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**Committee on Technical Barriers to Trade** 

# **GUIDELINES ON CONFORMITY ASSESSMENT PROCEDURES**

#### NON-PRESCRIPTIVE PRACTICAL GUIDELINES TO SUPPORT REGULATORS IN THE CHOICE AND DESIGN OF APPROPRIATE AND PROPORTIONATE CONFORMITY ASSESSMENT PROCEDURES

DECISION

Adopted at the meeting of 13-15 March 2024

The WTO Agreement on Technical Barriers to Trade (TBT Agreement) recognizes that WTO Members may require a positive assurance of conformity with technical regulations or standards to fulfil their legitimate objectives, such as the protection of human health or safety, or the environment; and national security requirements. Building on previous decisions and recommendations, including in the Eighth and Ninth Triennial Reviews, the TBT Committee agreed to develop non-prescriptive practical guidelines to support regulators in the choice and design of appropriate and proportionate conformity assessment procedures.<sup>1</sup>

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<sup>&</sup>lt;sup>1</sup> <u>G/TBT/41</u>, para. 4.17.b (Eighth) and <u>G/TBT/46</u>, para. 4.18.a (Ninth).

#### **1 GENERAL CONSIDERATIONS**

1.1. Regulators' have a fundamental responsibility to ensure that technical regulations are not more trade restrictive than necessary to fulfil the Members' legitimate objectives, such as the protection of human health or safety, or the environment; and national security requirements. Recognizing this, the TBT Agreement additionally requires that procedures used to demonstrate conformity with such technical regulations, or standards, do not create unnecessary barriers to trade.

1.2. The present guidelines are meant to provide key guidance principles and best practices to support regulators in the choice and design of appropriate and proportionate conformity assessment procedures to ensure that conformity assessment procedures are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. In assessing whether conformity assessment procedures are "appropriate and proportionate" in the context of these guidelines, Members should reference the provisions of the TBT Agreement relevant to conformity assessment procedures in Articles 5-9, Article 5.1.2 in particular.

1.3. These guidance principles and best practices should also serve as trade-facilitating tools, enhance trust between different regulatory systems and contribute to facilitating the acceptance of results of conformity assessment. As such, the guidelines should foster trust-building across different regulatory frameworks. The following general considerations apply:

- a. **Non-prescriptive**. The guidelines contain practical recommendations that are non-prescriptive and voluntary. The guidelines are non-binding.
- b. **Neutral.** The guidelines do not give preference to any specific approach. They are intended to be neutral and structured in a way that will enable regulators across the WTO Membership to understand and use them.
- c. **Flexible**. The guidelines are intended to provide flexibility for regulators and policymakers to innovate and select the conformity assessment procedure(s) most aligned with their particular needs, circumstances, and regulatory objectives.
- d. **Complementary**. The guidelines do not duplicate but seek to complement existing work and guidance at the national, regional and international levels.

1.4. These guidelines may complement regulatory impact analyses, risk assessments, or other methodologies used by Members prior to the preparation of technical regulations or conformity assessment procedures.

1.5. Nothing in these guidelines should be construed to add to or detract from the rights and obligations of WTO Members under the TBT Agreement or any other WTO agreement.

1.6. These guidelines may be reviewed and updated by Members as appropriate.

# 2 ELEMENTS

2.1. There are a range of possible elements that may support regulators in the choice and design of appropriate and proportionate conformity assessment procedures. The following elements are neither exhaustive nor mutually exclusive. They may not necessarily carry the same weight for all Members. Regulators may select the procedures that are most closely aligned with their specific local needs and circumstances.

