

TIC Council Recommendations on the new National Quality Infrastructure Policy in Brazil

The TIC Council is pleased to provide recommendations on Inmetro's new National Quality Infrastructure (QI) Policy. As the QI policy is currently being drafted and has not been made available to the public yet, the comments and recommendations below are preliminary. TIC Council looks forward to providing specific comments and recommendations once the draft policy is out for public consultation.

TIC Council fully supports the establishment of a national QI policy in Brazil. A strong QI system improves the quality of products and services, protects businesses from unfair competition, reduces barriers to trade and helps companies to compete in the global trading system. It is therefore important to establish policies that promote and create demand for quality infrastructure services and thus create a sustainable quality culture. Focus should be placed on identifying opportunities to streamline and enhance the current policy framework towards a system that enhances quality, safety and sustainability while promoting innovation, trade, and consumers' wellbeing. In this context, TIC Council offers the following recommendations:

Regulatory frameworks, Standardization, Conformity Assessment, Market Surveillance

1. **Implement good regulatory practices (GRP):** GRP include provisions for transparency, stakeholder participation, accountability, impact assessment, impartiality, and due process. These foundational policies function as a quality control mechanism for the development of regulations, fostering an open, fair, coherent, and predictable regulatory environment. They also help ensure policy objectives are more effectively met and barriers to trade minimized.
2. **Engage stakeholders early and often:** as part of GRP policy, transparent and ongoing engagement early in the policy design process allows for the inclusion of a wide range of stakeholders' perspectives and expertise.
3. **Strengthen Inmetro's role in coordinating the conformity assessment (CA) system in Brazil:** Inmetro should strengthen its role in providing guidance, support, and training to regulatory agencies as they apply a risk-based approach and develop CA programs as part of their regulatory schemes. Roles and responsibilities between Inmetro and other regulatory agencies must be clearly defined and established in policy. Inmetro should also work closely with industry, conformity assessment bodies (CABs), consumer groups and regulators in the establishment of mandatory and/or voluntary CA schemes, enhancing trust in the quality and safety of Brazilian products.
4. **Rely on international standards and conformity assessment schemes:** Inmetro should reference international standards and international CA schemes in its technical regulations whenever possible and remove redundant and prescriptive requirements, ensuring that the most recent version of the standard can be applied.

These will streamline the regulatory processes and make them more efficient and effective.

5. **Leverage public-private partnerships in CA programs:** Inmetro should follow international best practices and rely on private sector laboratories and CABs to fulfil its regulatory mission. CABs can 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.
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). This brings efficiencies, and more options and lower costs for industry partners (for more information about National Treatment please see item 14 below).
7. **Establish a risk-based approach to conformity assessment:** 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 to gather inputs from stakeholders. Risk assessment should be based on science, data, policy objectives, and regulatory authorities' confidence needs and resource availability. Some questions to be considered in developing a risk-based system:
 - a. Is a high level of confidence required?
 - b. Is the perceived risk high towards consumers and environment?
 - c. Are products primarily manufactured in countries with history of risk factors?
 - d. Are products manufactured in complex and fragmented supply chains?
 - e. Is there documented history of industry compliance? And of non-compliance?
 - f. Is there evidence that product liability is an effective deterrent?
 - g. Do regulatory authorizing/statutory provisions provide severe penalties and an effective deterrent?
 - h. Are there voluntary, market driven schemes that address confidence needs?
 - i. Are there accepted international schemes that can be relied upon and leveraged?

- j. What are the societal and environmental risks and impacts of non-compliance?
 - k. What are the resources needs for market surveillance and who bears the costs?
 - l. How likely is the need for recall or corrective action? Are these effective?
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. International experience shows that for SDoC to work, a set of conditions need to be in place to avoid high levels of non-compliance and an unlevel playing field for economic operators. Examples of such conditions are:
- a. Economic actors' liability must be clearly defined, including effective criminal and civil penalties, and other recourses.
 - b. Effective surveillance system in the ports and in the market and ability to quickly remove products from the market.
 - c. 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.
 - d. 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. **Consider international experience and lessons learned from other jurisdictions:** international experience and data show that most economies face challenges in ensuring that the conditions above are met, especially regarding the lack of enforcement capabilities and resources to fully fund market surveillance systems.

