



## APPROACHES TO CONFORMITY ASSESSMENT

### EIGHTH TRIENNIAL REVIEW

#### *Submission from the United States*

The following submission, dated 5 June 2018, is being circulated at the request of the delegation of the United States

### 1 RESPONSE TO THE EUROPEAN UNION

1.1. The United States continues to appreciate the exchange of views taking place in the 8th Triennial Review, and we welcome the proposal from the European Union on Approaches to Conformity Assessment.<sup>1</sup>

1.2. The United States shares the view of the European Union that conformity assessment procedures can be one of the most common and costly non-tariff measures, and that the WTO TBT Committee should discuss ways to reduce burdens that can be created by conformity assessment procedures. The 2010-2016 statistic presented by the EU, that 40% of specific trade concerns relate to conformity assessment procedures speaks for itself. A central priority of the TBT Committee is discussion of tools and programs available to Members to ease the exchange of information concerning, and results of, conformity assessment procedures.

1.3. The EU's proposal is to revitalize the Committee's agreement in the Fifth Triennial Review to initiate work on developing practical guidelines on how to choose and design efficient and effective mechanisms aimed at strengthening the implementation of the TBT Agreement, including the facilitation of acceptance of conformity assessment results.<sup>2</sup> Its suggestion to initiate work to develop recommendations or practical guidelines to support regulators to identify elements of conformity assessment that they can use in designing the appropriate procedures, reaches to the heart of regulatory decision-making to maintain a competitive, open market for products. As long as that work is not prescriptive, the United States can support this proposal moving forward.

1.4. The Indicative List of Approaches to Facilitate the Results of Conformity Assessment (the Indicative List) is relevant to further work.<sup>3</sup> While the Indicative List covers Supplier's Declaration of Conformity (SDOC) and adequate post market surveillance, which are also, addressed as important topics by the EU's in its proposal, it also covers other areas of conformity assessment. Equally important to any discussion of conformity assessment procedures in the TBT Committee are Mutual Recognition Agreements (MRAs), Mutual Recognition Arrangements (MRAs) between conformity assessment bodies (CABs), and use of accreditation to qualify conformity assessment bodies (CABs), government designation, and unilateral recognition of conformity assessment results. Each of these elements is necessary for consideration in the development of any guideline.

1.5. Two previous US proposals from the Seventh Triennial Review are also relevant. The first proposal was to improve the understanding of the trade- enabling benefits of a national quality infrastructure (NQI).<sup>4</sup> At the conclusion of the Seventh Triennial Review, Members agreed to

<sup>1</sup> G/TBT/W/462

<sup>2</sup> G/TBT/26

<sup>3</sup> G/TBT/1/Rev. 13

<sup>4</sup> G/TBT/W/411/Rev.1

discuss approaches to the use of quality infrastructure, both national and regional, for facilitating trade in respect of standards, technical regulations and conformity assessment procedures.<sup>5</sup> Developing countries are actively working to build their NQI; how regulators use NQI in technical regulations and mandatory conformity assessment procedures can either contribute to specific trade concerns or help reduce them. This discussion has not yet been conducted in the TBT Committee, but would contribute to any Committee efforts to understand how to better utilize conformity assessment procedures to meet our respective regulatory objectives.

1.6. The second US proposal called for Members to discuss best practices for notifying regional technical regulations.<sup>6</sup> The United States continues to see an increase in implementation of regional technical regulations and conformity assessment procedures. Any discussion of facilitating the acceptance of conformity assessment results should include a discussion of regional measures and WTO Member implementation of them.

1.7. In the Seventh Review, Members also agreed to exchange information on initiatives of Members to enhance regulators' reliance on international and/or regional systems for conformity assessment, including sectoral schemes, aimed at facilitating the recognition of conformity assessment results.<sup>7</sup> These international and/or regional systems for conformity assessment assist in facilitating trade and reduce the cost of conformity assessment to traders. Members could further the discussion on conformity assessment procedures held in March 2016, which focused on developments in international and regional systems, and regional trade agreements (RTAs) relating to the recognition and acceptance of conformity assessment results.<sup>8</sup>

1.8. The United States sees these three topics-- the implementation of NQI, consideration of regional measures, and use of international and/or regional systems of conformity assessment-- as integral to the development of a guideline for regulators to assist in the development or design of a conformity assessment program.

## 2 EXPERIENCE OF THE UNITED STATES

2.1. The United States is prepared to contribute its experience to this work, as the US National Institute of Standards and Technology (NIST) is developing a special publication, "Conformity Assessment Considerations for Federal Agencies".<sup>9</sup> The NIST advises agencies to consider certain factors when designing or developing conformity assessment programs central government bodies in order to assess the effectiveness of conformity assessment options and determine the type(s) of conformity assessment to employ. These may include:

- a. the objective(s) of the underlying regulation;
- b. the level of confidence required by the agency to ensure that the agency objective(s) has/have been achieved, weighing the risk of non-compliance and its associated consequences with the anticipated costs of demonstrating compliance (including time and resources) to the producers, suppliers, consumers, and the agency;
- c. whether there are existing private sector conformity assessment activities, acceptance schemes or arrangements, that may work in conjunction with or, where appropriate, in lieu of governmental conformity assessment activities, except where such activities are inconsistent with law, unfit for regulatory purpose, or otherwise impractical;
- d. consistency with statutory national, regional and international obligations;
- e. consideration of the available scientific and technical information, as relevant to the selection of the appropriate conformity assessment program;

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<sup>5</sup> G/TBT/37, para 3.9.c

<sup>6</sup> G/TBT/W/415/Rev.1

<sup>7</sup> G/TBT/37, para 3.9.b

<sup>8</sup> G/TBT/GEN/190

<sup>9</sup> US Federal Register Notice seeking comments on Conformity Assessment Considerations for Federal Agencies <https://www.federalregister.gov/documents/2017/12/27/2017-27892/nist-special-publication-2000-02-conformity-assessment-considerations-for-federal-agencies>

- f. relevant industry practice and experience, and the industry's history of compliance;
- g. the need to reduce duplication and complexity, and ensure consistency and coordination with the conformity assessment approaches of other agencies, where feasible, appropriate, and consistent with law;
- h. the appropriateness of recognizing the results of private sector conformity assessment programs being utilized in Member technical regulation, consistent with subsection c (above); and
- i. the degree of transparency to stakeholders and the public of the conformity assessment activity.

### **3 PROPOSAL**

3.1. In order to initiate work to develop recommendations or practical guidelines to support regulators' use of trade facilitative conformity assessment procedures when designing the appropriate technical regulations or mandatory programs, the Committee should consider these elements for thematic discussion, along with the development of practical guidelines:

- a. Exchange information on the development of NQI, including the development of systems for standardization, conformity assessment, and metrology. Those systems underpin the regulatory system of a Member and strengthen the regulator's ability to implement and enforce technical regulations and conformity assessment procedures.
  - b. Exchange information on initiatives of Members to enhance regulators' reliance on international and/or regional systems for conformity assessment, including sectoral schemes, aimed at facilitating the recognition of conformity assessment results. The thematic discussion should include what barriers or weaknesses within the system prevent regulators' use of these tools at a national or regional level.
  - c. Exchange information of national WTO Member experiences on considerations used in the development of conformity assessment programs, including the role of agencies or ministries that may serve as advisors to regulatory agencies when developing such programs.
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