EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Regulatory policy
Regulatory Approach for the free circulation of goods

NOTE TO THE SENIOR OFFICIALS GROUP ON STANDARDISATION AND CONFORMITY ASSESSMENT POLICY

Title:	**CERTIF 2009–03** **ORIENTATIONS FOR SELECTING AND IMPLEMENTING THE MODULES (AS LAID DOWN IN DECISION 768/2008 OF THE NEW LEGAL FRAMEWORK) – SMES SPECIFICITIES**		
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Doc. N.:	**SOGS N 593 EN**	**Issue Date:**	18th March 2009
Version:	1.0	**Meeting:**	1st April 2009
Status:	For information and discussion		

Abstract:

This document provides guidance to the sectoral legislator how to select conformity assessment modules from the "menu" of the Decision No 768/2008/EC (OJ L218, page 82 of 13 August 2008). Furthermore it provides guidance to Notified Bodies performing conformity assessment.

All procedures set out in the New Legal Framework for demonstrating compliance with regulatory requirements are considered as leading to the same level of conformity. However, in line with the better regulation objectives, the sectoral legislator, must take into account the complexity of the product, the size of the undertakings operating in the sector addressed (e.g. SMEs) the technology in question, the risk for the public interest, the mass or serial nature of the production process.

Notified bodies must, in a similar way, avoid unnecessary burden for the economic operators, maintaining however the required high level for the protection of the public interest.

Keywords:	**Conformity assessment modules/procedures, manufacturers, SMEs, Notified Bodies**
References:	**Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (OJ L218, page 30 of 13 August 2008)** **Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products (OJ L218, page 82 of 13 August 2008)**

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Certif doc 2009-03

Brussels, 17th March 2009

Orientations for selecting and implementing the modules (as laid down in Decision 768/2008 of the New Legal Framework) – SMEs specificities

1. Introduction

All procedures set out in the New Legal Framework for demonstrating compliance with regulatory requirements are considered as leading to the same level of conformity.

In this respect, the main purpose for providing more than one procedure is threefold:

- For the sectoral legislator to serve as a simple, coherent and complete menu to select the most appropriate module(s)/procedure(s) for the specific area of activity. By offering a choice of clear, transparent and coherent procedures, the system sets out the maximum possible variants and allows the legislator to take full account of SMEs specificities.

- For the manufacturer not to be unnecessarily overloaded with modules that are over-proportionate for the given circumstance

- For the consumer to ensure that public interest is fully protected and without any compromise

It has to be stressed that the legislator in a particular sector should not use the whole range of modules, but should opt for the most suitable one(s) appropriate to a concrete product category and proportionate to the level of risk involved and to the infrastructures of the sector in question.

In line with the better regulation objectives, the legislator should avoid to impose unnecessarily too onerous modules and always opt for the simplest and the least burdensome possible one(s) whilst – of course – ensuring the necessary level of safety and protection. Furthermore he should take account of the specific situation of small and medium-sized enterprises as regards administrative burdens Although all the procedures lead to the same result, which is the conformity of the product, it follows that the complexity of the chosen module should be proportional to the risk, design complexity etc of the product. These criteria are set out under Art 4.1, 4.4 and recital (50) of the text of the Decision.

2. Guidance for the sectoral legislator while selecting the appropriate modules

The legislator while selecting modules for his legislative instrument should follow the following principles

- As a general rule, products should be subject to both design and production modules before placed on the market.
- When appropriate in terms of protection of public interest, the manufacturer must be given as wide a choice of modules as possible. All conformity assessment procedures used in the market today in the sector in question should be reflected in the modules selected by the relevant legislative instrument.
- Avoid modules too onerous relative to the objectives of the directive concerned, without however compromising the protection of the public interest. It follows that the complexity of the modules should be proportional to the risk (impact on public interest, health, safety, environment)of the product, its design complexity, its character of production (large series/small series/custom-made), the size of manufacturers involved (e.g. SMEs) etc
- Specially regarding SMEs, the sectoral legislator must not provide for general exceptions and derogations for such enterprises, which might imply that they or their products are second-rate or sub-quality and which might result in a complex legal situation for the national market surveillance authorities to supervise.

  In this respect, the sectoral legislator must adapt, not the requirements for conformity with law but the means to achieve conformity, to the dimension of companies or to their particular situations (e.g. custom built products or small series, specificities of the technology involved) by selecting the most appropriate conformity assessment procedures.

