

## **ANEC POSITION PAPER ON THE REVISION OF THE NEW APPROACH**

### **COMMISSION WORKING DOCUMENT - CERTIF 2005-16 REV. 2: ELEMENTS FOR A HORIZONTAL LEGISLATIVE APPROACH TO TECHNICAL HARMONISATION**

#### **INTRODUCTION**

ANEC acknowledges that the New Approach to Technical Harmonization in the field of safety has contributed to the completion of the Internal Market, free movement of goods, product safety, and consumer protection. Nonetheless, we have come across many problems in defending consumer interests in the field of standardisation and in ensuring an adequate level of safety. For instance, in a recent enquiry carried out by the European Commission regarding the publication of references of standards in the Official Journal (OJ) that fall under the scope of the General Product Safety Directive, ANEC opposed the publication of seven out of nine proposed standards, dealing with childcare articles, due to significant flaws in these specifications.

The problems are generated by inherent shortcomings of the New Approach system, for instance that it is almost entirely based on standards bodies. Also, in technical committees at European level industry is normally in the majority, reflecting an imbalance in representation in many national standards bodies. This does not ensure balanced decision-making, all the more the set up and processes of the standards bodies disadvantage minority positions.

Therefore, ANEC believes that a fundamental review of the New Approach is needed, going beyond the Commission's current proposal, so as to improve the balance between public interests and business interests. This should be done by strengthening the role of public authorities when elaborating detailed specifications. For instance, standardisation ought to be complemented by the option to task a Committee of Member States (Comitology), complemented by an expert group (stakeholder advisory forum), to set limit values or other key requirements, to resolve problems encountered in the standards bodies and to react on market developments in a quick and flexible way. This procedure has to be transparent and open to all stakeholders, in particular public interest stakeholders, such as consumers.

Furthermore, ANEC is convinced that a democratic reform of the European Standards Organisations is needed. To this end, ANEC has elaborated a catalogue of measures to improve public interest stakeholder participation in CEN and CENELEC (ANEC-GA-2006-G-004).

Finally, we reiterate that consumers do not endorse the extended use of the New Approach in policy areas such as the environment, energy, food and health, unless

such reform has been implemented. The New Approach should not be considered as the general model applicable in the whole products or services area. Specific standardisation projects in these areas can be useful. But this should be decided on a case-by-case basis.

## **SPECIFIC COMMENTS**

### **Legislative strategy**

ANEC believes that there is a need for more consistency across the board of the New Approach Directives and therefore welcomes the initiative of the European Commission to set an overall framework for safety, to provide a legal base for accreditation and market surveillance and to set a joint framework for the essential requirements common to all New Approach Directives, such as common definitions, requirements for the development of European standards, common approach to conformity assessment as well as the rules and procedures for a common 'safeguard' mechanism.

However, ANEC is of the opinion that standardisation should not be the only option to establish detailed safety requirements for products. The existing Member States Committees (Comitology) could be such an alternative provided the procedures become transparent and are opened up for guaranteed stakeholder participation.

In a joint position paper regarding the revision of the Toy Safety Directive, ANEC and BEUC (ANEC2004/CHILD/059) proposed "the implementation of a Committee Procedure (Comitology) in order to allow for flexible adjustments of the Directive by detailing essential requirements (e.g. to establish limit values for chemicals, noise, speed and so forth). In addition, this procedure can be used to determine the products, which fall inside or outside the scope of the Directive and to determine those toys for which an EC type approval (third party testing) is needed". We believe that this would allow quick reaction to market changes (new products) or new identified risks. Moreover, it would allow the establishment of requirements (specify essential requirements) without having to revise the whole Directive, which is a long process involving the Parliament and the Council.

We would like to emphasise that the idea of stakeholder involvement in a committee pertaining to a New Approach Directive is already informal practice with the Toy Safety Experts Group. And the recently adopted Energy Using Products Directive makes also use of a 'Consultation Forum', involving stakeholders in addition to the regulatory committee restricted to Member States.

Delegating the elaboration of technical specifications to organisations other than the European Standards Bodies might offer new options, however, we consider it important to enshrine in the horizontal legislation that in such a case, adequate

procedures are in place that ensure the implementation of the acknowledged standardisation principles, including full participation of all stakeholders and balanced representation.

Finally, we identified an urgent need to align the safety concept of the New Approach with the safety concept of the General Product Safety Directive that is based on the notion of reasonably foreseeable use. This is of particular importance with respect to the Low Voltage Directive. ANEC believes that consumer products falling under the scope of the New Approach Directives should follow the same safety philosophy as other consumer products so that consumers enjoy the same level of protection irrespective of the competent legislation. This ought to be reflected in the framework legislation.

