

SUPPLIER'S DECLARATION OF CONFORMITY

Submission by the European Communities

I. INTRODUCTION

1. This note is intended to explain the European Communities' (EC) system on using "suppliers' declaration of conformity"¹ and the EC's experience in its use. It examines possible implications for market surveillance and product liability, as well as associated costs and benefits.

2. The definition of suppliers' declaration used in this document is the following. *The supplier himself declares conformity of his product with the requirements of the applicable legislation without any mandatory third party intervention – neither in the design phase nor the production phase of the manufacturing process – that would involve product tests according to the relevant legislation. The Suppliers' DoC is based on an assessment or test performed by the manufacturer himself or any other party.*

II. THE EUROPEAN COMMUNITIES' EXPERIENCE

3. EC experience in the use of supplier's declaration of conformity has been within the framework of New Approach Directives². New Approach Directives are regulations in the field of technical safety of a wide range of industrial products. They lay down the essential public interest requirements for families of products (dealing with safety, health and environmental protection), the relevant conformity assessment procedures tailored to the specific risks inherent to the respective product family and the "CE" marking to be affixed on the products by the manufacturer before placing them on the market.

¹ Please note that "supplier's declaration of conformity" sometimes is called "*manufacturer's declaration of conformity*" or "*self-declaration of conformity*". The underlying concept of the terms is the same. A supplier, according to the definition in ISO/IEC Guide 22:1996 is a party that supplies the product, process or service and may be the manufacturer, distributor, importer, assembler, etc.

² In 1985, the Council Resolution on "A New Approach to technical harmonization and standards" provided a new framework for the harmonization of national regulations for industrial products. Later, the Council Resolution of 21 December 1989 on a "Global Approach to conformity assessment", followed by Council Decision 93/465/EEC of 22 July 1993 gave more detailed specifications on certification procedures by introducing the "modules" for the conformity assessment and guidelines for the affixing and use of the CE conformity marking.

4. Conformity assessment using the supplier's declaration of conformity is applied in some New Approach Directives³, covering certain categories of products in the fields of: electrical equipment, machinery, toys, medical devices, personal protective equipment, recreational crafts, radio and telecommunication equipment and the equipment for use in potentially explosive atmospheres. As the basic model ("Module A") for conformity assessment in these fields, it also reflects broader EC policy to promote a system based on trust, transparency and competence. Use of the supplier's declaration of conformity is mostly linked to the application of harmonised European standards that are elaborated by the European standardization bodies CEN, CENELEC and ETSI following a mandate by the EC. They contain technical specifications for the fulfilment of the relevant essential requirements. The standardization process offers the possibility to transpose standards and incorporate international standards from ISO, IEC and ITU-T as they become available. However, the use of harmonised European standards remains voluntary and manufacturers are free to choose any technical solution to comply with the relevant essential requirements. Deviation from harmonised standards may however, depending on the applicable directive, entail mandatory third-party involvement.

5. For all products intended to be placed on the market, the supplier has to ensure that they satisfy the relevant legal requirements. Applying the DoC imposes the supplier to care for the requirements of documentation and declaration. The supplier has to establish a technical file containing the documentation that covers design, manufacture and operational aspects of the product reflecting the results of an appropriate risk assessment and, if applicable, the test results obtained from a competent laboratory. The supplier must also draw up and keep together with the file a copy of the declaration of conformity. The supplier must keep it for a period ending at least 10 years after the last product has been manufactured and must make it available to the relevant national authorities for inspection purposes. The supplier takes full responsibility for placing the product on the market and must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured products with the technical documentation and with the relevant legal requirements.

6. For some categories of higher-risk products covered by New Approach Directives, an additional step is required, which involves the intervention of a third-party certification body. This allows for an examination of a product type, the technical file or additional tests to be made prior to the product being placed on the market.

³ Council Directive 73/23/EEC on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits, Council Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys, Council Directive 89/336/EEC on the approximation of the laws of the Member States relating to electromagnetic compatibility, Directive 98/37/EC of the European Parliament and the Council on the approximation of the laws of the Member States relating to machinery, Council Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment, Council Directive 93/42/EEC concerning medical devices, Directive 94/25/EC of the European Parliament and the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft, Directive 96/57/EC of the European Parliament and the Council on energy efficiency requirements for household electric *refrigerators*, freezers and combinations thereof, Directive 97/23/EC of the European Parliament and the Council on the approximation of the laws of the Member States concerning pressure equipment, Directive 98/79/EC of the of the European Parliament and the Council on in vitro diagnostic medical devices, Directive 1999/5/EC of the European Parliament and the Council on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity, Directive 94/9/EC of the European Parliament and the Council on the approximation of the laws of the Member States concerning on equipment and protective systems intended for use in potentially explosive atmospheres.

