

EUROPEAN COMMISSION

ENTERPRISE DIRECTORATE-GENERAL

Single Market : regulatory environment, standardisation and New Approach Legal aspects linked to internal market

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NOTE TO THE FILE

Subject: Views of the Notified Bodies on the Modules

The Communication from the European Commission of 7 May 2003 on 'Enhancing the Implementation of the New Approach' dealt, among other things, with the potential problem of limited conformity assessment procedures when a product is covered by more than one Directive. All applicable directives may not share a common module, thus obliging manufacturers to apply different modules for different risk categories. Yet, even when one common module exists, this may limit the choice granted in the individual directives. This choice may have been justified where different certification infrastructures were developed in Member States or, where it enabled manufacturers to choose the most economic procedure according the branch of industry concerned.

Furthermore, the subsequent Council Resolution of 10 November 2003 called to consider whether a more consistent range of modules can be made available in the individual Directives.

To explore these issues, we need to look at the application of the conformity assessment procedures under the various directives. For that, it is necessary to draw upon the experience of the Notified Bodies. They are well-placed to identify bottlenecks or room for improvement in the modules that may be addressed by fine-tuning of the related requirements.

Notified Bodies should be invited to make freely any suggestions they consider necessary for improving the functioning of conformity assessment procedures, bearing in mind the principle of consistency. The Commission should ultimately ensure that only standard modules are used across the various directives.

We therefore, with the help of the sector units, envisage launching an enquiry amongst the Notified Bodies on this issue and request any contributions by December 10, 2004..

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