### **Motivations**

Whilst we agree that an EU legislative framework for those aspects common to all New Approach Directives will improve the efficiency of the New Approach, we do not believe that this is sufficient in light of the extension of the New Approach to new policy areas such as services.

Standardisation plays a prominent role in the 2005 re-launch of the Lisbon objectives and is considered one of the key factors to enhance Europe's competitiveness. The intention to use standardisation instead of legislation in the services area will have a direct impact on consumers and it is vital that the consumer view is an integral part of this concept. The challenge here is two-fold. First, there is no overarching legislative framework, in which standards could operate, as is the case in the product area. Second, there is a need to innovate the European standardisation system so as to ensure that it is equipped to cope with these future tasks.

Effective participation of public interest stakeholders in the standardisation process is a precondition for the legitimacy of the New Approach, promoted by all political institutions in the EU. Therefore ANEC believes that rules or rights for public interest stakeholders, such as consumer representatives, need to be reinforced, in particular in standardisation work related to the public interest and when extending New Approach principles to new policy areas.

In the longer term, the current standardisation system needs to change so as to ensure fair and equal rights for commercial and non-commercial interests in the field of standards of public interest. This future system would be based on balanced representation, with committees embracing defined numbers of seats and their allocation to stakeholder groups in a balanced way.

In the meantime, ANEC has proposed some reasonably straightforward changes to processes in CEN and CENELEC that could make significant improvements in

governance. The proposals aim at structural changes in order to enhance minority positions by counterbalancing existing inequalities, ensuring more equal and fair chances for all stakeholders to influence the standardisation process and to have their views taken into account<sup>1</sup>. We hope that our proposals will be taken into consideration in the course of the current review of the CEN Strategy 2010.

A clear concept of balanced representation is also needed when specifications other than standards are used to give a presumption of conformity to the requirements of directives. ANEC calls upon the Commission to develop a code of good practice which would be applicable to traditional and new standardisation institutions.

## **Contents of the possible horizontal legislative act**

### **1. Scope and essential requirements**

ANEC is of the opinion that the following elements need to be enshrined in the future horizontal legislative framework:

- Same safety concept as enshrined in the General Product Safety Directive, which is based on the concept of reasonably foreseeable use instead of intended use only;
- Possibility of a Committee Procedure, complemented by a stakeholder advisory forum, for the elaboration of specific requirements as described above, including adequate procedures that ensure full participation of all stakeholders and balanced representation;
- The scope should include accessibility as products should be safe for all consumers;
- Procedures to develop mandates to the ESOs including the need for public consultation, involvement and review of consultants involved, level of detail, need for adequate involvement and balanced decision making of stakeholders in the elaboration of standards;
- Quality criteria and supervision of New Approach consultants monitoring the compatibility of standardisation work with legal requirements;
- Quality assurance of the output (=the standards) in terms of content and procedure (e.g. compliance with mandates, adequately balanced stakeholder

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<sup>1</sup> ANEC acknowledges that apart from gearing up the CEN/CENELEC system for balanced representation, improved public interest stakeholder participation also requires the availability of financial resources. Therefore, we call upon the European Commission and Member States to enshrine in legislation the obligation for national governments to provide funds for public interest stakeholder participation in standardisation.

influence) prior to publication of the references of the standards in the OJ. We perceive the procedure applied under the General Product Safety Directive (stakeholder consultation prior to publication) as a good starting point;

- Obligation of the Commission to reject inadequate standards not fulfilling the criteria mentioned above (not only the MS should be able to formally object to a standard);
- Genuine European market control strategy with basic rules for enforcement.

Finally, we agree that essential requirements should be formulated in terms of performance rather than design where appropriate (which is, however, not always the case) and should be as precise as possible. Equally important is a concrete and precise wording of standardisation mandates as well as an adequate follow-up of the results.

### **3. Traceability requirements**

We welcome the listed obligations to ensure transparency about the manufacturer, importer and suppliers. We support the idea to record this data with the help of a European database.

### **4. Conformity assessment**

The existing guidelines remain unchanged except that Modules D, E and H would be modified to reflect two options:

- a. replacement by Module Q containing guidelines for directives on determining the requirements of the quality system (ISO 9001:2000) that apply in each sector
- b. reflect requirements of ISO 9001:2000.

In general, ANEC does not appreciate Modules D, E and H because we prefer third party testing. From a consumer's point of view, quality management systems may complement third party product performance tests but should on no account be regarded as a replacement.

### **5. Conformity assessment/Notified bodies**

ANEC welcomes all efforts, transparency measures and collaboration between Member States aiming at improving the consistency and reliability of the notification system.

