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CONFORMITY ASSESSMENT

Review of recent developments

Information note from the Government of Brazil

Note by the secretariat

At its sixteenth session, the Working Party invited national delegations and international and regional organizations to report on trade-related aspects of developments in conformity assessment and on an update on the current situation regarding international guides and standards.

This document contains an information note from the Brazilian National Institute of Metrology, Standardization and Industrial Quality (INMETRO) and is transmitted to the Working Party for information.

I. INTRODUCTION

1. In Brazil, the matters and activities related to Metrology, Standardisation, Industrial Quality and Conformity Assessment are all part of the National Metrology, Standardisation and Industrial Quality System (SINMETRO). This System was created in 1973, by means of the Federal Law number 5.900 and is comprised by public and private entities. Its main scope is to establish an infrastructure of technological services to assess the quality of products, of processes and of services by means of certification bodies, testing and calibration laboratories networks, training bodies, proficiency-tests laboratories and inspection bodies, all accredited by the National Institute for Metrology, Standardisation and Industrial Quality (INMETRO).
2. INMETRO acts as the executive secretary for the National Council for Metrology, Standardisation and Industrial Quality (CONMETRO), the legislative body of SINMETRO. The Council is composed by the Ministries of Development, Industry and Foreign Trade; Science and Technology; Health; Work and Employment; Environment; External Relations; Justice; Agriculture, Feedstock and Food Supply; Defence; INMETRO; the Brazilian Technical Standards Association (ABNT); the National Industry Confederation (CNI); and the Consumer's Protection Institute (IDEC).
3. CONMETRO acts through its technical committees, in this case, the Brazilian Committee for Conformity Assessment (CBAC), which are open to the participation of distinguished bodies of the academic field, industry and trade bodies, research centres and consumer's protection institutes, among other entities with special interest in metrology, standardisation and industrial quality in the country.
4. Established in December 2001, the Brazilian Committee for Conformity Assessment replaced the former Brazilian Committee for Certification (CBC). Among the CBAC duties, it is responsible to assist CONMETRO in structuring an internationally harmonised conformity assessment system and in proposing principles and policies on Conformity Assessment Procedures (CAPs) to be adopted under the Brazilian Conformity Assessment System (SBAC). INMETRO manages the SBAC, abiding to the policies issued by CONMETRO.
5. In addition, INMETRO is the official accreditation body of the Brazilian Government. As such, it adopts international guides and recommendations for accrediting purposes.
6. Within SINMETRO, the Brazilian Programme for Conformity Assessment (PBAC) is designed to develop a long-term strategy and a thorough management plan for CAPs in Brazil. The Programme establishes a Quadrennial Action Plan, which is annually updated with the participation of governmental and private entities associated with conformity assessment activities. From that basic infrastructure, the implementation of the PBAC demanded the creation of a routine for identification and prioritisation of demands, comprising different areas, along with the development of a methodology to choose the most adequate CAPs for the products, processes or services involved, based on four criteria: (i) health, safety, environment, (ii) strengthening competition, (iii) strengthening consumption relationship, and (iv) impacts on trade.

II. THE BRAZILIAN CONFORMITY ASSESSMENT PROGRAMME (PBAC)

7. Conformity Assessment Procedures (CAPs) in Brazil are supported by two basic principles: technical performance and credibility. In this sense, a body that assesses conformity must hold the technical apparatus required to do so, such as facilities, quality management systems, personnel and proper calibration of measurement instruments. The credibility of the body – as a result of a work guided by ethical and impartial action, as well as a committed concern to eventual impacts of conformity assessment in the market – must also be acknowledged. To achieve this goal it is imperative to have on-going mechanisms to observe and evaluate this “technical-confidence” relationship, especially in terms of market surveillance in conformity verification.

8. The existence of an official body to accredit calibration and testing bodies and laboratories (activities performed by INMETRO) served as a basis for the PBAC. Besides, accredited networks of calibration and testing laboratories, accredited conformity assessment bodies, a number of standards and technical regulations and, additionally, follow-up and evaluation procedures, all served as further elements to guide the conception and the establishment of the Programme.

9. Moreover, in order to establish the Quadrennial Action Plan, the existence of infrastructure for conformity assessment is analysed. Afterwards, each specific programme is developed and implemented, if consented. This consented implementation demanded: (i) debate among the different areas subject to the programme, (ii) previous public disclosure of the programme, and (iii) follow-up and market surveillance, with a view to providing feedback for the programme.

III. CONFORMITY ASSESSMENT MECHANISMS

10. In Brazil there are four types of conformity assessment mechanisms: (i) certification; (ii) inspection; (iii) supplier's declaration of conformity; and (iv) testing. The selection of the proper mechanism of conformity assessment is made taking into consideration elements such as: risk of failure of the product, process or service; impact and recurrence of the failures; volume of production; time windows for technological changes in the sector; size and capacity of the producers involved and their geographic dispersion; competitive impacts on the product and so on. Based in these elements the mechanism of the assessment of conformity will be determined (1st party or 3rd party), as well as its obligatory nature or not and the instruments for the evaluation, which may be type-approval tests, routine tests, manufacturing quality system assessments, evaluations of performed services, sampling, etc.