# **2.1** Considerations related to risk

# Product

2.2. It is important to identify the product to which the conformity assessment procedure(s) will apply, as well as the specified requirements to be assessed (as set out in applicable technical regulations or standards and based on product requirements in terms of performance rather than design or descriptive characteristics whenever appropriate). In selecting appropriate conformity assessment procedures, factors to consider may include: the complexity of the product and its

technology; the production method (e.g. mass production based on a "specimen" or small series production); the complexity and transparency of the supply chain; the intended use, user, and lifetime of a product; as well as the technical competencies and infrastructures of the particular sector or industry as they relate to regulatory compliance. Regulators may also consider, for instance, the level of risk the specific product poses to a consumer in the event of a safety incident or the quality record of a given product and the level of confidence between consumers and producers. In addition, regulators may consider the infrastructure of market surveillance available for the product (see paragraphs 2.9, 2.32, 2.33 and 2.35).

#### Nature and degree of risk

2.3. The choice and design of conformity assessment procedures should be appropriate and provide adequate confidence in relation to the nature and degree of the risk involved in the product(s) or their related processes and production methods, and/or sector(s) at hand (see paragraph 2.2) and the level of safety or protection of other relevant public interest(s). The conformity assessment development process is about appropriately identifying, analysing, evaluating, and managing risk in an efficient, effective manner while facilitating trade in line with international obligations. A risk assessment<sup>2</sup> may usefully include the identification, analysis, and evaluation of the particular risk(s), including by making full use of risk management methodologies and technologies. A regulator may also use methodologies such as regulatory impact analyses to define the best evidence-based regulatory solution to mitigate risk. A regulator may usefully determine its needed level of confidence that an objective(s) has/have been achieved, considering the type and degree of risks associated with non-conformity (and their respective consequences) and the expected costs of demonstrating conformity (e.g. for producers, suppliers, consumers, and the regulator). A range of risks may be considered, including in relation to: protection of human health or safety, animal or plant life or health, or the environment; consumer protection and the prevention of deceptive practices; and, national security requirements.

2.4. In assessing tradeoffs involved in managing risks, the local context should also be considered. The circumstances, experiences and capacities of each Member, and the allocation of public resources may differ from Member to Member. Developing and least-developed countries may face particular constraints in managing risks. What is perceived as high risk in one market may not necessarily be seen in the same way in another. However, an assessment of risks is not the only factor that Members may take into account in their decisions on conformity assessment.

#### Evidence

2.5. The choice and design of conformity assessment procedures should be evidence-based. Whenever possible, risk assessment should follow clear processes and be based on a scientific approach, including the use of criteria set out in relevant international standards, guides, or recommendations. This risk assessment should enable regulators to ascertain, based on the current available technical or scientific evidence, whether the risk and/or its magnitude is acceptable or not. Regulators may also rely on best current available evidence<sup>3</sup> and experience from relevant and recognized scientific bodies, specialised agencies, research by academic institutions, or other independent scientific expertise. Following the design of the conformity assessment procedures, an evidence-based validation of the procedures should be undertaken to evaluate if stated objectives are achieved. The validation process should involve relevant stakeholders.

#### Level of confidence

2.6. The regulator's needed level of confidence may also inform the type of conformity assessment procedures (e.g. *first-party* for low risk, *third-party* for high risk, or an appropriate selection of conformity assessment types for moderate risk<sup>4</sup>), and the impartiality and independence for bodies performing those activities (see section 2.4). For product categories that, based on a risk assessment, present risks for public interest that are generally considered to be low, the use of first-party conformity assessment is a preferred option. While all types of conformity assessment

<sup>&</sup>lt;sup>2</sup> Risk assessment may include associated regulatory impact assessment (RIA) analysis, as part of good regulatory practice.

<sup>&</sup>lt;sup>3</sup> This means peer reviewed, can be cited, and is accessible and verified information.

<sup>&</sup>lt;sup>4</sup> For a more detailed description of the types of conformity assessment, see the Annex 1 to this document. Annex 2 contains an index of reference material.

procedures may be rigorous, regulators may have different requirements for their level of confidence in those conducting that procedure and the integrity of the process used. The greater the risk and needed level of confidence, the more stringent a conformity assessment procedure may generally be, with greater oversight (by regulators) and independence (of conformity assessment bodies). Notwithstanding, regulators should avoid creating unnecessary barriers to trade, including by assessing the risks and concerns associated with non-conformity and the costs associated with demonstrating conformity.

