional and organizational aspects of the regulator, its management, its practices and performance.

This section deals with guidance on external governance only while internal governance will be covered in section 8.6.1.3 under “institutions”.

### 8.5.2. Oversight

Oversight is at one level below governance and is concerned more about the operational aspects of promoting regulatory quality. Its specific responsibilities is to monitor, oversee and promote progress across the whole of government and to maintain consistency between the approaches of the various actors involved in the regulatory process. The oversight function could also include the power to veto a regulation which does not fulfil the necessary requirements. Oversight thus involves both a management function and a coordination function in dealing with existing bodies involved in the rule-making process.

### 8.5.3. Coordination

The coordination function may take a variety of roles which may involve interaction with business, civil society and other stakeholders to provide a feedback loop for their views on the regulatory process. This function could also look into overall capacity-building needs and deploy continuous training to equip all personnel involved in developing technical regulations with the necessary knowledge and tools, e.g. conduct of Regulatory impact assessment, study of alternatives to regulation, public consultation, use of digital technology to increase efficiency, etc.

#### 8.5.4. Rationale for an effective governance, oversight and coordination

In accordance with the Technical regulatory policy (TRP) (Box 1, above), there should be mechanisms and institutions to provide oversight of the technical regulatory procedures and goals.

Moreover, ACTReF principles call for the setting up of national, regional and continental regulatory coordination mechanisms while it stipulates, in its section 9.2.2, that States should designate an authority at national level to coordinate the development, application, enforcement and review of TRs in the context of implementation of their respective NaTReFs.

The WTO TBT Committee<sup>15</sup> has called on its members to (voluntarily) institutionalize the various mechanisms, processes and procedures of regulatory practice through the creation and designation of institutions within Member governments to oversee regulatory processes.

The importance of governance and oversight is further underlined in the reports on “Regulatory capacity review” of various African countries, undertaken by the World Bank in 2010. These reports systematically recommended the establishment of a ministerial position to champion regulatory reform at Cabinet level and to coordinate regulatory reform across government as well as an oversight technical unit to support the minister in these activities.

OECD reviews find a strong relationship between an effective, comprehensive regulatory policy and the existence of a central oversight body.

Box 2 below provides guidance on this issue while Annex D gives more details to make a choice among several possibilities.

## Box 2 - Governance, oversight and coordination

### **Policymakers should**

- Designate an entity/individual close to core government executive functions (e.g. the Cabinet itself or a cabinet commission or committee, or a senior Minister or a similar position) and vested with the necessary authority to exercise leadership in the governance function of the technical regulatory system.
- Describe the power/authority and leadership roles and functions of governance, including its inter-linkages with other government branches.
- Designate or appoint an oversight body and describe its reporting modalities to the governance entity as well as its roles and functions (both the managerial and coordination functions).
- Ensure that the oversight body has access to technical expertise to be credible and be assured of political support and institutional stability over time, meaning the proper allocation of resources to allow it to function properly.
- Describe the coordination modalities among the governance, the oversight body and national structures/focal points having responsibilities with regard the WTO TBT and the AfCFTA Agreements.

### **Governance entity could be**

- A Minister responsible for the portfolio of either international trade or commerce or industry, or
- the Attorney General's (AG) office, or
- the office of the Solicitor-General (SG).

### **Oversight body could be**

- A central body overseeing all the technical regulatory functions, or
- a central body coordinating the technical regulatory functions with a network of units in various ministries, or
- an inter-ministerial committee.

## PART III – REGULATORY MANAGEMENT SYSTEM-BEST PRACTICES

### 8.6. Regulatory management system

Since technical regulations pervade all economic activities, ensuring proper regulatory management for improving the quality of the existing stock of technical regulations as well as for developing new technical regulations is an important concern for public officials. The OECD has led work relating to the concept of quality in regulatory management<sup>19</sup>, as developed by the *OECD Programme on Regulatory Reform*, which fundamentally refers to the way in which regulatory management systems are organised **in terms of institutions, tools and processes**. While a number of international efforts have been made to assess the economic impact of regulations, few indicators exist on regulatory management systems as such. Indicators of regulatory management systems quality serve to assess countries' regulatory practices. They can help to analyse regulatory governance performance and to diagnose success factors and priority areas for further reform. They contribute to a better understanding of what good regulatory governance is, and of the links between regulatory policies and outcomes such as economic performance.

This Part III concentrates on best practices for institutions, tools and processes as they should apply to NaTReF.

#### 8.6.1. Best practices for institutions

##### 8.6.1.1. Power to regulate

Regulatory bodies should draw powers to develop and enforce technical regulations from primary or secondary legislation. Once the power allocation is clear, there is a need to determine whether each regulator is able to match that power to its objectives, responsibilities, functions, capacity and resources. Any gap in power to achieve objectives should be taken up by the parent Ministry and resolved at the level of the Cabinet.

##### 8.6.1.2. Degree of regulatory independence

Government should decide on the degree of independence of each regulatory body. There may be situations where an independent regulator, at arm's length from the executive branch of government, is warranted. This could be the case where there is a need to ensure public confidence or where the regulator has to demonstrate neutrality/impartiality when dealing with both the government and the private sector as regulated parties. The regulatory body thus takes the administrative form of either

- a ministerial agency with its own governance structure and some level of management and budgetary autonomy although still subordinate to the ministerial authority, or
- an independent regulatory authority, e.g. utility companies or energy authority, which typically has autonomous management although its budget may be under a ministry.

In other situations, the regulatory body could be a ministerial department reporting to a minister, in which case its governance is merely the ministry's administrative set-up.

In all cases, the regulatory body's independence relative to regulated entities should be clearly established.

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<sup>19</sup> Jacobzone, S., C. Choi and C. Miguet (2007), "Indicators of Regulatory Management Systems", OECD Working Papers on Public Governance, 2007/4, OECD Publishing.

### 8.6.1.3. Organizational structure and internal governance

Government should ensure that the regulatory body has sufficient resources to fulfil its statutory duties, including its internal governance, management, staffing, access to technical expertise through advisory bodies/committees, enforcement capacity, etc.

When the regulatory body is a ministerial department, it may resort to advisory/consultative committees composed of multi-stakeholder interests to access technical expertise but also maintain communication and engagement with stakeholders.

### 8.6.1.4. Training and capacity building

Formal training and capacity-building programmes to consolidate the regulatory culture within the public service but also to facilitate communication with stakeholders and regulated entities is a clear demonstration of the political commitment. As States are now embarking on a journey towards bringing regulatory convergence in Africa through the implementation of ACTReF and NaTReFs, there is a strong need to conceive and deploy such training and capacity-building programmes. Box 3 details the measures.

## Box 3 - Training and capacity building

### Policymakers should

- Identify training and capacity-building needs across the whole cross-section of the technical regulatory system, including the public sector, the private sector and interested parties such as consumers and civil society.
- Deploy training/capacity building to various target groups including identifying the training institutions to be mobilized for this task.
- Adopt and deploy continental efforts under ACTReF to build awareness on actions needed to understand and apply ACTReF principles and policies on regulatory convergence.

### Regulators should train their staff on

- legal drafting principles and skills,
- understanding and applying GRP,
- setting technical regulatory objectives aimed at performance rather than on detailed specifications,
- how to conduct risk analysis and regulatory impact assessment,
- assessment and use of alternative policy instruments other than regulations,
- understanding quality policy and quality infrastructure as they relate to the technical regulatory system,
- referencing standards effectively in technical regulations,
- International Regulatory Co-operation mechanisms and their applicability to different situations to reduce regulatory differences,
- enforcement effort, including market surveillance, designed to be applied systematically, fairly and proportionate to risk,
- use of digital technology to increase efficiency with regard to data collection and sharing.

## 8.6.2. Best practices for regulatory management tools

### 8.6.2.1. Rationale for the step-wise approach in using tools of regulatory management

The tools that are essential for effective regulatory management, as shown in Figure 1, are regulatory risk and impact assessment, regulatory alignment, mutual recognition and international regulatory co-operation. These tools are increasingly being used worldwide to inform regulatory governance as to the allocation of regulatory resources based on risk levels. But the main constraint for developing countries is to have the qualitative or quantitative data and the necessary trained staff to apply these tools. A report of the Commonwealth Secretariat dated 2024<sup>20</sup> underlines that one lesson learned universally from 40 years of RIA is that countries will fail if they begin too rapidly or expect civil servants to comply with new procedures that they do not know and do not have the skills to implement. The report further indicates that the RIA universe is full of examples of countries that mandate the full-fledged classical RIA system without a single good RIA to show years later. The obvious solution suggested in the Commonwealth Secretariat report is to have a phased introduction of RIA in developing countries.

Through the same logic, this Guidance proposes that the various tools helping in regulatory decision-making should be carried in a phased and step-wise approach. Thus, a first step is to conduct a risk assessment to determine if Government has to intervene. If the answer is yes, then the next step is to look at regulatory alternatives to decide on a shortlist of possible ways to address the problem, including using technical regulations. Finally, at a final step, a RIA on these shortlisted solutions may provide the policy-maker a sound basis on which to make the final decision.

Clearly, countries may choose to combine all the above steps into one full-fledged RIA if they have the necessary data and skilled staff. In any case, the whole process is bound to be an iterative process of learning and improvement, and countries should use these tools as they deem fit in their respective situations.

### 8.6.2.2. Risk-based regulatory approach

Regulatory activity concerning technical regulations is inherently tied to the notion of risk.

From a trade perspective, Article 2.2 of the TBT Agreement states that technical regulations shall not be “more trade-restrictive than necessary” to fulfil a legitimate objective, taking account of the risks non-fulfilment would create.

But even outside the trade perspective, countries may need to conduct risk assessment when they are considering regulating to achieve a policy objective. Governments can improve the welfare of citizens and maximise the benefits of regulation to society through the efficient allocation of regulatory resources. This implies only regulating where the benefits of regulation outweigh the costs and applying the limited regulatory resources to those areas where the maximum benefit to society can be achieved. In both cases risk assessment can assist with the challenge of identifying these areas<sup>21</sup>.

Risk assessment is not a single method. While risk assessment methods for areas such as spread of disease, natural disasters, use of machinery or even management of organizations (e.g. *ISO 31000:2018, Risk management*), etc. are well established, dealing with national policies such as TRs is a challenge especially for developing economies. Lack of historic data to compare, uncertainty about outcomes or even the time lag before impacts or harm appear, are all elements that affect the assessment.

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<sup>20</sup> Handbook on Designing and Implementing Regulatory Impact Assessment Systems, Commonwealth Secretariat, 2024, <https://thecommonwealth.org/publications/handbook-designing-and-implementing-regulatory-impact-assessment-systems>

<sup>21</sup> RISK AND REGULATORY POLICY: IMPROVING THE GOVERNANCE OF RISK, OECD 2010, ([https://www.oecd-ilibrary.org/governance/risk-and-regulatory-policy\\_9789264082939-en](https://www.oecd-ilibrary.org/governance/risk-and-regulatory-policy_9789264082939-en))

However, even some level of risk assessment using qualitative or semi-quantitative assessment approaches are an aid to decision-making about the need for government to intervene to address a specific policy problem through regulation. Qualitative assessments typically employ a set of methods, principles, or rules for assessing risk based on non-numerical categories or levels (e.g., very low, low, moderate, high, very high). Semi-quantitative assessments typically use scales (e.g., 1-10) and they are an improvement over qualitative assessments methods as a risk communication for decision makers (e.g., a score of 9 out of 10 can be interpreted as very high risk and everybody understands that).

