



Guidelines: Approximation (Harmonization) of Technical Regulations Southern African Development Community (SADC)

SADCTRLC G001

SECTION ONE (1): SCOPE AND OBJECTIVES

1. These guidelines provide a framework for the determination of equivalence and approximation (harmonization) of the existing Technical Regulations /or Mandatory Requirements in the SADC region with a view to facilitate trade. The ultimate intention is to assist Member States in the development and implementation of Technical Regulations thereby protecting consumers from unsafe products, protecting the environment and animals and facilitating trade.

SECTION TWO (2): DEFINITIONS

2. **Technical Regulation** means a document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method;
 - 2.1. *Explanatory note:* The definition in ISO/IEC Guide 2 is not self-contained but based on the so-called "building block" system.
3. **Standard** means a document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method;
 - 2.2. *Explanatory note:* The terms as defined in ISO/IEC Guide 2 cover products, processes and services. These Guidelines deals only with technical regulations, standards and conformity assessment procedures related to products or processes and production methods. Standards as defined by ISO/IEC Guide 2 may be mandatory or voluntary. For the purpose of these Guidelines standards are defined as voluntary and technical regulations as mandatory documents. Standards prepared by the international standardization community are based on consensus. These Guidelines also cover documents that are not based on consensus.

3. **Equivalence** means technical harmonisation used to eliminate illegitimate barriers to trade where Member States accept that technical regulations different from their own fulfil the same objectives;
4. **Requirements** means the criteria set down by the mandated institution relating to trade in regulated products covering the protection of public health, the protection of consumers, environment and animals.
5. **Approximation** means an agreed exercise that identifies, aligns and equates requirements from SADC Member States' Technical Regulations for the purposes of facilitating trade.
6. **Transparency** means the sharing of information or acting in an open manner or measure of a degree to which information about official activity is made available to an interested party.

SECTION THREE (3): BACKGROUND

7. In July 2014, the SADC Committee of the Ministers of Trade approved a revised Technical Barriers to Trade (TBT) Annex to the SADC Protocol on Trade. The revised TBT Annex reconfirmed the establishment of the TBT Cooperation structures to facilitate cooperation in the areas of Technical Regulations, Standardisation, Quality Assurance, Accreditation and Metrology for the elimination of unnecessary technical barriers to trade, both in terms of the SADC Protocol on Trade and in terms of the commitments by Member States (MSs) with respect to the World Trade Organisation (WTO) Technical Barriers to Trade (TBT) Agreement.
8. The objective of the SADC Protocol on Trade is a progressive elimination of unnecessary TBTs amongst the Member States and between SADC and other Regional and International Trading Blocks and the promotion of an infrastructure for quality in the MSs, a formal framework, in which the cooperation amongst regulators, stakeholders and the national institutions in the areas Technical Regulations, Standardisation, Quality Assurance, Accreditation and Metrology can take place.

SECTION FOUR (4): METHODOLOGY

9. In accordance with Article six (6) of the TBT Annex, the following guiding principles of transparency, predictability and accountability will be upheld:
 - 9.2. the use of consultation, participation and exchange of information processes when technical regulations are developed, amended and implemented;
 - 9.3. the relevant use of risk impact assessment to inform technical regulatory decisions;
 - 9.4. the use of appropriate international measures to promote acceptance of conformity assessment results among Member States;
 - 9.5. the review, update and modification of technical regulations to meet changing needs; and
 - 9.6. the co-ordination amongst various institutions that are part of the technical regulation framework.

10. Member States recognize that the purpose of harmonization and equivalence is not to establish identical technical regulations, standards and conformity assessment procedures for the protection of human, animal or plant life and health, safety, prevention of deceptive practices and protection of the environment, but to facilitate and increase trade.
11. Before Member States develop, adopt and implement technical regulations, governments shall ensure that the intervention is based on objective evidence that action is justified given:
 - 11.2. the nature of the problem,
 - 11.3. the absence of suitable alternatives for addressing the problem,
 - 11.4. the likely socioeconomic benefits to the public and the environment,
 - 11.5. the costs of proposed actions, and
 - 11.6. the risks associated with proposed actions.
12. In order to secure proper operation of free trade agreements, in terms of the TBT Annex to the SADC Protocol on Trade, methodologies for approximation of the existing Technical Regulations need to be established. The approximation of legislation is a complicated and cumbersome process that requires well established structures and methodologies. Also, the approximation shall not take away the rights of Member States to draft laws and regulate for legitimate objectives in terms of the WTO TBT agreement.
13. The methodology is based on the idea that a comparison of the national legislations need to take place in a transparent and effective way. Based on the comparison the Member States are given the opportunity to assess the extent of the differences in the legislation and the effects that these differences might have on their national economic operators. The methodology further includes mechanisms to establish necessary dialogue to actually harmonise the existing mandatory requirements. The phases are (1) comparison of the national legislation to determine the convergences, divergences, and results thereof, results analysis and recommendation, (2) SADCTRLC presents recommendations to the AGM for consideration and adoption, (3) SADCTRLC submits the recommendations to relevant committees of Ministers via SADC for noting, (4) Member State shall then implement the recommendations where possible, and (5) SADCTRLC will thereafter incorporate the recommendations to its monitoring and evaluation toolkit.
14. The phase of the approximation project of Technical Regulations is a pilot approach and physical interaction amongst Member States. The aim is to familiarize Member States with the model. The second phase will be web based (through the SADCTRLC Website share-point) where the MSs shall provide detailed information on the administrative, legal and conformity assessment requirements for allowing products to be sold in the Member States. The facility is structured as a table of correspondence where each of the member States provide the requested information. The information includes the following:
 - a) name and type of the legislation;
 - b) the framework legislation or the regulation/mandatory standard is based on information regarding the adopting institution (parliament, ministry, regulatory institution, standards body etc.);

