TIC COUNCIL POSITION ON INMETRO'S REGULATORY REFORMS

September 2020

TIC Council welcomes Inmetro's efforts to modernize its regulatory and conformity assessment (CA) framework and the development of a new Institutional Strategic Plan for 2021-2023. There are opportunities to streamline and enhance the current regulatory model towards a system that enhances product quality and safety while promoting industry's competitiveness, economic development and consumers' wellbeing. To this end, TIC Council propose the following recommendations:

1. **Strengthen Inmetro's role in coordinating the CA system in Brazil:** Inmetro should strengthen its role in providing guidance and support to regulatory agencies as they apply a risk-based approach and develop CA programs as part of regulatory schemes. Inmetro should also work closely with industry and regulators and support the establishment of voluntary CA schemes, enhancing trust in the quality and safety of Brazilian products.

2. **Streamline the regulatory and CA process**: Inmetro should reference international standards in its technical regulations and remove redundant and prescriptive requirements, ensuring that the most recent version of the standard can be applied.

3. **Leverage international conformity assessment schemes:** Whenever possible, Inmetro should align with schemes (e.g. IEC CB Schemes) in order to facilitate recognition of CA results. Refraining from setting national requirements that contradicts with such schemes can streamline and reduce costs and time to market.

4. **Leverage public-private partnerships in CA programs**: Inmetro should follow international best practices and rely on private sector laboratories and conformity assessment bodies (CABs) to fulfil its regulatory mission. CABs have the ability to scale services, technical expertise, and innovative technologies to provide services in a cost-effective and efficient manner. Reliance on private sector also allows for governments to save scarce public resources and focus its legitimate role of oversight and supervision of a market-based approach.

5. **Implement good regulatory practices**: Good regulatory practices include having provisions for transparency, stakeholder participation, accountability, impact assessment, impartiality and due process. These foster an open, fair, and predictable regulatory environment.

6. **Establish effective accreditation processes**: Accreditation is an important contributor to trust in CABs. It is the internationally utilized method of assuring competence, consistency and impartiality of CABs. Accreditation should be applied uniformly for CABs within a national/geographic market as the principle of national treatment. National treatment allows properly accredited CABs that are approved / recognized by the regulator to provide services directly without localization requirements (the CABs do not need to be physically present in Brazil).

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Formerly known as IFIA and CEOC

7. **Establish a risk-based approach to CA**: Before deciding on the choice of CA (first-party or third-party) for a specific product category, Inmetro should develop risk-assessment profiles and submit them for public comment in order to gather inputs from stakeholders. Risk assessment should be based on science and on Inmetro's policy objectives and confidence needs (see Annex I).

8. **Consider the costs and implications of a post-market approach**: A post-market approach that relies on Suppliers' Declaration of Conformity (SDoC) requires a fully-funded market surveillance system to reduce the risk of dangerous product entering the market. Data shows that higher levels of resources are needed to fund such system resulting in lower levels of compliance compared to third-party CA (see Annex II). Other aspects to be considered in such model:

    - Economic actors' liability must be clearly defined, including effective criminal and civil penalties, and other recourses

    - Effective surveillance system in the ports and in the market and ability to quickly remove products from the market

    - Policies that provide incentives for compliance such as lessening penalties for manufacturers that voluntarily use third-parties as part of their risk-mitigation/ compliance strategy and reducing the level of inspections at the ports or at the market for certified components / products, among others

    - Data collection of injuries/deaths linked to faulty products (similar to the U.S. CPSC model), as well as of consumers' claim and manufacturers' disclosure of any potential harm related to a product provide additional tools to better assess risks and determine the appropriate regulatory and market surveillance actions.

9. **Engage stakeholders early and often**: Ongoing engagement early in the regulatory process allows for the inclusion of a wide range of stakeholders' perspectives and expertise

TIC companies are in the frontline of testing, inspecting and assessing products throughout all stages of supply chains across the globe, working with designers, manufacturers and retailers to enhance trust in their products and improve quality, performance and safety. They provide valuable expertise and data that can help Inmetro modernize its regulatory system, making it more flexible, risk-based and innovation-friendly. The TIC sector remains committed to supporting Inmetro's reforms and looks forward to contributing to the public debate and consultations.

