UNITED STATES – SADC EXCHANGE

ON

GOOD REGULATORY PRACTICES

1-2 JUNE 2015

OR TAMBO GARDEN COURT HOTEL, JOHANNESBURG

REPORT

1. BACKGROUND

During their meeting in November 2013, Southern Africa Trade Hub (USAID SATH) and American National Standards Institute (ANSI) and the SADC Cooperation in Standardisation (SADCSTAN) Task Team agreed to convene a workshop in collaboration with SADC Technical Regulations Liaison Committee (SADCTRLC) on Good Regulatory Practices. In addition, after consultations, SADC Secretariat endorsed the workshop and it was agreed that the workshop would take place 1-2 June 2015 in the Republic of South Africa. The workshop was funded by ANSI and USAID SATH.

2. WORKSHOP OBJECTIVE

The objective of the workshop was to explore the different experiences from the United States and also from SADC Member States. Discussions covered positive effects of Good Regulatory Practice (GRP) on trade and competition and contributions of GRP in the elaboration of technical regulations, standards and Conformity Assessment Procedures. The workshop was attended by thirty five (35) representatives from SADC Member States (Regulatory Agencies and National Standards Bodies), USA representatives from both the public and private sectors, a representative from the private sector in South Africa, representatives from USAID SATH and SADC Secretariat representatives.

3. INFORMATION AND EXPERIENCE SHARING

The workshop was facilitated by SADC Secretariat representative, Ms Kuena Molapo. The information and experience sharing sessions were done through a series of presentations followed by discussions from both United States and SADC Representatives.

The key note address was given by the Deputy Mission Director (regional) Mr Littleton Tazewell. In his remarks he highlighted some activities that USAID is supporting in the SADC region both at national and regional level. He reiterated that USAID would continue to support Quality Infrastructure development as necessary and relevant.

Resource persons from the United States included;

- ASTM International Representative - Mr Len Morrissey,
- Caterpillar (USA) Representative - Mr Dan Roley,
- Distilled Spirits Council of the United States Representative - Ms Christine LoCascio,
- American National Standards Institute - Ms Madeleine McDougall,
- Office of Information and Regulatory Affairs (USA) - Ms Shagufta Ahmed, and
- Office of the U.S. Trade Representative - Mr Kent Shigetomi.

Resource persons from SADC included;

- SADCSTAN Regional Coordinator - Mrs Margaret Lungu
- SADCTRLC Regional Coordinator - Mr Innocent Khumalo
- National Regulator for Compulsory Specifications Representative (NRCS) - Dr Zen Fourie.

The presentations made are summarised below.

3.1 Session 1: overview of US and SADC regulatory and standards systems

The SACDSTAN Regional Coordinator, Mrs Margaret Lungu gave an overview of the SADCSTAN operational structure, the standards harmonization process and stakeholder engagement. Benefits of regional standards and the challenges thereof were also highlighted. It was indicated that SADCSTAN is made up of National Standards Bodies and is responsible for harmonization of standards in the SADC Region. It has, to date, harmonized fifty six (56) standards covering management systems, construction and electrical appliances. While the harmonization process remains beneficial, participation by Member States and low adoption of these standards are a challenge which still needs to be addressed.

SADCTRLC Secretariat, Mr Innocent Khumalo, gave an overview of the SADCTRLC structure, functions and the current work programme. SADCTRLC's current work programme includes development of Risk and Impact Assessment Guidelines, data collection on Technical Regulations affecting Trade in the region and development of SADC Non-compliant products alert system. To date SADCTRLC has developed the SADC Globally Harmonised System on the Classification and Labelling of Chemicals policy, which was adopted in 2013.

An overview of the US regulatory process was given by the representative of the Office of Information and Regulatory Affairs Ms Shagufta Ahmed. The presentation covered interagency ccoordination of rulemaking, regulatory impact analysis and regulatory transparency and participation. The presentation emphasised that regulatory transparency, public participation in rulemaking, and accountability are required to address concerns about undue influence by special interests, allow all interested parties to be heard, and maintain political support for regulatory reform

The Representative of the American National Standards Institute (ANSI) Ms Madeleine McDougall indicated that ANSI is not a standards development body. ANSI is mandated with leading standards, conformity assessment, and related activities in the United States of America. Furthermore, an overview of the U.S. system for standards and conformity assessment and how standards support technical regulations in the U.S was highlighted. The ANSI Federation represents more than 125,000 companies and organizations and 3,5 million professionals worldwide. ANSI represents the U.S. globally; it also ensures integrity of the standards and conformity assessment system, while offering neutral forum for standard developers and stakeholders at large. In its mandate, ANSI accredits

standards developers and conformity assessment organizations and also coordinates partnerships between U.S. public and private sectors.