  The reason is that law must apply to all and SMEs must above all be able to demonstrate their compliance with the law, otherwise their consumers and customers could be disadvantaged.

  As a matter of example, a craftsman who makes windows should be able to make and sell his windows to individual customers in compliance with the law so that the customer can properly be insured. If the customer cannot demonstrate to the insurance company that his window is in compliance with the law he may have difficulties getting insured. Or the customer could find it difficult to obtain subsidies from public authorities for his construction, if he cannot demonstrate the conformity.

  The derogation is therefore not necessarily the answer. However, adapting the conformity assessment procedure and its implementing rules to the situation of one off or custom built products is more appropriate.

  In this respect, the sectoral legislator must provide for the situation of SMEs to be taken into account by selecting the most appropriate conformity assessment procedures and by setting the rules for their appropriate implementation. Furthermore he must place obligations on conformity assessment bodies to operate in a proportionate manner in relation to the size of undertakings and to the small serial or non-serial nature of the production concerned.
- The initial question the legislator has to ask himself, is if a simple statement (accompanied by the relevant technical documentation) of the manufacturer is enough to ensure the conformity of the product(s) in question against the relevant legislative

requirements. If this is the case, then the manufacturer may be allowed to select module A.

The legislator thus recognises companies the capacity of manufacturer to ensure himself the conformity of their products, especially when these product(s) are of low complexity (simple design and production mechanism) and present a low risk for the public interest as it is the case for a large number of SMEs

- In cases of mass production based on a prototype/specimen "representative of the production envisaged" and where the product in question is of complex design, the legislator may lay down the conformity assessment procedure in two steps: first the examination of conformity of the prototype/specimen against the relevant legal requirements (EC-type examination -module B) and then the determination of the conformity of the products against the approved EC-type (modules C and variants, D, E, F).

  This method not only reduces burden and costs but is also more efficient compared to a traditional examination of the conformity products directly against the legal requirements. Once the specimen type is approved (and this is done only once for a specific specimen), it must be checked only if the products to be placed on the market are in conformity with the specimen.

- While selecting module B, the legislator must recognise relevant practices where the examination of the complete specimen "representative of the production envisaged" is either not economically viable or not necessary, such as for well-known products applying standard technology. In such cases the determination of the conformity may be performed by examining only the technical documentation and/or critical parts of the specimen.

  As a matter of example, this is largely applicable to the components sector that constitutes a typical activity area for SMEs. The legislator may tackle this issue by selecting (according to empowerment given by Art 4.6.b of the Decision) the design type examination (examination only of the technical documentation) or the combination design/production type examination (examination of the technical documentation and critical parts of the product) instead of the pure production type examination.

- In cases where the legislator has opted for the demonstration of conformity assessment against a specimen (module B), he must examine the possibility if a simple statement (accompanied by the relevant technical documentation) of the manufacturer is enough to ensure the conformity of the product(s) in question against the approved specimen. If this is the case, then the manufacturer may select module C

  This case is similar to the use of module A; however the manufacturer demonstrates himself the conformity of his products not directly against the relevant legislative requirements (as in the case module A and variants) but against an approved specimen/EC-type that complies to the relevant legislative requirements.

  This method may be adequate when the products in question are of complex design (that one of the reasons of having already selected module B) but simple production mechanism and present a low risk for the public interest

- In many cases the legislator must acknowledge that quite often, manufacturers manage very well equipped testing laboratories or premises and their competence is sometimes higher than the abilities of certain notified bodies. This is usually the case for new innovative complex products for which the testing know-how remains inside the manufacturers. Typical examples are innovative SMEs active in the area of new materials.

  In such cases the legislator may consider selecting either modules A1, A2 (if he has not opted for the demonstration of conformity assessment against a specimen - module B), or, C1, C2 (if he has opted for the demonstration of conformity assessment against a specimen - module B) that allow the use of an accredited in-house body. In the mentioned modules, the manufacturer could either carry out tests and product checks through and under the responsibility of a third-party (notified body chosen by the manufacturer), or to implement them by an accredited body that forms a part of manufacturer's organisation. Thus the reliability of the tests and the level of safety could be even improved in this way.

  However, in this case the in-house body must be accredited. By allowing in-house assessment, the costs in administration and double testing would be reduced, which should result in reductions of the final price for users and consumers. SMEs benefit particularly from the use of an accredited in-house body, because due to their size, they monitor closer their testing mechanisms and facilities than bigger companies do.

