

TIC Council recommendations on the implementing regulation of Mexico's National Quality Infrastructure Law

The TIC Council is pleased to provide recommendations on the implementing regulation of Mexico's National Quality Infrastructure (QI) Law of 2020. As the implementing regulation is currently being drafted and has not been made available to the public at this time, the comments and recommendations below are based on the text of the QI law¹. TIC Council fully supports the goals of the QI law to streamline the current regulatory framework, increase competitiveness while ensuring quality, safety, and compliance. However, there are concerns regarding the lack of clarity on how some provisions of the law will be implemented and enforced. TIC Council has the following asks and recommendations to be considered in the development of the implementing regulation:

1. Submit the draft Regulation for public consultation

TIC Council supports open and transparent public debate and asks that a draft of the regulation be shared with stakeholders for 60 days public comment. There are a considerable number of provisions in the law that need to be clarified and further detailed in the regulation, and as such, the regulation will have considerable impact on stakeholders. Taking the appropriate time to review, discuss, and receive inputs from a wide range of experts is of primordial importance for a robust and effective implementation of the law.

2. Leverage private sector conformity assessment

Article 62 of title 6 of the law reads: "Conformity assessment may be carried out by the regulatory authorities, in the absence of infrastructure in the private sector to carry it out". The regulation should require regulatory authorities to follow international conformity assessment best practices by leveraging private-sector conformity assessment whenever possible to fulfill its mission to effectively protect health and safety of consumers and the environment - instead of the government providing these services directly. There is a solid and extensive private sector conformity assessment infrastructure in Mexico, and conformity assessment bodies can scale services, technical expertise, and innovative technologies to provide such services in a more timely, cost-effective, and efficient manner. In addition, government provision of conformity assessment services crowds out private sector investments and leads to unfair competition and unlevel playing field in the market. Reliance on private sector allows for governments to save scarce taxpayer

¹<https://catalogonacional.gob.mx/FichaRegulacion?regulacionId=5570#:~:text=Esta%20Ley%20tiene%20por%20objeto,desarrollo%20econ%C3%B3mico%20y%20la%20calidad>

resources and focus its role on oversight and supervision of a market-based approach.

3. Disclosure of pricing, fees and related information by Conformity Assessment organizations

There are significant industry concerns with the provisions of Article 45 and 55, which requires the disclosure of pricing while making the intellectual property of private Conformity Assessment Agencies publicly available in the form of methodology development and business planning. Further, depending on the complexity and scope and type of testing or conformity assessment required, it would not be possible to have standardized price lists. It is not clear what issue this is trying to address, and given the competitive nature of this type of information, TIC Council would like to better understand the rationale and identify potential alternative solutions.

4. Mutual Recognition Agreements and Equivalence Agreements

(art 70-72 of title 6) TIC Council asks that considerable stakeholder consultation take place before engaging in MRAs and EAs to ensure these instruments are effective and bring the desired benefits. It has been the experience of some of our members that the current MRA/MLAs in the accreditation area have limited value to the users of accreditation services offered by the signatories to these arrangements. Unless there is a benefit to the users of the service, these types of arrangements serve little purpose.

TIC Council members have expressed concern regarding provisions in the law that require that private agreements/arrangements signed by independent third-party conformity assessment bodies (CAB's) are fully published on the technology Platform, as these are considered intellectual property of the CAB. TIC Council would like to understand the rationale for these agreements to be published in full and asks that DGN discuss with the conformity assessment sector to ensure that confidential information is protected. Members view this as both a confidentiality and legal issue.

We understand and agree that Government MRA's and those by organizations such as ILAC/IAF, IAAC and similar shall be made available to any interested party for public consultation in the Technological Platform for Quality Infrastructure, and once subscribed, they will be published entirely in the same Platform.

A final note to reinforce that government-to-government MRAs or Equivalence Agreements require clearly delineated rules and agreement from regulatory agencies to implement fully within a specified time frame to be successful.

5. Ensure risk assessment is based on science, data and confidence level needed

Article 30 of title 3 reads: “each Mexican regulation shall contain the applicable Conformity Assessment Procedure according to the level of risk...”. TIC Council supports a risk-based approach to conformity assessment and asks that considerable stakeholder consultation take place before the risk assessment methodology is defined.

