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Standardization Policies

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MARKET SURVEILLANCE

Concepts and definitions

Note by the secretariat

Addendum

In accordance with the decisions taken by the Working Party on Regulatory Cooperation and Standardization Policies (WP.6) at its fifteenth session (TRADE/WP.6/2005/15/ para. 21 (i)), the secretariat prepared this document based on the discussions held at the Second UNECE International Forum on Market Surveillance and Consumer Protection held on 24 and 25 October 2005 and on documents TRADE/WP.6/2002/2/Add.6 and TRADE/WP.6/2005/11.

This document on the concepts and definitions used in market surveillance is submitted to the Working Party for comments. It will be further considered by the Advisory Group on Market Surveillance ("MARS" Group) at its next meeting in autumn 2006 with a view of consolidating a new version for final approval by the Working Party at its seventeenth session in 2007.

## **1. Introduction**

1. Surveillance is a broad concept, with many aspects, but could be defined as "Various measures taken to ensure that the intentions – and, ultimately, the requirements - of an item of legislation are complied with". The general surveillance concept then becomes synonymous with implementation of the legislation, covering everything from the publication of regulations based on the legislation to inspection and information activities.

2. The existence and performance of surveillance are regarded as duties for the State – i.e. as applied through or by a public authority – and are directed at individual parties and the general public. If the State has chosen to regulate some particular area, it must also ensure compliance.

3. A narrower and perhaps more relevant definition of surveillance, as applicable to a product and to the subject of this paper, is that of "actions intended to investigate whether those responsible for a particular product are complying with, or have complied with, the applicable regulations and, if not, to respond in an appropriate manner".

4. Another definition based on proposals submitted by countries of the Commonwealth of Independent States (CIS) is: "control/corrective actions by public or other authorized bodies regarding fulfilment of requirements set by legislation and/or mandatory regulations in respect of products or services placed on the market".

5. Regardless of the definition, this means that if a product is to be covered by surveillance, there must be legal requirements applicable to it, such as those relating to its design, manufacture, use or disposal.

6. In this paper, it is primarily the product and the regulations associated with it that are the objects of surveillance, and not the parties involved (e.g. the manufacturer, importer) as such.

7. Just what surveillance (inspection) is to involve, i.e. the object of the legislation, who is to perform the inspection, when/where it is to be performed and in what manner, can differ from one product, sector or country to another. Ultimately, this is determined by factors such as risk, functionality, proportionality, competition, economic conditions and political and legal considerations.

8. Many different ways exist in which surveillance can be carried out at the various stages of a product's life cycle. This can be illustrated using the time line of a product's life cycle, by giving a number of examples and by demonstrating the relationship between different forms of inspection and their mutual dependencies.

## **2. Stages of market surveillance**

9. Four stages can be distinguished, which are discussed below in greater detail:

(a) Design and manufacture

(b) Sales, retail sales and import

- (c) In-use stage
- (d) Recycling, recovery, disposal.

### **3. Area of market surveillance**

10. The aspects to be considered by surveillance (inspection) of a product can vary, but the following are common and a distinction can be made between minimum and more expanded functions:

- (a) Minimum requirements
  - (i) Health and safety
  - (ii) Documentation (formalities, marking, etc.)
- (b) Additional requirements
  - (i) Quality aspects
- (c) Environmental aspects (both the external environment and the user environment)
- (d) Fair competition aspects (such as respect or infringement of patents or trademarks, misleading or untrue marking or claims).

### **4. Organizational forms of market surveillance**

11. Usually all States have at least four specialized market surveillance bodies dealing with food products, medicines, industrial products and labour/safety issues. Within a specific sector further exceptions can be found. Thus, food products used in catering are usually not within the competence of market surveillance bodies.