It is important to note that risk management **decisions**— i.e. whether about how stringent to make a new regulation, what kind of regulatory instrument to use, what facilities to target with inspections, or what penalties to impose on non-compliers—are **normative or policy decisions**. Risk assessment provides scientific or empirical answers about probabilities, hazards, and their distribution; it **does not** supply the policy principle or normative reason needed to make regulatory or risk management decisions about these hazards. That principle must be grounded in policy or normative considerations that fall outside the scope of risk assessment. For example, a risk assessment result might give scores based on the following categories: biggest hazards; biggest risks; avoidance of excessive costs; and avoidance of unacceptable risk. A regulator would use these results and decide to reasonably target any one of these categories as a policy decision<sup>22</sup>, meaning that it may not be the highest risk scenario that is tackled as priority.

For the purpose of this methodology, a ‘risk assessment’ is the overall process of risk identification, analysis and evaluation:

- Risk factors include hazard source, hazard event, vulnerability, severity/magnitude/impact, likelihood;
- Risk identification is the process of finding, recognising and describing risks;
- Risk analysis is the process to understand the nature of the risk and to determine its magnitude, which results from the combination of consequences and their likelihood;
- Risk evaluation is the process of comparing the results of risk analysis with risk criteria to determine whether the risk and/or its magnitude is acceptable or not.
- Box 4 below and Annex E provide guidance on the risk-based approach.

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<sup>22</sup> What does risk-based regulation mean?, Cary Coglianese, The Regulatory Review, 2019, <https://www.theregreview.org/2019/07/08/coglianese-what-does-risk-based-regulation-mean/>

## Box 4 - Risk-based approach

### Policymakers should

- Clearly define the problem that needs to be addressed .
- Describe processes used to engage with stakeholders .
- Identify the scope of the risk assessment.
- Identify the specific assumptions and constraints under which the risk assessment is conducted.
- Identify the sources of information to be used in the risk assessment.
- Define the risk factors and the assessment approach (qualitative or semi-quantitative).
- Indicate the risk management options and any preferred option, if relevant .
- Report the risk in easily understood form, e.g. tables as in Annex E.

### Regulators should

- Identify hazard sources that are relevant to the regulatory proposal.
- Identify hazard events that could be produced by those sources.
- Identify vulnerabilities within all impacted individuals/organizations that could be exploited by hazard sources through specific hazard events.
- Determine the likelihood that the identified hazard sources would initiate specific hazard events.
- Determine the adverse impacts to people, damage to property, economic damage to consumers, damage to economic operators, damage to the environment, economic damage to the country, etc.
- Determine the risk to all affected individuals/organizations.

### 8.6.2.3. Regulatory alternatives

Government uses regulation to achieve its policy objectives. Regulation could be used in a strict legal sense as a rule-based “command and control” function in which laws and regulations are determined in black and white, such as a technical regulation. But Government can choose not to take a rule-based approach, in which case it has the possibility of using alternatives to regulation or alternative models of regulation<sup>23</sup> as described below. A step-by-step guidance to assess regulatory alternatives is given in the publication “Assessing Regulatory Alternatives” (Treasury Board of Canada Secretariat, Government of Canada)<sup>24</sup>.

<sup>23</sup> Using alternatives to regulation to achieve policy objectives (<https://www.nao.org.uk/wp-content/uploads/2014/06/Using-alternatives-to-regulation-to-achieve-policy-objectives1.pdf>)

<sup>24</sup> Assessing Regulatory Alternatives, Government of Canada, [https://www.dpac.tas.gov.au/\\_data/assets/pdf\\_file/0017/14822/18\\_Canadaassessing\\_reg\\_alternatives\\_e.PDF](https://www.dpac.tas.gov.au/_data/assets/pdf_file/0017/14822/18_Canadaassessing_reg_alternatives_e.PDF)

#### 8.6.2.3.1. Alternatives to regulation

Alternatives to regulation include the following:

- status quo, i.e. no new intervention/do nothing;
- reliance on general law, i.e. no new law or regulation;
- Information and education, educational programmes;
- Economic regulation instruments (taxes, incentives).

#### 8.6.2.3.2. Alternative models of regulation

Alternative models of regulation include:

- Self-regulation/Use of voluntary standards and codes of practice
- Enforced self-regulation/Co-regulation

A study<sup>25</sup> conducted by the Organisation for Economic Co-operation and Development (OECD) has shown that Governments, businesses and consumers can all benefit from industry self-regulation (ISR). For example, ISR could be more cost-effective for governments, to the extent that enforcement and monitoring burdens are lightened and/or shifted to business. Self-regulation by industry can take the form of adopting and applying voluntary standards and codes of practice. For example, while assuring food safety through regulation is one of the major concerns of government, yet industry can by itself apply codes of practice (e.g. the FAO Code of Good Hygiene Practices (GHPs) and HACCP principles<sup>26</sup>) to go a long way in achieving these objectives. Industry can apply voluntary standards where individual enterprises can be certified against the relevant standard by accredited certification bodies.

Whereas in self-regulation government has practically no role to play, in enforced self-regulation or co-regulation it has an explicit degree of involvement. Government could have a role in developing the code of practice to be applied, e.g. through the National Standards Body. Or government could impose enforcement modalities, such as use of specific accredited conformity assessment bodies, possibly from industry, to monitor compliance.

#### 8.6.2.3.3. Using alternatives

Which option or combination of options is chosen depends on the findings of the risk assessment undertaken under section 8.6.2.2 above. For instance, enhancing understanding of the regulatory objectives pursued by Government through information and education programmes combined with a decision to rely on the existing general law and not introduce new technical regulations could perhaps satisfactorily achieve the regulatory objectives. Another example could be a government decision to encourage targeted entities to use self-regulation and task the regulator to provide detailed guidance for the entities to themselves assess and monitor whether they are achieving the regulatory objectives. Box 5 offers guidance on using alternatives.

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<sup>25</sup> OECD (2015-03-01), "Industry Self-Regulation: Role and Use in Supporting Consumer Interests", OECD Digital Economy Papers, No. 247 ([https://www.oecd-ilibrary.org/science-and-technology/industry-self-regulation\\_5js4k1fjqkwh-en](https://www.oecd-ilibrary.org/science-and-technology/industry-self-regulation_5js4k1fjqkwh-en))

<sup>26</sup> FAO. 2023. Introduction and control of food hazards – Section 1. FAO Good Hygiene Practices (GHP) and Hazard Analysis and Critical Control Point (HACCP) Toolbox for Food Safety. Rome. <https://doi.org/10.4060/cc6226en>

## Box 5 - Regulatory alternatives

### Policymakers should

- Bring together all authorities and regulators dealing with the problem area and task them to consider whether existing legislation could be sufficient to address the problem.
- Engage regulated entities (under existing laws) or to-be regulated entities (under new proposed rule-based law) to understand their interests and incentives with respect to compliance, the associated costs and options to reduce economic burdens.
- Assess all economic regulation instruments, such as taxes, incentives, subsidies, government procurement conditions, etc., to encourage citizens and business to change behaviour.
- Engage consultation with manufacturing and agro-processing industries and trade associations, e.g. chambers of commerce or industry, to encourage them to develop and apply voluntary standards, codes of practice and similar instruments.
- Educate consumers to make informed choices about products for which regulation is envisaged.
- Assess the appropriateness of using regulatory alternatives.

### Regulators should

- Consider existing legislation and identify actions which could address the problem, such as those listed below.
- Simplification/clarification of the law.
- Improvement of enforcement by eliminating overlaps and duplication of responsibilities.
- Better communication with regulated entities to enable them to better understand their responsibilities and the risks of non-compliance for the public at large and to the image of the enterprises.
- Decreasing burdens on regulated entities by calibrating an appropriate regulatory response.

#### 8.6.2.4. Regulatory impact assessment (RIA)

In following a step-wise approach as described in 8.6.2.1, once a decision for government intervention is taken and after various alternatives have been assessed, which nevertheless point to a shortlist of a few possible regulatory options as solution, a RIA process should be undertaken to assist policy makers to decide on the option retained from the shortlist.

To start with, it is to be noted that there is no single definition or methodology for RIA. RIA – or some of its variants, such as impact assessment (IA) in the United Kingdom or the European Union, Regulatory Impact Statement (RIS) in Australia, etc. – encompasses a wide range of methods, procedures and governance arrangements<sup>27</sup>.

Regulatory impact assessment provides crucial information to decision makers on whether and how to regulate to achieve public policy goals. It is challenging to develop “correct” policy responses which also maximise societal well-being. It is the role of RIA to help assist with this, by critically examining the impacts and consequences of a range of alternative options. Improving the evidence base for regulation through RIA is one of the most important regulatory tools available to governments<sup>28</sup>.

<sup>27</sup> Regulatory Policy in Perspective: A Reader’s Companion to the OECD Regulatory Policy Outlook (2015), OECD Publishing, Paris. (<http://dx.doi.org/10.1787/9789264241800-en>)

<sup>28</sup> OECD (2020), Regulatory Impact Assessment, OECD Best Practice Principles for Regulatory Policy, OECD Publishing, Paris, <https://doi.org/10.1787/7a9638cb-en>.

The OECD has been leading work on regulatory reform and has produced a wide range of documents on RIA (See Annex F for a list of publications on RIA from the OECD and other organizations).

While RIA systems are common in developed countries, their adaptation to developing countries presents challenges due to limited capacities, governance and resources.

The World Bank proposes a tailored approach<sup>29</sup> called "RIA Light," suitable at first for developing contexts. "RIA Light" emphasizes practicality, focusing on transparency and decision-making quality without heavy reliance on quantitative analysis or full integration into policy processes, which may be unrealistic in low-resource settings. The OECD<sup>27</sup> also discusses the adoption and implementation of RIA worldwide, detailing its progress, challenges and examples from both developed and developing countries. Several developing and emerging countries, including Brazil, the Philippines, and South Africa, have piloted or adopted RIA, but these initiatives sometimes falter due to the absence of long-term strategies for integration into policymaking but also after donor or initial funding ends. Among lessons learned, it is observed that effective RIA systems require customization to a country's capacity and context. Developed countries provide models of success, but these must be adapted, not replicated, in developing country settings. An example of adaptation recommended in this Guidance is the use, initially, of qualitative data instead of quantitative data for the assessment of risk and also for the estimation of cost effectiveness in RIA.

A survey<sup>30</sup> of selected developing and emerging economies quite interestingly confirmed the above OECD findings with regard to the challenges in institutionalizing RIA in public policies. South Africa, Tanzania and Uganda were part of this survey. The findings for South Africa were that the few pilot RIAs were done mostly by consultants in an *ad hoc* fashion leading to a lack of ownership and the almost complete separation of RIA from the decision making process. In Uganda, the capacity to pursue regulatory reform (including RIA) had not developed since the end of the donor funded project, primarily because of a lack of funding.

A further snapshot on the use of RIA in Africa is provided by the World Bank's Global Indicators of Regulatory Governance (GIRG)<sup>31</sup> which measure inclusiveness of regulatory rulemaking processes as well as promotion of good regulatory practices, including implementation of impact assessment. The latest survey for collecting GIRG data was carried out between October 2017 and May 2018 and data for 46 countries in Sub-Saharan Africa show that 38 of these countries do not conduct an impact assessment of proposed new regulations. The situation may have changed since then but it nevertheless provides an informative snapshot of the situation in Africa.

All the above elements seem to indicate that a total, comprehensive and full-scale RIA implementation approach, the so-called "big bang" approach, would be a challenge for African countries and might not be the best approach. Instead, this Guidance proposes a phased strategy to introduce the RIA process in the technical regulatory system of African countries, notwithstanding the fact that any country may still choose to implement a full-scale RIA if it wishes to do so.