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TIC Council is an international association representing the independent third-party testing, inspection and certification sector. TIC Council engages governments and key stakeholders to advocate for effective solutions that protect the public, support innovation and facilitate trade. For more information: tic-council.org

ANNEX I: Risk-Based Approach to Conformity Assessment

In general, the requirement for a particular level of rigor in the conformity assessment process is determined by the risks associated with the product, process, or service and its scope of use. Other market factors, such as the legal system, product liability laws, and the risk of non-compliance to public safety, should also be factored in when selecting the appropriate conformity assessment mechanism. The confidence level needed is based on various factors including the risk of non-compliance and what market-driven mechanisms exist as mitigation tools for non-compliance. Part of a full analysis would include the pre-market and post-market structure that would be required. The choice of that structure has implications for costs of related government infrastructure, socio-economic costs, costs of establishing and sustaining technical competency levels, and capacity of those providing the service. In order to have a system that provides incentives for compliance, economic actors' responsibilities must be clearly defined including provisions for strict criminal and civil penalties, and other manners of recourse. Some questions that Inmetro should consider in developing a risk-based system:

1. Is a high level of confidence required?
2. Is the perceived risk high towards consumers and environment?
3. Are products regulated primarily manufactured in countries with a history of risk factors?
4. Are products manufactured in complex and fragmented supply chains?
5. Is there a documented history of industry compliance? And of industry non-compliance?
6. Is there evidence that product liability is an effective deterrent?
7. Do regulatory authorizing/statutory provisions provide severe penalties and an effective deterrent?
8. Are there voluntary, market driven schemes that address confidence needs?
9. Are there accepted international schemes that can be relied upon and leveraged?
10. What are the societal and environmental risks and impacts of non-compliant products?
11. What are the resources considerations for market surveillance and who bears the costs?
12. How likely is the need for recall or corrective action? Are these effective?

Below is a brief differentiation on when first-party and third-party conformity assessment models may be used in regulatory schemes:

First-Party conformity assessment may be appropriate when:

- The risk of noncompliance and the risk of the product is low
- There is confidence that manufacturers understand the technical, regulatory and market requirements and have satisfactory control over their supply chain
- There are adequate penalties for placing noncompliant products in the market, including civil and criminal penalties, product recall, and/or product bans
- There are data collection mechanisms to identify and analize accidents, injuries and deaths associated with consumer products
- There is a fully funded market surveillance system (at retailers, factory, online and at the ports), that quickly removes noncompliant products from the market in order to avoid injury, societal and environmental costs.

Third-Party conformity assessment may be appropriate when:

- There is a higher risk associated with non-compliance and with the product
- There is need for an independent demonstration to supply chains that a product fulfils specified requirements
- There is need for higher levels of confidence and assurance of compliance
- There are limited public resources available to fund market surveillance programs.

Third-party is also widely used voluntarily by manufacturers seeking to reduce in-house compliance costs or apply third-party as an added value to their own quality and conformity assessment procedures to gain global market access and protect their brands and reputation.

ANNEX II: Data Available on Implications of a Post-Market System

Research shows that a post-market approach that relies on Suppliers' Declaration of Conformity (SDoC) requires higher levels of government resources to fund such system, and presents lower levels of compliance with regulations:

- The joint IFIA and CEOC market survey in the US and Europe has shown that 17% of products with self-declaration of conformity (sDoC) presented safety-critical failures, resulting in a high risk of fire or permanent injury. This compares to less than 1% for products with third-party certification. This 17% non-compliance was mostly in Europe, which relies on a SDoC for the products surveyed (small household electrical appliances) and relies on a post-market approach. Survey can be found here: http://www.ifia-federation.org/content/wp-content/uploads/IFIA_CIPC_239_2014-2016_Market_survey_report.pdf

- The European Commission's (EC) own studies also show high levels of non-compliance in the EU market: as many as 32% of toys, 58% of electronics, 47% of construction products or 40% of personal protective equipment inspected do not meet the requirements for safety or consumer information foreseen in EU legislation: http://europa.eu/rapid/press-release_IP-17-5301_en.htm

The data above demonstrates that for post-market approach based on SDoC to work, it needs to have strong incentives for compliance such as stringent penalties and a fully funded market surveillance program, which when properly implemented requires significant public resources. For example, in 2008, the U.S. Occupational Safety and Health Administration (OSHA) estimated that implementing a first-party system, in lieu of the current use of accredited third parties, would cost the Agency approximately $360 million annually (approximately $430 million in today's dollars), compared to $1 million annually required to operate the third-party Nationally Recognized Testing Laboratory (NRTL) program: https://www.regulations.gov/document?D=OSHA-2008-0032-0099