#### Traceability and transparency in supply chains

2.7. The choice and design of conformity assessment procedures should, where appropriate, explore opportunities presented by new technologies to promote supply chain transparency and traceability. Promoting transparency and traceability through access to conformity assessment data will enhance regulator and consumer confidence in the marketplace, improving supply chain resilience. The increasing complexity of digital and transnational supply chains also present new challenges which should be considered. These include protection of intellectual property, the need for other data protection, the impact on MSMEs, as well as opportunities for the traceability and verification of conformity assessment data.

#### *Regular review of conformity assessment procedures*

2.8. The choice of the conformity assessment procedures should not be seen as permanent. It should benefit from regular review as the elements that influenced the original choice of conformity assessment procedure may change over time. Regular review of relevant measures and procedures based on developments in technology, improvements in data availability, the market, evolving capabilities of Members, and outcomes of market surveillance should be taken into account.

# 2.2 Market surveillance

#### Members' capacities

2.9. The choice and design of conformity assessment procedures is linked to Members' capacities and approaches to market surveillance, including the formal and informal roles of the private sector, law enforcement systems, consumer protection legislation and product liability, and other relevant legal and administrative frameworks. In this context, regulators may need to strike an appropriate balance between pre- and post-market control.

# Risk-based: including sampling and testing

2.10. As it may not be possible or desirable to check *all* products placed on the market, market surveillance systems or approaches should be risk-based. Regulators or other bodies may assess possible risks posed by the objects of conformity assessment and take targeted post-market measures, including sampling and testing. A risk-based approach may take into account factors, such as possible dangers and non-compliance associated with the products and, where available, data on their occurrence on the market, activities and operations under the control of economic operators (including manufacturers, importers, distributers, sellers), their past record of non-compliance, consumer compliants and other information that might indicate non-compliance.

2.11. Regulators or other bodies performing market surveillance carry out sampling and testing based on possible risks posed by the products being assessed. Such activities require adequate resources and prioritisation, targeting based on sound data and evidence, as well as regular evaluation of results. Collecting and analysing information on product accidents, or on products withdrawn from the market, also helps in reviewing and improving performance of the conformity assessment system.

#### Authorities

2.12. The powers of regulatory and of market surveillance authorities may impact their choice and design of conformity assessment procedures. These powers should be well-defined and be exercised in a way that ensures procedural fairness. They may include the right, within their territories, to:

- i. conduct inspection, whether announced or unannounced, sampling and verification of goods;
- ii. request information (documents or data) related to compliance;
- iii. enter into any premises, lands or means of transportation related to producers;
- iv. adopt measures that are not applied more strictly than necessary when products present a risk or do not comply, including requiring preventive and corrective action; product recall, when there is a high probability that accidents or safety problems may occur with a product; and,
- v. impose sanction mechanisms, such as the ability to impose penalties.

#### Strategic planning

2.13. Strategic planning is key to ensuring the effectiveness of market surveillance and supervision of conformity assessment. A market surveillance strategy can help provide ongoing confidence in manufacturers' operating under first-party conformity assessment and in the results of conformity assessment bodies operating under third-party conformity assessment. Strategies should take into account not only short-term risks but also medium- to long-term developments of the market and sector, including the development of new technologies. For example, in the context of the rapid development of e-commerce, public authorities in charge of market controls may need to rely on new types of interventions, such as requesting conformance records for review from relevant economic operators. Depending on the production method (e.g. mass production based on a "specimen" or small series production) differing approaches to market surveillance may be required.

2.14. Constant risk monitoring and foresight should be promoted and encouraged such that emerging risks can be identified as early as possible. In this exercise, dialogue with the various interested parties, including the private sector, is crucial.

