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Legal Opinion

Comments on the Law of Ukraine “On Market Surveillance”

**Draft law submitted to the Verkhovna Rada by the Secretariat of the
President of Ukraine (No 1365 of 17 January 2008)**

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CONTENTS

Introduction: background and methodology

Market surveillance system in the EU Member States

Trends on the EU level

European context for market surveillance activities in Ukraine

I - Scope of market surveillance activities

1.1. Relevant provisions

1.2. Areas of public interest taken into consideration by the draft law

1.3. Areas formally excluded from the scope of the draft law

1.4. Services and work in relation to the scope of the draft law

1.5. Discrepancies in relation to the GPSD

1.6. Requirement for the safety of products based mostly on technical regulations

1.7. Intellectual property rights and market surveillance

1.8. Product safety and international trade

1.8.1. Safety of imports

1.8.2. Safety of exports

1.9. Other comments on certain definitions in the draft law

II – Main principles governing market surveillance activities

III – Obligations of manufacturers and distributors

IV – Market surveillance authorities

4.1. Relevant provisions

4.2. Central authority

4.2.1. Vertical organization of market surveillance

4.2.2. Integration of the new institution within or beside existing structures dealing with standardization and consumer protection

4.2.3. Legal protection of officials

4.3. Other executive bodies

4.4. Involvement of other stakeholders

V – Market surveillance measures

5.1. Relevant provisions

5.2. Extent to which the draft law provides for a balanced and gradual enforcement

5.2.1. Decision making process

5.2.2. Planning of activities based on risk analysis

5.2.3. Grounds for inspection

5.2.4. Injunctions issued by market surveillance officials

5.2.5. Sampling and testing as central operations of market surveillance

5.3. Response to emergency situations

5.4. Sanctions

5.4.1. Administrative offences

5.4.2. Criminal prosecutions

5.4.3. Other offences defined in other pieces of legislation

VI– Protection of the rights of manufacturers and distributors

6.1. Relevant provisions

6.2. Right to defence

6.3. Sampling and testing

6.4. Responsibility incurred by officials

6.5. Confidentiality

VII – Information Support System and international co-operation

Conclusions

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Introduction: background and methodology

The approach used in this legal opinion takes account of the following benchmarks.

Market surveillance system in the EU Member States

A market surveillance **system** is in place in all EU Member States because that is a fundamental element to ensure the free movement of goods within the Internal Market.

On the one hand, this system derives from the effective enforcement of the national legal measures implementing the EC Directives “New Approach” where the correct affixing of the CE marking on a wide range of industrial products is controlled by public authorities **after the placing of the products on the market**.

On the second hand, the existence of a market surveillance system is a condition for the correct implementation of the Directive 2001/95/EC on **General Product Safety** (GPSD)¹⁰⁵.

In addition, it is observed that, beside the two main functions mentioned above the public authorities in charge of market surveillance in most of the EU Member States are also empowered to **enforce the legislation on consumer protection** (protection of economic interests beside the protection of health and safety of consumers).

Nevertheless none of the 27 EU Member States has adopted a specific piece of legislation to address market surveillance as a whole. The system in place stems generally from a combination of various pieces of legislation where the dominant legal framework is set out in the legislation implementing the GPSD or in the legislation on the inspection of economic activities or the enforcement of consumers rights.

¹⁰⁵ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety.

Trends on the EU level

In order to enhance the competition on equal footing among the economic operators throughout the EU and to reinforce accordingly the confidence of consumers on the free movement of goods within the Internal Market, the European Commission has put forward a proposal to allow comparable results in market surveillance activities carried out by the EU Member States. This proposal has been examined by the European Parliament and the amendment proposed by the European Parliament have been accepted by the European Commission (agreement of 21 February 2008).

This legal opinion takes stock of those two documents:

- Proposal for a Regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products (COM(2007)0037).
- Session document of the European Parliament A6-0491/2007 of 4.12.2007 containing legislative resolutions on the text proposed by the European Commission.

European context for market surveillance activities in Ukraine

The performance of market surveillance activities is one of the ENP-AP priorities and a key condition for the signature of an ACAA (Agreement on Conformity Assessment and Acceptance of Industrial Products) 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.

Ukraine is not bound by the European legislation on the General Safety of Products or the conformity assessment modules applicable for compliance with EC Directives “New Approach”. Nevertheless, depending on the continuing political willingness to take a stake in the Internal Market of the EU and the completion of the necessary steps for the **successful conclusion of the ACAA**, it is assumed that market surveillance in Ukraine should lead to **results comparable to those achieved in the EU**. This objective can be met only by a closer approximation of the Ukrainian legislation to that of the EU and the effective functioning of the national legislation.

Moreover, since Ukraine became a WTO Member on 16 May 2008, commitments undertaken to comply with the TBT agreement imply that the effective implementation of the distinction between voluntary standards and technical regulations cannot be delayed anymore¹⁰⁶. The correct application of this basic distinction¹⁰⁷ is deemed to give a new picture of the context of market surveillance activities

¹⁰⁶ See for example the point 301 of the Report of the Working Party on the Accession of Ukraine to the World Trade Organization (WT/ACC/UKR/152 of 25 January 2008):

The representative of Ukraine also confirmed that.... from the date of accession Ukraine would prepare, adopt, and apply standards and technical regulations only in conformity with the TBT Agreement..... The Working Party took note of these commitments.

¹⁰⁷ In the WTO agreement on Technical Barriers to Trade (TBT):

“Technical regulation” means “A technical specification, including the applicable administrative provisions, with which compliance is mandatory.” In addition, for the purposes of this Agreement, this definition covers also a standard of which the application has been made mandatory not by separate regulation but by virtue of a general law.

“Standard” means “A technical specification approved by a recognized standardizing body for repeated or continuous application, with which compliance is not mandatory.”

in Ukraine beyond the current prevalent approach where market surveillance is commonly and mistakenly understood as more stringent official controls on products and economic operators.

I - Scope of market surveillance activities

1.1. Relevant provisions

The scope of market surveillance activities mainly derives from the following:

- Definitions (Article 1)
- Areas excluded from the scope of the draft law (Article 2)
- Applicable legislation (Article 3)

Other indications on the subject-matters covered by the draft law stem from the description of responsibilities and powers of market surveillance authorities under the section 2 of the draft law and various references to the background against which safety of product is assessed (including amendments proposed to the existing legislation in the Section 8 of the draft law on Transitional and Final Provisions).

1.2. Areas of public interest taken into consideration by the draft law

The safety of product in the definition laid down under the Article 1 of the draft law intends to address the **“health and safety of persons”**.

That is also the main concern of the GPSD (article 2b). However in the proposal of a Regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products, amendments proposed by the European Parliament address a broader scope of public interests. For example, in the amendment 1 to Recital 1, against the proposal of the European Commission which mentions “a high level of protection of public interests, such as health and safety”, the European Parliament specifies “high level of protection of public interests, such as **health and safety, protection of consumers and of the environment**”.