3.2 Session 2: Examination of Principles of Good Regulatory Practice (GRP)

Office of the U.S. Trade Representative Mr Kent Shigetomi provided a brief explanation of what GRP is and its governing principles and its importance. GRP refers to internationally recognized processes and procedures that can be used to improve the quality and cost-effectiveness of domestic regulations. GRPs include administrative procedures that govern intra-governmental coordination of rulemaking activity, impact assessment, regulatory transparency, participation, and accountability. The benefits of the GRPs include; contribution to more informed policy decisions and promotion of economic efficiency. Furthermore, transparency and accountability address concerns about undue influence and allows all interested parties to be heard. GRPs facilitate trade and investment by reducing regulatory burdens and improving the quality and cost-effectiveness of regulations and also reducing non-tariff barriers to help increase economic growth and trade.

3.3 Session 3: Regulatory Impact Assessment (RIA)

The Office of Information and Regulatory Affairs Representative, Ms Shagufta Ahmed, indicated that Regulatory Impact Analysis (RIA) assesses the anticipated consequences of a regulation and estimates associated benefits and costs. It helps to organize and consolidate all the possible impacts and elements for decisions at various stages of policy development. It provides clear and transparent methodologies and criteria for new or existing regulations. RIA is a flexible and adaptable tool. Its underlying analytical approach should always be proportional to the situation and follow consistent guidance for complexity and level of analysis. Goals of the RIA include maximizing net benefits to society or at least ensuring that benefits justify costs. These goals further include promotion of economic efficiency by regulating only where markets fail, and when regulating, by using cost-effective and market-based approaches and increasing the transparency of the regulatory system. Critical elements of a RIA are a statement of need for the proposed rule that identifies the nature and significance of the problem (e.g., identification of the market failure), examination of alternative approaches to addressing the problem and analysis of the costs and benefits of each alternative.

National Regulator for Compulsory Specifications (NRCS) Representative, Dr Zen Fourier provided an overview of the South African model for development of technical regulations or compulsory specifications as they are currently called. It was highlighted that the Regulatory Research and Development of the NRCS is responsible for Risk- and Impact assessments, which they usually do to assess the feasibility of the proposed Technical Regulations (TRs) or Compulsory Specifications (VCs). It was highlighted that unlike the US model where Risk and Impact Assessment are conducted on a very detailed scale, the South African model tends

to determine the need for a full RIA if the personnel are unable to conduct it themselves.

3.4 Session 4: Scientific and Evidence Based Rulemaking

In providing information on scientific and evidence based rulemaking, ASTM International Representative, Mr Len Morrissey, anchored his presentation on the Consumer Product Safety Improvement Act of 2008 ("CPSIA", Pub. L. 110-314) which was enacted on August 14, 2008 as implemented in conjunction with toddler beds. He indicated that the law requires that these standards are to be "substantially the same as" applicable voluntary standards or more stringent than the voluntary standards if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. In order to emphasise the importance of scientific and evidence based rule making, it was indicated that data were drawn from two databases: (1) Actual injuries and fatalities of which the Commission is aware; and (2) estimates derived from reports of emergency room treatment in a statistical sample of hospitals that makes up the National Electronic Injury Surveillance System ("NEISS"). However, while preparing the final rule, a new search of CPSC's epidemiological databases found that further 41 toddler bed-related incidents were reported between June 23, 2009 and December 12, 2010.

Caterpillar representative Mr Dan Roley further highlighted the importance of scientific and evidence based rule-making by highlighting the ISO process in the development of standards. For the development of any new standard, it was emphasized that there should be a verification of the need for the standard, which must address any additional safety risks, advances in technology and new types of machines and applications, if need be. The need to base the technical requirements on machine incident, data use, risk reduction principles, ergonomics of operators and workers, data, logic and processes and reasonable and achievable requirements, was also highlighted. In addition, in order to create performance criteria for standards to meet machine users expectations for safety, be acceptable to health and safety organizations and enable using the standards as technical requirements to address safety risks in regulations, scientific data and evidence cannot be overemphasised.