ANEC also supports the idea of a horizontal guidance document on best practices and a set of stringent essential requirements for the assessment, designation and

monitoring of conformity assessment bodies. Notified bodies shall be fully independent third-party bodies. This has to be based on transparent criteria.

Finally, ANEC endorses an on-line notification system for notified bodies as well as joint working groups between Member States.

## **6. Accreditation**

We agree with the European Commission that public authorities must recognise accreditation as their own obligation and therefore commercial competition is to be excluded between accreditors. Ideally there would be only one accreditation body in each country operated or controlled by authorities. In any case the government must have the final responsibility.

Essential requirements and operational obligations must be as such to guarantee the safeguard of the public interest mission of the European accreditation system.

National accreditation bodies have set up a private association at the European level (EA), in order to coordinate their activities and to operate a peer evaluation system. We would agree with the recognition of the EA provided all members fulfil the criteria.

## **7. CE Marking of conformity**

*“Lack of understanding in the meaning of the CE marking by the consumers, and poor policing of its rules undermines the confidence in the New Approach. The option of abolishing it should be an object of public debate.”* This is one of the conclusions from the European Commission’s reflection paper on the role and significance of the CE marking. In our comment (ANEC2005/GA/037), ANEC welcomes this option because we are concerned about the misuse of the CE marking.

Consumer advocates know too well that not all products circulating in the Internal Market are safe, even though they bear the CE marking. Faulty and unsafe products, however, trigger a loss of consumer confidence in the European Internal market. On top of this misuse of the CE marking, which is directly linked to deficiencies in market surveillance, the majority of European consumers misread the CE marking, which is not addressed to consumers but to public authorities.

We understand that apparently most of the consulted parties would like to maintain the CE marking but not as it is. Bearing in mind that we still believe that it would be best to abolish the CE marking in all communications to consumers in order to avoid further erosion of the credibility of the New Approach, we propose as an alternative to remove the CE marking from the product itself and to affix it on the technical file.

## **8. Market surveillance**

ANEC welcomes the Commission's intention to improve market surveillance in the European Internal Market as deficiencies in enforcement of standards and safety law allow unsafe products to circulate in the Internal market and thus undermine the consumer confidence. We call for establishing a genuine European market control strategy with basic rules for enforcement, which Member States would be obliged to comply with, including sanctions. Proper implementation of such basic rules requires a legal framework. However, the essential elements, as listed in the Commission document, do not appear to be stringent and detailed enough.

We believe that improving market surveillance in the European Union will only be feasible by allocating adequate resources to national authorities in terms of people and funds. Funds should be made available also at the European level to carry out some spot checks independently of the Member States.

ANEC also endorses the efforts to reinforce administrative co-operation and information exchange amongst Member States and with the European Commission. We welcome the extension of the existing RAPEX system. Reliable accident data is not only an important tool for consumer organisations but also for strategic market surveillance in order to identify areas for action. Therefore, ANEC reiterates its call for long-term maintenance and improvement of the former EHLASS/ISS meanwhile IDB system and retention of its product safety basis.

ANEC would like to stress the importance of full transparency regarding enforcement activities. European citizens have a right to know which products have been subject to national measures (in particular, of non-compliances) and also how active their authorities are. To this end, all national enforcement agencies should be obliged to prepare annual reports summarising the main results at an appropriate level of detail, which ought to be available in the public domain. Guidelines should be elaborated for this.

We appreciate that the ICSMS database will be available to all stakeholders and not only to authorities; however, we believe that the system will have to be improved significantly in terms of user-friendliness. For instance, consumers should have a possibility to search for faulty products found in one particular country.

Finally, ANEC welcomes the recommendation to modify the safeguard clause procedure in the New Approach Directives in order to ensure a uniform approach, to simplify and shorten the process. However, we believe that it is insufficient that other Member States are just informed about enforcement activities of a Member State in the national procedure. As in the case of the community procedure (where a Member State or a manufacturer disagrees with a national measure) there should be an

obligation for all Member States to take action and to make sure that unsafe products are removed from the market. END

**ANEC in brief - [www.anec.org](http://www.anec.org)**

*ANEC is the European consumer voice in standardisation, representing and defending consumer interests in the process of standardisation and certification, including policy and legislation matters related to standardisation. Our aim is a high level of consumer protection.*

*ANEC was set up in 1995 and represents consumer organisations from the EU Member States and EFTA countries. The European Commission and EFTA fund ANEC, while national consumer organisations contribute in kind. Our areas of priority are: Child Safety, Design for All, Domestic Appliances, the Environment, the Information Society, Services and Traffic Safety.*