

WORLD TRADE ORGANIZATION

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Committee on Technical Barriers to Trade

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CONFORMITY ASSESSMENT PROCEDURES: SUPPLIER'S DECLARATION OF CONFORMITY

Contribution from the United States

I. INTRODUCTION

1. In the first Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade (G/TBT/5), the Committee noted the growing concern with respect to the restrictive effect on trade of multiple testing and conformity assessment procedures, and that the principle of "one standard, one test" and if required "one certification, one time" should be pursued to facilitate trade and reduce costs (para. 26). The Committee recognized the supplier's declaration of conformity as saving costs associated with assuring conformance. At the same time the Committee acknowledged this procedure was not appropriate in all cases, particularly where technical infrastructure was lacking or it would compromise health, safety or environmental protections. The Committee agreed that it would be useful for Members to exchange information on their experience in the various types of conformity assessment procedures and their conditions of application. The following submission by the United States is intended to provide additional background on the use of suppliers' declaration of conformity as well as information on the US experience.

II. USE OF SUPPLIER'S DECLARATION OF CONFORMITY AS A TOOL FOR DEMONSTRATING PRODUCT CONFORMITY

2. A supplier's declaration of conformity is but one tool for indicating the conformity of a product, process or service to a standard or technical regulation. It is a procedure by which a supplier (as defined in ISO/IEC Guide 22:1996, a supplier is the party that supplies the product, process or service and may be a manufacturer, distributor, importer, assembler, service organization, etc.) provides written assurance of conformity to the specified requirements. The declaration identifies the party responsible for making the declaration of conformity and for the conformity of the product/process/service itself.

III. HOW DOES IT WORK?

3. A purchaser or government authority may rely upon a declaration of conformity as an assurance that a product, process or service complies with a particular standards or technical regulation. As stated in ISO/IEC Guide 22:1996 (General Criteria for Supplier's Declaration of Conformity), "the declaration normally has the form of a separate document. It may alternatively be given in, for example, a statement, catalogue, invoice, or user's instructions relevant to the product, process or service." The supplier makes such a declaration based on: (1) the manufacturer's confidence in the quality control system, or (2) the results of testing or inspection the manufacturer undertakes or authorizes others to undertake on his/her behalf. ISO/IEC Guide 22:1996 lays out criteria for supplier's declaration of conformity. According to Guide 22, the manufacturer has the option of using an accredited laboratory or inspection body and indicating this on the declaration; this is not a requirement. The choice of where to test is left to the manufacturer. This approach allows

manufacturers to use laboratories in whom they have confidence and which are most conveniently located in relation to where the product is produced, reducing the cost and time associated with testing. For regulatory purposes, authorities can ensure that the integrity of a supplier's declaration of conformity is maintained by establishing requirements for who signs the declaration of conformity, requiring access to the declaration and/or compliance records, etc.

IV. US EXPERIENCE

4. In the United States, reliance on a declaration of conformity is most prevalent with respect to assuring conformity to voluntary standards (e.g., telecommunications interoperability). A number of US regulatory agencies also rely upon a declaration of conformity to technical regulations. The US Department of Transportation, for example, recognizes a declaration of conformity by manufacturers (or importers) of motor vehicles and motor vehicle equipment. Under US law, manufacturers are required to certify that their products comply with all applicable Federal Motor Vehicle Safety Standards (FMVSS). This certification is in the form of a permanent label affixed to the product. This label is required for all vehicles and equipment covered by the FMVSS, and must be present if a vehicle or equipment covered by the FMVSS is to enter the United States. For purposes of enforcement, the Department of Transportation's National Highway Traffic Safety Administration (NHTSA) may test the vehicle or equipment for compliance with one or more of the FMVSS after the product is on the market. If the product fails the test, and either the manufacturer or NHTSA determines that the product, in fact, does not comply, the manufacturer must notify the product's owner and remedy the noncompliance at no cost to the owner. Additional penalties may apply. A manufacturer outside the United States who offers its product for importation into the US must submit itself to the jurisdiction of Federal courts in the US by designating an agent in the United States who will receive legal papers on behalf of the manufacturer.