It is also clear that there is no "one size fits all" when considering the diversity of States, e.g. with regard to different legal systems, public service set-up, governance, etc. The guidance offered in this document should therefore be adapted, as necessary, by States when they establish and implement the RIA process. It should always be remembered that the RIA findings and report are an aid to policy decision-making and for this process to be useful, it should be carried out in the best of conditions as fits each country's situation. Box 6 and Annex G provide guidance on RIA.

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<sup>29</sup> Making it work: 'RIA light' for developing countries (Better regulation for growth- Governance frameworks and tools for effective regulatory reform), World Bank group, 2010) (<https://documents.worldbank.org/en/publication/documents-reports/documentdetail/184141468167049021/making-it-work-ria-light-for-developing-countries>)

<sup>30</sup> Adelle, C., Weiland, S., Dick, J., González, D., Marquart, J., Rots, G., Wübbeke, J., Zasada, I. (2016) Regulatory Impact Assessment: A Survey of Selected Developing and Emerging Economies. *Public Money and Management*, 36(2) 89-96 ([https://repository.up.ac.za/bitstream/handle/2263/51899/Adelle\\_Regulatory\\_%202016.pdf?sequence=1](https://repository.up.ac.za/bitstream/handle/2263/51899/Adelle_Regulatory_%202016.pdf?sequence=1))

<sup>31</sup> <https://rulemaking.worldbank.org/en/methodology>

## Box 6 - Regulatory impact assessment

### Policymakers should

- Develop guidance material on RIA and publish it as a guide, manual or procedure.
- Set a threshold for applying RIA to major technical regulation proposals and define the criteria for qualifying “major”.
- Ensure that the RIA system is standardized for the whole of government in terms of how the RIA process is carried out and the RIA content.
- Set out responsibilities for RIA preparation.
- Decide about adopting a phased approach to RIA implementation and define the time frame.
- Task the oversight body to exercise quality control on RIAs prepared by various regulators.
- Consider RIA to be an ongoing process and arrangements should be in place to learn from past experience.
- Clearly communicate RIA results to ensure transparency in decision-making.
- Validate the real impacts of adopted technical regulations sometime after their implementation to improve the RIA development process.

### Regulators should

- Report performance in the implementation of RIA and be accountable.
- Have internal RIA units to prepare RIAs.
- Provide adequate training for civil servants responsible for RIA preparation.
- Keep RIA simple and flexible while covering key features .
- For Cost-effectiveness Analysis (CEA), start with least cost or multi-criteria qualitative analysis, and then gradually moving to quantitative analysis.
- Use existing data as far as possible for CEA.
- Determine the size and scope of consultations or engagement with stakeholders at early stages and maintain constant dialogue.
- Make a realistic assessment of the likely rate of voluntary compliance to pre-empt the type and level of enforcement.
- Estimate resources required to enforce each option and their availabilities.
- Have detailed arrangements for in-built monitoring, evaluation and refinement mechanisms.

### 8.6.2.5. Regulatory alignment

ACTReF defines regulatory alignment as proper use of international standards in technical regulations and also the need for international standardizing bodies to strive for better international standards governance (*Source: WTO*).

Similar to the WTO TBT Agreement, the AfCFTA Agreement, through its Annex 6 on Technical Barriers to Trade, also advocates for the use of international standards or parts thereof as the basis of technical regulations so as not to create unnecessary obstacles to international trade. In Africa, standards are mainly developed by national standards bodies (NSBs), Regional Economic Communities (RECs) and African standards organizations (e.g. the African Organisation for Standardisation (ARSO) or the African Electrotechnical Standardization Commission (AFSEC)).

For priority products traded among States and which may be covered by different national standards, there is scope for harmonized African Standards (ARS) to be developed and aligned, whenever appropriate, with relevant international standards. The use of such ARS as a basis for technical regulations is deemed not to create unnecessary technical barriers to trade. Harmonization of standards thus could lead to regulatory convergence. Furthermore, if the harmonization is based on international standards, it conveys the message that Africa is replicating best international practice. Box 7 provides guidance.

## Box 7 - Regulatory alignment

### Policymakers should

- Make a commitment to use international standards or, in the absence of such international standards, ARSO/AFSEC harmonized African Standards, as relevant, as basis for technical regulations.
- Make a commitment to use ARSO/AFSEC harmonized African Standards, developed specifically upon the request of States for use in TRs.
- Make a commitment to withdraw any conflicting national standard or alternatively apply the principle of standards equivalence when relevant.
- Make a commitment to use, as far as possible, performance standards rather than specification based standards when referring to standards in technical regulations.
- Make a commitment to work with other States to align, among themselves, national standards that are referenced in their technical regulations, in case relevant international standards or ARSO/AFSEC harmonized African Standards do not exist and their development is not due in the short-term.

### Regulators should

- Use guidelines developed under ACTReF in the matter of referencing international standards or harmonized African Standards in technical regulations with a view to referencing only the essential requirements of a standard necessary to meet the desired objectives.
- Have plans to organize training courses for regulators in matters of referencing standards in technical regulations using training materials developed under ACTReF.

## 8.6.2.6. Mutual recognition (MR)

### 8.6.2.6.1. MR of accreditation and conformity assessment procedures

Accreditation is the ultimate element that builds trust in trade as to the results of conformity assessment of goods to technical regulations. Conformity assessment procedures in turn rely on an internationally recognized accreditation system as well as on a metrology system that has access to an internationally recognized measurement system traceable to the International System of Units (SI Units). Results of conformity assessment produced by different conformity assessment bodies (CABs) are mutually recognized when the CABs are accredited by an accreditation body that is signatory to the AFRAC MRA, or alternatively signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC MRA) or the International Accreditation Forum Multilateral Recognition Arrangement (IAF MLA) or any MRA operated by international accreditation bodies as recommended by AFRAC.

Note: It is to be noted that ILAC and IAF will merge to create the Global Accreditation Cooperation (GLOBAC) and that the GLOBAC MRA will replace the ILAC MRA and IAF MLA as from January 2026. The AFRAC MRA which is recognized under the ILAC MRA and IAF MLA will continue to be recognized under the GLOBAC MRA.

### 8.6.2.6.2. MR of technical regulations

ACTReF specifies that mutual recognition of TRs result from a determination that the TRs are equivalent when their regulatory objectives/outcomes are similar. The AfCFTA Agreement also has as objective to facilitate trade through instruments aimed at equivalence of technical regulations. Box 8 provides guidance on MR.

## Box 8 - Mutual recognition

### Policymakers should

- Have a clear policy for recognizing and accepting results of conformity assessment from any conformity assessment body (CAB), whether a national or foreign CAB, provided that it is accredited by any national, regional or multi-economy accreditation body which is internationally-recognized.
- Support national conformity assessment bodies to engage in voluntary Mutual Recognition Arrangements (MRAs) with CABs from other States.

### Regulators should

- Consider as equivalent and recognize TRs from other States provided that the regulatory objectives/outcomes of these TRs have been harmonized with any technical regulation on the same subject which is in force in the country.

### 8.6.2.7. International Regulatory Co-operation (IRC)

ACTReF defines International Regulatory Co-operation (IRC) as any agreement or organisational arrangement, formal or informal, between countries to promote some form of co-operation in the design, monitoring, enforcement, or ex post management of regulation.

IRC between trading partners is an effective means of building confidence by enhancing mutual understanding of regulatory systems, thereby supporting efforts that aim at removing unnecessary barriers to trade. One of the objectives of NaTReF is to apply relevant mechanisms of IRC for the purpose achieving regulatory convergence in dealing with other States. This follows from one of the objectives of the AfCFTA Agreement to facilitate trade through cooperation in technical regulations.

The OECD<sup>32</sup> has proposed 11 IRC mechanisms (list reproduced in Annex H) that countries may use to pursue their regulatory objectives. The list of mechanisms highlights the distinction between formal agreements involving supranational and intergovernmental cooperation 'at the top'; and more informal, trans-governmental agency-to-agency cooperation arrangements (or networks) lower down. Annex H also presents a table to illustrate the use of these mechanisms in Africa extracted from the publication at footnote<sup>33</sup>. Box 9 provides guidance on IRC.

## Box 9 - International Regulatory Cooperation

### Policymakers should

- Adopt a formal (written or otherwise) practice of undertaking regulatory co-operation with other States in matters of technical regulations.
- Have a clear process to select one or more IRC mechanisms to undertake regulatory co-operation with States in general and within the Regional Economic Community(ies) to which the country is member.
- Support regulators and other relevant quality infrastructure institutions, such as conformity assessment bodies, in engaging in IRC at agency level among peers, mainly in the area of non-regulated products.

### Regulators should

- Consider whether the country will use the simplest and most informal level mechanism to engage in IRC and upscale gradually or any other preferred mechanism.
- Use guidance developed under ACTReF in engaging with other States as well as within the REC (s) to which the country is member.

<sup>32</sup> OECD (2013), International Regulatory Co-operation: Addressing Global Challenges, OECD Publishing (<http://dx.doi.org/10.1787/9789264200463-en>)

<sup>33</sup> DESK STUDY ON REGULATORY COOPERATION ARRANGEMENTS AND MECHANISMS IN AFRICA, PAQI (2022), [https://www.qi-africa.ptb.de/fileadmin/user\\_upload/PAQI-Desk-study-Budoo-en-final-web.pdf](https://www.qi-africa.ptb.de/fileadmin/user_upload/PAQI-Desk-study-Budoo-en-final-web.pdf)

## 8.6.3. Best practices for processes

### 8.6.3.1. Good regulator practice

Since the regulatory body is at the centre of the whole regulatory system, its operations should adhere to practices termed as “good regulator practice”.

The “**OECD Best Practice Principles for Regulatory Policy: The Governance of Regulators**”<sup>34</sup>, is intended to assist countries in developing a consistent policy covering the role and functions of regulatory agencies in order to provide greater confidence that regulatory decisions are made on an objective, impartial and consistent basis, without conflict of interest, bias or improper influence. Efficient and effective regulators, with good regulatory management and governance practices, are needed to administer and enforce regulations.

There is a consistency in literature about what constitutes good regulator practice. They are as follows:

- a) Regulators should base their regulatory activities on risk<sup>35</sup>;
- b) Regulators should take an evidence based approach to determining the priority risks in their area of responsibility, and should allocate resources where they would be most effective in addressing those priority risks;
- c) Regulators should consider risk at every stage of their decision-making processes, including choosing the most appropriate type of intervention or way of working with those regulated; targeting checks on compliance; and when taking enforcement action;
- d) Regulators designing a risk assessment framework, for their own use or for use by others, should have mechanisms in place to consult on the design with those affected, and to review it regularly;
- e) Regulators, in making their assessment of risk, should recognise the compliance record of those they regulate, including using earned recognition approaches and should consider all available and relevant data on compliance, including evidence of relevant external verification;
- f) Regulators should review the effectiveness of their chosen regulatory activities in delivering the desired outcomes and make any necessary adjustments accordingly.

Box 10 provides guidance on good regulator practice.