#### Transparency and independence

2.15. It is important to maintain transparency in the development of draft technical regulations, as well as in the designation and role of the authorities responsible for their enforcement, whether in specific geographic areas, or for specific products or sectors. Other public policies, such as disclosure of information on market surveillance, product accidents or publication of recalls, can help promote and support compliance.

2.16. Regulators should ensure the independence of market surveillance functions from conformity assessment functions with a view to avoiding conflicts of interest.

# 2.3 International standards, guides or recommendations

2.17. Harmonization with international standards, guides or recommendations facilitates global trade and reduces costs for industries, including by avoiding duplicative conformity assessment procedures as well as technical barriers to trade. Pursuant to Article 5.4 of the TBT Agreement, Members shall use relevant guides or recommendations issued by international standardizing bodies. For example, Members may make use of conformity assessment standards, such as the ISO Committee on Conformity Assessment ("CASCO") toolbox. Nevertheless, regulators are not limited in their choice of international standards, guides, or recommendations for conformity assessment.

# **2.4 Confidence**

2.18. Confidence in conformity assessment bodies can facilitate trade by contributing to the acceptance of results of conformity assessment. Confidence can be established in different ways depending on whether first-, second- or third-party conformity assessment is chosen. The use of international standards, guides, or recommendations helps to establish confidence in the technical competence, impartiality, independence, and consistent operation of conformity assessment bodies carrying out conformity assessment activities. Amongst others, accreditation (ISO/IEC 17011) and peer assessment (ISO/IEC 17040) are recommended approaches that can be used to confirm that conformity assessment is undertaken in accordance with relevant international standards (e.g. ISO/IEC 17025 (testing), 17020 (inspection), 17021-1 (management systems certification), 17029 (validation and verification) and 17065 (product or process certification)).<sup>5</sup> Regulators may specify additional programme requirements (e.g. minimum competency requirements, administrative procedures) to ensure conformity assessment activities are undertaken consistently to address specific public policy and regulatory objectives.

# Impartiality

2.19. In order for conformity assessment bodies to perform their activities, it is important to ensure they are impartial and free from bias of manufacturers, importers and other interested parties, including their clients.<sup>6</sup> Conformity assessment bodies should identify potential and actual conflicts of interests and establish strategies to minimize them. Conformity assessment bodies and their personnel should be free from any commercial, financial, or other pressure that might influence their judgment. The structure of the conformity assessment body, its policies, and procedures, should also safeguard its impartiality, especially if the body has activities other than those of assessing conformity. Where subcontractors are used to perform testing, inspections or other conformity assessment body itself should meet the same requirements that the contracting conformity assessment body itself should meet in order to perform the sub-contracted activities.

# Oversight

2.20. Establishing an adequate level of oversight is important. This should include, for example, ways for handling complaints (e.g. a stakeholder indicating that program requirements are not being met) and appeals (e.g. a stakeholder disagreeing with a decision of a conformity assessment body). The complaint process is useful for discovering non-conformities and provides information for programme improvement.

# Information

2.21. Regulators should ensure the protection of confidential information and data for conformity assessment purposes and avoid unnecessary information burdens for applicants, so that information provided to conformity assessment bodies is limited to that which is required solely for the purpose of assessing conformity and determining fees.

# Openness

2.22. Where appropriate, conformity assessment approaches should foster openness by recognizing all conformity assessment body applicants that can fulfil the requirements for qualification or recognition.

# Digital technologies

2.23. Digital technologies and solutions can help improve the transparency of conformity assessment procedures and enhance supply chain integrity. For example, they may support the

<sup>&</sup>lt;sup>5</sup> "Indicative List", <u>G/TBT/1/Rev.15</u>, Annex 1.

<sup>&</sup>lt;sup>6</sup> For example, a government-designated body can establish whether a laboratory is adequately impartial when it determines conformity with ISO/IEC 17025. In addition, if Manufacturer's/Supplier's Declaration of Conformity (SDoC) is supported by testing undertaken by in-house bodies belonging to the supplier's organisation, such supplier should, as far as possible, establish conditions that guarantee the independence of the activities of in-house testing bodies.

acceptance and recognition of conformity assessment results, by providing real-time access to conformity data, and facilitating post-market activities.