11. In cases of 3rd party assessment, the evaluating bodies are accredited by INMETRO, according to the International Organization for Standardization (ISO) international standards and guides. In the same manner, calibration and testing laboratories used in 1st or 3rd party assessments are accredited in accordance with international practices.

A. Certification

12. Certification is, by definition, a 3rd party-performed mechanism of conformity assessment for products, processes, services, personnel, quality management and environmental management systems. The certification model will be determined depending on the product, production process, raw material characteristics, economic aspects and the necessary level of confidence required, among other factors.

13. The certification mechanism is applied to products, processes or services that may represent hazards to the environment or to the health and safety of the consumer. It is not applied, in general, to performance assessment processes. It is the conformity assessment mechanism most adopted in Brazil.

B. Supplier's Declaration of Conformity (SDoC)

14. By means of this mechanism, the supplier is responsible to certify that a product, process or service conforms to specific requisites. The minimum amount of information that must be in the Declaration, in accordance with Guide 22 of ISO and the International Electrotechnical Commission (IEC) (ISO/IEC Guide 22), includes the following: name and address of the declaring manufacturer, identification of the product, process or service, declaration of conformity, regulatory documents used, place and date of issuance of the Declaration and signature, name and duty of the authorised person.

15. In the case of SDoC of a product, process or service, the following steps must be observed: (i) choose an accredited laboratory; (ii) make the test of the product; (iii) acquire the proper form and fill out the Supplier's Declaration; (iv) send the Declaration, with relevant documents enclosed (test report, Quality system certificate, etc.) to INMETRO; (v) evaluation by INMETRO of the completeness of the conformity assessment process; and (vi) obtain the license to bear the conformity mark in the product.

16. It is applied only to products, processes or services that present a mild risk to the health and safety of the consumer and to the environment. It is not, therefore, a substitute for certification, once the field of application of both mechanisms is different. Additionally, when the goal is to evaluate the performance of a product, SDoC is also used.

17. It is important to emphasise that SDoC, like all other conformity assessment mechanisms, is regulated by a set of pre-established rules that should ensure the same level of conformity safety as 3rd party conformity assessment programs. In this sense, when 1st party programs are put into practice, more active follow-up and market surveillance initiatives become necessary. Besides, an adoption of SDoC for a determined product must take into consideration its "quality record", the level of confidence of consumer-producer relations in the specific sector and distribution and manufacture logistic aspects, which represent an impact on the market surveillance.

18. Until 2006 seven SDoC programs were put into practice, on installation system for vehicle natural gas, on disposable lighter, on steel profile for power transmission towers, on vehicle catalyst, recycled tyre, non-metrological traffic register and fire extinguisher maintenance.

19. Some important programs also apply the SDoC in the labelling activity. The use of a label to display the performance of products is becoming more and more frequent, being a strong mechanism to instruct consumers.

20. For instance, in Brazil, labelling is helping the National consumer save electric energy, especially with “white line” (refrigerators, freezers, air conditioning devices, etc.) home appliances and with other products such as lamps, electric showers, heaters and gas ovens. Another example of labelling in Brazil is the “Noise Label”, which informs the level of noise made by home appliances, within the Silence Programme, developed by INMETRO in partnership with the Ministry of Environment.

21. The label, especially when associated with the establishment of performance goals could represent an important tool to optimise the use of energy in a country, since it stimulates on-going technological developments in electric equipment in the National market. It fosters the supply of products with improved energy performance, thus elevating the quality of these products in international terms.

C. Inspection

22. Inspection, applied mainly to conformity assessment of services, is accomplished by analyses and judgements along with measurements, tests or calibration, when applicable. These activities, fundamental to conformity assessment, may comprise the testing of products, materials, installations, plants, processes and work procedures in all life cycles of these items and aim to determine conformity to technical regulations, standards or specifications, as well as to issue the reports related to the inspected items.

23. Inspection is normally applied in areas such as safety, operational performance and safety maintenance for the whole life cycle of the equipments installation. Its main goal is to reduce the risk of the purchaser, proprietor, user or consumer. Thus, the competence, the impartiality and the integrity of inspection organisms are vital to the system. Inspection organisms must have qualified and experienced personnel, besides an internal quality system that underscores its technical performance.

D. Testing

24. It is the conformity assessment mechanism in which, by means of testing, one could determine and further inform the consumers on the characteristics of products, processes or services, accordingly with specific procedures. It is a very frequently applied mechanism and it may be taken together with inspection.

25. To promote confidence on testing results, quality and safety are essential criteria. Therefore, INMETRO accredits laboratories which comply with international requirements,

promoting formal recognition on its quality system and technical competence to perform specific testing, following the Brazilian Association of Standardization (ABNT) ISO/IEC 17025 and the International Laboratory Accreditation Cooperation (ILAC) and the Inter-American Accreditation Cooperation. (IAAC) orientations.