12. In reality, the number of market surveillance bodies even in the area of industrial products can vary significantly. For example, in Croatia there is one centralized body which also deals with labour matters, but at the same time does not cover telecom products. On the other hand, in Sweden there are more than a dozen market surveillance bodies. Each organizational approach has its merits and disadvantages; but in countries with several market surveillance bodies it is useful to have a mechanism for inter-agency cooperation (such as exists, for example, in Romania and Bulgaria) for coordination of their work and that of other agencies (customs, consumer protection, etc.).

13. An important issue for market surveillance authorities is setting priorities for their controls, as it is impossible to check all goods and services placed on the market. This is done taking into account the results of previous inspections, complaints received from consumers and by risk-assessment of specific product groups (for instance, based on scientific and statistical data on risk hazards, impact of controls on minimizing risks, degree of health protection authorities would like to achieve).

**5. Examples of different types of inspection at various stages**

(a) Design and manufacture

14. When a pre-market approval is required (usually for a new product) national type approvals are issued by national authorities or State -owned testing houses. In such cases pre-market inspection and testing are obligatory. The State has overall responsibility after the product has been released onto the market, as it approved the product prior to release. State inspection of product handling can be carried out during the production stage (e.g. foodstuffs and medicines). Private third-party inspection of a product or its manufacturing system and handling can be done also by independent private parties, whose competence for the purpose has been assessed and approved by the State. Responsibility for the design of the product lies with the manufacturer, while the third-party inspection body is responsible to the manufacturer and to the State for the quality.

15. When manufacturers carry out their own inspection, without involvement of the State or private parties, the responsibility for the condition of the product rests wholly with the manufacturer.

(b) Sales, retail sales and import, from market access to the end user

16. The State can carry out inspection of products, product storage facilities (e.g. foodstuffs) and sales competence (authorization of personnel).

17. The State can also subcontract private companies to perform inspection functions. However, responsibility for the work and for any actions as a result of inspection rest with the State. Manufacturer's liability and the responsibility of other parties vary, depending on the type of inspection that was decided upon for the respective design/manufacturing stages.

(c) In-use stage

18. Recurrent inspection can be carried out by the State of products in use. The owner/user is responsible for the condition of the product.

19. Private recurrent inspection can be delegated to assessed and approved third-party inspection bodies on behalf of the State. The State is responsible for acquiring and paying for the inspection services, as well as for determining and applying any responses to the results of inspection.

20. Producers/users can have their equipment/product etc. inspected without the involvement of the State by private inspection companies. The producers/users are then responsible for the condition of the equipment/product. The State checks that the regulations are complied with by the owners/users, and that the inspection bodies possess the necessary competence.

(d) Recycling, recovery, disposal

21. State or private inspection of recycling and final storage/disposal, can be caused by environmental aspects of legislation. These aspects may also be considered during the design stage, e.g. through the use of low-environmental-impact materials or the matching of products to existing recycling/recovery systems.

22. The above forms of inspection are described in only very general terms. Surveillance and the various forms of inspection can look very different, depending on whether, how and/or when they are applied, and on how the requirements for a product are specified and applied. In other words, extensive inspection at one stage in a product's life cycle can result in lack of inspection at some other stage.

23. The Working Party concentrates mainly on the surveillance and various forms of inspection that can be relevant over the period from the introduction of a product to the market until it reaches its end user. Some practical matters relating to market surveillance are addressed below.

**6. Definition of a safe and of a dangerous product**

24. A “safe product” is one which poses no threat or only a reduced threat in accordance with the nature of its use and which is acceptable for maintaining a legally required level of protection for the health and safety of consumers. A product is deemed safe once it conforms to the specific legislation governing its safety. In the absence of such provisions, the product must comply with the specific national regulations of the country in which it is being marketed or sold, or with the voluntary national standards.

25. A “dangerous product” is defined as one where the safety of the product is not in conformity with legal norms or with such requirements that consumers are generally entitled to expect. This definition provides an objective test of the defectiveness.

26. A product will not be considered defective/dangerous solely because it is of poor quality nor will a product be considered defective/dangerous simply because a safer version is subsequently put on the market.