Regardless of the definition laid down under its Article 1 the draft law mentions throughout the text other areas subject to the protection granted by the law. Life and health of people, **animals, plants and environment** is mentioned under several provisions of the draft law:

- Article 1 on the definitions of “minor violations”
- Article 18(4) on the criteria for the drawing up or the updating of the national market surveillance plan
- Article 20(1) on the grounds for inspections of products
- Articles 20(5) and 21(5) on the policy of sampling

This extended notion of public interests for the purpose of market surveillance is in line with the most recent approach on the EU level and the public interests protected by market surveillance systems in place in a number of EU Member States, but for the sake of legal certainty, it would be relevant to seek more consistency along the text of the draft law.

Moreover, it seems that **the protection of the economic interests of consumers** is also under the remit of the market surveillance authority.

The Law “On Consumers Rights Protection” is not included under the Article 3 concerning the Legislation of Ukraine on Market Surveillance but amendments to this Law under the Section 8 of the draft law indicate that the “central consumer rights protection authority” is the same as the “central market surveillance and consumer rights protection authority”. That is fully in line with the best practices in a number of EU Member State where, the general market surveillance authority is also in charge of the enforcement of the wide range of consumers rights.

1.3. Areas formally excluded from the scope of the draft law

Are explicitly excluded from the scope of the draft law (Article 2) a number of areas covered by other pieces of legislation.

The chart below shows the differences between the draft law and the European legal framework on market surveillance with regard to the regulated areas subject to a specific regime of official controls.

Regulated area excluded from the scope of the draft law on market surveillance (Article 2)	Regulated areas excluded from the scope of general framework on market surveillance in the EC legislation (Proposal for a Regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products - COM(2007)37
<p>Foodstuffs, food additives including flavorings, dietary supplements and support materials for their processing. Products of animal origin</p> <p>Veterinary drugs.</p> <p>Medicinal products. (blood and vaccines?)</p> <p>Perfumery and cosmetic products, personal hygiene products.</p> <p>Narcotic substances, psychotropic substances and their precursors.</p> <p>Tobacco products.</p> <p>Pesticides and agrochemicals</p>	<p>Requirements of food law and procedures in matters of food safety. Official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.</p> <p>Veterinary medicinal products. Authorisation and supervision of medicinal products for human and veterinary use.</p> <p>Medicinal products for human use. Medical devices, in vitro diagnostic medical devices, active implantable medical devices. Standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components. Standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.</p> <p>Cosmetic products (which comprise any substance or preparation intended to be placed in contact with various external parts of the human body).</p> <p>Drug precursors.</p> <p>Manufacture, presentation and sale of tobacco products.</p> <p>No equivalence.</p>

Ethyl alcohol, cognac and fruit spirit, alcoholic beverages.	No equivalence.
Nuclear materials and other products deriving from the use of nuclear power	No equivalence.
Products for military purpose.	No equivalence. The EC Treaty does not cover goods used only for military purpose (but garments and other equipments which can be used also for civil purpose are covered by the EC Treaty).
Urban development projects (clarification is needed, does that mean construction work?).	No equivalence.
No equivalence.	Type-approval of two or three-wheel motor vehicles. Type-approval of motor vehicles and their trailers. Type-approval of agricultural or forestry tractors, their trailers and interchangeable towed machinery, together with their systems, components and separate technical units.
No equivalence.	Measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery.
No equivalence.	Rules in the field of civil aviation.

The comparison between the EC horizontal legal framework on market surveillance in the chart above has not the purpose to encourage similar exemptions in the draft law.

First the two legal systems are not interconnected.

Second, the practice of market surveillance in the EU Member States varies considerably as regards the economic areas subject to officials controls of the main market surveillance authority in each individual Member State.

Third, the approach proposed by the European Parliament is to give the broadest base to the horizontal legislation on market surveillance in accordance with the principle *lex specialis*¹⁰⁸. As a result, in its final version (document A6-0491/2007), the draft Regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products, does contain any exclusion regarding the scope of activities covered by of the Regulation.

The application of the principle *lex specialis* would simplify considerably the Article 2 of the draft law. Otherwise it is recommended to review carefully the scope of the law to ascertain that there are no other categories of products to add or to exclude with, where appropriate, a less peremptory wording to introduce the relevant differentiations on the specific aspects of the products covered by other pieces of legislation.

It is also necessary to draw the attention of the law-maker on the fact that, in the context of the establishment of a Rapid Alert System (article 31), which could be at a later stage connected to the EC RAPEX system (Article 33), the wording of the provisions of the Article 2 of the draft law on the activities excluded from the scope of the law could be more circumstantiated to allow for the notification of risks posed by products covered by RAPEX.

The products excluded from RAPEX because they are covered by specific and equivalent notification mechanisms established by Community legislation concern the following:

- Pharmaceuticals covered by Directives 75/319/EEC3 and 81/851/EEC;
- Medical devices (covered by Directive 93/42/EEC), active implantable medical devices covered by Directive 90/385/EEC, in vitro diagnostic medical devices covered by Directive 98/79/EC;
- Food and feed covered by Regulation (EC) No 178/2002.

¹⁰⁸ See, for example, the Amendment 4 to the Proposal for a Regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products (COM(2007) 37) as amended by the European Parliament (document A6-0491/2007) where it is laid down that the new Regulation “*should apply only in so far as there are no specific provisions with the same objective as those established hereby in other, existing or future, rules of Community law, such as Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product Safety*”.

1.4. Services and work in relation to the scope of the draft law

Article 2 of the draft law (item 10 of paragraph 2) specifies that work and services do not fall within the scope of the law. The doubt arises when the draft law refers to the definition of “product” contained in the law “On Consumers Rights Protection”. The definition of products laid down in the article 1(19) of the law “On Consumers Rights Protection” would mean that the draft law covers goods, work and services.

In several EU Member States, services fall within the scope of the national measures implementing the GPSD despite the fact that the GPSD does not cover the safety of services but only the safety of goods provided through the provision of certain services.

There would be no objection from the EU to include services within the scope of the draft law.

With regard to work, market surveillance authorities in the EU Member States always deal with the safety of goods used by workers (for example Personal Protective Equipments or machinery used by workers at their workplace) despite the scope of the GPSD which covers only the safety of products for personal use or mixed use – personal and professional. That is part of the enforcement of the EC Directives “New Approach” and other pieces of EC legislation on health and safety at work.

A definition of “product” in the draft law would clarify whether or not services and work fall within the scope of the draft law.

1.5. Discrepancies in relation to the GPSD

The draft law does not mention that product safety applies to new and second-hand products but under the Article 2(4) the draft law reflects that antiques and products to be repaired or reconditioned, where the customer is informed of this situation, are excluded from the scope of the duty to place safe products on the market. However “works of art and folk artistic crafts” excluded in the draft law are covered by the GPSD as far as they are made available in the course of a commercial activity.

In addition the draft law does not mirror that products have to be safe whatever the selling techniques (Recital 7 of the GPSD) and regardless of their free supply/availability or not.

1.6. Requirement for the safety of products based mostly on technical regulations

The definition of “safe product” in the Article 1 of the draft law duplicates some elements of the GPSD (article 2 b). For example, it reflects the notions of “normal or reasonably foreseeable conditions of use”, conditions of “putting into service, installation and maintenance requirements”, presentation of any risk or only the minimum risk compatible with the product’s use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons..”