26. Testing laboratories can be operated by a variety of organizations, such as governmental agencies, academic and research institutions, business corporations and standardization institutes.

E. Available Infrastructure for Conformity Assessment

27. In the annex there are data available about the infrastructure for Conformity Assessment in Brazil.

IV. MARKET SURVEILLANCE

28. In Brazil, there are three mechanisms for Market Surveillance, as follows:

A. The inspection

29. This modality is characterized by its administrative policy power. Regional public institutions (the IPEMs) coordinated by INMETRO, perform such a role. The procedure is related to the conformity label evidence, identified in the product on the market. The irregular products identified withdrew the market. On following, data on inspection:

- (a) Number of products inspected in 2006: 94.964.378 units,
- (b) Percentage of irregular products in 2006: 0,97 %.

B. The Conformity Verification Programme

30. It comprises all products and services with conformity assessed within the Brazilian Conformity Assessment System (SBAC), taking into account specific criteria such as complaints statistical data received by INMETRO, type of complaints and irregularities and also the level of irregularities identified on the inspection process. Additionally, the conformity assessments regulations requirements, the needs identified by the Quality Department and the Accreditation Co-ordination of INMETRO, as well as needs identified by the regulatory agencies and the society, through the CBAC, are taken into account.

31. It consists on verifying, by INMETRO, in the market, on a regular basis, by the means of samples of products, the conformity presumably possessed by them. It also plays a fundamental role in the SBAC. In those cases where the assessment of the conformity identifies non-conformities, we deem necessary to identify opportunities to improve the specific regulation, the conformity assessment procedure, as well as technical standards. On following, data on verification:

- (a) Number of verifications, since 2002: 24,
- (b) Number of manufacturer/ brands verified, since 2002: 1002,
- (c) Number of samples tested: 19106 units,
- (e) Percentage of Non-Conformities, at least one, identified: 32%

C. The conformity verification programme by external agents

32. It is in implementation phase the external agents market surveillance modality, which shall be performed by competing actors. Such modality provides a more comprehensive capacity to the public authorities to follow up the market. It shall be conducted by recognized organizations duly authorized by the competent public authority.

33. As well as on the Verification Program, it is possible to collect samples from the market to be tested in accredited laboratories. These activities provide subsidies to the public authority to exert its administrative policy prerogative, contributing for a fair competition.

V. INTERNATIONAL RECOGNITION

34. For international recognition purposes, CONMETRO policies and international practices are followed. In the field of conformity assessment, INMETRO holds Mutual Recognition Arrangements and Agreements with the following:

- (a) International Accreditation Forum (IAF);
- (b) International Laboratory Accreditation Co-operation (ILAC);
- (c) European Co-operation for Accreditation (EA);
- (d) International Organisation of Legal Metrology (OIML);
- (e) Bureau international des poids et mesures (BIPM);
- (f) Program for the Endorsement of Forestry Certification (PEFC).

VI. FINAL CONSIDERATIONS

35. When properly designed and implemented, the Conformity Assessment Programmes (CAPs) become instrumental in providing developing countries with the necessary technological infrastructure for increasing market access with sustainability and transparency.

36. This is particularly relevant when considering mandatory CAPs, which aim at providing consumers with the required level of protection on what concerns health and environmental issues.

37. On the other hand, it is important to keep in mind the absolute necessity to avoid turning such a key instrument in increasing global trade and welfare into an unnecessary obstacle, particularly for developing countries. The latter highlights the importance of developing mutually compatible and worldwide-accepted CAPs.

Annex

AVAILABLE INFRASTRUCTURE FOR CONFORMITY ASSESSMENT

1. Current numbers concerning the activity of conformity assessment in Brazil are:
 - (a) Number of mandatory programs for conformity assessment procedures:
80 families of products
 - (b) Number of voluntary programs for conformity assessment procedures:
208 families of products
 - (c) Issued ISO 9001 Certificates: approx. 8000
 - (d) Issued ISO 14001 Certificates: approx. 2000
 - (f) Number of products with INMETRO mark: approx. 140.000
 - (g) Accredited certification bodies: 55
 - (h) Accredited inspection bodies: 220
 - (i) Accredited testing and calibration laboratories: 550
2. Accredited Certification Bodies:
 - (a) Accredited Certification Bodies:
 - (b) Quality Management Systems Certification (ISO 9000): 37
 - (c) Product Certification: 55
 - (d) Environmental management system certification (ISO 14001): 22
 - (e) Forest management certification: 03
 - (f) Social accountability certification: 01
 - (g) Certification of Hazard Analysis Critical Control Point (HACCP): 01
 - (h) Personnel certification: 08
 - (i) Performance assessment: 09
 - (j) Quality management system certification for civil construction: 12

3. Accredited Performance Assessment Bodies:

(a) Noise Label: 6

(b) Red-light violator: 5

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