

Date: 27 May 2021

Portaria:	Consulta Publica N 8 de 25 de Marco de 2021 - Inmetro's Proposed Regulatory Model
Nome completo do proponente:	Roberta Telles
CPF do proponente:	
Instituição:	TIC Council
Telefone:	1 240 507 3392
E-mail para contato:	rtelles@tic-council.org

General Comments:

Thank you for the opportunity to provide comments on INMETRO's proposed regulatory model. TIC Council welcomes Inmetro's efforts to modernize its regulatory and conformity assessment (CA) framework towards a system that enhances product quality and safety while promoting industry's competitiveness, economic development and consumers' wellbeing. TIC Council also welcomes the principles and guidelines that were published for public consultation and supports the intent to have a regulatory and conformity assessment model that is flexible, non-prescriptive, transparent, consultative, and accountable that provides effective policy outcomes. How effective the new regulatory model will be in practice and the impacts it will have on industry and society will depend on how INMETRO will implement and apply these principles, which it is not clear based on the document published as it is very broad at this stage. INMETRO is correct to identify on 7.10.2 the need for instruments, tools and changes to the current legal framework for a successful implementation. It is essential that these instruments be developed following the provisions of the World Trade Organization Technical Barriers to Trade Agreement (WTO/TBT) as well as established international Good Regulatory Practices (GRP). This will ensure openness, transparency and extensive public participation throughout the implementation process and robust regulatory outcomes. This means that all rules and ordinances related to the regulatory model should be drafted and sent for public consultation before they are finalized. In addition, such rules and ordinances should be developed after careful consideration and incorporation, as appropriate, of the comments received in this public consultation number 8 of March 25, 2021 on the proposal of Inmetro's Regulatory Model.

TIC Council asks that INMETRO:

- Define a roadmap for then implementation plan with all the tasks and timeline as well as sequencing of activities and share with the public for consultation.
- Continue engaging stakeholders in an open and transparent manner in each step of the process so there are opportunities for comments and course corrections early on and not after time and resources and invested.
- Provide, during the scheduled public meetings with stakeholders, a summary of the main comments received and INMETRO's responses to them and any changes that will be incorporated.

Item	Redação original	Proposta de alteração, acréscimo ou exclusão	Justificativa/Comentários
	Be an instrument of protection and dynamization of the market and 5 facilitator of business.	Be an instrument of protection of consumer's health and safety and of dynamization of the market and facilitator of business.	Is the intent to say that the objective is to protect the market? Protection of market as is written can mean shielding the market from competition. Or it is meant to say protect the public? The goal of regulating the types of consumer products that Inmetro has in its scope should be first and foremost to protect the health and safety of the public.

6.6	<p>Harmonization</p> <p>The regulatory model must ensure that the elaboration and execution of its processes are in line with good national and international regulatory practices.</p>	<p>Harmonization Good Regulatory Practices</p> <p>The regulatory model must ensure that the elaboration and execution of its processes are in line with good national and international regulatory practices to ensure that regulations are crafted in open, transparent and participatory manner.</p>	<p>Harmonization implies harmonizing with international or other countries' standards and regulations, which does not seem to be the objective of this principle.</p> <p>The text describing this principle refers to adhering to national and international good regulatory practices. This means ensuring that regulations are crafted in open, transparent and participatory manner, among other provisions.</p> <p>TIC Council fully supports that Inmetro's proposed regulatory model adheres to international Good Regulatory Practices (GRP), including the requirements of the Organisation for Economic Co-operation and Development (OECD) and other international agreements that Brazil may have, including the new Agreement on Trade and Economic Cooperation with the United States (annex II on GRP).</p>
7.2	<p>Take necessary measures when a product or service does not meet the requirements or can cause damage to the consumer, informing the authorities of the actions implemented.</p>		<p>What are these necessary measures that producers must undertake to make corrective actions? And what are the consequences for failing to do so and how will Inmetro enforce these provisions? It is essential that these be clearly defined.</p>