27. Other aspects to look at in determining safety of consumer products:

- (a) Product characteristics;
- (b) Instructions for use, assembly and maintenance;
- (c) Packaging;
- (d) Labelling and other relevant information;

- (e) Categories of potential consumers at risk when using the product (particularly children and the elderly);
- (f) Possibility of a product “migrating” (when products that are safe in the hands of trained professionals and indeed designed with such groups in mind are then supplied to untrained consumers, it is said that they have “migrated”. In such cases, general product safety principles shall be taken into account and applied ).

## **7. Powers of market surveillance authorities**

28. In order to ensure that only safe consumer products are circulating on the market, enforcement authorities have a wide range of powers at their disposal. Such powers and corrective action may include:

- (a) To enter the production and marketing facilities;
- (b) To request the necessary documentation and explanations (e.g. on the use of trademarks, verification of marking);
- (c) To take samples of products and carry out the necessary tests;
- (d) To request the elimination of non-conformity problems identified during an inspection, suggest appropriate measures and take other corrective action;
- (e) In case of unsafe goods, to forbid their supply, marketing; order their removal from the market (recall from consumers), oblige operators to issue warnings to the public and, if necessary, demand the destruction of goods (all such actions are at the expense of the producer concerned);
- (f) To impose fines, to seize the unsafe or unlawful goods (placed on the market without proper documentation); inform the public of the risks; distribute information to economic operators and consumers; ban exports to third countries;
- (g) To subcontract some functions (e.g. sampling or testing) to other State or private bodies, with the responsibility staying with the designated State authority.

## **8. Aspects of a product controlled during market surveillance**

29. The characteristics and aspects of a product to be controlled by trade inspectors differ depending on national legislation and may include:

- (a) Safety, quantity, measure, weight of a product;
- (b) Time of selling (and/or age of customers, for example, for spirits and tobacco products) and place (e.g. perishable produce requiring refrigeration); expiry date;
- (c) Quality of goods and if a product corresponds to its normally expected use;

- (d) Conditions of storage of goods and of their transport; their disposal;
- (e) Required marking and labelling (e.g. consumer information, hazard warning);
- (f) Intellectual property rights and unfair competition (trademarks and logos; false or misleading labelling and advertising, etc.).

30. The measures taken by market surveillance authorities shall be proportionate to the nature of the non-conformity identified and to the potential danger caused by it. The main responsibility for the safety of products lies with the manufacturer. Hence, market surveillance officers shall work closely with economic operators, in particular on measures to prevent non-conformity. Voluntary action by manufacturers shall be especially encouraged (including in legislation) as an alternative to formal enforcement action.

31. When possible, dialogue is initiated with manufacturers, which also gives them an opportunity to take steps to correct any faults before the adoption of legal actions. This approach is considered to be more effective and produces better results than direct enforcement of consumer product legislation.

## **9. Issues for future discussion**

32. At UNECE and other meetings on market surveillance, experts raised a number of matters and problems relating to the practical work of trade inspectors, which requires further analysis and exchange of experience and information. These issues include:

- (a) Scope, definition, sectors and areas for market surveillance;
- (b) Choice of priorities for surveillance (risk-assessment methodology);
- (c) How to avoid potential abuse of business by inspectors;
- (d) Which terms and definitions in the area of market surveillance need to be “harmonized”;
- (e) The link between market surveillance and consumer protection on the national level (what activities shall fall under each area);
- (f) Experience with the cooperation and involvement of industry and consumers in surveillance activities;
- (g) Experience with inter-agency cooperation on a national level.

34. Besides national issues, an exchange of experiences would be useful on matters relating to examples of trans-border cooperation and information exchange opportunities within the framework of surveillance.

35. Reality, of course, is more complex than as described in this paper. This document is only an attempt to describe various forms of surveillance and their relationships to each other, without making any judgements on their efficiency.

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