  Nevertheless, it is necessary to stress that a specific sectoral legislative instrument remains free to require the use of an accredited third party where this is felt necessary.

- If the demonstration of conformity of products against an approved EC-type cannot be left to the manufacturer but requires that products are fully checked (neither supervised tests only as in C1 nor at random intervals as in C2) by a notified body, then the legislator may require from the manufacturer either to operate an approved quality system (modules D, E) or that the conformity of his products are verified be means of tests/checks (module F).

  If the production mechanism is relatively "simple" then the legislator may consider that it sufficient that the quality system of manufacturer focuses only on the test of the final product without including the pure manufacturing part. If this is the case, then module E is the most appropriate. Furthermore the legislator acknowledges in this way to SMEs, that as they (thanks also to their size and flexibility) dispose a better monitor of their manufacturing process, there is not need for third-party assessment of this process.

- In the case of products of simple design but complicated production/manufacturing, in order to check the design, instead of an EC-type examination, reduces also burdens on manufactures as well as costs. In this context the legislator may consider selecting modules D1, E1, F1 and using thus the advantages of modules D, E and F respectively, without the necessity of recurring to type examination (module B) in the design phase. This reduces also burdens on manufactures as well as costs. This is an important relief for SMEs, that due to their size are more sensitive to test costs.

- For products, produced in extremely small series (only one or few pieces, e.g. turbines or niche instruments) the legislator may consider selecting module G.

- In complex cases where it is necessary that the manufacturer must operate a full quality system covering both design and production phase, the legislator may opt for module H

- When the manufacturer operates a full quality assurance system, but the verification of the conformity of design and the issuance of EC design examination certificate by a notified body is necessary, it is ensured that the manufacturer undergoes only once the control of the design phase and the production phase. That would not be the case of a combination of other seemingly appropriate modules or procedures, such as B + H, when the design phase would be evaluated twice. In both modules H, H1 product design is examined; however module H1 goes beyond H, as the design examination leads (upon positive assessment by the notified body) to the issuing of an EC-type examination certificate

- Whenever directives provide the manufacturer with the possibility of using the nodules based on quality assurance techniques, the manufacturer must also be able to have recourse to a combination of modules using direct product certification (e.g. B+F, F1) and not quality assurance, and vice versa; except where compliance with the requirements laid down by the directives requires the exclusive application of a certain procedure. Both ways of demonstrating compliance (quality assurance or not) with regulatory requirements should continue to be considered as leading to the same level of conformity. Such a choice takes full account of specificities of SMEs, which sometimes, for costs reasons, opt for not operating a quality assurance system

- In certain industrial sectors, inspection of products in use or in service is of paramount importance in determining the level of conformity of the product to the requirements of the legislation. In such cases legislator must select modules that tackle in-service control, giving however the freedom to the manufacturer to use or not use a quality assurance system, as stated above.

  Thus he may select either module B (EC-type examination - see B.6, 2nd paragraph) or module H1 (EC design examination - see H1.4.3, 2nd paragraph). Both require that the EC type/design examination certificate includes all relevant information for in-service control. Furthermore the legislator may make use of art 4.5.f of the Decision, that allows him to specify the information for conformity assessment and in service control to be included in the EC type/design examination certificate or its annexes

3. Guidance for the notified bodies while implementing the modules

Notified bodies, while implementing the modules must follow the following principles

- They should apply the modules without unnecessary burden for the economic operators. This principle of proportionality should especially also be followed by the Notified Bodies in the case of SMEs, where the directive and related guidelines allow some flexibility. As a matter of example in case where an SME operates a quality assurance system, it is unrealistic that the notified body requires from the enterprise the same kind and amount of documentation/information as from a big company.
- For custom-made products and small series production, the technical and administrative conditions relating to the implementation of conformity assessment procedures shall be alleviated, while maintaining the required high level for the protection of the public interest

4. Additional benefits for SMEs

In addition to what has been stated under §2, SMEs profit also from some other measures set out in the New Legal Framework:

- The role of the “authorised representative” is strengthened. Upon manufacturer's mandate, the authorised representative can fulfil more tasks than in the past. That constitutes a major relief for all the companies, but SMEs (due to their size) benefit more than big companies from scale economies.

- Art R17.3 of the New Legal Framework stipulates that a body belonging to a business association or professional federation (e.g. SMEs associations) representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which this body assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, perform conformity assessment in the sense of the New Legal Framework. Thus SMEs may benefit from the services offered by bodies close to SMEs environment and aware of SMEs specificities and needs.