7.3	Adopt appropriate conformity assessment procedures for regulation of products, services and legal metrology, according to the identified risks, the objectives that are intended to be achieved and the categories of products and services		<p>How will Inmetro define risk for the purpose of selecting the appropriate conformity assessment procedure to be used?</p> <p>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.</p> <p>Some questions that Inmetro should consider in developing a risk-based system:</p> <ol style="list-style-type: none"> 1. <input type="checkbox"/> a high level of confidence required? 2. <input type="checkbox"/> the perceived risk high towards consumers and environment? 3. <input checked="" type="checkbox"/> Are products regulated primarily manufactured in countries with a history of risk factors? 4. <input checked="" type="checkbox"/> Are products manufactured in complex and fragmented supply chains? 5. <input type="checkbox"/> Is there a documented history of industry compliance? And of industry non-compliance? 6. <input type="checkbox"/> Is there evidence that product liability is an effective deterrent? 7. <input checked="" type="checkbox"/> Do regulatory authorizing/statutory provisions provide severe penalties and an effective deterrent? 8. <input checked="" type="checkbox"/> Are there voluntary, market driven schemes that address confidence needs? 9. <input checked="" type="checkbox"/> Are there accepted international schemes that can be relied upon and leveraged? 10. <input checked="" type="checkbox"/> What are the societal and environmental risks and impacts of non-compliant products? 11. <input checked="" type="checkbox"/> What are the resources considerations for market surveillance and who bears the costs?
7.3	Identify risks, costs and effectiveness and efficiency when selecting conformity assessment procedures to ensure the maximization of conditions of conformity and competition		<p>As mentioned above, it is essential to assess the risks and the costs of non-compliance such as costs related to potential injuries, hospitalization, death, loss of productivity, loss of income etc. Also consider costs to the regulatory authority to fund post-market surveillance activities, which are considerably higher when utilizing supplier's declaration compared to third-party conformity assessment. For instance, the U.S. Occupational Safety and Health Administration (OSHA) has estimated that it would cost OSHA USD360 million annually if it switched to supplier's declaration, compared to USD1 million annually required to operate the program that relies on third-party conformity assessment.</p>

7.3	Predict the scalability and specific conditions of Micro and Small Enterprises, ensuring the treatment of risks and the effectiveness of regulation.		Third-party conformity assessment is essential to support small businesses who lack technical expertise and economies of scale to set up their own internal laboratories. The tests and procedures that are essential for ensuring quality, performance and safety require the same equipment, expertise, and resources regardless of who is performing the evaluation (first- or third-party). The economies of scale for providing these services generally make the use of independent third-party services more efficient and cost effective.
7.3	Establish an articulated set of conformity assessment procedures that can be used in regulation either for products or services or for Legal Metrology		It is not clear what “establish an articulated set of CA procedures” means.
7.3	Provide for the use of the supplier's declaration as one of the conformity assessment procedures, according to the risks	Provide for the use of the supplier's declaration as one of the conformity assessment procedures, according to the risks and according to the available and appropriate post-market and other mechanisms that must be in place for supplier's declaration to work	Supplier's declaration can be used when risks of product are low, and risks of non-compliance are also low. This means that there is historic data suggesting that industry has incentives to comply due to market dynamics and that there is effective deterrent mechanism in place such as fully funded market surveillance, application of stringent penalties etc. Otherwise, rogue operators will cut corners and not do the conformity assessment internally, which will generate unsafe products on the market AND unfair competition as these operators will steal market share from credible and responsible economic operators that invest in in-house conformity assessment. Various studies demonstrate that suppliers' declaration results in lower levels of compliance compared to third-party conformity assessment: - Data from the IFIA survey shows that products with suppliers' declaration in Europe presented 17% non-compliance with safety requirements, compared to less than 1% for products with third-party certification in the U.S (https://www.tic-council.org/application/files/1415/5903/8639/IFIA_CIPC_239_2014-2016_Market_survey_report.pdf). - The European Commission's (EC) studies shows that 58% of electronics, 32% of toys, 47% of construction products in the EU market were non-compliant (https://ec.europa.eu/commission/presscorner/detail/en/IP_17_5301). - Prosafes found that 40% of household refrigerators, 79% of professional refrigerators and 71.8% of network stand-by related products tested were non-compliant with EU's eco-design and energy labelling rules. (https://eepliant.eu/index.php/new-about-eepliant/about-eepliant-2). - A study commissioned by the EC found that supplier's declaration would bring considerable disadvantages to South Africa, leading to a flood of non-compliant and dangerous products on the market. The study recommended that third-party conformity assessment be maintained until there is sufficient public resources to fully fund a market surveillance system (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)