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<sup>34</sup> OECD (2014), The Governance of Regulators, OECD Best Practice Principles for Regulatory Policy, OECD Publishing (<http://dx.doi.org/10.1787/9789264209015-en>)

<sup>35</sup> Regulators’ Code, 2013, Better Regulation Delivery Office, Department for Business, Innovation and Skills, UK (<https://assets.publishing.service.gov.uk/media/5f4e14e2e90e071c745ff2df/14-705-regulators-code.pdf>)

## Box 10 - Good regulator practice

### Policymakers should ensure that

- Each piece of legislation relating to a technical regulation clearly defines the powers, duties, roles and functions of the regulator so as to avoid overlaps and conflicts of interest with other regulatory bodies.
- The regulator has appropriate resourcing, including funding, and technically capable personnel whose skills are continuously enhanced through training and capacity-building efforts.
- The regulator is shielded from undue influence and maintains trust, integrity and independence by demonstrating transparency and accountability to the public and the parliament.
- The regulator maintains efficient and cohesive processes aimed at achieving regulatory coherence within and between regulators.
- The regulator focusses on outcomes and carries out evaluations to check whether the technical regulations meet their objectives and deliver benefits to the public.

### Regulators should

- Maintain consistency, coherence, timeliness and predictability in their decision-making process as well as in enforcement.
- Publish clear rules to provide access to regulated entities who wish to contest decisions of the regulator as well as rules to provide timely decisions on such appeals.
- Have adequate engagement with stakeholders and regulated entities.
- Have clear rules on public consultation mechanisms when a new technical regulation is being envisaged or when one is being reviewed as well as rules to provide feedback on how submitted comments were treated.
- Publish a regulatory planning agenda detailing technical regulations being proposed or envisaged, preferably on an annual basis but at least on a biennial basis, to give advance notice to the public and projected regulated entities to start planning their inputs.
- Consider whether the country will use

### 8.6.3.2. Setting regulatory objectives

Under ACTReF, the basis on which TRs on the same subject in force in different countries are recognized as equivalent is through the harmonization of regulatory approaches which target the same regulatory objectives/outcomes. The ACTReF policy states that “for the development of new TRs or the revision of the existing stock of TRs, States are encouraged to design their TRs to achieve regulatory objectives aiming at performance rather than on detailed specifications”.

It is thus important to set regulatory objectives so that they are clear to all parties and that the purpose of the technical regulation is attained. Normally the purpose would be framed by policy-makers to achieve a high-level policy objective while the operational regulatory objectives would be the domain of the regulators. Useful guidance is provided in the document in footnote<sup>36</sup> regarding the elements to be considered when drafting purpose and regulatory objectives.

Policy coherence may be achieved at the stage of policy development and decision, considering that policies are becoming more complex and interrelated, only to be lost at the stage of implementation, e.g. as a technical regulation. The framing of the regulatory objectives should therefore address the aspect of policy coherence too. Box 11 provides guidance on setting regulatory objectives.

## Box 11 - Setting regulatory objectives

### Policymakers should

- Take a formal decision to give priority to framing regulatory objectives in terms of performance.
- Give clear guidance which describes how the overall purpose of a proposed technical regulation is translated into objectives.

### Regulators should

- Carry out an analysis of any tension or trade-off between objectives, and explain how such conflicts should be managed and resolved.
- Apply a mechanism to coordinate with other national bodies having similar regulatory objectives in order to ensure policy coherence.
- Communicate with all stakeholders on the above points during the process of consultation .

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<sup>36</sup> Technical Regulations - Recommendations for development and enforcement: (Alex Inklaar, Elisabeth Stampfl-Blaha, Elisabeth Sperlich), PTB/ITC 2023, [https://www.ic.ptb.de/media/fileadmin/Publications/PTB\\_Info\\_Technical\\_Regulations\\_EN.pdf](https://www.ic.ptb.de/media/fileadmin/Publications/PTB_Info_Technical_Regulations_EN.pdf)

### 8.6.3.3. Ensuring transparency

Good transparency involves clearly articulating the principles and reasoning behind the regulatory approach and major decisions, and reporting openly on performance and outcomes. Transparent, non-discriminatory and efficient regulatory processes involves consulting with all significantly affected parties and also ensuring that administrative procedures for applying regulations contain an appeal process. The ability of citizens and businesses to understand fully their regulatory environment and to have a voice in regulatory decision making is a key feature of efficient and participative regulatory systems. Box 12 provides guidance on transparency.

Note: This Guidance and this section do not cover the statutory transparency requirements of the WTO TBT and AfCFTA Agreements which are well laid out and are part of the obligations of their members. Rather transparency in this Guidance and in this section is understood to be all the measures taken to build trust in regulation and regulators with regulated entities, stakeholders and the wider public.

## Box 12 - Ensuring transparency

### Policymakers should

- Have a public document which describes the respective roles and duties of regulators and regulated entities, including the perimeter of their responsibilities.
- Make publicly available and readily accessible policies, guidance and risk-based systems covering matters such as compliance, enforcement, decision-making and review.
- Have a procedure to report and publish regulatory performance against key criteria, measures and indicators.

### Regulators should

- Provide the means, e.g. through “one-stop shops”, of ensuring that domestic and foreign businesses can easily identify all requirements applicable to them.
- Have a procedure to ensure that the processes used to engage with stakeholders guard against any risk of potential (actual or perceived) preferential treatment or conflicts of interests.
- Have a procedure to ensure that regulated citizens and businesses have access to administrative and judicial review procedures for raising issues related to the rules that bind them, as well as timely decisions on their appeals.

### 8.6.3.4. Enforcement and compliance

The notion of risk was used in section 8.6.2.2 to determine if government intervention is warranted to address a policy problem, i.e. before a regulatory solution is envisaged. But it is also good practice and useful to use risk for the purpose of enforcement of existing TRs to secure compliance. Since resources to enforce TRs is always likely to be limited, it is good practice to have a methodology to render interventions both effective and efficient.

The term “risk-based targeting” is used<sup>37</sup> to refer to:

- the selection of the most appropriate intervention to drive better regulatory outcomes, which may be education, provision of information, inspection, etc.,

<sup>37</sup> PROPOSALS FOR DEVELOPING A COMMON APPROACH TO RISK ASSESSMENT, Better Regulation delivery office, UK, [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/263921/risk-assessment-paper.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/263921/risk-assessment-paper.pdf)

- the allocation of resource against the various interventions;
- the criteria against which businesses are targeted for those interventions.

The terms compliance, enforcement, intervention and inspection are explained in the Definitions section at the beginning of this Guidance.

Risk-based targeting allows for enforcement activities that is proportionate to the risk posed by a hazard event, based on information on the compliance status of a business, judgement about the likelihood of its future compliance, and what (if any) intervention is required. It also leads to reducing regulatory burdens on compliant businesses. This approach brings transparency in dealing with regulated entities since businesses receive meaningful feedback from regulators on their compliance performance and how to improve it. It also help businesses to understand the criteria against which they are being assessed, and how reducing levels of risk can result in different types of and/or less frequent interventions. Box 13 provides guidance on enforcement and compliance.

## Box 13 - Enforcement and compliance

### **Policymakers should**

- Have systematic procedures for making regulations known and accessible to affected parties.
- Implement measures to educate and engage with people and businesses to help them understand their obligations and encourage better behavior.
- Have procedures to make data collection efficient to minimize unnecessary burdens on regulated entities, including exploring the feasibility of digitizing data collection.

### **Regulators should**

- Apply measures to understand the context of the regulated entity and look at ways to minimize the regulatory burden.
- Apply measures to ensure that regulatory responses are consistent, efficient and proportionate to the risk while serious non-compliance will result in strong enforcement action.
- Have a procedure to monitor and identify where the technical regulations are being followed and where they are not while assisting businesses and individuals to understand and comply with the law.
- Apply measures to ensure that decisions are fair, reasonable, respectful and reliable and that actions will be informed by evidence.
- Apply measures for collection and analysis of high-quality relevant data to identify where intervention may be needed and to inform regulatory decision-making.

### 8.6.3.5. Monitoring, review and evaluation

Technical regulations must be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained. Unchecked, ongoing growth in the stock of technical regulations over time can reduce its relevance and effectiveness, and increase the risk of regulated entities having to comply with duplicate or conflicting compliance obligations applied by different regulators. Besides, redundant, irrelevant and/or out-of-date regulation that is inconsistent with technology, community expectations and priorities that change over time tie up regulatory resources and increase costs unnecessarily. Box 14 provides guidance on monitoring, review and evaluation.

## Box 14 - Monitoring, review and evaluation

### Policymakers should

- Have arrangements for a continuous performance measurement framework that includes appropriate measures and indicators of inputs, regulatory activities, outputs and outcomes to enable a meaningful assessment of regulatory performance across different objectives and responsibilities.
- Have measures to establish periodic reviews of the regulatory framework to ensure it is comprehensive and meaningful, and reflects priorities and regulatory objectives.
- Have measures to establish mechanisms for review of the existing stock of technical regulations with a view to assessing the need for amendment, simplification or possible repeal.
- Develop guidance material and tools, supported by training, for regulatory agencies on the purpose, requirements, processes and different approaches to undertake proportionate and effective ex post evaluations.

### Regulators should

- Have measures to implement timely and appropriate use of evaluations and post-implementation reviews of regulatory changes to determine whether intended outcomes have been achieved and to examine the impact of interventions.
- Have measures to ensure that the regulatory framework has the necessary flexibility and resources to assess emerging risks, and the likelihood of them crystallizing and impacting on regulatory objectives, based on an overall forward-looking approach.

## **PART IV – IMPLEMENTATION**

### **8.7. Implementation of NaTReF**

As mentioned earlier, NaTReF should be a public document, along the structure suggested in Annex A, and adopted at the relevant level of Government. Through this formal document, Government demonstrates its over-arching technical regulatory policy and the commitment to apply best practices in developing, applying, enforcing and reviewing technical regulations.

At present, all African countries will already be having their respective technical regulatory systems along which they operate. So, implementation here means that countries will not be pushing a start button to launch NaTReF but rather will be putting the whole issue on the drawing board so as to consolidate the existing technical regulatory framework.

However, for those countries which were not applying regulatory impact assessment at all, for example, implementation arrangements would mean a roll-out plan and time-frame for using this tool.

It is not expected that countries will immediately adopt and launch all the NaTReF elements described in this Guidance. For many countries, applying the NaTReF guidance will amount to a change in approach and therefore the Guidance should be considered as a menu from which countries can select the aspects they feel are priority for them. While the overall objective for States is to align with international best practices, the Guidance takes account of Africa's special situation in terms of resource constraints (e.g. lack of trained personnel and data).

Thus, a step-wise approach is recommended generally. For example, government should decide to regulate on the basis of a risk assessment and if this assessment shows that government intervention is required, then the next step consists of deciding on which regulatory management tools should be used. Again, it is recommended to start considering non-rule based alternatives to regulation as a first step, then considering alternative models of regulation and finally rule-based regulations.

Another example of a step-wise approach is to use certain tools, such risk assessment or regulatory impact assessment, based on using qualitative data at first then moving on to using quantitative data.

The Africa Quality Policy (AQP) Action Plan does provide for training and capacity-building on the application of NaTReF and it is expected that all States will have the opportunity to benefit from that.