3.5 Session 5: Public Consultation and related tools

SADC Member States were asked to share their experiences on public and private sector consultations on both standards and technical regulations. While many different experiences were shared between the represented Member States, the challenges faced in this area seemed to be similar. The apparent lack of interest in the development of standards through lack of participation in technical committees is a common challenge. It was noted that some Member States have at one point paid for committee members for participation in standards development. On the other hand, there remains a need for further engagement between National Standards Bodies and regulatory authorities and government departments on the referencing of standards in technical regulations. Most Member States still struggle with convincing

regulators to use standards in technical regulations. Nonetheless, on public consultations on technical regulations the experiences vary because of varying methods of consultations and because stakeholders may be directly affected by technical regulations.

The Office of Information and Regulatory Affairs Representative, Ms Shagufta Ahmed, provided an overview of the US government perspective on public consultation in the regulatory context. Legal Framework for Public Comments on U.S. Regulations, tips for submitting effective public comments and the Agency's Perspective on Public Comments were covered in the presentation. It was indicated that the law gives interested persons an opportunity to participate in the rule making through the submission of written data, views, or arguments with or without an opportunity for oral presentation. During the comment period, members of the public can submit comments in a variety of ways. All of these comments, regardless of submission method, are "docketed" on www.regulations.gov, for agency consideration. This url provides the public with tips for submitting effective comments.

Several suggestions on how to effectively comment were developed by a working group that consisted of participants across Federal agencies. It is important to note that a comment can express support or dissent for a regulatory action. However, a constructive, information-rich comment that clearly communicates and supports its claims is more likely to influence regulatory decision-making. In the case of disagreement with a proposal, a person submitting comments is expected to suggest an alternative (including not regulating at all). An explanation and/or analysis of how the alternative might meet the same objective or be more effective should be included. Justification must be based on sound reasoning, scientific evidence, and/or how business will be impacted. Quantitative and qualitative data, explanation of pros and cons and trade-offs must be included. It is also critical to consider other points of view, and respond to them with facts and sound reasoning. This can include expert opinions and personal experiences. It was emphasized that the comment process is not a vote and therefore, one well supported comment is often more influential than a thousand (identical) form letters. Identify credentials and experience that may distinguish your comment from others. If you are commenting in an area in which you have relevant personal or professional experience (i.e. fisherman, businessman, scientist, attorney, etc.) state this. If a regulation raises many issues, do not feel obligated to comment on every one rather select those issues that concern you the most, affect you the most, and/or you understand the best. There is no minimum or maximum length for an effective comment, but all comments are expected to be concise.

While each rule is different and agency practices vary, public comments tend to be approached in a structured manner. Significant comments are identified and categorize based on type of issue for example, feasibility, costs, compliance period, etc. Comments are usually analysed and evaluated on their merits to: determine whether recommended changes are feasible, to determine whether recommended changes are enforceable, to determine whether recommended changes are within program goals and are legal. The merit of a comment is measured by the

persuasiveness of supporting arguments and the quality of supporting data, not the identity of the commenter. Responses to comments are developed including any possible changes to the regulation.

The Distilled Spirits Council of the United States Representative, Ms Christine LoCascio, provided a private sector perspective on public consultation in the regulatory context. It was highlighted that private sector views are important because regulated industry is often best placed to assess the likely impact. It was indicated that the relevant industry can help regulators determine answers to key questions such as whether the regulation will achieve the stated goals, improve efficiencies, impose unnecessary roadblocks, reduce costs, have a positive or negative impact on industry, sales, jobs and any other relevant factor. It was highlighted that industry and regulators often share the same goals for health and safety and therefore consulting early in process with regulated industry can help identify and avoid costly implementation issues. A broad range of input ensures that all potential impacts have been considered, resulting in better regulations and ensures stakeholder buy-in resulting in greater compliance.