Many questions still need to be answered, such as: how will the levels of risk be defined? what will be the guidelines and considerations for assessing risks? will each regulatory agency determine their own risk-assessment model? how will regulatory authorities determine on the use a first (SDoC) versus third-party approach to conformity assessment? How will stakeholders be able to participate and contribute to the determinations of risk?

TIC Council’s view is that risk assessment should always 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?

6. Consider the conditions, costs and implications of SDoC:

Article 69, title 6 reads: “The Regulations of this Law shall establish the terms according to which Suppliers Declaration of conformity (SDoC) may be used...”. 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. Low levels of risk associated with the product
- b. Low level of risk of non-compliance
- c. Economic actors’ liability must be clearly defined, and regulatory authorities’ enforcement capabilities strengthened
- d. Stringent criminal and civil penalties, well-functioning judicial system, and product liability laws
- e. Resources to fully fund surveillance systems in the ports and on the market and ability to quickly remove products from the market
- f. 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
- g. Data collection of injuries/deaths linked to faulty products (similar to the U.S. CPSC model²), 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

International studies and data show that many 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 much higher rates of non-compliance with regulations compared to third-party conformity assessment, as well as with much higher costs to regulatory authorities:

- I. **A market survey³** has shown that 17% of products with SDoC in Europe presented safety-critical failures, resulting in a high risk of fire or permanent

² <https://www.cpsc.gov/Research--Statistics/NEISS-Injury-Data>

³ http://www.ifia-federation.org/content/wp-content/uploads/IFIA_CIPC_239_2014-2016_Market_survey_report.pdf

injury, compared to less than 1% for products with third-party certification in the US:

TIC Sector Contribution



Study Compares compliance rates of small household appliances in the U.S. and Europe

Self-declared (SDoC)

Third-Party certified

17% safety-critical failures¹

<1% safety-critical failures

Safety-critical failures: high risk of fire / permanent injury



1. Mostly found in the EU, which relies on SDoC for these types of products

* Consumer Product Market Survey 2014-2016: https://www.tic-council.org/wp-content/uploads/2017/05/2017-05-03-0839/PIA_CIPC_2014-2016_Market_survey_report.pdf

- II. The European Commission's (EC) studies⁴ 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:

Studies from the European Commission

High levels of non-compliance in the EU market:

- 32% of toys
- 58% of electronics
- 47% of construction products
- 40% of personal protective equipment



Challenge: insufficient level of resources to fully fund a market surveillance system



*Safe products in the EU Single Market: Commission acts to reinforce trust: https://ec.europa.eu/commission/presscorner/detail/en/IP_17_5301

⁴ http://europa.eu/rapid/press-release_IP-17-5301_en.htm

III. A study assessing the feasibility of using SDoC in South Africa⁵ concludes 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.

South Africa Study

- ❑ Analysis of potential change to Suppliers' Declaration (SDoC)
- ❑ It concludes that the perception that SDoC offers advantages is erroneous
- ❑ Recommends maintaining third-party conformity assessment



Source: EU-South Africa (EU-SA) Partners for Growth: Assess the Viability of Self-Declaration as a Suitable Mechanism for the Mandatory Registration of Electro-Technical Products with the National Regulator for Compulsory Specifications. March 2021. 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

IV. 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 Nationally Recognized Testing Laboratory (NRTL) program⁶.

OSHA Studies in the U.S.



Costs to the regulatory authority



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

⁵ 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

⁶ <https://www.regulations.gov/document?D=OSHA-2008-0032-0099>



In conclusion, the data from multiple international studies demonstrates that for SDoC to work, it needs to have strong incentives for compliance and appropriate levels of public funding. Policies that rely on third-party conformity assessment 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.

Thank you again for the opportunity to provide comments. We are available to discuss the questions/comments above and answer any question you might have.

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About TIC Council: TIC Council is the global trade federation representing the independent third-party Testing, Inspection and Certification (TIC) industry which brings together more than 90-member companies and organizations from around the world to speak with one voice. Its members provide services across a wide range of sectors: consumer products, medical devices, petroleum, mining and metals, food, and agriculture among others, and promote best practices in safety, quality, health, ethics and sustainability. The TIC Council supports the development of international standards and regulations that protect consumers without hindering innovation or adding unnecessary burden on industry. Moreover, all members of the TIC Council are committed to the highest standards of ethics and integrity as TIC Council membership requires the mandatory implementation of a compliance code annually verified by an external audit.