The Revision of the New Approach

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Abstract. For more than twenty years the New Approach is a successfully example for better regulation which helps to complete the single European market. Up to now more than 25 product related directives follow the conception of the New Approach. But the experience in the implementation of this legislation has shown that there are still some elements in this successfully system which have to be improved.
Therefore the European Commission presented in February 2007 - after years of consultation with the member states and the involved parties - its package for the revision of the New Approach. This package consists of two proposals. On the one hand a proposal for a regulation concerning the introduction of accreditation and the reinforcement of market surveillance. And on the other hand a sui generis decision to set the framework for future legislation concerning the marketing of products.

The regulation intends to organise accreditation at the national and European levels, irrespective of the different sectors of activity in which accreditation is used. Furthermore the proposal insists on the public authority nature of accreditation in order for it to be the last level of public authority control.
Concerning market surveillance the regulation ensures that national authorities are given equivalent means of intervention and the necessary authorities to intervene in the market to be able to restrict or withdraw non compliant or unsafe products. It ensures cooperation as between the international authorities and the customs authorities controlling products entering the market from third countries and sets a framework for the exchange of information between national authorities.

The decision sets the general framework for futural sectoral legislation and gives guidance on how to use the common elements to ensure as much coherence in future sectoral legislation as possible. Main elements of the decision are for example harmonised definitions, common obligations for the economic operators, criteria for the selection of conformity assessment bodies and rules for the notification process. Furthermore the decision provides rules and conditions for the CE marking and safeguard procedures.

Since February the New Approach proposals are discussed in the council working group responsible for technical harmonisation and found general approval. The first reading on the New Approach proposals in the European Parliament is expected in the beginning of 2008.

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New Approach

Revision

- Successfully example for better regulation
- Well established since more than 20 years
- Completion of the single market
- Over 25 product related directives
- Includes a trading volume of more than 1,500 Bill. €

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New Approach - Revision

Milestones

1983 Directive „Standardisation and technical regulations"

1985 Council decision for the „New Approach" – the hour of birth

1993 Council decision about „Modules for conformity assessment" – the „Global Approach"

2003 Council decision for the revision of the New Approach – incorporate practical experience

2005 Document N529 – elements for a legal act

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Presentations by the Commission

February 14th. 2007:

- Proposal for a regulation setting out the requirements for accreditation and market surveillance, COM(2007)37 final
- Proposal for a decision on a common framework for the marketing of products, COM(2007)53 final

February 15th. 2007:

- Proposals are communicate to the Parliament and Council

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Regulation - scope

- Organisation and operation of accreditation of conformity assessment bodies
- Framework for the market surveillance of any substance, preparation or other transformed product
- Framework for controls on products originating from third countries

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Accreditation

- used on a compulsory or voluntary basis
- whether it is required or not under legislation
- irrespective of the legal status of the body performing acc.
- A single national accreditation body (NAB) shall:
  - act with public authority and in the public interest
  - operate on a non profit distribution basis
  - not compete with conformity assessment bodies
  - not compete with other national accreditation bodies within the territory of the European Union
  - be a member of a recognised body for a peer evaluation
- Cross-border accreditation only under certain conditions

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Market surveillance

- Apply to products, covered by Community harmonisation legislation
- Few exemptions
- National measures against products, which compromises health or safety or other issues of public interest protection
- Communication and co-ordination between different national market surveillance authorities
- Where appropriate, physical and laboratory checks on the basis of representative adequate samples
- Exchange of information – Community Rapid Information System and a general information support system
- Cooperation between the Member States and Commission

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External border controls

- Appropriate checks on the characteristics of a product on an adequate scale before it is released for free circulation
- customs authorities shall suspend release of a product for free circulation when the product:
  - presents a serious risk to health or safety or to any other issue of public interest protection
  - is not accompanied by the documentation required by the relevant Community harmonisation legislation or is not marked in accordance with such legislation
- Free release of the product after 3 working days, if the customs authorities have not been notified of any action taken by the market surveillance authorities
- Free release, if the market surveillance authorities find that the product does not present a serious risk to health and safety

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Decision – scope/ level of protection

Decision sets out common principles determining the content of Community legislation for marketing of products

- Community legislation
  - shall have recourse to the general principles of the Decision
  - shall restrict itself to setting out essential requirements
- Harmonized Standards
  - concretize the essential requirements
  - gives the presumption of conformity, if applied in full
- If recourse to essential requirements is not possible, detailed specifications may be set out in legislation

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Conformity assessment procedures

- choice of clear, transparent and coherent conformity assessment procedures, restricting the possible variants
- such assessment to be carried out by public authorities, by manufacturers or by conformity assessment bodies

EC Declaration of conformity

- Statement by the manufacturer that fulfilment of requirements relating to a product has been demonstrated

Definitions

- Definition shall used in the same way as possible to get a coherent system

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Obligations of Economic Operators

- Manufacturer, authorised representatives
- Importers, distributors
- Cases in which obligations of manufacturers apply to importers and distributors

CE marking

- Rules and conditions for the affixing of the CE marking
- CE marking may only be affixed by the manufacturer or his authorised representative
- Endanger the GS-Mark!

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Notification of conformity assessment bodies

- bodies authorised to carry out third-party conformity assessment tasks
- Member States
  - shall designate a notifying authority
  - may decide that the assessment and monitoring shall be carried out by their national accreditation bodies
- Requirements relating to notifying authorities
- Requirements and operational obligations for notified bodies
- Subsidiaries and subcontracting of notified bodies
- Measures due to changes to the notification

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Safeguard procedures

1. Procedure for products presenting a risk at national level
   - Where national authorities consider that the non-compliance is not limited to the national territory, they shall inform the Commission and the other Member States
2. Community safeguard procedure
   - If the national measure is considered as being justified, all Member States shall take the necessary measures
   - Measures in cases of non-compliance of the product due to shortcomings in the harmonised standards
   - Complying products which nevertheless present a risk to health and safety
   - Measures in cases of formal non-compliance

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Future prospects - timetable

- First reading agreement is expected
- 2007-09-14: Deadline for amendments of the Parliament
- 2007-10-04: Consideration of amendment
- 2007-11-22: Adoption of the draft report
- January or February 2008: Plenary

Source: European Parliament

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Thank you for your attention