## ANNEXES

### ANNEX A - TYPICAL STRUCTURE OF A NATREF

#### Part I –

##### Scope, objectives, rationale, principles

Scope of NaTReF

Objectives of NaTReF

Overall objective

Specific objectives

Justification for a NaTReF

Principles guiding NaTReF

#### PART II –

##### Governance and oversight

Technical regulatory policy (TRP)

Governance, oversight and coordination of the regulatory system

Governance

Oversight

Coordination

Rationale for an effective governance, oversight and coordination

#### PART III –

##### Regulatory management system-Best practices

###### Best practices for institutions

Power to regulate

Degree of regulatory independence

Organizational structure and internal governance

Training and capacity building

###### Best practices for regulatory management tools

Rationale for the step-wise approach in using tools of regulatory management

Risk-based regulatory approach

Regulatory alternatives

Regulatory impact assessment (RIA)

Regulatory alignment

Mutual recognition (MR)

International Regulatory Co-operation (IRC)

###### Best practices for processes

Good regulator practice

Setting regulatory objectives

Ensuring transparency

Enforcement and compliance

Monitoring, review and evaluation

#### PART IV – Implementation

Implementation of NaTReF

## ANNEX B - SELF-ASSESSMENT CHECKLIST

Chapter reference in Guidance	Chapter heading	Yes	No
<b>8.4</b>	<b>Technical regulatory policy</b>		
a)	Is there an explicit, published technical regulatory policy to pursue high quality regulation?	<input type="checkbox"/>	<input type="checkbox"/>
b)	Whether or not an explicit, published technical regulatory policy exists, is there any type of public policy guidance or advice or instruction about the following aspects:		
	i) setting out explicit whole-of-government principles of good technical regulatory quality?	<input type="checkbox"/>	<input type="checkbox"/>
	ii) adhering to principles of open government, including transparency and participation in the regulatory process?	<input type="checkbox"/>	<input type="checkbox"/>
	iii) addressing the requirements of the WTO TBT and AfcFTA Agreements as well as the principles and policies of ACTReF?	<input type="checkbox"/>	<input type="checkbox"/>
	iv) considering the likely effects of technical regulations on other States?	<input type="checkbox"/>	<input type="checkbox"/>
	v) establishment of mechanisms and institutions to actively provide oversight of technical regulatory policy procedures and goals?	<input type="checkbox"/>	<input type="checkbox"/>
	vi) considering risk assessment to decide on government intervention and to the design and implementation of technical regulations?	<input type="checkbox"/>	<input type="checkbox"/>
	vii) integrating regulatory impact assessment (RIA) into the early stages of the policy process for the formulation of new technical regulation proposals?	<input type="checkbox"/>	<input type="checkbox"/>
	viii) conducting systematic programme reviews of the stock of technical regulations to ensure that technical regulations remain up to date?	<input type="checkbox"/>	<input type="checkbox"/>
	ix) regularly publishing reports on the performance of regulators?	<input type="checkbox"/>	<input type="checkbox"/>
	x) developing a consistent policy covering the roles and functions of regulatory agencies?	<input type="checkbox"/>	<input type="checkbox"/>
	xi) ensuring the effectiveness of systems for the review of the legality and procedural fairness of technical regulations and of decisions made by bodies empowered to issue regulatory sanctions?	<input type="checkbox"/>	<input type="checkbox"/>
	xii) promoting, where appropriate, regulatory coherence through co-ordination mechanisms between all levels of government?	<input type="checkbox"/>	<input type="checkbox"/>
	xiii) fostering the development of technical regulatory management capacity and performance at all levels of government through awareness, training and other capacity-building programmes?	<input type="checkbox"/>	<input type="checkbox"/>

Chapter reference in Guidance	Chapter heading	Yes	No
<b>8.5</b>	<b>Governance, oversight and coordination of the regulatory system</b>		
a)	Is there an entity/individual close to core government executive functions (e.g. a cabinet commission or committee, or a senior Minister or a similar position) and vested with the necessary authority to exercise leadership in the governance function of the technical regulatory system?	<input type="checkbox"/>	<input type="checkbox"/>
b)	If answer to above (a) is “yes”, is the power/authority and leadership roles and functions of governance, including its inter-linkages with other government branches clearly defined?	<input type="checkbox"/>	<input type="checkbox"/>
c)	Is there an oversight body to monitor, oversee and promote progress across the whole of government and to maintain consistency between the approaches of the various actors involved in the technical regulatory process?	<input type="checkbox"/>	<input type="checkbox"/>
d)	If answer to above (c) is “yes”, are the reporting modalities to the governance entity described?	<input type="checkbox"/>	<input type="checkbox"/>
e)	If answer to above (c) is “yes”, are the roles and functions of the oversight body clearly described?	<input type="checkbox"/>	<input type="checkbox"/>
f)	If answer to above (c) is “yes”, are the coordination modalities among the governance, the oversight body and national structures/focal points having responsibilities with regard the WTO TBT and the AfCFTA Agreements clearly described?	<input type="checkbox"/>	<input type="checkbox"/>
<b>8.6</b>	<b>Regulatory management system</b>		
<b>8.6.1.</b>	<b>Best practices for institutions</b>		
<b>8.6.1.1</b>	<b>Power to regulate</b>		
a)	Are the powers to develop and enforce technical regulations for each regulator clearly identified in primary or secondary legislation?	<input type="checkbox"/>	<input type="checkbox"/>
b)	If answer to above (a) is “yes”, is there a regular examination to determine whether each regulator is able to match that power to its objectives, responsibilities, functions, capacity and resources?	<input type="checkbox"/>	<input type="checkbox"/>
c)	If answer to above (b) is “yes”, are gaps in power to achieve objectives properly addressed by the relevant authority?	<input type="checkbox"/>	<input type="checkbox"/>
<b>8.6.1.2.</b>	<b>Degree of regulatory independence</b>		
a)	Is the degree of regulatory independence of each regulator clearly established relative to the executive branch of government?	<input type="checkbox"/>	<input type="checkbox"/>
b)	Is the degree of regulatory independence of each regulator clearly established relative to regulated entities?	<input type="checkbox"/>	<input type="checkbox"/>
c)	Does the administrative form for each regulator enable it to carry out its objectives, responsibilities and functions efficiently?	<input type="checkbox"/>	<input type="checkbox"/>
d)	If answer to above (c) “no”, are there arrangements and procedures to modify the administrative form to enable efficient operations?	<input type="checkbox"/>	<input type="checkbox"/>

Chapter reference in Guidance	Chapter heading	Yes	No
<b>8.6.1.3.</b>	<b>Organizational structure and internal governance</b>		
	Does each regulatory body have sufficient resources to fulfil its statutory duties, including its internal governance, management, staffing and enforcement capacity?	<input type="checkbox"/>	<input type="checkbox"/>
	Does each regulatory body have access to technical expertise through advisory bodies/committees composed of multi-stakeholder interests?	<input type="checkbox"/>	<input type="checkbox"/>
<b>8.6.1.4.</b>	<b>Training and capacity building</b>		
a)	Has there been a formal process to identify training and capacity-building needs across the whole cross-section of the technical regulatory system, including the public sector, the private sector and interested parties such as consumers and civil society?	<input type="checkbox"/>	<input type="checkbox"/>
b)	Is there a formal training programme to better equip civil servants with the skills to develop high quality regulation?	<input type="checkbox"/>	<input type="checkbox"/>
c)	Whether or not there is a formal training programme, is there any sort of plan or programme meant to train civil servants on the following:		
	i) legal drafting principles and skills?	<input type="checkbox"/>	<input type="checkbox"/>
	ii) understanding and applying Good regulatory practice (GRP)?	<input type="checkbox"/>	<input type="checkbox"/>
	iii) setting technical regulatory objectives aimed at performance rather than on detailed specifications?	<input type="checkbox"/>	<input type="checkbox"/>
	iv) how to conduct risk analysis and regulatory impact assessment?	<input type="checkbox"/>	<input type="checkbox"/>
	v) assessment and use of alternative policy instruments other than regulations?	<input type="checkbox"/>	<input type="checkbox"/>
	vi) understanding quality policy and quality infrastructure as they relate to the technical regulatory system?	<input type="checkbox"/>	<input type="checkbox"/>
	vii) use of international standards in TRs to achieve regulatory alignment?	<input type="checkbox"/>	<input type="checkbox"/>
	viii) referencing standards effectively in technical regulations and using performance-based rather than specification-based standards?	<input type="checkbox"/>	<input type="checkbox"/>
	ix) helping regulated entities understand what is expected of them and assure voluntary compliance while continuously endeavouring to reduce burdens to business?	<input type="checkbox"/>	<input type="checkbox"/>
	x) <i>ex post</i> evaluation of regulatory outcomes to verify whether regulations achieve objectives?	<input type="checkbox"/>	<input type="checkbox"/>
	xi) International Regulatory Co-operation mechanisms and their applicability to different situations to reduce regulatory differences?	<input type="checkbox"/>	<input type="checkbox"/>
	xii) enforcement effort, including market surveillance, to be applied systematically, fairly and proportionate to risk?	<input type="checkbox"/>	<input type="checkbox"/>
	xiii) use of digital technology to increase efficiency with regard to data collection and sharing?	<input type="checkbox"/>	<input type="checkbox"/>
d)	Are identified training and capacity-building activities being deployed systematically to their identified target groups?	<input type="checkbox"/>	<input type="checkbox"/>

Chapter reference in Guidance	Chapter heading	Yes	No
e)	Is there a plan to build awareness on actions needed to understand and apply ACTReF principles and policies on regulatory convergence including harmonization of regulatory approaches, mutual recognition, harmonization, regulatory distance, over- and under-regulation?	<input type="checkbox"/>	<input type="checkbox"/>
<b>8.6.2</b>	<b>Best practices for regulatory management tools</b>		
<b>8.6.2.2.</b>	<b>Risk-based regulatory approach</b>		
a)	Is there any legal or administrative requirement for carrying out a risk assessment when government proposes to address a policy problem with a possibility of resorting to technical regulations?	<input type="checkbox"/>	<input type="checkbox"/>
b)	If the answer to above (a) is “yes”, is there a written guide, manual or procedure for carrying out the risk assessment?	<input type="checkbox"/>	<input type="checkbox"/>
c)	Whether or not a written guide, manual or procedure exists, is there any type of guidance or advice or instruction about how to:		
	i) formulate a detailed definition of the problem that needs to be addressed?	<input type="checkbox"/>	<input type="checkbox"/>
	ii) engage with stakeholders?	<input type="checkbox"/>	<input type="checkbox"/>
	iii) define the scope of the risk assessment in terms of all the individuals, groups or economic operators, etc. affected by the regulatory proposal?	<input type="checkbox"/>	<input type="checkbox"/>
	iv) lay down the specific assumptions and constraints under which the risk assessment is conducted?	<input type="checkbox"/>	<input type="checkbox"/>
	v) specify the sources of information to be used in the risk assessment?	<input type="checkbox"/>	<input type="checkbox"/>
	vi) define the risk factors and the assessment approach (qualitative or semi-quantitative) to be used?	<input type="checkbox"/>	<input type="checkbox"/>
	vii) identify hazard sources that are relevant to the regulatory proposal?	<input type="checkbox"/>	<input type="checkbox"/>
	viii) identify hazard events that could be produced by those sources?	<input type="checkbox"/>	<input type="checkbox"/>
	ix) identify vulnerabilities within all impacted individuals/organizations?	<input type="checkbox"/>	<input type="checkbox"/>
	x) determine the likelihood that the identified hazard sources would initiate specific hazard events and the likelihood that the hazard events would be successful?	<input type="checkbox"/>	<input type="checkbox"/>
	xi) determine the adverse impacts to people, damage to property, economic damage to consumers, damage to economic operators, damage to the environment, economic damage to the country?	<input type="checkbox"/>	<input type="checkbox"/>
	xii) determine the risk to all affected individuals/organizations from hazard events of concern?	<input type="checkbox"/>	<input type="checkbox"/>
	xiii) consider the risk management options and procedure to retain any preferred option?	<input type="checkbox"/>	<input type="checkbox"/>
	xiv) present the results of the risk assessment?	<input type="checkbox"/>	<input type="checkbox"/>

