High Level Symposium to Enhance Regulator Expertise on Good Regulatory Practices and the WTO Agreement on Technical Barriers to Trade

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Standards Alliance: SE & USAID

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How does the US Approach Conformity Assessment

- The US considers the provision WTO TBT agreement
- Considers the risk and all options when designing a conformity assessment program
- We need to ensure confidence in the conformity assessment process
- We consider the impartiality and competency of the process.

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How does the US Approach Conformity Assessment

- Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled." (Annex 1 of the WTO TBT Agreement)

- All conformity assessment activities depend on the quality of standards

- The determination to use a voluntary consensus standard from the private sector

- Use of international standards as basis for conformity assessment procedures

- Participate in the development of appropriate international standards for conformity assessment

- Encourage transparency using public notification and balanced stakeholder representation

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How does the US Approach Conformity Assessment

- The extent to which the CA activities may be carried out by the private sector
- How much confidence is needed
- Risk of the product
- Risk of non compliance
- Independence and rigor of conformity assessment
- Cost

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How does the US Approach Conformity Assessment

- The market structure and size
- The import and export situation
- The industry structure
- The industry's capability, integrity and reputation as well as its track record
- The complexity of the manufacturing process (can the product be made only by well establish companies?)
- The effectiveness/existence of enforcement
- The effectiveness of penalties for non compliance

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How does the US Approach Conformity Assessment Approaches to Consider

- Supplier's declaration of conformity
- Supplier's declaration of conformity with testing in accredited laboratories
- Third Party Certification – specific schemes
- Inspection
- Accreditation of laboratories, certification bodies and inspection bodies

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What is the role of Accreditation as it relates to Conformity Assessment

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What is the role of Accreditation as it relates to Conformity Assessment

- Third party recognition of the competence and impartiality of testing and calibration laboratories, certification bodies and inspection bodies.

- Demonstration that an entity is competent to carry our specific conformity assessment tasks

- It is achieved through an independent evaluation by accreditation bodies,

based on international standards requirements

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What is the role of Accreditation as it relates to Conformity Assessment

-Accreditation is based on ISO/CASCO tool box of standards; ISO/IEC 17011, ISO/IEC 17020, ISO/IEC 17021, ISO/IEC 17024, ISO/IEC 17025, ISO/IEC 17065

-Additional requirements from US Government agencies are included as necessary to reflect national codes or regulations

-Accreditation is offered by government and member organizations of the ILAC/IAF MLA.

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How does the US private sector support government oversight for compliance

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How does the US private sector support government oversight for compliance

Product Certification

- Used when the risks associated with non conformity are moderate to high
- Includes evaluation, compliance decision and attestation
- May include a variety of activities, depending on the scheme requirements
- May include sampling, testing, assessment of the manufacturing process, surveillance

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How does the US private sector support government oversight for compliance

- Supplier's declaration of conformity
- Supplier's declaration of conformity with testing in accredited laboratories
- Third Party Certification – specific schemes
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How does the US private sector support government oversight for compliance

First Party Declaration of Conformity

- A supplier's declaration does not mean that conformity assessment is not conducted. It is carried out without the intervention of a third party.

- The manufacturer remains responsible and needs to make sure that its product meets the requirements.

- Testing at an accredited laboratory is a very good practice.

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First Party Declaration of Conformity – Examples

- Department of Energy; Declaration of minimum efficiency for appliances
- Outdoor Lawn Equipment such as gasoline lawn mower
- Some personnel propective equipment such as hearing protection

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How does the US private sector support government oversight for compliance

Third Party Conformity Assessment

- Any activity carried out by an entity that is independent of the buyer and the seller
- Certification is the most common type of 3rd party conformity assessment
- Certification of products, of management systems and of persons

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How does the US private sector support government oversight for compliance

Third Party Conformity Assessment

Several federal agencies mandate product conformity and accredit private sector providers

- OSHA National Recognized Testing Laboratory Program (NRTL)
- Food and Drug Administration
- FCC Telecom Certification Body
- Consumer Product Safety Commission (CPSC)

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Benefits of these Third Party Conformity Programs

- A Process that Preserves Confidence
- Reduces Government Costs, frequently a full cost recovery program
- Improves Market Surveillance when properly monitored
- Positively Affects the Development of Standards
- Promotes International Trade

Thank You

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