- c) detailed information regarding the administrative provisions in the legislation, article by article;
 - d) detailed information regarding the technical requirements in the legislation, article by article;
 - e) how will compliance be achieved identifying the conformity assessment procedures that are used at national level; and
 - f) which standards are used as references in the mandatory requirements.
15. The methodology foresees that the SADCTRLC Member States shall co-operate with the SADCTRLC Secretariat to establish a preference list of products or product areas (Technical Regulations) that shall be harmonised each year. Also, to be considered are the Technical Regulations identified by the base line study and these will be incorporated in the harmonization process. This list will then be the basis of the tables that will be contained in the database.
16. The respective SADCTRLC Member States shall then initiate that the relevant authorities fill in the requested information. When a table has been filled out by all the SADCTRLC Member States, the relevant Member States' mandated institution shall study the information to identify the differences between the Technical Regulation in the Member States. When the differences in the national legislations have been identified, the need for amendments and changes in the national legislation shall be analysed by the national authorities. Differences in the legislations do not necessarily mean that amendments and changes are needed. In most cases it is sufficient for the Member State to know the differences and understand their background. They will then be able to adapt their conformity assessment procedures allowing the selling of the products based on the equivalence principle. The decision on using the equivalence principle will then have to be added to the information in the Approximation Table to ensure that full transparency is provided both to the national authorities but also to the economic operators.
17. In some cases, changes and amendments in the national legislation will be necessary. As the first step, each Member State shall analyse if the Member State can make changes that will fulfil the requirements of the other countries without further dialogue with the other MS.
18. In the quest to reach agreement on divergences in accordance with article 13 (3) (d) SADCTRLC shall conduct mediation and conciliation in respect of the affected Technical Regulations.
19. To enable the effective process in harmonising the existing mandatory requirements the following national and regional facilities need to be identified:
- 19.1 **National Level:** The SADCTRLC Member shall be given the responsibility of initiating the national proposal for priority products and product areas that shall be harmonised each year. They shall further be responsible for the coordination amongst the relevant national authorities that shall provide the information needed, on time. A web based database (SADCTRLC Website – SharePoint) shall be the means of submitting the requested information according to the requirements seen in the attached Table of Correspondence (see annex 1). The SADCTRLC shall further initiate that the relevant authorities participate in the necessary dialogue to amend the national mandatory

requirements with the view of harmonising the effects of the legislation in the Member State.

- 19.2. **Regional Level:** The SADCTRLC shall initiate the development of the priority list of products and product areas that shall be harmonised every year. This shall be done through the SADCTRLC Member States initiative. The SADCTRLC shall be given the responsibility of maintaining a database containing all mandatory requirements in the Member States. The database shall include the harmonisation facility described. Based on the results of the comparisons done under that framework of approximation facilities, the SADCTRLC shall initiate a dialogue between the relevant MSs with the aim of negotiating a common level of protection, preferably based on common regulatory objectives.

SECTION FIVE (5): APPROXIMATION TABLE

Annex 1

Product or product area:

National Authority responsible for filling out the table: SADCTRLC

		MS	MS	MS	MS	National Comments (need for amendments, further explanations)
1	Name of legislation. (List all relevant national laws or equivalent):					
1.1						
1.2						
....					
2	Type of legislation: (technical regulation, mandatory standard, others)					
2.1	A:					
2.2	B:					
....					
3	Reference to framework legislation (If the listed legislation is not primary legislation the framework legislation shall be listed for each of the referred legislations)					
3.1	A:					
3.2	B:					
.....						

		MS	MS	MS	MS	National Comments (need for amendments, further explanations)
4	Adopted by: (The institutions that has adopted the legislations shall be listed, parliament, miniseries, institutions)					
4.1	A:					
4.2	B:					
					
5	Enforcement institution: (the responsible competent authority for enforcing each of the legislations shall be listed)					
5.1	A:					
5.2	B:					
					
6	Administrative provisions:					
6.1	Art no:					
	Art no:					
					
6.2	Art no:					
....					

		MS	MS	MS	MS	National Comments (need for amendments, further explanations)
7	Technical provision					
7.1	Art no:					
7.2	Art no:					
....					
8	Provisional requirements					
8.1						
8.2						
....					
9	How is compliance achieved (describe which conformity assessment procedures are used)					
	Law no: Law no:					
9.1	Law no:					
10	Referenced to standards: (International, regional, national, standards referenced in the legislation)					
10.1	(Name and number)					
10.2						
....					

		MS	MS	MS	MS	National Comments (need for amendments, further explanations)