Factors to be taken into considerations to assess the safety of products are also similar to the four sub-items of the second paragraph of article 2(b) of the GPSD¹⁰⁹.

¹⁰⁹ Points taken into consideration in the GPSD to assess the risk presented by a product:

In line with the GPSD, the feasibility of obtaining higher levels of safety does not constitute a ground for considering a product to be dangerous.

Surprisingly the draft law translates the factual notion of foreseeable “duration” of the use of the product in the GPSD by legal considerations deriving from of “expiry date” as defined in the law “On Consumers Rights Protection”. In this law, the expiry date refers to normative and legal acts or terms in contracts.

Despite the multiple points of convergence between the draft law and the EC legislation on the scope of market surveillance activities, there is a considerable and crucial discrepancy between the draft law and the rationale behind the nature and objectives of the market surveillance in the EU.

In the draft law, the criteria to determine that a product is deemed to be safe refer only to the compliance with technical regulations while in the EU the elements to be taken into consideration include also international and national standards, good practice in force in the sector concerned, the state of art and technology and, more generally, the reasonable consumer expectations concerning safety (article 3 (2) and (3) of the GPSD).

The draft law contains extensive references to compliance with technical regulations, conformity assessment procedure and use of the National Compliance Mark, for example:

- Definition of “product safety requirements” in article 1 of the draft law which refers only to technical regulations;
- Article 7(5) which mentions the necessary steps to launch a product on the market (implementation of conformity assessment procedures, use of the National Compliance Mark, launch of the products with the compliance declaration or certificate of compliance);
- Article 8(1) on the emphasis put on the duty of distributors to ensure compliance with technical regulations providing for mandatory compliance assessment and affixing of the National Compliance Mark;
- Article 19(3) on the analysis of samples on the ground of safety requirements set out in technical regulations;
- Articles 20 and 21 on non-conformities detected during inspections which relate exclusively from the failure to apply technical regulations and conformity assessment procedures;

This fully-fledged regulatory approach of market surveillance could not produce similar results as those achieved in the EU because in the specific context of Ukraine the practical distinction between standards and technical regulations is not yet effective.

1.7. Intellectual property rights and market surveillance

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- “(i) the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;
 - (ii) the effect on other products, where it is reasonably foreseeable that it will be used with other products;
 - (iii) the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;
 - (iv) the categories of consumers at risk when using the product, in particular children and the elderly.”

The draft law does not empower directly and clearly market surveillance authorities to ensure the protection of intellectual property rights. That is however a classic area of intervention of the market surveillance authorities in a number of EU Member States because uncovered unsafe products are very often linked to products infringing intellectual property rights or at least unfair practices.

Amendments to the Law of Ukraine “On Consumer Rights Protection” (under Section 8 “Transitional and Final Provisions” of the draft law)¹¹⁰ do not provide either for a definition of counterfeit products compatible with the EC legislation¹¹¹ and this shortcoming impairs also other amendments to the Law of Ukraine “On Consumer Rights Protection”¹¹².

¹¹⁰ Article 1 (27) shall read as follows:

“counterfeit products” shall mean products, the composition of which does not correspond to the information about such products, as specified on such products, or products manufactured with technological violations, or with the illegal use of a certain trade and service mark, or by way of copying of another form, packaging or exterior design, as well as by way of illegal reproduction of another person’s product”

¹¹¹ Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights.

Article 2 (1)

For the purposes of this Regulation, ‘goods infringing an intellectual property right’ means:

(a) ‘counterfeit goods’, namely:

(i) goods, including packaging, bearing without authorization a trademark identical to the trademark validly registered in respect of the same type of goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the trademark-holder’s rights under Community law, as provided for by Council Regulation (EC) No 40/94 of 20 December 1993 on the Community trademark or the law of the Member State in which the application for action by the customs authorities is made;

(ii) any trademark symbol (including a logo, label, sticker, brochure, instructions for use or guarantee document bearing such a symbol), even if presented separately, on the same conditions as the goods referred to in point (i);

(iii) packaging materials bearing the trademarks of counterfeit goods, presented separately, on the same conditions as the goods referred to in point (i);

(b) ‘pirated goods’, namely goods which are or contain copies made without the consent of the holder of a copyright or related right or design right, regardless of whether it is registered in national law, or of a person authorised by the right-holder in the country of production in cases where the making of those copies would constitute an infringement of that right under Council Regulation (EC) No 6/2002 of 12 December 2001 on Community designs or the law of the Member State in which the application for customs action is made

(c) goods which, in the Member State in which the application for customs action is made, infringe:

(i) a patent under that Member State’s law;

(ii) a supplementary protection certificate of the kind provided for in Council Regulation (EEC) No 1768/ 92 (1) or Regulation (EC) No 1610/96 of the European Parliament and of the Council;

(iii) a national plant variety right under the law of that Member State or a Community plant variety right of the kind provided for in Council Regulation (EC) No 2100/94

(iv) designations of origin or geographical indications under the law of that Member State or Council Regulations (EEC) No 2081/92 (4) and (EC) No 1493/1999;

(v) geographical designations of the kind provided for in Council Regulation (EEC) No 1576/89.

¹¹² In the draft law, amendment proposed to Article 26

- in the first sentence of clause 3 of part one, the word “quality” shall be replaced with the word “regarding counterfeiting”; counterfeit”;

- in the second sentence of clause 3 of part one, the words “products of improper quality and/or counterfeit products” shall be replaced with the words “counterfeit products”;

- in clause 5 of part one, the words “characterize the quality of products, raw materials, materials, and components used for production of such products” shall be replaced with the words “allow to detect the fact of counterfeiting the products”

In the draft law, amendment proposed to Article 28

1.8. Product safety and international trade

1.8.1. Safety of imports

The draft law does not foresee specific actions of market surveillance carried out by Customs authorities at the external borders of Ukraine.

This cross-border dimension is an important element of the European policy on market surveillance. In the EU more than half of non-conformities detected and notified through RAPEX relate to products manufactured in third countries (48% from China, 14% from other non-EU countries and 17% from unknown countries¹¹³). Customs authorities which perform checks for the purpose of customs clearance are better placed than other executive authorities to uncover unsafe products before the release for free circulation of the products on the market. It is at this stage that a preventive action is the most efficient.

That is the rationale behind the Regulation (EEC) No 339/93 on checks for conformity with the rules on product safety in the case of products imported from third countries¹¹⁴.

1.8.2. Safety of exports

Article 13(3) of the GPSD prohibits export from the Community of dangerous products for which corrective actions have been ordered to remedy non-conformities. This provision is not reflected in the draft law.

1.9. Other comments on certain definitions in the draft law

Some definitions under the Article 1 of the draft law may overlap or even contradict concepts and definitions laid down in other pieces of legislation. As a general rule, to ensure consistency of the overall legal framework and prevent diverging interpretation it is recommended to stick to uniform definitions of the same concepts. For example, it should be carefully considered whether the definition of “marking” and “unlawful use of the National Compliance Mark” are useful and whether it would not be preferable to make reference to definitions laid down in other pieces of legislation (e.g, legislation on standardisation and conformity assessment, legislation on consumer protection) as far as those definitions are already in line with similar concepts in the EU legislation.