Chapter reference in Guidance	Chapter heading	Yes	No
8.6.2.3.	<b>Regulatory alternatives</b>		
a)	Is there any process, procedure or manual at national level which lays down the steps to follow to consider regulatory alternatives before a proposal for a technical regulation is adopted?	<input type="checkbox"/>	<input type="checkbox"/>
b)	Whether or not a process, procedure or manual exists, is there any type of guidance or advice or instruction about how to:		
i)	Bring together all authorities and regulators dealing with the problem area and task them to consider whether existing legislation could be sufficient to address the problem through		
	<ul style="list-style-type: none"> <li>• simplification/clarification,</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
	<ul style="list-style-type: none"> <li>• improvement of enforcement by eliminating overlaps and duplication of responsibilities,</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
	<ul style="list-style-type: none"> <li>• better communication with regulated entities to enable them to better understand their responsibilities and the risks of non-compliance for the public at large and to the image of the enterprises,</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
	<ul style="list-style-type: none"> <li>• decreasing burdens on regulated entities by calibrating an appropriate regulatory response, for example, light-touch for compliant organisations; advice for those needing guidance; or warnings and potential enforcement action against the non-compliant and potential offenders?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
ii)	Engage regulated entities (under existing laws) or to-be regulated entities (under new proposed rule-based law) to understand their interests and incentives with respect to compliance, the associated costs and options to reduce economic burdens?	<input type="checkbox"/>	<input type="checkbox"/>
iii)	Assess the feasibility and impact of educating consumers so that they may make informed decisions about products for which regulation is being envisaged?	<input type="checkbox"/>	<input type="checkbox"/>
iv)	Assess all economic regulation instruments, such as taxes, incentives, subsidies, government procurement conditions, etc., to encourage citizens and business to change behaviour?	<input type="checkbox"/>	<input type="checkbox"/>
v)	Engage consultation with manufacturing and agro-processing industries and trade associations, e.g. chambers of commerce or industry, to explore to what extent these bodies can take ownership in developing and applying voluntary standards, codes of practice and similar instruments to achieve a stated objective?	<input type="checkbox"/>	<input type="checkbox"/>
vi)	Assess the appropriateness of using regulatory alternatives against a framework based on criteria such as effectiveness, efficiency, ability of targeted entities to comply, etc.?	<input type="checkbox"/>	<input type="checkbox"/>
8.6.2.4.	<b>Regulatory impact assessment (RIA)</b>		
a)	Is there any legal or administrative requirement for carrying out a RIA when government proposes to address a policy problem by resorting to technical regulations?	<input type="checkbox"/>	<input type="checkbox"/>
b)	If the answer to above (a) is “yes”, is there a written guide, manual or procedure for carrying out the RIA?	<input type="checkbox"/>	<input type="checkbox"/>

Chapter reference in Guidance	Chapter heading	Yes	No
c)	Whether or not a written guide, manual or procedure exists, is there any type of guidance or advice or instruction about how to:		
	i) set a threshold for applying RIA to major technical regulation proposals and define the criteria for qualifying “major”?	<input type="checkbox"/>	<input type="checkbox"/>
	ii) ensure that the RIA system is standardised for the whole of government in terms of how the RIA process is carried out and the RIA content?	<input type="checkbox"/>	<input type="checkbox"/>
	iii) set out responsibilities for RIA preparation, including the establishment of internal RIA units which could be supported in their work by an external multidisciplinary RIA team, e.g. an RIA helpdesk?	<input type="checkbox"/>	<input type="checkbox"/>
	iv) keep the methodology to assess impacts simple and flexible while covering key features?	<input type="checkbox"/>	<input type="checkbox"/>
	v) apply least cost or multi-criteria qualitative analysis to carry out Cost-effectiveness Analysis (CEA)?	<input type="checkbox"/>	<input type="checkbox"/>
	vi) collect reliable data from various sources?	<input type="checkbox"/>	<input type="checkbox"/>
	vii) implement constant dialogue and consultation with stakeholders, including communication of RIA results?	<input type="checkbox"/>	<input type="checkbox"/>
	viii) estimate the likely rate of voluntary compliance with the proposed technical regulation?	<input type="checkbox"/>	<input type="checkbox"/>
	ix) evaluate the effectiveness and efficiency of proposed implementation, enforcement and compliance strategies?	<input type="checkbox"/>	<input type="checkbox"/>
d)	Has Government taken, or due to take, a formal decision about adopting a phased approach to RIA implementation and defined the time frame?	<input type="checkbox"/>	<input type="checkbox"/>
e)	Has Government designated an oversight body to look at all aspects of RIA implementation?	<input type="checkbox"/>	<input type="checkbox"/>
f)	Has Government detailed a plan for training of civil servants in the implementation of RIA?	<input type="checkbox"/>	<input type="checkbox"/>
g)	Has Government detailed arrangements for in-built monitoring, evaluation and refinement mechanisms to allow validation of the real impacts after the technical regulation is implemented?	<input type="checkbox"/>	<input type="checkbox"/>
<b>8.6.2.5.</b>	<b>Regulatory alignment</b>		
a)	Is there a clear commitment to use international standards or, in the absence of such international standards, ARSO/AFSEC harmonized African Standards, as relevant, as basis for technical regulations?	<input type="checkbox"/>	<input type="checkbox"/>
b)	Is there a clear commitment or general policy to withdraw any conflicting national standard or alternatively apply the principle of standards equivalence when using ARSO/AFSEC harmonized African Standards, as relevant, as basis for technical regulations?	<input type="checkbox"/>	<input type="checkbox"/>
c)	Is there a clear commitment to use, as far as possible, performance standards rather than specification based standards, when referencing standards in technical regulations?	<input type="checkbox"/>	<input type="checkbox"/>

Chapter reference in Guidance	Chapter heading	Yes	No
d)	Is there a clear commitment to work with other States to align, among themselves, national standards that are referenced in their technical regulations, in case relevant international standards or ARSO/AFSEC harmonized African Standards do not exist and their development is not due in the short-term?	<input type="checkbox"/>	<input type="checkbox"/>
e)	Is there a clear guidance in the manner of referencing international standards or harmonized African Standards in technical regulations with a view to referencing only the essential requirements of a standard necessary to meet the desired objectives?	<input type="checkbox"/>	<input type="checkbox"/>
f)	If answer to above (e) is “yes”, does Government implement training for regulators to apply the guidance?	<input type="checkbox"/>	<input type="checkbox"/>
g)	If answer to above (e) is “no”, does Government commit to use the guidelines and the training materials developed under ACTReF in matter of referencing international standards or harmonized African Standards in technical regulations to train regulators?	<input type="checkbox"/>	<input type="checkbox"/>
<b>8.6.2.6.</b>	<b>Mutual recognition (MR)</b>		
a)	Is there a clear policy of recognizing and accepting results of conformity assessment from any conformity assessment body (CAB), whether a national or foreign CAB, provided that it is accredited by any national, regional or multi-economy accreditation body which is internationally-recognized?	<input type="checkbox"/>	<input type="checkbox"/>
b)	Is there a clear guidance supporting national conformity assessment bodies to engage in voluntary Mutual Recognition Arrangements (MRAs) with CABs from other States?	<input type="checkbox"/>	<input type="checkbox"/>
c)	Is there a clear guidance for considering as equivalent and recognizing TRs from other States provided that the regulatory objectives/outcomes of these TRs have been harmonized with any technical regulation on the same subject which is in force in the country?	<input type="checkbox"/>	<input type="checkbox"/>
<b>8.6.2.7.</b>	<b>International Regulatory Co-operation (IRC)</b>		
a)	Is there a formal (written or otherwise) practice of undertaking regulatory co-operation with other States in matters of technical regulations?	<input type="checkbox"/>	<input type="checkbox"/>
b)	If answer to above (a) is “yes”, does the cooperation involve only the States which are members of the regional economic community (ies) to which the country belongs?	<input type="checkbox"/>	<input type="checkbox"/>
c)	Is there a clear guidance as to the preferred mechanism for undertaking IRC from among the 11 mechanisms proposed by the OECD?	<input type="checkbox"/>	<input type="checkbox"/>
d)	If answer to above (c) is “yes”, does the government guidance imply the use the simplest and most informal level mechanism and upscale gradually?	<input type="checkbox"/>	<input type="checkbox"/>
e)	Is there a clear guidance to support regulators and other relevant quality Infrastructure institutions, such as conformity assessment bodies, in engaging in IRC at agency level among peers, mainly in the area of non-regulated products?	<input type="checkbox"/>	<input type="checkbox"/>
f)	Does Government have a clear commitment to use guidance developed under ACTReF in engaging with other States as well as within the REC (s) to which the country is member?	<input type="checkbox"/>	<input type="checkbox"/>

Chapter reference in Guidance	Chapter heading	Yes	No
<b>8.6.3.</b>	<b>Best practices for processes</b>		
<b>8.6.3.1.</b>	<b>Good regulator practice</b>		
a)	Does Government, through regulatory governance and oversight entities, if they exist, have a clear guidance to ensure that:		
i)	legislation relating to a technical regulation clearly defines the powers, duties, roles and functions of the regulator,	<input type="checkbox"/>	<input type="checkbox"/>
ii)	the regulator has appropriate resourcing, including funding and technically capable personnel,	<input type="checkbox"/>	<input type="checkbox"/>
iii)	the regulator is shielded from undue influence and maintains trust, integrity and independence,	<input type="checkbox"/>	<input type="checkbox"/>
iv)	the regulator maintains efficient and cohesive processes aimed at achieving regulatory coherence within and between regulators,	<input type="checkbox"/>	<input type="checkbox"/>
v)	the regulator focusses on outcomes and carries out evaluations to check whether the technical regulations meet and their objectives and deliver benefits to the public,	<input type="checkbox"/>	<input type="checkbox"/>
vi)	the internal Governance of the regulator has set clear management processes and procedures,	<input type="checkbox"/>	<input type="checkbox"/>
vii)	the regulator maintains consistency, coherence, timeliness and predictability in its decision-making process as well as in enforcement,	<input type="checkbox"/>	<input type="checkbox"/>
viii)	the regulator publishes clear rules to provide access to regulated entities who wish to contest decisions of the regulator as well as rules to provide timely decisions on such appeals,	<input type="checkbox"/>	<input type="checkbox"/>
ix)	the regulator has adequate engagement with stakeholders and regulated entities,	<input type="checkbox"/>	<input type="checkbox"/>
x)	the regulator has clear rules on public consultation mechanisms when a new technical regulation is being envisaged or when one is being reviewed,	<input type="checkbox"/>	<input type="checkbox"/>
xi)	the regulator publishes a regulatory planning agenda to give advance notice to the public and projected regulated entities to start planning their inputs on a proposed regulation?	<input type="checkbox"/>	<input type="checkbox"/>
<b>8.6.3.2.</b>	<b>Setting regulatory objectives</b>		
a)	Is there a clear guidance from the oversight entity which describes how the overall purpose of a proposed technical regulation is translated into objectives?	<input type="checkbox"/>	<input type="checkbox"/>
b)	Does the regulator carry out an analysis of any tension or trade-off between objectives, and an explanation about how such conflicts should be managed and resolved?	<input type="checkbox"/>	<input type="checkbox"/>
c)	Is there a formal decision to give priority to framing regulatory objectives in terms of performance?	<input type="checkbox"/>	<input type="checkbox"/>
d)	Is there a mechanism for the regulator to coordinate with other national bodies having similar regulatory objectives in order to ensure policy coherence?	<input type="checkbox"/>	<input type="checkbox"/>
e)	Is there a clear process for communication with all stakeholders on the above points during the process of consultation?	<input type="checkbox"/>	<input type="checkbox"/>

