



European Coordination of Notified Bodies

Karl-Heinz NOETEL

Berufsgenossenschaft der Bauwirtschaft

Prävention Hochbau, Viktoriastr. 21, D – 42115 Wuppertal

Background

The free movement of goods within the European single market is made possible by Europe-wide legislation governing the placing of products on the market. However, in accordance with the European Union's New Approach, legislation is harmonized by specifying general requirements in EU directives rather than legal provisions describing detailed requirements for product features. The general requirements can then be fleshed out on a product-specific basis by means, for example, of European standards.

Manufacturers must confirm their products' compliance with the requirements in the directives by furnishing a declaration of conformity and affixing a CE mark to the products. Consequently, the EU directives also include provisions concerning assessment of products' conformity with directive requirements. The "notified bodies" play a key role in the assessment process since they are called in to perform type examinations and to review manufacturers' quality-assurance measures in accordance with the individual product directives.

Notified bodies' assessment of products' conformity with the EU directives is thus extremely important not only for manufacturers but also for market-surveillance activities. If the notified body does not issue the required certificate of conformity, the product cannot be placed on the European market. If a product which does not comply with the requirements is given a certificate, fair trade can no longer be guaranteed. It is therefore important to ensure that the notified bodies make comparable decisions when assessing conformity.

In various product segments, the notified bodies thus soon founded European coordination structures, along the lines of earlier, national knowledge exchange groups, to serve as a forum for them to discuss conformity assessment procedures. The European Coordination of Notified Bodies for PPE, for example, was set up in 1992 by Germany's BGIA and "PPE" committee of experts.

Consultation between notified bodies via such European coordination structures has now become a well-established procedure. As Section 6.6, "Notified bodies"/"Coordination and cooperation", of the EU Commission's "Blue Guide" on the implementation of directives based on the New Approach states,

"A coherent application of the conformity assessment procedures requires close cooperation between the notified bodies, the Member States and the European Commission.

...

The Commission, in coordination with Member States, also ensures that cooperation is organised between the notified bodies."

The EU Commission has created the framework required for such cooperation by installing and supporting coordination groups for most directives. It provides funding to an administrative secretariat which performs tasks on behalf of the coordination groups' technical secretariats, i.e. organization of meetings and distribution of documents and information. In addition, it provides financial support for technical secretariats for each of the directives. The technical secretariats' work concerns concrete issues involved in the coordination of the testing and certification activities. Their tasks include, for example, preparing documents, running meetings and reporting to the European Commission. They also act as a source of information on conformity assessment/notified bodies for all stakeholders (e.g. the EU Commission, member states, manufacturers' associations, etc.).

This paper is intended to give an outline of the structures of the notified bodies' coordination groups, those groups' objectives, methods of work and how they interact with the other European bodies. It essentially refers to the coordination groups in the field of PPE and machinery but the points addressed can be considered as generally applicable to the other coordination groups.

Structure, objectives and work of the coordination groups for notified bodies

Generally speaking, the coordination groups consist of a horizontal committee and various vertical groups. The horizontal committee is the forum in which all of the notified bodies for a particular directive, along with representatives of the EU Commission and European organizations and associations, discuss issues concerning the implementation of that directive for all products covered by it. Such issues include general aspects of the conformity assessment procedures and directive requirements. The vertical groups enable the notified bodies for directives which encompass various product categories to address specific issues relating to, for example, testing methods for particular products, ways of interpreting standards, testing regulations used for certifying non-standardized products, etc. and to summarize the results of their discussions in the form of recommendations.

The exact structures, however, can be specially tailored to the individual coordination groups depending on the requirements in the directives. In the coordination group for PPE, for instance, the horizontal committee has an ad hoc group assigned to it for issues concerning Article 11 of the PPE directive. The quality-assurance monitoring topics it deals with are of interest for all types of PPE and thus require a "horizontal" discussion. However, since notified bodies in the field of PPE do not necessarily cover quality assurance monitoring and such topics are consequently not of equal relevance to all members of the horizontal committee, this special group was set up below the horizontal committee.

There are also two other special features in the PPE segment. The first is an advisor group set up to support the technical secretariat, particularly in its preparation activities for meetings. And the second is a group from the technical secretariat, comprising all of the vertical group convenors and created for the purpose of discussing questions arising from vertical groups that could have horizontal significance, e.g. procedural issues.

The vertical groups also conduct round robin tests to ascertain the reproducibility of testing methods and the comparability of test results and to elaborate proposals for improvements to testing methods.

In a number of vertical groups, the administrative secretariats have installed newsgroups. These discussion forums are restricted to the vertical group members and enable them to exchange information and experiences quickly.

The members of the vertical groups are not exclusively notified bodies in the respective product area. Depending on the requirements, test houses which do not perform certification themselves and observers from different fields such as standardization or manufacturers' associations may be permitted as members.

If solutions to be used by all notified bodies are agreed on for specific scenarios, the proposed solutions are set out in "recommendation for use" sheets for the notified bodies. Since the questions discussed in the horizontal committee generally concern interpretation of directives, the recommendations are always forwarded for confirmation or approval to the standing committee responsible at the EU Commission. The procedure for "vertical" issues currently differs according to the category of directive.

Coordination of notified bodies within the New Approach system

The EU Commission sets great store by the work of the coordination groups for the notified bodies. The technical secretariats act as a source of information, providing the answers to any questions concerning the notified bodies' activities which the committee responsible at the EU Commission might have.

The expert groups of the EU Commission's standing committees are one of several ways in which the member states can harness the notified bodies' experience in the implementation of directive requirements.

In the field of PPE, the coordination group's technical secretariat is not only an observer at the meetings of the relevant expert group in Brussels, it also reports to the AdCo group (European group of experts for PPE market surveillance), which is thus also able to utilize the notified bodies' experience. In addition, a representative of the technical secretariat is a member of the PPE Sector Forum at CEN/BT. This enables both sides to keep each other informed and to discuss issues which concern both the notified bodies and the realm of standardization.

Last but not least, the coordination groups for notified bodies are key players in the ongoing work to produce an EU-wide guide on how to implement the PPE directive, the intention being that a good number of points in the recommendation for use sheets should be incorporated into the guide.

This short overview of the tasks and fields of activity of the European coordination groups for notified bodies demonstrates the importance of this network of notified bodies for the continued success of the implementation of the New Approach.