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Committee on Technical Barriers to Trade

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AGENDA ITEM 3: TECHNICAL COOPERATION ACTIVITIES

UPDATE BY ANSI ON ACTIVITIES RELATED TO THE WORK OF THE TBT COMMITTEE

This document contains the statement provided by the United States at the TBT Committee meeting of 13-15 June 2022 under Agenda Item 3.

1. The United States takes our commitment to capacity building seriously. As such, we would call member attention to our continued efforts to support the understanding and implementation of the TBT Agreement through the Standards Alliance program. The Standards Alliance is a public-private partnership between the U.S. Agency for International Development (USAID) and the American National Standards Institute (ANSI), which coordinates with developing and least developed countries to identify and prioritize areas for technical assistance.

2. The Standards Alliance was established in 2012 with a focus on the implementation of the TBT Agreement in 10 country/regions and was expanded in 2016 to include West and Southern Africa. The first phase of the Standards Alliance ended in September 2021; however, the program was renewed for a second phase in 2019. Phase 2 of the Standards Alliance remains active and builds upon the successes and measured impacts of first phase to provide targeted technical assistance to developing countries. The second phase focuses on support related to the development and implementation of National Quality Infrastructure and Good Regulatory Practices that are rooted in the principles of the TBT Agreement.

3. Altogether, the Standards Alliance Phase 1 completed 107 trainings, workshops, and delegation visits. Under Phase 2, the Standards Alliance has so far delivered 31 events, reaching 5021 participants. These activities have advanced partner countries' understanding and application of the TBT principles and transparency mechanisms. All Standards Alliance Phase 2 activities have begun work, and in particular between April to June 2022 have included the following:

- In response to the COVID-19 pandemic, the Standards Alliance continues to support technical capacity in the **medical devices sector**, while also helping participating nations identify technical and regulatory barriers to trade. This activity, the "**Medical Device Regulatory Convergence (MDRC) project**", builds the capacity of partner countries to effectively implement standards and conformity assessment procedures related to medical devices; remove technical barriers to trade for medical devices; increase patients' access to needed high-quality Personal Protective Equipment (PPE) and other medical technologies in response to COVID-19 and future global health crises; and foster private sector engagement in the (medtech) regulatory space. The project countries of focus include Brazil, Colombia, Mexico, Peru, Indonesia, Vietnam, Ghana, Kenya and South Africa.
- The MDRC has hosted 22 trainings and workshops to advance objectives for global, regional, and local stakeholders in the public and private sectors. These workshops convened an estimated 4,650 participants, of which about 2,860 were from the private sector and about 2,880 were women (61.9%). This group includes experts and professionals from academia, the private sector, Standards Developing Organizations (SDOs), national regulatory authorities (NRAs), international organizations, and numerous other vital stakeholders.
- The MDRC has packaged the findings of its Phase One, Tier One gap analyses and literature reviews from all project countries in a unified Tier One report. This report includes assessments

of GRP implementation by country as well as an overarching chart to allow for comparison across project countries. In April, the MDRC published a Tier One GRP review that is intended to be a live document to keep track of the progress made in the different member countries towards regulatory convergence around medical devices. While this is the final draft, it remains a live document. As more input and feedback from governments and relevant stakeholders are received, this report may be updated throughout the project.

