



## Conformity assessment and notified bodies

**Karl-Heinz NOETEL**

European co-ordination of notified bodies for PPE

For a large number of products, conformity assessment by a notified body is required before the product may be placed on the market. These bodies are notified by the Member States for particular product areas and must fulfil uniform criteria. Their work is often subject to criticism because of a lack of uniformity in certification procedures and in the application of harmonised standards, and because of differences in test results. The co-ordination groups of notified bodies, which exist for different product areas, are expected to resolve these problems. The status of the co-ordination groups, little participation in the groups and the fact that the documents drafted by them (e.g. Recommendation for Use Sheets) merely take the status of recommendations make this task a very difficult one, however.

The new EU legislation concerning the New Approach is expected to improve the situation. Besides requirements addressed at the Member States to improve market surveillance, the regulation also contains approaches to harmonising notification. While these will likely have only indirect implications for the notified bodies, the adopted regulation also suggests direct measures aimed at ensuring sustained competence of notified bodies and promoting uniform procedures, e.g. by obliging the notified bodies to participate in standardization and co-ordination activities and to apply the jointly drafted documents.

Implementation of this and other points of the Decision presupposes the adaptation of the individual product directives, however.

The revision of the product directives would also provide an opportunity to contribute to product safety, by addressing existing difficulties associated with implementation of the directives. Although interpretative documents such as the Guidelines on the application of the PPE Directive are valuable tools for clarifying questions, manufacturers and notified bodies wish for binding documents that provide legal security.

The paper will address topics such as limited validity of certificates, impacts of new EU directives, conformity assessment modules, and categorization issues, with the PPE Directive serving as an example.