In parallel, we suggest to pay attention to references made to definitions contained in other pieces of national legislation. The related definitions may have no equivalence in the EU system of market surveillance and may therefore conduct to undesirable results. This consistency is addressed by the draft

Article 28 clause 3 shall read as follows:

if any products, which do not comply with their safety requirements, as prescribed by the technical regulations for this particular type of products, or any counterfeit products are detected, promptly notify respective territorial consumer rights protection units and other authorities in charge of control and supervision of the safety of products”.

¹¹³ Annual Report 2006 on the operation of RAPEX.

¹¹⁴ This Regulation (EEC) No 339/93 of 8 February 1993, slightly amended, is now integrated in the Proposal for a Regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products (COM(2007)0037).

law in its Section 8 (in particular, through amendments to provisions of the existing legislation). Unfortunately complementary efforts are still needed to bring in line with the EU legislation key pieces of national legislation which may impact the results of market surveillance activities: Law of Ukraine “On Consumer Rights Protection”, Law of Ukraine “On Confirmation of Conformity”, Law of Ukraine “On Standardization”, Law of Ukraine “On Standards, Technical Regulations and Conformity Assessment Procedures”.

In addition, it is observed that the draft law intends to define the concept of “market surveillance”¹¹⁵. That is not an easy exercise. Since the borderlines of market surveillance may vary from one country to another and are also very flexible and evolving in individual countries, the EU did not set out any formal definition of this concept. At our best knowledge, when transposing the GPSD, the EU Member States escaped this difficulty as well.

II – Main principles governing market surveillance activities

The principles underlying market surveillance activities are exposed under the Article 5 of the draft law. They contain all the elements of a modern market surveillance system:

- Use of a sufficient number of qualified and experienced staff with the necessary professional integrity;
- Functional independence;
- Operations carried out in an impartial and non-discriminatory way;
- Prevention of conflict of interest with bodies in charge of conformity assessment;
- Proportionality (actions are commensurate with the degree or risk of non-compliance and strike a proper balance between consumer safety and trade opportunities);
- Co-operation with economic operators on actions to prevent or reduce risks caused by certain products;
- Promotion of voluntary actions by economic operators;
- Planned nature and consistency of market surveillance activities (implementation of market surveillance programmes);
- Observance of confidentiality and professional secrecy.

Other principles are more specific to Ukraine and reflect the requirements of the Law No 877 V of 5 April 2007 on the fundamental principles for State inspections in the field of economic activities:

- Lawfulness of measures;
- Non-duplication of market surveillance operation by various state authorities.

¹¹⁵ Reference is made to compliance with technical regulations, correct affixing of the National Compliance Mark and reliable comprehensive information on product safety.

See also in Section 8 (Transitional and Final Provisions), amendment to the Law of Ukraine “On Standards, Technical Regulations, and Compliance Assessment Procedures”

Paragraph sixteen of Article 1 shall read as follows:

“market surveillance” shall mean a kind of state surveillance (control) over the compliance of launched products with the relevant technical regulations, the lawfulness of applying the National Compliance Mark on them, and the completeness and authenticity of information about such products”.

Nevertheless a central element is missing (probably in line with the logic that one single authority could deal with market surveillance). Whatever the importance and prevalence given to a central authority, it should be set out, among the basic principles of market surveillance, **the obligation to ensure communication and co-ordination between the central authority and authorities which carry-out inspections in accordance with other pieces of legislation**¹¹⁶.

It is also suggested to give more substance to the principle of proportionality in expressing the idea of **graduation in the scale of remedial measures** to be ordered by the market surveillance authorities. Furthermore, it is recommended to mention the role of market surveillance in relation to direct interests of consumers (follow up of complaints¹¹⁷, alert about products presenting a risk¹¹⁸) and the role of market surveillance in **gathering intelligence on accidents** and developing **scientific and technical knowledge concerning safety issues**.

III – Obligations of manufacturers and distributors

Obligations of manufacturers and distributors are mainly contained in the Articles 7 to 9 of the draft law.

In line with the definition laid down in the GPSD, the draft law assimilates the importer to the manufacturer when the manufacturer is not represented otherwise in Ukraine. The generic concept of distributors in the GPSD (which prevent any sterile discussion on the role of the economic operator in the supply chain) is replaced by the concept of “suppliers and sellers” in the draft law. To facilitate the implementation of the law, it is suggested to come back to the formulation of the GPSD and to assimilate also to manufacturers (or producers) **other professionals in the supply chain whose activities may affect the safety properties of a product**.

Most of the provisions under the Article 7 of the draft law on “Responsibilities of Manufacturers of the Products” derive from the GPSD or are compatible with this Directive:

- Placing on the market of safe products;
- Provision of adequate information to consumers on risks posed by products;
- Adoption of measures to be informed on the risks products may present;

¹¹⁶ See, in this respect, Article 16(1) of the Proposal for a Regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products (COM(2007)0037).

¹¹⁷ Complaints from consumers represent an important mean to uncover unsafe products. That is recognised in the provisions of the draft law on the planning of market surveillance operations. However, the draft law does not provide for concrete measures to organise and facilitate complaints of consumers in relation to the safety of products. The only provision to address indirectly and partially this issue is found in the Final Provisions of the draft law concerning amendments to the article 26(2) of the law on Consumer Rights Protection: “*A consumer shall file his or her application in writing and shall specify therein his or her full name, place of residence, series and number of the passport or another document establishing identity, as well as the details of the respective consumer rights violation. Consumer rights protection authorities shall not disclose any information about the consumers that have filed such applications.*”

¹¹⁸ The draft law does not mention any action (for example press release or other urgent communication in the media to alert consumers on risks presented by certain products). It seems that the data gathered through the National alert system is used only for the purpose of the needs of the administration.

- Keeping of original documents on conformity assessment, tests results, other technical documentation and provision of those documents upon request of market surveillance authorities;
- Immediate notification of information on dangerous products;
- Organisation of withdrawal or recall of dangerous products;
- Cooperation with market surveillance officials.

The only drawback results from the paragraph 5 of which the provisions overlap with requirements of other pieces of legislation on conformity assessment (implementation of compliance assessment procedures, lawful use of the National Compliance Mark and launch the products with the compliance declaration or certificate of compliance). That is an indication that market surveillance activities within the draft law put the focus on the enforcement of technical regulations providing for mandatory conformity assessment of mandatory standards. **This confusion between the stages of production (where conformity assessment is organised) and control of products already placed on the market is not compatible with the EU approach on market surveillance.**

With regard to the responsibilities of distributors (suppliers and sellers, in the draft law)

Article 8(1) still puts the emphasis on the duty of distributors to ensure compliance with technical regulations providing for mandatory compliance assessment and affixing of the National Compliance Mark.

Article 8(4)(5)(6)(7)and (8) mirrors almost strictly the duties of manufacturers while it would be desirable to introduce a duty of “due care to help to ensure compliance” (passing on information on product risks, co-operation with the market surveillance authority, notification of dangerous products). This idea of participation more than the direct obligations laid down in the draft law is contained in the Article 5(2) of the GPSD.