# 2.5 Acceptance of results

#### "Indicative list"

2.24. The TBT Committee provided a range of approaches that governments might choose to apply across different sectors to ease the burdens associated with duplicative testing and certification (the Indicative List of Approaches to Facilitate Acceptance of the Results of Conformity Assessment, the "Indicative List").<sup>7</sup> This includes the consideration that certification undertaken by Members is consistent with Article 5 of the TBT Agreement and the Indicative List.

#### Accreditation

2.25. Accreditation, when operated according to relevant international standards, guides and recommendations, promotes confidence in the technical competence of conformity assessment bodies. Using (or taking account of) international treaties, agreements or arrangements involving cooperation among accreditation bodies can usefully contribute to reinforcing the acceptance of conformity assessment results. Multilateral recognition arrangements, such as the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC) can play an important role in supporting wider the acceptance of conformity assessment results around the world.

2.26. Conformity assessment procedures may include the acceptance of conformity assessment results (e.g., certificates of conformity, laboratory tests or inspection reports) performed by conformity assessment bodies recognized by signatories to international accreditation fora.

#### Arrangements

2.27. Arrangements between domestic and foreign conformity assessment bodies, such as the IECEE CB Scheme<sup>8</sup>, can also help facilitate acceptance of results. Conformity assessment bodies are encouraged to join relevant functioning international agreements or arrangements for harmonisation and/or facilitation of acceptance of conformity assessment results. For the purposes of establishing new mutual recognition agreements and arrangements, or equivalence agreements, some of the minimum elements to be considered include: Objective; Scope (including the standards and technical regulations covered); Competent authorities; Cooperation modalities; Procedures that guarantee compliance with the MRA / MRA compliance verification system; Duration; Consultations; Contact points.

#### Other approaches

2.28. The Indicative List identifies other approaches to facilitate the acceptance of conformity assessment results, including MRAs for conformity assessment to specific regulations, government designation, unilateral recognition of results of conformity assessment, and Manufacturer's/Supplier's Declaration of Conformity (SDoC).<sup>9</sup> Regulatory cooperation can also facilitate acceptance of conformity assessment results, such as through joint or shared inspections. Whenever possible, economic operators should be offered alternative procedures to demonstrate compliance, and the possibility of carrying out the conformity assessment procedure in more than one step, provided these meet a regulator's needed level of confidence.

<sup>&</sup>lt;sup>7</sup> See <u>G/TBT/1/Rev.15</u>, Annex 1.

<sup>&</sup>lt;sup>8</sup> IEC System for Conformity Assessment Schemes for Electrotechnical Equipment and Components

<sup>(</sup>IECEE) Certification Body (CB) Scheme. <sup>9</sup> See <u>G/TBT/1/Rev.15</u>, Annex 1.

#### Reliance on the work of other regulators

2.29. Regulators may also consider opportunities to rely on the work of other trusted regulators in areas such as inspection, evaluation, and market surveillance, in order to make the best use of available resources.

# 2.6 Transparency and consultation

2.30. For a chosen conformity assessment procedure to be effective and achieve the desired policy objectives, its content needs to be communicated to relevant stakeholders and opportunities for consultations provided. This entails providing clear and transparent information about specified requirements. Criteria and procedures for the appointment or recognition of conformity assessment bodies to perform specified conformity assessment activities should be made public, informed to relevant stakeholders and undergo a transparent selection or recognition process. Regulators should consider input from relevant stakeholders when proposing and establishing conformity assessment procedures. Meaningful consultation with relevant stakeholders, parties and trading partners on proposed and existing conformity assessment procedures helps ensure that the procedures are fit for purpose and adapted to the level of risk identified. Timely notification to the WTO according to existing disciplines of the TBT Agreement, as well as reference to the collected decisions and recommendations by the TBT Committee, is vital. Transparency, including publication of draft conformity assessment procedures for comment, in the design, development, operation, and evaluation of conformity assessment procedures fosters greater acceptance and understanding of governmental decisions and contributes to effective policy. Members' TBT national notification authorities and enguiry points play a crucial role in providing transparency to relevant stakeholders, including WTO Members. Transparency also involves providing - and making publicly available information about the bodies that regulators have designated to perform conformity assessment, including on the scope of activities of each body. Transparency should also be ensured in relation to the fees imposed for conformity assessment performed by government bodies, as well as information relating to market surveillance and recall program.