Chapter reference in Guidance	Chapter heading	Yes	No
<b>8.6.3.3.</b>	<b>Ensuring transparency</b>		
a)	Is there a procedure for ensuring that domestic and foreign businesses can easily identify all regulatory requirements applicable to them?	<input type="checkbox"/>	<input type="checkbox"/>
b)	Is there a public document which describes the respective roles and duties of regulators and regulated entities, including the perimeter of their responsibilities?	<input type="checkbox"/>	<input type="checkbox"/>
c)	Are there publicly available and readily accessible policies, guidance and risk-based systems covering matters such as compliance, enforcement, decision-making and review?	<input type="checkbox"/>	<input type="checkbox"/>
d)	Is there a procedure to report and publish regulatory performance against key criteria, measures and indicators?	<input type="checkbox"/>	<input type="checkbox"/>
e)	Is there a procedure to ensure that the processes used to engage with stakeholders guard against any risk of potential (actual or perceived) preferential treatment or conflicts of interests?	<input type="checkbox"/>	<input type="checkbox"/>
f)	Is there a procedure to ensure that regulated citizens and businesses have access to administrative and judicial review procedures for raising issues related to the rules that bind them, as well as timely decisions on their appeals?	<input type="checkbox"/>	<input type="checkbox"/>
<b>8.6.3.4.</b>	<b>Enforcement and compliance</b>		
a)	Are there systematic procedures for making regulations known and accessible to affected parties?	<input type="checkbox"/>	<input type="checkbox"/>
b)	Are there measures to educate and engage with people and businesses to help them understand their obligations and encourage better behaviour?	<input type="checkbox"/>	<input type="checkbox"/>
c)	Are there measures for regulators to understand the context of the regulated entity and look at ways to minimise the regulatory burden?	<input type="checkbox"/>	<input type="checkbox"/>
d)	Are there measures to ensure that regulatory responses are consistent, efficient and proportionate to the risk while serious non-compliance will result in strong enforcement action?	<input type="checkbox"/>	<input type="checkbox"/>
e)	Is there a procedure to monitor and identify where the technical regulations are being followed and where they are not while assisting businesses and individuals to understand and comply with the law?	<input type="checkbox"/>	<input type="checkbox"/>
f)	Are there measures to ensure that decisions will be fair, reasonable, respectful and reliable and that actions will be informed by evidence?	<input type="checkbox"/>	<input type="checkbox"/>
g)	Are there measures for collection and analysis of high-quality relevant data to identify where intervention may be needed and to inform regulatory decision-making?	<input type="checkbox"/>	<input type="checkbox"/>
h)	Is there a procedure to make data collection efficient to minimise unnecessary burdens on regulated entities, including exploring the feasibility of digitising data collection as far as possible?	<input type="checkbox"/>	<input type="checkbox"/>
<b>8.6.3.5.</b>	<b>Monitoring, review and evaluation</b>		
a)	Are there arrangements for a continuous performance measurement framework that includes appropriate measures and indicators of inputs, regulatory activities, outputs and outcomes to enable a meaningful assessment of regulatory performance across different objectives and responsibilities?	<input type="checkbox"/>	<input type="checkbox"/>
b)	Are there measures to establish periodic reviews of the technical regulatory framework to ensure it is comprehensive and meaningful, and reflects priorities and regulatory objectives?	<input type="checkbox"/>	<input type="checkbox"/>

Chapter reference in Guidance	Chapter heading	Yes	No
c)	Are there measures to establish mechanisms for review of the existing stock of technical regulations with a view to assessing the need for amendment, simplification or possible repeal?	<input type="checkbox"/>	<input type="checkbox"/>
d)	Are there measures to implement timely and appropriate use of evaluations and post-implementation reviews of regulatory changes to determine whether intended outcomes have been achieved and to examine the impact of interventions?	<input type="checkbox"/>	<input type="checkbox"/>
e)	Are there any guidance material and tools, supported by training, for agencies on the purpose, requirements, processes and different approaches to undertake proportionate and effective ex post evaluations?	<input type="checkbox"/>	<input type="checkbox"/>
f)	Are there measures to ensure that the regulatory framework has the necessary flexibility and resources to assess emerging risks, and the likelihood of them crystallising and impacting on regulatory objectives, based on an overall forward-looking approach?	<input type="checkbox"/>	<input type="checkbox"/>

## ANNEX C - ACTREF PRINCIPLES

- i. a comprehensive approach, i.e. covering all relevant economic, social and environmental impacts, all interested parties and every phase in the policy cycle;
- ii. a participative approach, i.e. all interested parties should be able to contribute to policy making by expressing their views;
- iii. transparency and public consultation mechanisms i.e. preparing laws and regulation in a transparent way (i.e. openly documenting the process, making available the evidence underpinning political decisions and explaining the underlying rationale);
- iv. proportionate approach, i.e. while comprehensive, the approach should also be proportionate to the expected impacts and analysis should focus on areas where it matters most;
- v. a coherent approach, i.e. taking account of all relevant high-level and long-term policy objectives of the AU to identify important linkages and develop policies to achieve those objectives;
- vi. an evidence-based approach, i.e. policy decisions need to be informed by the best available evidence;
- vii. mechanisms for assessing policy options, including the need to regulate (e.g. how to evaluate the impact of alternatives through an evidence-based process, including through the use of regulatory impact assessment (RIA) tools);
- viii. national, regional and continental regulatory coordination mechanisms;
- ix. approaches to minimizing burdens on economic operators;
- x. implementation and enforcement mechanisms (e.g. how to provide practical, timely and informative guidance needed for compliance) are transparent and non-discriminatory;
- xi. mechanisms for review of existing technical regulations and conformity assessment procedures (e.g. how to evaluate the efficiency, effectiveness and continued adequacy of existing measures, including with a view to assessing the need for amendment, simplification or possible repeal);
- xii. mechanisms for taking account of the development and capacity needs; and learning from and sharing experience.

## **ANNEX D - GUIDANCE ON GOVERNANCE, OVERSIGHT AND COORDINATION**

### **D.1 The governance entity/individual close to core government executive functions could be:**

- i. the ministers responsible for the portfolios of either international trade or commerce or industry are the more likely candidates for leading the governance functions;
- ii. in countries where all primary or secondary legislative texts have to be vetted by the Attorney General's (AG) office or the office of the Solicitor-General (SG) before they are processed further (i.e. for primary legislation submitted to the Parliament/National Assembly and for secondary legislation to be published in the Official Journal/Government Gazette), either the AG or the SG could also lead;
- iii. the designation of governance among the above options depends upon whether the country in question is already tackling regulatory reform in general and not only technical regulations. In the first case, the governance is more likely to be closer to the Cabinet. If only technical regulations are under consideration, probably a Minister would be more likely to be designated.

### **D.2 Aspects regarding the oversight body to fulfil the functions indicated in section 8.5.2:**

- i. The oversight body should have access to technical expertise to be credible and be assured of political support and institutional stability over time, meaning the proper allocation of resources to allow it to function properly.
- ii. The institutional form the body may take depends on the political and public administration culture of the country concerned. The following options are the most common: (a) a central body overseeing all the technical regulatory functions, (b) a central body coordinating the technical regulatory functions with a network of units in various ministries, (c) an inter-ministerial committee. Each option has its pros and cons; for example, in option (a), it can be expected that the process would be more effective and efficient but there is also a risk that ministries or departments having exercised the regulatory functions since a long time may feel undermined or threatened. On the other hand, in option (c), sectoral interests (e.g. trade versus environmental protection) could lead to deadlocks and dilution of accountability. In option (b), accountability rests with the central coordinating body which may also have the necessary authority and power if housed near the highest political level. However, this option also gives a leeway to other Ministries to contribute to the process.
- iii. The terms of reference for the oversight body should go beyond overseeing the rule-making process and also address objective assessments of the quality of technical regulatory proposals submitted for its consideration, including the quality of the RIA findings. This function also gives a "gatekeeper" role to the oversight body, meaning that a proposal may be withheld until it is deemed to be fit for consideration higher up in the chain.

## ANNEX E - MODEL TABLES FOR RISK ASSESSMENT RESULTS

The tables below represent model assessment scales for assessing levels of risk<sup>38</sup>

Table 1- Assessment scale – Level of risk (combination of likelihood and impact)

Likelihood (Hazard event occurs and results in adverse impact)	Level of Impact				
	Very low	Low	Moderate	High	Very high
Very High	Very Low	Low	Moderate	High	Very High
High	Very Low	Low	Moderate	High	Very High
Moderate	Very Low	Low	Moderate	Moderate	High
Low	Very Low	Low	Low	Low	Moderate
Very Low	Very Low	Very Low	Very Low	Low	Low

Table 2- Assessment scale – Level of risk

Qualitative Values	Semi-Quantitative Values	Description
Very High	10	<b>Very high risk</b> means that a threat event could be expected to have <b>multiple severe or catastrophic</b> adverse effects
High	8	<b>High risk</b> means that a threat event could be expected to have a <b>severe or catastrophic</b> adverse effect
Moderate	5	<b>Moderate risk</b> means that a threat event could be expected to have a <b>serious</b> adverse effect
Low	2	<b>Low risk</b> means that a threat event could be expected to have a <b>limited</b> adverse effect
Very Low	0	<b>Very low risk</b> means that a threat event could be expected to have a <b>negligible</b> adverse effect

<sup>38</sup> Guide for Conducting Risk Assessments (2012), National Institute of Standards and Technology, U.S. Department of Commerce

## ANNEX F- PUBLICATIONS ON RIA

- 1) (OECD, 2008), Introductory Handbook for Undertaking Regulatory Impact Analysis (RIA)
- 2) “Chile Evaluation Report: Regulatory Impact Assessment”, 2017, OECD Reviews of Regulatory Reform, Paris, [https://www.oecd.org/en/publications/chile-evaluation-report-regulatory-impact-assessment\\_e791d04e-en.html](https://www.oecd.org/en/publications/chile-evaluation-report-regulatory-impact-assessment_e791d04e-en.html)
- 3) BETTER HANDBOOK REGULATION-How to design and review regulation, and prepare a Regulatory Impact Statement., Government of South Australia, 2022, <https://www.dpc.sa.gov.au/resources-and-publications/Better-Regulation-Handbook.pdf>
- 4) Better Regulation Guidelines, EU Commission staff working document, Brussels 2021. [https://commission.europa.eu/document/download/d0bbd77f-bee5-4ee5-b5c4-6110c7605476\\_en?filename=swd2021\\_305\\_en.pdf](https://commission.europa.eu/document/download/d0bbd77f-bee5-4ee5-b5c4-6110c7605476_en?filename=swd2021_305_en.pdf)
- 5) Building an Institutional Framework for Regulatory Impact Analysis (RIA): Guidance for Policy Makers (2008), Paris, <http://www.oecd.org/regreform/regulatory-policy/40984990.pdf>
- 6) Handbook on Designing and Implementing Regulatory Impact Assessment Systems (<https://thecommonwealth.org/publications/handbook-designing-and-implementing-regulatory-impact-assessment-systems>)
- 7) Making it work: ‘RIA light’ for developing countries (Better regulation for growth- Governance frameworks and tools for effective regulatory reform), World Bank group, 2010 (<https://documents.worldbank.org/en/publication/documents-reports/documentdetail/184141468167049021/making-it-work-ria-light-for-developing-countries>)
- 8) OECD (2010) INTRODUCTORY HANDBOOK FOR UNDERTAKING REGULATORY IMPACT ANALYSIS (RIA), <https://regulatoryreform.com/wp-content/uploads/2015/02/OECD-HANDBOOK-FOR-UNDERTAKING-RIA.pdf>
- 9) OECD (2020), Regulatory Impact Assessment, OECD Best Practice Principles for Regulatory Policy, OECD Publishing, Paris, <https://doi.org/10.1787/7a9638cb-en>
- 10) OECD Regulatory Policy Outlook 2015, Paris, <https://doi.org/10.1787/9789264238770-en>
- 11) OECD Regulatory Policy Outlook 2018, Paris, <https://doi.org/10.1787/9789264303072-en>
- 12) Promoting inclusive growth through better regulation: The role of regulatory impact assessment (Deighton-Smith, Erbacci and Kauffmann, 2016), OECD Regulatory Policy Working Papers, No. 3
- 13) Recommendation of the Council on Regulatory Policy and Governance, OECD Publishing, Paris, <http://dx.doi.org/10.1787/9789264209022-en>
- 14) Regulatory Impact Analysis (RIA) Inventory (2004), Paris, <http://www.oecd.org/gov/regulatory-policy/35258430.pdf>
- 15) Regulatory Impact Analysis in OECD Countries Challenges for developing Countries (Rodrigo, 2005), Paris, <http://www.oecd.org/gov/regulatory-policy/35258511.pdf>