Studies show that **SDoC is associated with higher rates of non-compliance and higher costs to regulatory authorities compared to third-party conformity assessment:**

- a. **A market survey**¹ has shown that 17% of products with SDoC in Europe presented safety-critical failures, resulting in a high risk of fire or permanent injury, compared to less than 1% for products with third-party certification in the US.

¹ http://www.ifia-federation.org/content/wp-content/uploads/IFIA_CIPC_239_2014-2016_Market_survey_report.pdf

- b. **The European Commission's (EC) studies²** also show high levels of non-compliance related to SDoC 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.
- c. **An EC study assessing the feasibility of using SDoC in South Africa³** concluded that the perception that SDoC offers advantages is erroneous, and that in the case of South Africa it would bring significant disadvantages with an avalanche of non-compliant products and distortion of competition in the market.
- d. **The U.S. Occupational Safety and Health Administration (OSHA)**, a division of the US Department of Labor, estimated that implementing a SDoC system would cost the regulatory authority approximately \$360 million annually, compared to \$1 million annually required to operate the current third-party certification program (Nationally Recognized Testing Laboratory (NRTL)⁴.
- e. The data above from multiple international studies demonstrates that **for SDoC to work, it needs to have strong incentives for compliance and appropriate levels of public funding to fully implement markets surveillance programs.**
- f. Policies that rely on third-party conformity assessment, such as the OSHA NRTL mentioned above, provide a cost-effective solution for regulatory authorities to fulfil its mission to protect health and safety while focusing its time and resources on the oversight of the system.

Digitalization

- 10. **Leverage digital solutions for effective management of QI system:** digital solutions, whether in the form of increasingly smarter and interconnected digital devices, self-learning software or better connectivity networks, enable the efficient collection, processing, analysis, and use of huge amounts of data and algorithms that in turn enable governments, companies and consumers to make better, more efficient and agile decisions that helps enhance quality, safety, performance, innovation and sustainability while minimizing barriers to trade. These tools can support effective oversight and management of QI systems.
- 11. **Design policies that encourage innovation and the use of new digital solutions in QI services:** CABs are strengthening their commitment to embrace new digital solutions by building up its technical expertise and capabilities. One example of how technologies are being leveraged by CABs is remote assessments. The increasing digitalization has led to the development of specialized tools and

² http://europa.eu/rapid/press-release_IP-17-5301_en.htm

³ https://www.euchamber.co.za/wp-content/uploads/2021/04/NRCS-Self-Declaration_EU-South-Africa-EU-SA_Partners-for-Growth-Final-and-Approved-13-April-2021.pdf

⁴ <https://www.regulations.gov/document?D=OSHA-2008-0032-0099>

technologies which have improved remote assessment capabilities, thus providing more opportunities to integrate this practice into daily operations.⁵ For example, drones or robotic cameras can perform assessments by remotely accessing the physical infrastructure, and more and more industrial buildings are deciding to install sensors directly embedded in their machinery so that they can continuously monitor the data that is generated in real time. The use of digital technologies for remote assessments allows companies around the world to collect data with extreme accuracy. The expected benefits include an increase in productivity maintenance, efficiency, cost reductions and a better overview of their performance, making it easier to detect and solve problems. Some conformity assessment organizations have even developed their own proprietary software/downloadable applications for the performance of remote inspections.

12. **Ensure QI system supports the design of effective digitalization policies:** countries around the globe are developing transparent and comprehensive policies and regulatory frameworks that address safety and security of connected infrastructure, systems, components and devices, including Internet of Things (IoT). The increasing number of security incidents across the globe are good indications that such frameworks are critically needed:
 - a. **Level Playing Field.** Manufacturers should be encouraged and rewarded for taking ownership in cybersecurity, securing their part of the supply chain by securing their products and services and building their cybersecurity capacity.
 - b. **Compliance to regulatory frameworks will require the extension of existing and development of new evaluation procedures.** Cybersecurity levels often cannot be tested by the end user or verified by the manufacturer. Equally, public authorities often do not have the necessary internal resources to conduct evaluations and have traditionally relied on third-party conformity assessment services. Independent third-party certification can help meet this need in a reliable and efficient manner.
 - c. **Incorporating existing international conformity assessment schemes would reduce the cost and time-to-market for manufacturers and harmonize processes across industries.** By leveraging such schemes from various segments and ensuring evaluation rules and procedures are applied consistently, it would be possible to reduce the cost and time needed to develop a regulatory program and ensure fast implementation within industry.
 - d. **Ensuring interoperability.** Interoperability is a critical function in the smooth cooperation of securely connected devices. Rules and technical specifications applying to connected devices should require interoperability from their manufacturers.