III. REQUIREMENTS FOR THE USE OF SUPPLIER'S DECLARATION

7. According to the EC experience supplier's declaration of conformity can facilitate market access without prejudice to the fulfilment of legitimate public policy objectives, when it is combined with well developed market surveillance systems and effective product liability laws.

A. PRODUCT CHOICE

8. Before deciding to apply supplier's declaration of conformity, several elements should be taken into consideration. In particular, issues such as the appropriateness of the supplier's declaration of conformity in view of the nature of the risks involved, the economic infrastructures of the given sector (e.g. existence or non-existence of certification laboratories) and the production system. Supplier's declaration of conformity is the preferred option for product categories presenting risks that are generally considered to be low.

B. MARKET SURVEILLANCE

9. An essential tool for the enforcement of any legislation – and in particular for goods that are placed on the market following a supplier's declaration of conformity – is market surveillance. Market surveillance involves monitoring products to ensure they comply with legislation and taking remedial action when products do not comply. It also includes penalties for false or misleading declarations. In the EC this is the responsibility of national authorities specially nominated or established by the Member States. To help ensure the fulfilment of legitimate public policy objectives, the less involvement by a third party during the conformity assessment before the product is placed on the market, the greater the need for efficient market surveillance.

10. There is a range of market surveillance structures. The responsible market surveillance authorities need to have sufficient and appropriate resources, staff and powers to conduct effective surveillance activities. Overall, a distinction should be made between conformity assessment (pre-market), which is a task for the manufacturer or the conformity assessment bodies and market surveillance (post-market) which is carried out by market surveillance authorities, and is often financed from public funds. Conformity assessment bodies should not be responsible for market surveillance, as there would be a risk of conflict of interest

C. PRODUCT LIABILITY

11. In the EC, regardless of the decreed or chosen conformity assessment procedure, manufacturers and importers are always liable in the case of a product causing damage to an individual or private property according to the Directive on product liability.⁴ The Directive covers all products with a limited number of exceptions. If the manufacturer or an importer can demonstrate that the product was not defective when it was placed on the market, the manufacturer or an importer will not be liable for damages. The injured party will be paid only if he proves that he has suffered damage because the product was defective and that the damage was caused under normal conditions of use including foreseeable misuse. The injured party does not need to prove that the producer was negligent.

12. The defectiveness of the product shall be determined by reference to the lack of the safety, which the public at large is entitled to expect. The required risk assessment of the product includes the foreseeable misuse of the product under the given circumstances.

⁴ Directive 1999/34/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.

IV. CONCLUSION

13. As mentioned in the EC submission G/TBT/W/197, EC experiences are that the introduction of supplier's declaration of conformity coupled with ex-post market surveillance and effective product liability laws works well in certain specific sectors and has not created problems with regard to the fulfilment of the legitimate public policy objectives pursued.

14. Moreover the use of supplier's declaration of conformity also facilitates imports from third countries and can be considered to help developing countries fully benefit from the opportunities offered by the world trading system. More generally, the supplier's declaration of conformity holds a significant potential for effective elimination of barriers to trade in that it is a standards-receptive model oriented towards the fulfilment of regulatory objectives (like safety, health and environmental protection) that are globally recognised⁵.

15. While the use of supplier's declaration of conformity implies certain costs for administrations, in particular higher costs for market surveillance, it tends to imply lower costs for industry and importers, resulting in cheaper products for consumers and possibly, in the long run, higher level of competitiveness and job creation. An appropriate balance should be struck, taking into account the imperative objectives of protecting health, safety and the environment, and the constraints on the resources of administrations.

16. For further details on the suppliers' declaration of conformity and other conformity assessment procedures, reference is given to the Guide to the implementation of Directives based on the New Approach and the Global Approach. This Guide can be obtained at the URL:

<http://europa.eu.int/comm/enterprise/newapproach/legislation/guide/legislation.htm>

⁵ United Nations Economic Commission For Europe, Recommendations on Standardization Policies: Recommendation "L": "An International model for technical harmonization based on good regulatory practice for the preparation, adoption and application of technical regulations via the use of international standards"; http://www.unece.org/trade/tips/wp6/wp6_major.htm