2.31. It is important to participate in formal and informal information-sharing between regulators across WTO Members to promote transparency, the sharing of best practices, and understanding in the choice and design of conformity assessment procedures. Information-sharing of this nature can reduce unnecessary technical barriers to trade and promote international trade by fostering trust and supporting foreign acceptance of conformity assessment results.

# 2.7 Domestic coordination

# Mechanisms

2.32. Coordination between relevant government agencies, national quality infrastructure (NQI) institutions (metrology, standardization, conformity assessment, and accreditation), customs authorities, the private sector and other relevant stakeholders can help avoid unnecessary duplication of conformity assessment and leverage existing domestic, regional, and international efforts, both public and private. Such coordination can help ensure that the requirements proposed by regulators are appropriate and practical, with respect to the Member's NQI as well as international conformity assessment practices, systems, schemes, and capacity. Members may consider forming a committee of representatives from each government agency to serve as a forum for information exchange and discussion of best practices for conformity assessment, and to facilitate compliance with international obligations. This can include (but should not be limited to) advisory, consultative or review (including peer review) meetings, committees, or panels. If one agency has overall responsibility for conformity assessment activity or policy, that agency would be a logical focal point for such coordination.

# NQI supports coordination

2.33. It is important to liaise with the NQI institutions early in the regulatory development process to help achieve effective regulatory outcomes. Consultation with NQI institutions can also identify gaps in capacity which might limit the effectiveness of conformity assessment procedures. A responsive, coordinated, technically competent and efficient NQI is an important support for regulators in the choice and design of conformity assessment processes. The NQI should be

developed as a fully integrated system, rather than treating each part in isolation. A quality policy can help ensure the overall arrangements and interactions of quality infrastructure institutions and improve overall coordination of the NQI. Regulators should be informed of the obligations contained in the TBT Agreement.

# 2.8 Development dimension

#### Considering the needs of developing country Members

2.34. The needs and difficulties encountered by developing country Members in implementing conformity assessment procedures should be fully considered, including with respect to variations in the level of development of their NQI. For example, if economic operators in developing or least developed Members (LDCs) have limitations in fulfilling certain conformity procedures, regulators may seek to accommodate these limitations while still taking into account the risk associated with the product. Consistent with Article 11 of the TBT Agreement, Members with financial, human and technological resources shall, if requested, provide advice and grant technical assistance and capacity building on mutually agreed terms to assist in the development of conformity assessment, including in the area of NQI.

# Evaluation of adequate NQI

2.35. WTO Members have differing economies, industry bases, systems for quality infrastructure, and regulatory frameworks. Some Members may be constrained by insufficient capacity in establishing and managing conformity assessment systems, including oversight of conformity assessment bodies and market surveillance activities; or by other specific challenges, such as fundamental technological or infrastructural problems. Such difficulties may also create barriers to developing country Members' exports. In such cases, Members should consider how other Members' technical assistance can help overcome such constraints, while looking to draw upon international best practices in conformity assessment that both facilitate trade and provide regulator confidence. Regulators are an important element of any NQI system and should be supported to play an active role in furthering its development. Regulators should assess the adequacy of national quality infrastructure and design conformity assessment procedures and market surveillance that facilitate trade, to support the implementation of the TBT Agreement.