Article 8 (2) on the duty to keep commercial documents in order to allow for the identification of manufacturer is in line with the EC requirement on the traceability of the product (Article 5(2) first paragraph of the GPSD).

Concerning the obligations of manufacturers and distributors to notify dangerous products to the market surveillance authority (Article 9 of the draft law) it is observed that the notice to be prepared corresponds globally to the content of the notice form provided for in the context of the operation of RAPEX¹¹⁹. This notice covers in particular precise identification of the product, description of the hazard and corrective actions undertaken.

The notice in the draft law envisages also the provision of information which is necessary to identify the product origin and its turnover. This additional requirement does not allow for a better evaluation of the risks presented by products circulating on the market and it overlaps with the information already required. It is recommended to simply reproduce the requirements of information as they are laid down in notice used by RAPEX because the objective is to establish a national system allowing the exchange

¹¹⁹ See annex 1(3) of the GPSD and Section 5 of the “Guidelines for the management of the Community Rapid Information System (RAPEX) and for notifications presented in accordance with Article 11 of Directive 2001/95/EC pursuant to the Commission Decision 2004/418/EC of 29 April 2004.

information between the EU and Ukraine (accession to RAPEX is foreseen in the Article 33 of the draft law).

It is questionable that the objective of the notification of dangerous products is really met where the draft law (paragraph 4 of Article 9) envisages a formal notification by registered mail instead of any other faster mean of communication commensurate with the crisis management (for example e-mail or fax).

IV – Market surveillance authorities

4.1. Relevant provisions

The comments below relate to the following articles of the draft law:

- Article 10 on market surveillance authorities
- Article 11 on functions of market surveillance authorities
- Article 15 on legal protection of officials of market surveillance authorities
- Article 17 on market surveillance council
- Article 34 on the financing of market surveillance activities
- Section 8 of the draft law (Transitional and Final Provisions) as far as organization of market surveillance is concerned

4.2. Central authority

4.2.1. Vertical organization of market surveillance

The definition of “market surveillance agencies” under the Article 1 of the draft law implies that there are **no other market surveillance authorities than the central market surveillance and consumer protection agency and its territorial branches** described in the draft law.

This vertical organization under the responsibility of the Minister in charge of the Economy consists of a central authority “central authority of market surveillance and consumer rights protection” and decentralised territorial units (a special status with a certain autonomy is granted for territorial authorities in the Autonomous Republic of Crimea, in oblasts and in the cities of Kyiv and Sevastopol).

The central market surveillance authority coordinates and monitors the activities of territorial market surveillance authorities. A number of its functions match the best practice of market surveillance in the EU and its Member States.

- Centralization of the information on the causes of accidents to better target future measures;
- Implementation and monitoring of market surveillance programmes;
- Creation and the management of a system for rapid exchange of information on dangerous products;
- Periodic review and assessment of the functioning of their surveillance activities;
- Advisory services (under request) provided to economic operator on the requirements for product safety;
- Administrative review (appeal) of decisions taken by the heads of territorial authorities.

The draft law mentions also the duty to provide regular information to other government authorities and local self-government bodies on the state of affairs in the field of product safety. It is suggested to describe this duty in more binding terms, for example the duty to prepare an annual report, the duty to establish a computerised network of information with specific central and local authorities duly designated. Whatsoever, the low involvement of local government is confirmed by the financing of the market surveillance activities by the State Budget.

Territorial market surveillance authorities have more operational functions (field inspections and free advisory services to economic operators on requirements for product safety) but they ensure also the proper feedback to improve the overall system of market surveillance and to make effective the system for rapid exchange of information on dangerous products.

Information campaigns designed and organised by market surveillance authorities in the EU Member State are considered as important policy tools to prevent risks. Unfortunately this dimension is neglected in the draft law.

4.2.2. Integration of the new institution within or beside existing structures dealing with standardization and consumer protection

Paragraph 6 of Section 8 (Final Provisions) of the law is rather unclear regarding the place of the newly created market surveillance authority in relation to other public authorities exercising their powers in connected areas.

“b) within three months after this Law comes into force, the Government ...ensure that within the structure of the central executive authority on economic policy there be created the central market surveillance and consumer rights protection authority on the basis of respective structural units of the apparatus of the central executive authority in charge of technical regulation and consumer policy issues, and that territorial market surveillance and consumer rights protection units be created on the basis of structural units in charge of control over compliance with standards, norms and rules of state centers for standardization, metrology and certification, and territorial consumer rights protection units.”

It is expected that this provision will be interpreted as an indication of the desirable collaboration (and consequently the territorial proximity) between the market surveillance authorities and the bodies in charge of standardization and certification. **The merger of the functions of market surveillance, standardization and certification would be contrary to the EU legislation.**

An other area of concern is the situation of the current inspectors at the DSSU (State Committee of Ukraine on Technical Regulations and Consumer Policy). Is it necessary for all officials of market surveillance authorities to be certified by the Minister in charge of the Economy (Article 10 of the draft law) when they are transferred from the DSSU to the new body? Do the former DSSU inspectors keep their former status with the same benefits? The response to those questions and many others on social issues deriving from the dismissal, the requalification and the transfer of civil servants could be regulated by the draft law.

4.2.3. Legal protection of officials

This specific legal protection granted to officials of market surveillance authorities by the article 15 of the draft law has not equivalence in EU Member States where all civil servants are granted the same protection against damage suffered in the course of their official activities. If there are special threats evidenced in the past pertaining to official controls, this specific protection may be justified in Ukraine.

4.3. Other executive bodies

It is significant that only the ninth sub-item of the article 11(1) of the draft law mentions shortly the “co-operation with other specially authorized authorities for surveillance and product safety monitoring, law-enforcement bodies, public organizations (associations) of consumers and other public organizations.” That shows again **the draft law establishes a rather closed system of market surveillance with one key player¹²⁰. The most familiar system in the EU Member States corresponds to the existence of a principal or prominent body in charge of a wide range of market surveillance operations and in charge also of the co-ordination of market surveillance activities carried out by other line institutions within their sphere of competences.**

¹²⁰ Nevertheless, the draft law considers the role of other authorities in prosecuting offences. See, in particular, amendments to Article 244-4 and Article 244-7 of the Administrative Offences Code of Ukraine in the Section 8 of the draft law.

4.4. Involvement of other stakeholders

The Market Surveillance Council established by the Article 17 of the draft law exists in a number of EU Members States with various appellations to involve a wide range of stakeholders in the policy making on market surveillance. This advisory body under the Cabinet of Ministers of Ukraine is composed of 17 members of whom half of them represent business and consumer associations. The other members represent public authorities and scientific institutions. This Council has to convene meetings at least twice a year. Its role is to make recommendations regarding improvement of market surveillance activities, to help in the development of the national market surveillance plan and to ensure a permanent dialogue with the civil society on issues of market surveillance. A Regulation of the Cabinet of Ministers will provide for the detailed organisation.