- 16) Regulatory Impact Analysis: A Tool for Policy Coherence (2009), Paris, <http://dx.doi.org/10.1787/9789264067110-en>
- 17) Regulatory Impact Analysis: Best Practices in OECD Countries (1997), Paris, <https://doi.org/10.1787/9789264162150-en>
- 18) REGULATORY IMPACT ASSESSMENT TOOLKIT - A PRATITIONER'S GUIDE IN DEVELOPING COUNTRIES CUTS international, [https://cuts-ccier.org/pdf/Regulatory\\_Impact\\_Assessment\\_Toolkit.pdf](https://cuts-ccier.org/pdf/Regulatory_Impact_Assessment_Toolkit.pdf)
- 19) Regulatory Policy in Perspective: A Reader's Companion to the OECD Regulatory Policy Outlook (2015), OECD Publishing, Paris. (<http://dx.doi.org/10.1787/9789264241800-en>)
- 20) Regulatory Policy in Perspective: A Reader's Companion to the OECD Regulatory Policy Outlook 2015, Paris, <https://doi.org/10.1787/9789264241800-en>
- 21) Sustainability in Impact Assessments: A Review of Impact Assessment Systems in Selected OECD Countries and the European Commission (Jacob, Ferretti and Guske, 2012), OECD Publishing, Paris, [http://www.oecd.org/gov/regulatorypolicy/sustainability%20in%20impact%20assessment%20sgsd\(2011\)6-final.pdf](http://www.oecd.org/gov/regulatorypolicy/sustainability%20in%20impact%20assessment%20sgsd(2011)6-final.pdf).

## ANNEX G - ADDITIONAL GUIDANCE NOTES ON RIA

### G.1 Roll-out plan:

Rolling out Regulatory Impact Assessment (RIA)<sup>39</sup> systems should embrace an approach tailored to each country's unique conditions, including political commitment, resources, and readiness.

Key principles for effective RIA implementation include:

1. **Planning:** Develop a phased, multi-year plan (3-5 years) detailing the institutions to be involved, the processes and methods to be followed. It should integrate ongoing reforms, such as public consultation and inter-ministerial coordination.
2. **Communication and preparation:** Clear directives and guidelines are crucial. Civil servants need to understand their roles and the expectations.
3. **Assessment:** Regularly evaluate RIA performance, focusing on quality outputs (RIA documents) and outcomes (better legislation, transparency and participation). Annual reviews and civil society involvement in assessments are recommended.
4. **Scaling Up:** Start small and expand as capacities grow. Begin with limited RIAs and gradually increase their scope and depth, incorporating better methodologies, quantifications, and analytical rigor.

Additional guidance includes ensuring resources align with goals, building capacity among staff, and fostering transparency and public consultation. Accountability mechanisms like annual performance reviews and key performance indicators (KPIs) are critical for ongoing improvement and ensuring the RIA process informs policy decisions effectively.

### G.2 Cost-effectiveness analysis

As indicated in the guidance notes in Box 6, it is recommended that AU Member States start using cost-effectiveness analysis (CEA) as the basis for conducting RIA. The OECD Handbook<sup>40</sup> describes CEA as a more limited methodology than benefit-cost analysis and is less demanding of resources and expertise to complete. It essentially takes the benefits of regulation as given and asks the question: "Which of the possible ways of achieving the regulatory objective has the lowest cost?" The lowest cost option is said to be the most "cost-effective". It can also be regarded as being the most efficient option. The key benefit of CEA for officials conducting RIA is that there is no need to quantify benefits, or to value them in monetary terms. Instead, only costs must be considered. Valuing costs will be significantly easier than valuing benefits in most cases.

However, CEA does not answer the basic question of whether technical regulation should proceed at all. Instead, it answers the question:

"If technical regulation is to proceed, which option is preferable?"

This means that CEA can only be used after a clear decision has been reached that it is appropriate to regulate. In light of the foregoing deduction, it is appropriate to use CEA for RIA since a decision to

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<sup>39</sup> Handbook on Designing and Implementing Regulatory Impact Assessment Systems, Scott Jacobs, 2024, Commonwealth Secretariat (<https://thecommonwealth.org/publications/handbook-designing-and-implementing-regulatory-impact-assessment-systems>)

<sup>40</sup> OECD (2010) INTRODUCTORY HANDBOOK FOR UNDERTAKING REGULATORY IMPACT ANALYSIS (RIA), <https://regulatoryreform.com/wp-content/uploads/2015/02/OECD-HANDBOOK-FOR-UNDERTAKING-RIA.pdf>

regulate would already have been taken ahead of undertaking the RIA process, namely through the risk assessment process and consideration of alternatives to regulation (as at 8.6.2.2 and 8.6.2.3).

### G.3 Multi-Criteria Analysis (MCA)

Multi-Criteria Analysis (MCA) is a methodology that allows systematic and transparent decisions to be made even where quantification of major regulatory impacts is not possible. MCA involves identifying the underlying policy objectives and then determining all of the factors (the criteria) that would indicate achievement of these objectives. These criteria are then ranked in terms of their relative importance. Once this has been done, each of the available policy options can be “scored” on each individual criterion. The weighted scores can then be added together to determine which option best meets the policy objectives. Table 1 below, reproduced from the Handbook<sup>40</sup> provides an example of a MCA. It considers a range of options for addressing a problem of improving dental health. The options are a) to regulate to require all water companies to put fluoride in drinking water, b) to adopt a government advertising program to encourage people to brush their teeth regularly with fluoride toothpaste and visit the dentist regularly and c) to regulate to require all local government bodies to provide free dentist visits for the poor.

Table 3 - Sample presentation of a Multi-Criteria Analysis

Criterion	Weighting	Fluoride regulation	Advertising campaign	Free dentist visits
Effectiveness in improving dental health	4	5 (20)	3 (12)	3 (12)
Ability to address existing dental problems	2	0 (0)	1 (2)	5 (10)
Ability to improve dental health of the poorest groups	2	4 (8)	2 (4)	5 (10)
Ability to improve health in all regions	1	5 (5)	5 (5)	3 (3)
Cost <sup>2</sup>	4	5 (20)	4 (16)	2 (8)
<b>Score</b>		<b>53</b>	<b>39</b>	<b>43</b>

In this example, five criteria have been used. The most important are the overall effectiveness of the regulation or policy in improving dental health and its cost. Thus, these are weighted more heavily. The fluoride regulation scores most highly, largely because it is judged to be the most effective option in achieving these two criteria, while also being quite effective in improving dental health for the poorest groups.

The option of funding free dental visits is the most effective on the criterion of being able to address existing dental problems and is also most effective in improving the dental health of the poor – since the program is entirely targeted on the poor, where fluoridation assists all people. However, it will be more costly if it is made available to all in need.

The advertising campaign will be less costly than the free dental visits, but will also be less effective than fluoridation in improving dental health. One way of testing the reliability of the results of an MCA is to compare the results of a weighted analysis with one where weights are not used. In the above example, the fluoridation regulation will still score most highly if weights are not used (19 points versus 18 points for free dental visits. This suggests that the result is quite reliable. If the results of the weighted and unweighted analysis are different, a careful reconsideration of the weights is needed to make sure that they accurately reflect real policy priorities.

A more detailed description on the use MCA is provided in the publication mentioned in the footnote<sup>41</sup>.

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<sup>41</sup> Multi-criteria analysis: a manual (2009), Department for Communities and Local Government: London, [https://www.betterevaluation.org/sites/default/files/multicriteria\\_analysis.pdf](https://www.betterevaluation.org/sites/default/files/multicriteria_analysis.pdf)

## ANNEX H- IRC MECHANISMS

### H.1 The OECD list of 11 IRC mechanisms

- iv. Integration/harmonisation through supranational institutions;
- v. Specific negotiated agreements (treaties/conventions);
- vi. Regulatory partnership between countries;
- vii. Intergovernmental organisations;
- viii. Regional agreements with regulatory provisions;
- ix. Mutual recognition agreements (MRAs);
- x. Trans-governmental networks;
- xi. Formal requirements to consider IRC when developing regulations;
- xii. Recognition of international standards;
- xiii. Soft law;
- xiv. Dialogue/informal exchange of information.

## H.2 Examples of IRC mechanisms in Africa

Table 4- IRC mechanisms in Africa

IRC mechanism	Known examples in Africa in the area of technical regulations
Integration/harmonization through supranational institutions	East African Community (EAC) provision for declaring compulsory standards
Specific negotiated agreements (treaties/conventions)	<ul style="list-style-type: none"> <li>• Treaty Establishing the African Economic Community popularly referred to as the Abuja Treaty</li> <li>• Various Regional trade agreements (RTAs)</li> <li>• African Medicines Agency Treaty</li> </ul>
Regulatory partnership between countries	EAC Pesticide regulatory system
Intergovernmental organizations	IRENA with objective of certifying persons with Sustainable Energy skills and work on standards and quality for small wind turbines
Regional agreements with regulatory provisions	No known cases except for the RTAs
Mutual recognition agreements (MRAs)	MRA for EAC Engineers signed in 2012
Trans-governmental networks	<ul style="list-style-type: none"> <li>• Pan African Quality Infrastructure (PAQI) institutions</li> <li>• Algeria, Tunisia, Egypt status as individual signatories of bilateral arrangements with the European co-operation for Accreditation (EA)</li> </ul>
Formal requirements to consider IRC when developing regulations	<ul style="list-style-type: none"> <li>• Various RTAs</li> <li>• Tripartite Free Trade Area (FTA)</li> </ul>
Recognition of international standards	<ul style="list-style-type: none"> <li>• AfCFTA</li> <li>• Various RTAs</li> <li>• Tripartite FTA</li> </ul>
Soft law	<ul style="list-style-type: none"> <li>• African Agenda 2063</li> <li>• Boosting Intra-African trade (BIAT).</li> <li>• Accelerated Industrial Development for Africa (AIDA)</li> </ul>
Dialogue/informal exchange of information	<ul style="list-style-type: none"> <li>• East African Business Council</li> <li>• African Manufacturers Association (AMA)</li> <li>• The African Business Council (ABC)</li> </ul>

# ANNEX I – IMPLEMENTATION FLOWCHART