# 2.9 Flexibility and agility in the face of uncertainty

2.36. Broader challenges and uncertainty in an increasingly complex global environment and rapidly changing technological, societal, geopolitical and economic trends are unavoidable. To adequately account for new risks and challenges, foreseen and unforeseen events, as well as emergencies (such as the COVID-19 pandemic), regulators and policymakers need to work closely together, and with private sector and subject matter experts, to ensure that conformity assessment systems and approaches are adaptive, responsive, and remain relevant. Continuous dialogue with various experts and interested parties is a particularly important element. To effectively respond to new challenges and benefit from new technologies, regulators are encouraged to use digital or electronic means to enhance the quality of conformity assessment procedures. The elements listed above may be reconsidered or given different weight by regulators in the context of crises.

# **3 ANNEX 1: TYPES OF CONFORMITY ASSESSMENT**

3.1. Annex 1.3 to the TBT Agreement defines "conformity assessment procedure" as:

Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.

Explanatory note

Conformity assessment procedures include, inter alia, procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations.

3.2. Three types of conformity assessment can be differentiated according to who controls or directs the relevant procedures or activities, and who reviews, decides, and attests that that fulfilment of specified requirements has (or has not) been demonstrated.<sup>1</sup>

- a. *First-party conformity assessment* is performed by the person or organization that provides or that is the object<sup>2</sup> of conformity assessment. For example, such activities are performed by providers, designers or owners of the object, investors in the object, and advertisers or promoters of the object.<sup>3</sup> First-party conformity assessment for example, SDoC is generally used for low-risk products or sectors.
- b. Second-party conformity assessment is performed by a person or organization that has a user interest in the object of conformity assessment. Persons or organizations performing second-party conformity assessment activities include, for example, purchasers or users of products, or potential customers seeking to rely on a supplier's management system, or organizations representing those interests (e.g. consumer advocacy organizations).<sup>4</sup>
- c. Third-party conformity assessment is performed by a person or organization that is independent of the provider of the object of conformity assessment and has no user interest in the object.<sup>5</sup> Third-party conformity assessment for example, accredited testing, inspection, certification or verification and validation is generally used for high-risk products or sectors.

3.3. Both first- and third-party conformity assessment are widely used in regulator conformity assessment schemes.<sup>6</sup> They offer differing levels of confidence and require appropriate frameworks in place to support their reliable use.

# **4 ANNEX 2: INDEX OF REFERENCE MATERIAL**

• ISO Policy Committee on Conformity Assessment (ISO/CASCO), Conformity Assessment Tools to Support Public Policy, at <a href="https://casco.iso.org/conformity-assessment.html">https://casco.iso.org/conformity-assessment.html</a>.

<sup>&</sup>lt;sup>1</sup> Adapted from ISO/IEC 17000:2020(en) Conformity assessment — Vocabulary and general principles

<sup>&</sup>lt;sup>2</sup> The object of conformity assessment can include a product, process, service, system, installation,

project, data, design, material, claim, person, body or organization, or any combination thereof (Adapted from ISO/IEC 17000:2020(en) Conformity assessment — Vocabulary and general principles, para. 4.2).

<sup>&</sup>lt;sup>3</sup> Adapted from ISO/IEC 17000:2020(en) Conformity assessment — Vocabulary and general principles, para. 4.3.

<sup>&</sup>lt;sup>4</sup> Adapted from ISO/IEC 17000:2020(en) Conformity assessment — Vocabulary and general principles, para. 4.4.

<sup>&</sup>lt;sup>5</sup> Adapted from ISO/IEC 17000:2020(en) Conformity assessment — Vocabulary and general principles, para. 4.5.

<sup>&</sup>lt;sup>6</sup> A conformity assessment scheme is the construction of the conformity assessment activities, roles, and the types of organizations performing each role. The scheme also includes the set of requirements, specifications, standards, and methods for determining conformity. A conformity assessment scheme can be operated at an international, regional, national, sub-national, or industry sector level.