3.6 Session 6: Use of Good Regulatory Practices in the elaboration of technical regulations and standards

The ASTM International Representative, Mr Len Morrissey, provided an overview of the use of standards in product safety. He highlighted that the product safety landscape is very complex and also has many actors, each with unique and changing roles. The actors include government agencies and regulators, consumer groups, standards developers, trade associations, testing laboratories, research and academic institutions and industry. He further indicated that the type of product, intended market and hazards are important factors that must always be considered. It was indicated that there several ways in which standards can be incorporated into regulation. These include incorporating the technical requirements in the regulation, general requirements or directives followed by rulemakings, static reference which include year date (most references) and ambulatory Reference which is a dated reference but with ability to keep pace with change. The use of voluntary standards was, however, still emphasised due to their effectiveness and relevance across diverse markets, their ability to help consumers, businesses, manufacturers, innovators and governments speak the same language, and the fact that they can be incorporated into contracts, regulations, codes, and laws around the world. It was reported that 6,525 ASTM standards have been adopted, used as a reference, or used as the basis of national standards outside of the USA.

The Caterpillar USA representative, Mr Dan Roley, shared the Caterpillar perspective on standards and conformity assessment in regulations. Conformity Assessment Process for the Construction and Mining Machines was used as an example. He indicated that best practice is to allow manufacturers to do their own conformity assessment testing, defined in ISO 17050-1 as Supplier's Declaration of Conformity (SDoc). It was indicated that ISO/TC 127 Standards Define Test Methods

and Performance Criteria that manufacturers can use for conformity assessment testing and certification. Manufacturers ensure that machines comply with standards and regulations during the development process, including the replacement parts for machine repairs and then manufacturers certify machine design compliance. While emphasis was made on Supplier's Declaration of Conformity, conformity assessment testing already completed by the manufacturer should be accepted if the manufacturer has the following: a quality plan that is at least equivalent to ISO 9000, a documented conformity assessment process, a conformity assessment group/person to manage the conformity assessment, access to conformity assessment facilities (manufacturers facility or independent labs) and documentation of test results. Nevertheless, best practice is to define the general machine safety risks/requirements in national or regional regulations.

3.7 Session 7: Defining the elements to achieve effective regulatory cooperation

On regulatory cooperation, the Office of the U.S. Trade Representative, Mr Kent Shigetomi, highlighted that non-tariff barriers reduce economic growth and trade and international regulatory cooperation is one of the best ways to identify and address existing barriers and to prevent future barriers. Furthermore exchange of best practices improves regulatory outcomes at home and promotes cooperation abroad, and recognizes that the regulatory approaches taken by other governments may differ from those taken by U.S. regulatory agencies to address similar issues. It was highlighted that in meeting shared challenges, international regulatory cooperation can identify approaches that are at least as protective as those that are, or would be adopted, in the absence of such cooperation. Several examples were made on the US cooperation with North America, Mexico, the EU and APEC.

Regulatory cooperation does not encompass all regulatory activities within agencies. Focus on areas where benefits can be realized by regulated parties, consumers, and/or regulators without sacrificing outcomes such as protecting public health, safety and the environment. The identification of these priorities needs to be the product of careful consideration. Reliance and agreement on good regulatory practices is an essential foundation for successful regulatory cooperation.

Regulatory divergences are not necessarily due to different regulatory objectives, and additional planning, coordination, and communication at all stages of rulemaking, including development and implementation, can help avoid unnecessary differences. Stakeholders have a critical role to play in identifying unnecessary differences that create costs and challenges, as well as in suggesting opportunities for new initiatives. Meaningful and consistent opportunities for stakeholder engagement are important to success.

3.8 Session 8: Panel Discussions Case Studies/Best Examples of Effective Regulatory Cooperation in other countries, regions or fora.

A panel discussion was conducted on the Effective Regulatory Cooperation in other countries, regions or fora. The panellists were ASTM International Representative Mr Len Morrissey, Caterpillar representative Mr Dan Roley and Distilled Spirits Council of the United States Representative Ms Christine LoCascio.

The case studies considered included cooperation with China and how ISO assisted China with the development of appropriate regulatory requirements. China was encouraged to participate in the development of ISO Standards. Best practices training provided was provided for Standards and Regulations to Global Industry Associations, Chinese Manufacturers and Mirror Committee Leaders. Assistance was also provided on the adoption of ISO Standards. Examples of good regulatory cooperation and effective utilization of standards to support regional needs were also highlighted on the strong relationships ASTM has with National Standards Bodies. ASTM has 88 individual Memorandums of Understanding (MoU) and 4 regional agreements. ASTM finds both public and private partnerships for the development of high quality standards and global relevance with focus is on science and technology. MoU nations are authorized to use ASTM International standards (with appropriate permission and attribution) if they meet the needs of the end users. Bilateral Agreements were also established by the US, Canada and Mexico on the Tequila standard in order to facilitate exports of Tequila from Mexico. In 2006, US and Mexico sign an agreement on trade in Tequila, agreeing to no prohibition on bulk exports of Tequila to US, no burdensome registration process for US bottlers, recognition of US regulatory system as sufficient (inspections, etc.) and therefore resulted in imports increasing from $402M in 2003 to $980M in 2014.