V – Market surveillance measures

5.1. Relevant provisions

The observations under this section relate to the following articles of the draft law:

- Article 12 on the powers of the Chief State Market Surveillance Inspector
- Article 13 on the powers of the Chief Market Surveillance Inspectors
- Article 14 on the rights and obligations of market surveillance officials
- Articles 18 on market surveillance methods
- Article 19 on the purchase of samples in the distribution sector
- Article 20 on the inspection of products in the distribution sector
- Article 21 on the inspection of products in the manufacturing sector
- Article 22 on sampling, expert examination and testing of samples
- Article 23 on the documentation of the results of inspection
- Article 24 on instructions issued by market surveillance officials
- Article 25 on the recall of products
- Articles 28 on fines imposed to manufacturers
- Article 29 on fines imposed to distributors
- Article 30 on decisions to impose fines
- Section 8 of the draft law on amendments to existing pieces of legislation (Article 227 of the Criminal Code of Ukraine)
- Section 8 of the draft law (Transitional and Final Provisions) on organizational measures and regulations to be adopted by the Government.

5.2. Extent to which the draft law provides for a balanced and gradual enforcement

5.2.1. Decision making process

The Chief State Market Surveillance Inspector is responsible of implementation of the policy of market surveillance decided by the Minister in charge of the economy.

The conduct of market surveillance operation is decided on the level of the heads of territorial authorities in the Autonomous Republic of Crimea, Oblasts, the cities of Kyiv and Sevastopol (Chief

Market Surveillance Inspectors) under the responsibility of the Chief State Market Surveillance Inspector of Ukraine.

The panorama of decisions taken by the heads of territorial authorities include:

- Order to conduct individual inspections and to purchase samples;
- Instructions to economic operators (preventive and corrective measures);
- Referral to administrative courts to seek for penalties or, to criminal courts, in more serious cases;
- Application to the accreditation authority to take measure against conformity assessment bodies which fail to carry out satisfactorily their duties;
- Request to get the support of law-enforcement bodies in case of obstacles to conduct inspections.

Basic inspectors may only execute instructions of their hierarchy (execution of certificates authorizing inspections and other instructions, purchase of samples) and they establish notices of administrative offences. General procedural rules to conduct inspections (Paragraphs 8 to 13 of Article 18) reinforce also this centralization of the power of decision. Actually there is no room for initiatives to be taken by yield inspectors without a written authorization of the head of the competent territorial authority.

This centralization and the corresponding bureaucratic red tape¹²¹ is sometimes rather excessive. For example, it is questionable whether “solely issues constituting the subject of inspection shall be examined in the course of such inspection” (Paragraph 10 of Article 18). Such a restriction may hamper the effectiveness of random checks.

As a whole it seems that, in the context of the rampant corruption in Ukraine, the draft law does not intend to strike a proper balance between the detection of non-conformities and the rights of economic operators but, on purpose, the draft law puts the emphasis on the protection of economic operators against abuses from inspectors.

5.2.2. Planning of activities based on risk analysis

Market surveillance is based on a national market surveillance plan approved on an annual basis by product types and degrees of risk (paragraph 2 of Article 18). This planning is required in the GPSD¹²² and the European Commission) and is already implemented in a number of EU Member States (but more frequently this planning takes the form of pluri-annual orientations updated each year).

Elements for the drawing up or the updating of the national market surveillance plan (paragraph 4 of Article 18) correspond to the best practice in the EU (monitoring of causes of accidents, data entered into the national rapid exchange of information system or RAPEX).

¹²¹ Beside the application of the Law No 877 V of 5 April 2007 on the fundamental principles for State inspections in the field of economic activities, the draft law sets out new procedural rules and additional procedural rules will be determined by the Cabinet of Ministers of Ukraine(procedure to purchase samples and use of them, documentation on results of inspections, appeals against orders, instructions and decisions).

¹²² It is also a requirement of Proposal for a Regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products (COM(2007)0037).

The wide publication of the national plan (paragraph 5 of Article 18) is also a component of the European policy¹²³ together with the production of an annual report on the implementation of the plan (paragraphs 6 and 7 of Article 18).

The main divergence with the pragmatic approach (mainly reactive) implemented in the EU Member States comes from the assertion that the plan is to be based on “scientifically grounded approaches”.

The paragraph 3 of Article 18 specifies that to plan market surveillance activities (including the planning of purchase of samples), risks **presented by products are ranked into three degrees of risk: high, medium and low**. The elements of this risk assessments have to be approved by the Government.

There are abundant publications on the relevance and the feasibility of an inventory of risks. The conclusions is that risk assessment cannot be limited to an univocal scientific approach but calls upon several disciplines. As a result, it has been observed in various countries that formal inventories are mainly conceived as tools for public information (communication). An inventory should “leave each individual free to construct, with all the available knowledge, his or her own hierarchical ranking”.¹²⁴ We think accordingly that the ambition to list the wide range of products already present on the market and to rank them on a scale of risk for the purpose of market surveillance is not appropriate. Either this list, on which would be based technical regulations (within the logical framework of the draft law) would hamper any innovation or it would be permanently outdated. By contrast, as it is the case in the EU in the context of the operation of RAPEX, an assessment grid for the evaluation of any risk could be defined by the Government.

5.2.3. *Grounds for inspection*

The draft law introduces a differentiation between manufacturers and distributors (Articles 20 and 21) concerning the grounds for inspections.

The draft law introduces also another distinction between sellers and suppliers (sub-items 4 and 5 of paragraph 1 of Article 20). This distinction is questionable (all of them are distributors within the GPSD) even if the drafter had the purpose to show that the seller has to be inspected first and that the supplier is controlled only where a non-conformity has been detected within the seller. By contrast, the detailed rules on the power of the inspector to determine the responsibilities in the supply chain are useful (paragraph 4 of Article 20).

In all cases, the rationale behind inspections of manufacturers and distributors corresponds to familiar practices in the EU (planning, complaints from consumers, information provided by other authorities-executive authorities, executive bodies of local councils and prosecution agencies – on casualties or risks).

¹²³ Global market surveillance programme communicated to the other Member States and made available to the public in the Amendment 91 of the European Parliament to the Proposal for a Regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products.

¹²⁴ Extract from the Opinion No 42 of the French National Committee on Foodstuff concerning the relevance of an inventory of risks (November 2002).

The main drawback is that the purpose of inspection is limited to the detection of non-conformities deriving from failure to apply technical regulations, conformity assessment procedures and lawful affixing of the National Compliance Mark (paragraph 2 of Article 20 and paragraph 2 of Article 21).

Furthermore, the procedural rules on the maximum duration of inspection (paragraph 3 of Article 20 and paragraph 3 of Article 21)¹²⁵ without any allowance to extend this period (even under the control of a court) does not fit the needs to fight against massive fraud. Market surveillance authorities in the EU Member States apply the principle of proportionality. The safeguard for economic operators laid down in the draft law derives from the Law No 877 V of 5 April 2007 on the fundamental principles for State inspections in the field of economic activities.

5.2.4. Injunctions issued by market surveillance officials

To some extent, the draft law introduces a graduation in the measures taken by market surveillance authorities to address non-conformities uncovered during inspections (Article 24).

