



European Organisation for Conformity Assessment

"Market Surveillance in Relation to the New Approach Directives"

4 and 5 April 2000, Brussels, Belgium

EOTC Critical Issues Workshop

Market Surveillance in Relation to the New Approach Directives: principles and broader framework

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Interesting time to look back at almost 15 years of experience of the New Approach (7.5.85 Council Resolution on a New Approach to technical harmonisation and standardisation) and to see the role of market surveillance in this context.

Introduction to cover the following elements:

- a) the principles of the NA
- b) the importance of MS in this context
- c) the contribution of MS to enforcement and DG Entr approach towards it.

1. Basic elements of NA

• An approach which:

- covers wide fields of product or risk in one Directive
- defines generic requirements which do not require frequent updating and do not therefore risk being outdated as Old Approach legislation (lengthy adoption/revision process)
- limits government intervention to what is essential, while leaving technical solutions to specialists
- encourages industry innovation and competition and thus offers manufacturers scope for alternatives; choice of how to comply with "essential requirements"

A useful tool for construction of the Internal Market – to overcome difficulties involved in previous legislative approach (very slow adoption; constraints on manufacturers; difficult to adapt to technical progress).

- In trying to establish both well-defined policy objectives, and the conditions for their flexible and cost-effective implementation, it represents a **classic example of "co-regulation"** ("target-oriented legislation; integrated approach).

Policy objectives in this case are:

- to achieve a high level of consumer protection
- to ensure free circulation of products in the Internal Market and eliminate unfair competition

These objectives implemented both by:

- Council and EP essential legal requirements
- private sector freedom to find appropriate technical solution, either individually or via the collaborative standardisation process

2. a) **Confidence** is vital if the Internal Market is to operate effectively.

- economic operators must see proof of a level playing field which allows safe products to circulate freely and penalises those who do not play by the rules. Aim is uniform application of EU law;

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- consumers must be able to trust the safety of the products sold;
- third country operators must be assured that they will not face discrimination;
- all actors must be confident that notified bodies operate to high standards.

Market surveillance has an essential role in creating this confidence. INTEGRAL part of our Internal Market legislation.

- b) To avoid misunderstanding, important to **clarify what we mean by market surveillance** in today's discussions:
 - NOT surveillance by Notified Bodies carrying out quality assurance
 - ONLY surveillance by public authorities of products on the market
- c) Also important to remember that, while consumer protection is one key goal of market surveillance, surveillance also has a broader role as an essential element of **enforcement** of Internal Market legislation. Instrument to determine whether all essential requirements defined in the relevant legislation are in fact being respected.
- d) Relationship between New Approach Directives and General Product Safety Directive: Commission has recently adopted a proposal for revision of the GPSD (will be presented by DG Sanco in a little more detail tomorrow afternoon).
 - The Directive is intended to function as a safety net – its safety requirements apply to consumer products for which other Community law does not contain provisions on safety and risks. NA Directives regulate all aspects of product safety and categories of risk in the sectors concerned – if necessary, by means of simultaneous application of more than one Directive. GPSD definition of safe product does NOT therefore apply in NA regulated areas.
 - However, where sectoral legislation (NA or other) covering consumer products does not contain detailed provisions regarding means of enforcement, the relevant provisions of the GPSD are intended to be applicable. Such provisions would include, for example:
 - the system for rapid exchange of information between surveillance authorities in emergency situations;
 - the obligation on manufacturers to order the recall of dangerous products if necessary to ensure consumer safety;
 - and the requirement for Member States to define the organisation and tasks of their surveillance authorities.

3. **How** does market surveillance contribute to enforcement?

Integral part of New Approach regulatory framework. Directives do not generally contain detailed provisions on surveillance, but national surveillance authorities have a fundamental responsibility to:

- check whether products placed on the market comply with relevant legislation
- and if necessary, take action to establish conformity.

There is clearly a **broad range of different structures** in place and different approaches used by Member States to fulfil these responsibilities. Natural consequence of subsidiarity, of different administrative cultures and market structures.

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4. What is the Commission doing? What is its role?

- a) Experience of New Approach market surveillance is highlighting the need to **develop administrative co-operation** between enforcement authorities.
- Communication across borders is essential if surveillance is to be effective throughout the Internal Market. With products circulating freely throughout the EU, enforcement authorities have to look much further than their own national borders.
 - Also, opportunities to benchmark with counterparts, learn from their experiences, identify good practice which could be applied
 - Should also avoid overlaps / allow economies of scale

Last year's Mutual Joint Visit Programme was important in this respect. By visiting their counterparts in other Member States, surveillance experts were able to observe different structures and strategies in operation, and to identify both good practice and points to be addressed, not just in the host country, but also at home in their own system.

Experts' reports from Visit Programme are being discussed in sector-specific **Administrative Co-operation Groups**. These Groups bring together surveillance experts from national administrations for an exchange of views on implementation of Directives and aim to improve cross-border co-operation in a very practical way. Ideal forum for information exchange and reflection on issues like notifications, co-ordinated testing campaigns.

Will hear more tomorrow about follow-up to Visit Programme.

Key point - Commission is clearly committed to **supporting and promoting administrative co-operation** between market surveillance authorities. Essential if goal of equivalent high level of effective enforcement throughout EU is to be reached.

- b) Must, however, **place market surveillance in the continuum of elements which contribute to confidence and the effective enforcement** of Internal Market legislation.

Other key aspects in this context are:

- Conformity assessment.
The experience of New and Global Approaches has demonstrated the need to reflect upon the complementarity of conformity assessment and market surveillance activities; and we could imagine a relationship between these two pillars as being inversely proportionate.
- Notified Bodies: criteria for designation and operation in practice have to be clear enough to support the confidence that MS also tries to achieve.
- CE marking constitutes another element in this context.

- 5. The anniversary of NA in May is an occasion not only to look back at NA achievements so far, but also to look ahead.** Some areas will benefit from reflection based on the experience of the New and Global Approaches in practice and the Commission is ready to make every effort to undertake justified improvements as efficiently as possible.



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The programme for this Workshop highlights a number of areas where it would certainly be useful to discuss and reflect on future development: the Safeguard Clause procedure for notifications, for example, and the scope for co-operation between customs officials and market surveillance authorities.

But the Workshop will also allow presentation and discussion of initiatives which are already contributing to more effective market surveillance – practical examples of administrative co-operation from which we should learn as much as possible. (Examples: work of EMC AdCo Group; Trapex information exchange system in the CEECs; Nordic co-operation.)

6. NA model has already proved itself to be of interest on the **international** stage – and a successful effort to achieve equivalent surveillance throughout the Internal Market can only serve to increase this interest.

Looking ahead, this could also help in considering the application of NA in **new areas of activity** which would benefit from this type of co-regulatory approach.....