4. Lessons learnt

Throughout the presentations questions and answers sessions created discussions that led to several observations on lessons to learn from the SADC and the US experiences. The lessons learnt are tabulated in Table 1 and the way forward in Table 2 below.

TABLE 1: Lessons Learnt In Relation To Standards and Technical Regulations

	Lessons learnt		
	Standards		**Technical regulations**
1.	Standards should be demand/market driven	1.	Regulators need to understand the importance of TR and standards
2.	It is important to devise a mechanism to effectively engage the private sector to drive the standards development agenda	2.	Public consultations are vital hence
3.	Expertise required to develop standards can be developed by involving students in standards development	3.	Importance of using scientific and economic data and facts in the development of standards and TR
4.	Standards referred in TR should be performance based rather than prescriptive	4.	TR should facilitate trade and not restrict it.
5.	Consumers, Regulators, labour associations and other relevant associations should be involved in the development of standards	5.	TR should not be a barrier for business to grow especially for Micro, Small and Medium Enterprises (MSMEs)
6.	Adhere to WTO code of good practice in the development of standards and TR	6.	TR should reference standards
7.	Concept of harmonization appears not to be interpreted the same in various regions	7.	Interests of private sector should be taken into consideration when developing TR
8.	In the USA no single government agency has control over standards	8.	Encourage regulatory cooperation between MS and private sector
9.	It is important to engage with peers on standards and enhance collaboration between regulators and National Standards Bodies (NSBs)	9.	GRP should reflect current international trend in the development and implementation of TR
10.	Economic benefit can be measured at a micro economic level e.g. single company using a standard and results thereafter can accrue on export access, increase in sales figures and employment creation.	10.	Development of TR should take into account the prevailing economic and technological environment as one size does not fit all.
11.	Messages should be tailored to specific audience to have impact *e.g. High level engagement on commitments made at national/regional level should be specific*	11.	TR should not pose a challenge to the development of the private sector

12.	International standards should be used as a basis for developing national standards	12.	TR should be consistent with government policy
13.	Importance of using scientific & economic data and facts in the development of standards	13.	TR should be transparent and notified to WTO
14.	MS in SADC to work together at regional level	14.	

TABLE 2: Way Forward In Relation To Standards and Technical Regulations

	Way forward		
	Standards		**Technical regulations**
1.	Devise a mechanism to effectively engage the private sector to drive the standards development agenda with specific goals and time frames	1.	Create awareness to regulators (stakeholders) on TR and Standards
2.	Start with one item that is important to all	2.	Share information on RIA with stakeholders in MS
3.	Conduct Educational campaign /advocacy and create awareness on the importance of standards. Standards and TR should be given priority at national level	3.	Share success stories of application of TRs
4.	Engage US private sector to share and exchange information on the value of standards with the private sector in the SADC region	4.	MS should study their legal systems in light of the knowledge gained and suggest how to harmonize the same
5.	Encourage the general public to participate in standards development	5.	Continue to engage with the Standards Alliance on development of SQAM matters in the SADC region
6.	Devise better ways to harness comments on draft standards at public enquiry stage	6.	Establish guiding principles on the development of TR
7.	Usedata to assist in development of Standards and TR e.g. trade flows	7.	Review Conformity Assessment procedures at the ports of entry to minimize TBTs
8.	Develop capacity in industry, MSMEs in particular to effectively participate in standards development	8.	Training model to be developed for regulators on the development of TR and have exchange programs between MS (attachments)

9.	Continued cooperation and take advantage of available resources	9.	
10.	Development is Long term,,however, do what is practical within available resources	10.	Engage authorities at high level in cooperation and coordination of activities
11.	Review the standards adopted under ASTM MoUs signed among MS and consider the common standards for harmonization at regional level	11.	Develop a model for development of TR to be adopted by MS
12.	Practice/implement lessons learnt based on capacity		
13.	Take action and get involved		
14.	Work with private sector on success stories		
15.	Guidelines on how to conduct effective consultations with stakeholders need to be developed		

Attachment

Attendance register