7.3	Promote the creation of voluntary conformity assessment programs, inclusive for sectoral entities, when appropriate		<p>How will INMETRO determine when to pursue voluntary conformity assessment programs?</p> <p>It is important to note that voluntary programs only works IF appropriate incentives are in place. The effectiveness of such programs will depend on historical/cultural/juridical conditions in a particular market, as well as on specific characteristics / history of compliance of a particular industry.</p>
7.4	<p>Identify and publish the list of selected technical standards that give presumption of compliance to technical regulations</p> <p>Recognize that technical standards are voluntary, establishing a mechanism by which a supplier can demonstrate that it meets the essential requirements without necessarily following the technical standards identified as conferring a presumption of conformity. In this case, the burden of demonstrating compliance with the essential requirements falls on the supplier with regard to its role as a regulator</p>	Remove or reestruture text	<p>TIC Council recommends removing language on presumption of conformity and/or restructuring section 7.4 as it is confusing as written.</p> <p>Presumption of conformity is a concept that is widely used in the context of the European “New Approach” better regulation technique, and it is not clear the benefits/costs/implications of adopting this model in Brazil.</p> <p>According to the European Union own data, they have significant challenges on how the model works in practice, given the extremely high levels of non-compliant products that are found on the European market (see data above). This is due to the lack of resources in many European countries to fund post-market surveillance activities, which are essential for suppliers’ declaration to work.</p>
7.5	Establish financing mechanisms to fund the market surveillance activities to ensure its financial sustainability		<p>Market surveillance is an important tool for an effective regulatory system, and it requires considerable levels of resources and expertise. Third-party conformity assessment provides regulators with a cost-effective solution to fulfill its policy objectives, as the levels of resources needed for market surveillance is considerably reduced when leveraging third parties early in the chain before products are placed on the market. See U.S. OSHA NRTL study that estimates that it would cost OSHA \$360 million annually if it relied on a post-market approach, compared to \$1 million annually required to operate the program that relies on third-party conformity assessment: https://www.regulations.gov/document?D=OSHA-2008-0032-0099</p>
7.5	Consider the activities or initiatives of private entities that contribute to achieving the regulatory objectives, including voluntary conformity assessment initiatives and the participation of private entities, in accordance with the legal responsibilities and limits		<p>TIC supports 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 (for lower risk products that does not requires mandatory certification).</p>

7.5	Include an educational approach, in particular when new regulations or revisions are launched, in this case without giving rise to sanctions		Conformity assessment bodies play an important role worldwide educating industry on regulatory requirements and therefore the sector has extensive expertise and accumulated know-how and best practices. TIC Council suggests that Inmetro explores opportunities for public-private partnerships in its educational efforts.
7.7	Analyze the risks and check for other methods such as self-regulation and co-regulation that can be tested before regulation should apply		When assessing the need for government intervention, it is essential to have a robust data collection system that allows the regulator to see the trends in injuries/deaths associated with the products. Data analyses and in-depth investigations as part of enforcement activities will also help identify the cause of the problem and appropriate course of action. Example of such data collection is the U.S. CPSC: https://www.cpsc.gov/Research--Statistics/NEISS-Injury-Data). Besides the data collected via emergency rooms, additional data collection sources are compiled from consumers' claims, from media, as well as from manufacturers' disclosure of any potential harm related to a product. These data provide tools to better assess risks and determine the appropriate regulatory and market surveillance actions.
7.8	of foreign conformity assessment results, with the adoption of the appropriate acceptance and validation mechanisms, when relevant to the regulations and whenever possible seeking reciprocity and respecting the national legislation		TIC Council supports international conformity assessment schemes that help to facilitate trade by allowing manufacturers to test their products once for acceptance across multiple markets with the same or similar requirements. So long as international standards meet the needs of the local regulator and the organizations conducting the conformity assessment are accredited, international schemes can provide assurance in a cost-effective manner for regulators and for industry.
7.10.2	For the implementation of the model, it is necessary to develop and establish a set of rules and instruments, tools and support methods.		How does INMETRO plan to consult stakeholders in the development of such tools? What is the sequencing / timeline for the development of such tools? What is the need for legislative changes to institutionalize the new model (how to ensure some level of stability so that the framework will not keep changing when leadership changes)? TIC recommends that INMETRO identify what can be implemented in the short, medium and long term.
7.10.7	Pilots		What is envisioned by the pilots? What INMETRO has in mind for the scope of the first pilot? What would be the timeline (when would the pilot start and duration of pilot etc). What are the metrics on how the pilots will be evaluated?