



The Project is implemented  
by European Consultants Organisation (ECO)  
in consortium with THALES Services SAS,  
STELLA Consulting, ESTEP and EFICOM



The Project is funded  
by the European Union

## **EXPERT OPINION ON THE RECENT DRAFT LAW ON MARKET SURVEILLANCE**

### **1. Introduction**

The performance of market surveillance activities is one of the ENP-AP priorities and a key condition for the signature of an ACAAs (Agreement on Conformity Assessment and Acceptance of Industrial Products) 1 between the EU and Ukraine for some categories of products. To this end a preliminary agreement has been concluded between the Services of the European Commission and Ukraine in Brussels on 19 December 2005.

In this context, at least two preliminary draft law (not yet registered at the Verkhovna Rada) are circulated. One of them is originating from the Ministry of Economy while the second one has been drafted by the DSSU (State Committee for standardisation, technical regulations and consumer protection).

UEPLAC got one of those papers from the IFC Project “SME Policy development” and takes this opportunity to expose the main shortcomings and the best practices to keep in mind on the occasion of the regulation of market surveillance activities. Whatever the author of the draft law and the fact that this draft law might be never registered, the objective of this background paper is to use a concrete example on the main issues liable to be dealt with in any draft law on the same subject-matter, duly submitted to the scrutiny of the Verkhovna Rada. The approach used in this background paper may apply *mutatis mutandis* to any draft law on market surveillance.

The criteria used to provide the observations on the draft law are drawn on the following background:

- Guidelines of the European Commission for the correct implementation of the Directives New Approach.<sup>2</sup>
- Provisions on the “Community market surveillance framework” contained in the “Proposal for a Regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products”.<sup>3</sup>

### **2. Concept of market surveillance in the draft law**

Originally the concept of “Market Surveillance” on the EU level is designating enforcement measure to be taken by Member States to ensure that only those products

---

<sup>1</sup> See, on this instrument available to third countries, Commission staff working paper: Agreements on Assessment and Acceptance of Industrial Products, SEC(2004)1071 of 25.08.2004.

<sup>2</sup> Vademecum on European standardisation, 1st March 2004.

<sup>3</sup> See, in particular, Chapter III of this proposal for a Regulation in the document COM(2007) 37 final of 14.2.2007.

which conform to the appropriate requirements of the New Approach Directives or the Directive 2001/95/EC on general product safety (all of them, concerning only the non-food sector) can be placed on the market.

Actually, the practice of market surveillance in the EU Member States is extended also to the control of all products at the end of the chain of production and distribution and includes therefore the control of the compliance with the requirements of the Old Approach Directives, especially with regard to the requirements on labelling.

Nevertheless, market surveillance, does not comprise controls carried out in specific sectors such as veterinary products, pharmaceuticals, motor vehicles where the EU legislation set out specific procedures. Furthermore, market surveillance, is always distinguished from the control on the safety and hygiene of foodstuffs.

Implicitly, the draft law retains the narrow concept of market surveillance, but saying the law does not cover the control on the “conformity with safety requirements of food products and food additives” is not so appropriate. First, by mentioning only food additives beside food safety may imply that, *inter alia*, control of food contaminant falls within the scope of the law. One may think also that control of food labelling falls within the scope of the law.

The scope of the law has to be specified very carefully because it entails the allocation of responsibility between public authorities. Not paying specific attention to this issue could lead to overlapping duties and multiplicity of controls of economic operators by various authorities, which is already a very serious concern in Ukraine.

While retaining the concept of market surveillance, as described by the services of the European Commission, the law forgets anyway that it is clear in the EU legislation that the notion applies as well to market surveillance operations at the external borders (see, Regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries). The draft law never mentions the participation of Customs Authorities in market surveillance operations at the borders of Ukraine.

### **3. Content of market surveillance activities in the draft law**

#### **3.1. Best practice**

In the draft law, market surveillance duties and obligations are compliant with the EU recommendations on the following:

- Necessary powers and resources of market surveillance authorities are well detailed.
- Power to require economic operators to make available documentation and information.
- Power to enter the premises of the economic operators concerned where it appears to them to be necessary.
- In the case of destructive tests, the market surveillance authority is bearing the cost but it is reimbursed by the economic operator if the product appears to be unsafe.
- Establishment, implementation and periodic updating of market surveillance programmes through annual national and regional plans.
- Statement of reasons where there is a prohibition or a restriction for the marketing of products.
- Rights of the economic operator to put forward its viewpoint prior to the adoption of a restrictive measure.
- In case of decision for the withdrawal of the product from the market or for the recall of the product, provisions on the deadline to communicate this decision to the economic operator concerned.
- Co-operation with economic operators on actions which could prevent or reduce risks caused by products made available by them.
- Definition of a national system of exchange of information for the withdrawal or the recall of products.
- Views to be “associated” to the Community Rapid Information System (RAPEX) through the Article 32 on international co-operation based on the conclusion of specific agreements.