- In Latin America, the project further strengthened its online module development and virtual resource library, which can be accessed here: [Standards Alliance Phase 2 COVID-19 Medical Device Regulatory Convergence Project \(MDRC\) – Regulatory Convergence](#). Finally related to this region representatives of the MDRC participated in the 9th Summit of the Americas as well as outside meetings on June 5–8, 2022, in Los Angeles. The Summit brought together public- and private-sector representatives from across the Americas for presentations and discussions on national quality infrastructure (NQI), good regulatory practices (GRP), national policy reform, and the importance of global partnerships. Leveraging the first meeting of the Summit of the Americas on U.S. soil in a generation, the event saw the official launch of the Inter-American Coalition for Business Ethics and Regulatory Convergence in Medical Technology to promote regional and bilateral cooperation, knowledge exchange, and medical device regulatory convergence and GRP across the Western Hemisphere. A comprehensive readout of the Coalitions Sessions as well as key Summit outcomes, including links to the presentations and recordings of each session, including a printable version of the report can be accessed [here](#).
- An ongoing web series on **international best practices for cosmetics standards with the African Organization for Standardization (ARSO)**. ANSI, ARSO and the Personal Care Product Council (PCPC) hosted a sixth webinar on May 9, 2022 in coordination with members of the GCC Standardization Organization (GSO) on international cosmetics frameworks. This webinar, as well as the past five events were developed to support the harmonization of African personal care and cosmetics standards. With guidance from PCPC and ARSO Technical Committee 40 (TC40) on cosmetics, ANSI and ARSO have launched a virtual series including ten 90-minute webinars on international best practice for cosmetics standards as well as a thematic session for TC40 members during the ARSO GA.
- ANSI is continuing to support a multi-year "Harmonization of **Petroleum Standards in West Africa**" project, targeting four of the largest petroleum producing/ extraction and refining economies: Nigeria, Ghana, Côte d'Ivoire and Senegal. The project aims to encourage testing laboratories to use harmonized testing protocols that are up to date and fit for purpose in the ECOWAS region. During April to June the efforts were focused on preparing a petroleum standards workshops that would take place in conjunction with the Nigeria Oil and Gas Conference and Exhibition in early July 2022.
- In coordination with the **Economic Community of West African States (ECOWAS) Centre for Renewable Energy and Energy Efficiency (ECREEE)**, the Standards Alliance continues its work in the region on clean renewable fuel (for transport and household use). After organizing workshops in Togo and the Gambia in March 2022 ANSI and Pivot have developed with ARSO a webinars series on Bioethanol as well. The parties have agreed to host five sessions, scheduled to occur as monthly events from May through September 2022. Therefore, two session have occurred already on May 12 and June 16, 2022.
- **Utility Management Standards Training for Water Sector Utilities.** Effective management of water sector utilities is crucial to providing reliable and water supply and sanitation services, and a well-managed utility can be a driver to promote economic development. The use of standards, such as AWWA's Utility Management Standards, assists water sector entities in addressing these challenges by improving utility management and performance over time, increasing utility efficiency, reliability, consistency, and providing safer water to the general public. This project is taking place in India and Africa (Malawi, Lesotho, and Zambia). AWWA Utility Management Standards will be introduced to water sector utilities through a series of in-person and virtual workshops. AWWA has finalized and circulated the needs assessment survey for the African countries and is coordinating dates for African workshops. In India, AWWA completed its needs assessment, set dates for workshops, and conducted follow-up monthly user group calls for India participants. Introducing these standards and providing instruction on how to implement them at utilities in India will provide social, economic, and public health benefits to the local communities.

- **Plumbing the Legal Depths — Creating a Pipeline Between Legal Enabling and NQI.** This project performs diagnostics of the existing legal, policy and institutional frameworks governing NQI related to the WASH sector in Ghana, Uganda, and Zambia. These diagnostics assess the enabling environment to increase access to drinking water and sanitation, support the adoption and application of international WASH standards, and enable the removal of WASH NQI barriers to trade in WASH products. Legal gaps and shortcomings will be identified, and recommendations made on how these gaps can be addressed by aligning them to international standards and best practices. Further, the findings and recommendations will be validated with stakeholders and completed reports will be disseminated widely with government agencies, creating opportunities for reform. Deskwork and interviews in each of the target countries have been conducted to support comprehensive diagnostic reports for each country.
- **Increase the Flow of Wash Services.** This project will work with foreign ministries, local industry and manufacturers to develop a roadmap focused on improving countries' access to safe and efficient WASH products, removing technical barriers to trade, standardizing conformity assessment practices and helping to develop much-needed supply chains of safe products. In Indonesia, IAPMO is assisting the National Standardization Agency of Indonesia (BSN) to develop and adopt a new national standard related to faucets and to provide technical assistance to relevant ministries on its adoption and enforcement. As the final endpoint of water delivery systems, this new standard will ensure that these products meet basic levels of safety and efficiency. Standardization and enforcement in this area is critical to protecting the performance and health of drinking water systems for Indonesian's citizens. To date IAPMO continues to coordinate BSN Technical Committee 77-02 meetings to support national adoption of this new standard. The draft standard has been finalized and the draft has been put on BSN's website for public comment.
- **Community Water Systems – Standards For Safety And Risk Management.** Quality of life can be reduced as a result of the burden of disease from chemical and microbiological contaminants in community and household drinking water systems. NSF Drinking Water standards establishes minimum health effects and requirements for chemical contaminants and impurities that are directly imparted to drinking water from components used in drinking water systems and chemicals used to treat drinking water. In this project, NSF Drinking Water standards on drinking water treatment chemicals and drinking water system components will be introduced to stakeholders by NSF International to build consensus for standards that validate the safety and efficacy of materials, chemicals and water treatment devices that come into contact with drinking water systems. NSF Drinking Water standards will inform and strengthen existing in-country efforts to better provide safe drinking water in Morocco and Brazil. Training events will be held to inform regulators, operators, manufacturers, NGOs, and other stakeholders about NSF Drinking Water standards. In Brazil, the needs assessment work was completed and NSF conducted stakeholder outreach for its first online workshop. In Morocco, NSF has conducted initial outreach to in-country stakeholders and has been developing the needs assessment.

4. Additionally, the Standards Alliance has a robust pipeline of activities in implementation. These include activities focused on **best practices for water and sanitation in Latin America, Africa, and the Middle East**; as well as awareness building trainings on **reinforced concrete standards and building code adoption in Kenya**. This initiative continues to emphasize transparency and to promote the foundational principles of the TBT Agreement. The MDRC also plans to have regional forums with public and private stakeholders in Africa and the Indo Pacific region later in 2022.

5. More information regarding the overall Standards Alliance Phase 2 (2019-2024) can be found [here](#).