5. The US Federal Communications Commission has adopted a rule which permits recognition of supplier's declaration for personal computers (PC's) and PC peripherals, provided supporting test results are obtained from an accredited laboratory (both accreditation programmes cited in the rule conform to ISO/IEC Guides 58 and 25). This programme benefits manufacturers in two ways -- by reducing costs and time to market -- while maintaining a high level of protection of health and safety. We are aware that other Members also rely on supplier's declaration as a demonstration of conformity to regulatory requirements.

6. An effective market surveillance system is an essential underpinning to reliance on supplier's declaration. Another factor which may be relevant to the willingness of regulators to rely on supplier's declaration is the extent to which national laws regarding manufacturers' liability supplement (or do not supplement) efforts by a regulatory agency to assure compliance with regulatory requirements. In addition, a regulator may believe that a different approach to conformity assessment is necessary for confidence that the product/process/service fulfils the technical regulation.

7. In the United States, laws on mandatory information disclosure between seller and buyer and consumer education/information programmes are also important mechanisms supporting reliance on supplier's declaration of conformity. For example, the Fair Packaging and Labelling Act and similar Federal/state legislation provide manufacturers with flexibility in labelling and advertising conformity of their products to standards and requirements established by the manufacturers themselves. Such legislation can help promote product innovation and improvements and can be an alternative to imposing mandatory product requirements. It also allows consumers the freedom to select products which have the characteristics that they (not the regulator) deem important, while at the same time protects the consumer from false or misleading labelling or advertising. This approach can reduce the need for more intrusive regulatory interference in the marketplace. It should be noted that this approach alone may not be appropriate for characteristics which may impose serious health or safety risks.

V. IMPACT ON TRADE

8. Reliance upon a declaration of conformity by suppliers is normally considered to be a trade friendly approach to conformity assurance. As noted above, from a manufacturer's perspective, the supplier's declaration of conformity allows flexibility in the choice of location to have a product tested, reduces the uncertainty associated with mandatory testing by designated laboratories based in foreign countries as well as associated costs. Reliance on a supplier's declaration of conformity can also be a cost-saving and efficient tool for regulators to meet their legitimate policy objectives, such as ensuring protection of the environment and the health and safety of consumers. It can provide an assurance that a product conforms to regulatory requirements by identifying an accountable party in the event that non-compliance is detected. Regulatory reliance on a declaration of conformity can be enhanced when "spot checks" are conducted and penalties are imposed for non-compliance. Additional safeguards can be provided by customs inspections to verify the presence of the supplier's declaration of conformity documents and by affording an opportunity for market participants to inform regulatory authorities of perceived non-conformance. A supplier's declaration of conformity is also beneficial in that there is no discrimination on the basis of the geographic location of a testing or other conformity assessment body -- conformity is, in short, the responsibility of the supplier. Under such a system, the question of "portability" of conformity assessment, or of the need to negotiate political agreements on mutual recognition, become moot.

VI. FUTURE WORK

9. The Committee on Technical Barriers to Trade has acknowledged the importance of avoiding unnecessary obstacles to international trade in cases where a positive assurance of conformity with a technical regulation or standard is required. While the Committee has noted that the supplier's declaration of conformity can save costs, it also acknowledged that such an approach to conformity assurance may not always be appropriate. The United States continues to support the voluntary exchange of information foreseen in the Triennial Review on the use of supplier's declaration and alternative approaches to conformity assessment and would welcome information from other Members on their experience. Such experience could include a further definition of the conditions supporting effective use of a declaration of conformity; considerations that may deem such an approach inappropriate from a regulatory perspective; an identification of technical infrastructure components which would be necessary to support reliance on this approach.