## **3.2. Shortcomings**

3.2.1. The draft law is not sufficiently clear or detailed on the following issues:

- Where the EU requirements relate to appropriate checks on the characteristics of products on an adequate scale, through documentary, and, where appropriate, physical and laboratory checks on the basis of representative samples, the draft law does not express the same idea of proportionality between the risk incurred and the response to prevent the occurrence of the risk.
- With regard to the necessary independence of market surveillance authorities from standardization, accreditation and conformity assessment bodies, the draft law just mentions shortly that the functions of market surveillance bodies are not compatible with the functions of certification bodies and the functions of various state bodies.
- On the question of monitoring of accidents and damage to health which are suspected to have been caused by unsafe products, the response in the draft law is limited to the obligation made for the market surveillance body to take stock of the results of market surveillance activities and to propose measures for improvement of the legal framework and the annual programme.
- Concerning the follow up and updating of scientific and technical knowledge concerning safety issues, the indirect and insufficient response given in the draft law is that representatives of scientific establishments will be members (among other members) of the Board of the Central Market Surveillance body.

3.2.2. The draft law does not fully comply with the EU requirements on market surveillance as far as it does not address the following issues:

- Organisation of procedures (or reference to other procedures in the national legal framework) in order to follow-up complaints or reports on issues related to risks arising from products falling under the national legislation laying down mandatory requirements for such products or providing on marking of such products.
- Periodic review and assessment of the functioning of the surveillance activities.
- Provisions on the confidentiality or information obtained in the course of market surveillance operations and provisions on professional secrecy which have been deliberately removed from the draft law.
- Provisions on the duty to inform the economic operator on the remedies available (administrative and/or judicial review) and the time limits to bring such actions.

#### **4. Authorities in charge of market surveillance activities**

Article 10 of the draft law deals with the bodies in charge of market surveillance activities. Provisions of this article are still “under construction”. As a result - maybe also because that is a controversial issue - there is no indication on the designation of the supervisory body for market surveillance.

Other provisions make it clear that there will be a Central body and regional and local authorities. This networking is welcome.

The provision on collaboration/exchange of information with other State authorities, bodies of local Government, NGO and general public is welcome as well, although being rather vague.

To deal with the co-ordination of market surveillance bodies, the draft law simply skips the issues by providing that powers and activity of market surveillance bodies are defined in this draft law, in the law “on consumers’ rights protection” and “other laws”.

Furthermore the draft law envisages the creation of a new body without the removal of existing inspection bodies. In other words, it adds another layer of inspection.

That is the heart of the draft law and, unfortunately, the most questionable part of it.

Where it is established through various reports of the international community that the business environment in Ukraine suffers from an excess of inspections that are not conducted in the proper way<sup>4</sup> and where it is question to remedy the issue of overlapping functions of bodies in charge of market surveillance and official controls to set up a coherent system to ensure quality and safety of goods, the draft law is fully missing the desirable target.

Market surveillance is a system which cannot be limited to the allocation of responsibilities to a unique body. The point is to build a formal network where resources of various line institutions and their decentralised administrative bodies/laboratories (e.g., Ministry in charge of consumer protection<sup>5</sup>, Ministry of health, Ministry in charge of agriculture, Customs authorities) may be used in common under the supervision of a coordinating body.

To this end any draft law aiming at establishing a market surveillance system should put the focus on the following:

- **Delimitation of responsibilities** between various market surveillance authorities.
- **Communication and co-ordination** between market surveillance authorities on the **national and local** levels.

---

<sup>4</sup> See, for example the results of a survey in the report “Business Environment in Ukraine – 2005” co-funded by the EU and IFC/World Bank.

<sup>5</sup> Market surveillance is crucial to protect the consumers from unsafe or non-compliant products and to fight against unfair competitive advantage for operators making savings on the compliance costs and consequently offer their products to lower prices than their competitors who respect the law.