⁵ https://www.tic-council.org/application/files/6016/4863/1552/TIC_Council_Publication_-_Remote_Activities_of_Conformity_Assessments.pdf

- e. **Ensuring Safety.** With the increasing digitalization and connectivity of products and machines we must do more than merely protect people from machines, but also machines from people to avoid unauthorized influence (cyber-attacks) from external sources. This requires that manufacturers, integrators, and operators of functionally safe products and systems redefine the diverse measures of IT-Security in their development, manufacturing, and operating processes.

13. **Conformity assessment sector organizations are key partners in supporting the security and compliance of digital products, processes, and services** by working with industry and regulators to develop new standards for emerging areas such as IoT and wearable devices, and to pursue security solutions. As reported in the TIC Council Value of TIC Study⁶, the conformity assessment sector worked closely with the U.S. Consumer Product Safety Commission (CPSC) and ASTM International to develop a new standard for connected consumer products. It was estimated that just a 1% reduction in injuries due to the development of this standard can save up to \$27 million annually.

International Trade

14. **Design policies that facilitate market access such as National Treatment to CABs:** CABs have an essential role in promoting competitiveness, innovation, and international trade, and TIC Council supports policies that aim at facilitating market access for all sectors, including the conformity assessment sector.

National treatment would provide the ability for CABs based in Brazil to be accredited by the other jurisdiction's accreditation body without having to be physically present in that market. Conversely, CABs based in another jurisdiction would be accredited by Brazil's accreditation body to test, inspect, certify to Brazil's regulatory and technical requirements without needing to be physically established in Brazil.

National treatment reduces costs and time to market for manufacturers wanting to place their product in multiple markets, as it allows the manufacturer to streamline operations and procedures and have more choice of conformity assessment providers.

Third-party conformity assessment services provide manufacturers, trading partners, governmental bodies, and consumers the basis for confidence and trust in the conformity of products, process, and services, which is essential for companies looking to export their products in multiple markets. TIC Council position and recommendations related to international trade can be found here: [https://www.tic-](https://www.tic-council.org/application/files/1216/2211/4719/Value_of_the_Testing_Inspection_and_Certification_Sector_-_2020-12-23_Final_report.pdf)

⁶ https://www.tic-council.org/application/files/1216/2211/4719/Value_of_the_Testing_Inspection_and_Certification_Sector_-_2020-12-23_Final_report.pdf

Sustainable development

15. **Design QI policies that support sustainable development:** policymakers across the globe are designing new policies to address climate change, and industry has begun to shift towards more sustainable ways of doing business. This requires policies that incentivizes the creation of sustainable supply chains, employing sustainable technologies, and ways to measure the impact and demonstrate compliance. Investors are also increasingly searching for sustainable investment opportunities and need ways of measuring and reporting this in a way that can be trusted. More and more consumers are seeking ethical and sustainable products, while understanding and trusting environmental product labels remains challenging.

Third-party conformity assessment is essential to confirming the credibility of sustainability approaches by providing assurance of compliance and proof that environmental and social commitments are backed up by concrete facts and actions. Third-party conformity assessment is also essential to minimize greenwashing, a practice that undermines the policy objectives and the trust of consumers and investors in companies' sustainability efforts. Below are some examples of the role third-parties play in sustainability:

- a. Sustainability due diligence throughout manufacturing processes and supply chains. This may include conformity with environmental requirements, equality policies, human rights protection, and healthy working conditions throughout the value chain.
- b. Support manufacturers in assessing the compliance of their products with all forms of legislation including energy, resource efficiency, traceability, social compliance, and safety. It also helps them translate complicated requirements into simple and understandable labels.
- c. Help businesses identify carbon and environmental hotspots throughout processes and value chains. These include a product's life cycle impact, Ecodesign and carbon foot printing assessments, auditing for energy, and environmental management throughout the supply chain.
- d. Help enable the proper introduction of new technologies by testing, verifying and certifying renewable energy technologies, technologies for smart manufacturing, and technologies for e-mobility and fuel efficiency.