- Remedial measures are ordered in the case of “insignificant violations”, which relate mostly to non-substantial requirements: availability of documents, missing mentions on documents and certificates, missing supporting documentation attached to the product.
- Other violations are subject to a temporary ban of the marketing of the products (under specific circumstances, restrictions of the placing of products on the market may result also from missing information and documents).
- The next step is the prohibition of sale and recall/withdrawal¹²⁶ of the product when samples of the products do not meet the safety requirements established by the technical regulations or in the case of discrepancies in the technical documentation.

This progressive enforcement is far to meet the requirements of the GPSD on the implementation of measures proportional to the seriousness of the risk, as they are detailed under the article 8 of the Directive.

Apart from the compliance with legal requirements the draft law never envisages a graduation of measures based on the existence of serious risks and “the assessment of each individual case on its merits”¹²⁷.

Nevertheless, worth noting that the market surveillance authority may agree a deadline with the economic operator to remove the non-conformity (Paragraph 6 of Article 24). That is more in line with the constant practice of market surveillance in the EU. Unfortunately, in the draft law this facility is granted only when risks are more formal than actual (not in the case of substantial failures). Failing to

¹²⁵ For distributors, the maximum duration of inspection is five business days (or two business days for small enterprises). For manufacturers this duration is 15 business days (or 5 business days for small enterprises).

¹²⁶ The distinction between recall and withdrawal of products is not fixed in the draft law.

¹²⁷ GPSD paragraph 3 of Article 8.

reach this agreement, the time span to comply with the instructions of the market surveillance authority is 5 or 15 working days.

At last, it does not seem practicable to impose to economic operators the duty to inform individually consumers and users of products when the trade of those product has been restricted (provisionally or permanently) by decision of market surveillance authorities (paragraph 8 of Article 24). Press releases at the expenses of the economic operators concerned would be sufficient.

5.2.5. Sampling and testing as central operations of market surveillance

Market surveillance measures in the draft law rely extensively on the collection of samples.

In the sub-item 5 of paragraph 2 of Article 20 that is the only way recognized to detect non-conformities. Nevertheless this provision is contradicted by the paragraph 5 of the same article and the paragraph 5 of Article 21 which specify that in the event of any reasonable doubts as to defects in the product that may cause damage to the life and health of people, animals, plants or environment, the state market surveillance inspector is entitled to select product samples for examination or testing in order to determine the consistency with the safety requirements.

Should the draft law express in unambiguous terms the idea that the first checks concern the documentation and thereafter a visual inspection before taking samples (only where there are already concordant indications of a presumption of non-conformity), efficiency, proportionality and gradual enforcement would be better addressed.

In addition, it is also symptomatic of the dominant approach of the draft law that the paragraph 3 of Article 19 entails that sampling for testing relates only to the assessment of the conformity with the safety requirements established by technical regulations for this type of product and that is a preliminary step before inspection.

Moreover, several provisions of the draft law (Article 19 and paragraph 1 of Article 18) give the impression that the purchase of samples concerns only products sold by distributors. Fortunately, the paragraphs 3 and 5 of Article 21 indicate that sampling and testing concerns also manufacturers. In this respect, a better consistency of the provisions mentioned above is needed.

5.3. Response to emergency situations

The definition of “product recall” under the Article 1 of the draft law forgets to mention that the recall of dangerous products may concern not only the manufacturer but also the distributor who supplied the product (in particular the distributor responsible for the first stage of distribution on the national market).

“Product withdrawal” (measures to prevent distribution, display and offer of dangerous products which are not yet placed on the market) is not defined.

This drawback is transferred in the proposed amendments to the article 14 of the Law “On Consumer Rights Protection” (Section 8 of the draft law on Transitional and Final Provisions).

It is recommended therefore to introduce in the draft law the correct definitions of “recall” and “withdrawal” as they are set out in the GPSD.

Other provisions of the draft law on the recall of products (Article 25) are fully in line with the GPSD. In particular, it is well expressed that the recall is an extraordinary measure on the initiative of the manufacturer or pursuant to instructions of market surveillance authorities when other actions would not eliminate the risk.

The relevant procedure is to be established by the Government. Maybe it would be preferable to refer to the development of Codes of Good Practice by the market surveillance authorities¹²⁸ in collaboration with the interested parties (represented by the Market Surveillance Council of the article 17 of the draft law)

It is however important to observe that the provisions laid down under the paragraphs 3 and 4 of Article 25 on the immediate repayment to be made by the manufacturer of the full value of the recalled products has no equivalent in the EU. For example, in accordance with the principle of proportionality, the recall of a car by a car manufacturer or distributor in the EU to replace a small component affecting the safety of the vehicle does not will give rise to the obligation of repayment of the car to its owner. The defective spare part is replaced free of charge and sometimes a compensation is offered for the immobilization of the car for a reasonable period of time.

5.4. Sanctions

5.4.1. Administrative offences

Section 4 of the draft law on “Liability for Failure to Meet Product Safety Requirements” actually covers administrative penalties and reserves the right of victims to claim for compensation for damage but does not develop a system similar to those of the Directive 85/374 EEC concerning liability for defective products.

Administrative fines are imposed by Courts following a submission by the competent head of the market surveillance authority. Fines are credited to the national State Budget.

Paragraph 1 of Article 28 (concerning manufacturers) and paragraph 1 of Article 29 (concerning distributors) provides for various levels in the scale of fines.

As for manufacturers offences relate to the following:

- Launch of a product non-compliant with technical regulations;
- Default in complying with instructions of market surveillance authorities;
- Unlawful use of the National Compliance Mark.

¹²⁸ See, for example, Product Safety in Europe – A guide to corrective actions including recalls (June 2004) prepared by Market Surveillance Authorities of Belgium, Denmark, the Netherlands, Sweden and the UK.

As for distributors offences relate to the default in complying with instructions of market surveillance authorities and the non-observance of technical regulations concerning the storage and transportation of products.

The definition of offences and exemptions from penalties indicates that the **storage and transport of products fall also within the scope of market surveillance activities.**

An important provision under the paragraph 13 of Article 24 specifies that voluntary notification of unsafe products to the market surveillance authority and deadline agreed to remedy the defects do not open an infringement case.

It is questionable that manufacturer might be exempted from fine where unsafe components of the product are made by another manufacturer. In the GPSD a general duty of placing safe products on the market lies on the manufacturer¹²⁹. The manufacturer of the final product is deemed to collect sufficient information on the safety of components produced by other manufacturers. It is recommended therefore penalties to be imposed on each manufacturer involved in the manufacturing process, as far as the unsafe component bears the marks of other manufacturers.

5.4.2. Criminal prosecutions

The draft law envisages criminal penalties only in case of “intentional launch of dangerous products” (new article 227 of the Criminal Code of Ukraine under the Section 8 “Transitional and Final Provisions” of the draft law). The offence is defined in relation to “products that do not comply with their safety requirements, as prescribed by the technical regulations for this particular type of products, provided that such products are launched in big volumes”.

5.4.3. Other offences defined in other pieces of legislation

A number of articles of the Administrative Offences Code of Ukraine are amended:

- Article 155: “Violation of Rules for Rendering Commercial, Household, and Other Services”;
- Article 156-1 on the duty to provide information to consumers;
- Article 167: “supply of products not complying with the requirements of state sanitary and epidemiological rules and norms, release or sale of oil products with environmental characteristics below the established standards, norms, and rules, established standards, norms, and rules in the process of manufacturing, storage, transportation, sale, or use of medicinal products”;
- Article 168-1: compliance with the “established norms and rules for the performance of works and provision of services for consumers”;

¹²⁹ Furthermore, in Article 3(1) of Directive 85/374 EEC concerning liability for defective products 'Producer' means the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer .

- Article 169: “provision of documents not complying with product safety requirements”;
- Article 170: “compliance with sanitary and epidemiological rules and norms when transporting, storing and using products, provided that such failure resulted in the damaging of the products”;
- Article 188-2 on obstacles to conduct inspection of to provide the required materials.

The article 23(9) of Law of Ukraine “On Consumer Rights Protection” is revised as well to establish a fine for “failure to comply or to timely comply with the instructions given by officials of the central consumer rights protection authority or its territorial units demanding that consumer rights violations be eliminated”. In this case there is a risk to impose a double offence in relation to penalties already laid down in the articles 28-1(2) and 29-1(2) of the draft law.

VI– Protection of the rights of manufacturers and distributors

6.1. Relevant provisions

The comments under this section address the following articles of the draft law:

- Article 6 on the rights of manufacturers, suppliers and sellers of the products
- Article 14 on the rights and obligations of market surveillance officials
- Article 16 on liability of officials
- Article 22 on sampling, expert examination and testing of samples
- Article 23 on the documentation of the results of inspection
- Article 26 on the duty of confidentiality
- Article 27 on appeal of the decisions and instructions of market surveillance authorities

6.2. Right to defence

Within the Article 6 of the draft law, manufacturers and **distributors are entitled to provide written comments concerning the inspection certificate and may avoid coercive measures and sanctions by taking voluntary actions**. Appeal against decisions of the Market Surveillance Authority is possible but it is not clear how administrative appeal and judicial review are organised to co-exist.

More generally, economic operators benefit from the rights laid down in the Law No 877 V of 5 April 2007 on the fundamental principles for State inspections in the field of economic activities.

Procedural rules set out under this Article 6 are classic and they ensure the fairness of the controls : communication of documents and other materials, oral explanations, sampling (purchase of products) for testing, access to storage facilities and commercial premises, transparency of results.

Other very detailed provisions under the Article 23 of the draft law regulate the content and the delivery of the certificate of inspection and supporting documents.

All those measures aim at preventing abusive or arbitrary decisions.

The requirements of the Article 18 of the GPSD¹³⁰ are unquestionably met.

6.3. Sampling and testing

The procedural rule on the collection and analysis of samples are set out in the Article 22 of the draft law. Here again, the rights of economic operators are well treated (presence of a representative of the enterprise, storage by the enterprise of at least two samples, appeal to court, referral to a second expertise, etc).

Worth noting as well because that is a benchmark in the EU Member States that *“expert examination and testing of products shall be made in testing laboratories or other institutions accredited for carrying out this kind of activities according to the law and based on the agreements concluded by market surveillance authorities”*.

Are also compatible with best practices:

- provisional prohibition to market the product before the results of the analysis of samples;
- costs of samples their transportation and expertise born by the State except where a non-compliance is detected.

6.4. Responsibility incurred by officials

In the EU Member States, the responsibility incurred by civil servants on the occasion of the performance of official duties is normally regulated by the administrative law or by specific statutory regimes. It seems that the general legal framework applicable in Ukraine does not provide for similar solutions. That explains the system established under the Article 16 of the draft law.

This responsibility of officials limited to the cases of inexcusable mistakes or abuses would be welcome (some decisions might be disastrous for the existence or sustainability of enterprises whose products are suspected to be dangerous) but opening so widely actions of economic operators to apply to court for compensation of damage may have undesirable and disproportionate results. In the area of market surveillance, it is sometimes difficult to reconcile the precautionary principle and the real risk posed by some products.

6.5. Confidentiality

The protection of commercial secret and other legally protected information by market surveillance authorities under the Article 26 of the draft law is in line with the requirements of the GPSD and the Proposal for a Regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products (COM(2007)0037). There is also no objection to remove the duty of non-

¹³⁰ When a measure involves restrictions on the placing of a product on the market:

- Notification of the measure as soon as possible to the party concerned
- Statement of the reasons on which the measure is based
- Remedies available and time-limits applying to such remedies are indicated
- Parties concerned are whenever possible given the opportunity to submit their views before the adoption of the measure or, in case of an urgent measure taken, in due course after the measure has been implemented
- Measure can be challenged before the competent courts

disclosure where the information relates to a hazard in connection with the use or consumption of unsafe products. By contrast, it is recommended to envisage other safeguards to disclose information which enables identifying manufacturers and distributors of unsafe products. The content of the data disclosed to the general public should be assessed on a case by case basis taking into account the principle of proportionality.

VII – Information Support System and international co-operation

The draft law plans the creation of System for Rapid Exchange of Information on the national level to monitor unsafe products (Articles 31). The detailed features of this electronic database have to be set out by the Government. A number of EU Member States have also developed national management information systems dedicated to market surveillance developed: National Rapex Network in Finland, RIPRIS in Lithuania, specific database operated by the central market surveillance authority in France, Information and Communication System for Market Surveillance (ICSMS) used by market surveillance authorities in Germany, The Netherlands, Austria, Belgium, Estonia, Luxembourg, Malta, Slovenia, Sweden, Switzerland, and the United Kingdom.

One of the issues to be decided by the Government is whether some sections of this database will be accessible to economic operators¹³¹.

Worth also to welcome in the Article 31 of the draft law that beside the Central Market Surveillance Authority, which operates the MIS, other central executive authorities and customs authorities are authorised “to exercise State control over safety of products” and are therefore invited to enter data in the system. That is **one of the rare occasions where the draft law recognises that market surveillance is also an area of concern for a number of line institutions and State Agencies.**

The paragraph 3 of Article 33 of the draft law concerning the participation of Ukraine in “The International Alert System for Dangerous Products” recognises also the involvement of other authorities, distinct from the Central Market Surveillance Authority, in market surveillance activities:

“Central executive authorities, which exercise state control over safety of products within their respective spheres of competence, shall submit information about any dangerous products detected by them to the central market surveillance authority for such information to be further provided to relevant foreign authorities.”

The Central Market Surveillance Authority will cooperate with relevant foreign authorities and international organizations on product safety and market surveillance issues within the framework of applicable international agreements (Article 32 of the draft law). As a result, it is foreseen the

¹³¹ The openness of the database managed by the European Commission within the RAPEX system is encouraged by the European Parliament. In the amendment 113 to the Proposal for a Regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products (COM(2007)0037, it is proposed the setting up of a common, public database, accessible to the Member States’ public administrations and economic operators, listing all cases where a product was found to present a serious risk to health and safety or was in breach of Community harmonisation legislation. The justification is that the common database would enable economic operators in good faith to avoid to enter into business with no reliable counterparts, both from outside and inside the Community.

participation of Ukraine in RAPEX (paragraph 1 of Article 33). Only the paragraph 4 of Article 33 may pose problems. Is it reasonable to envisage an open participation in a system of exchange of information where the nature of data exchanged are not identical? Is it realistic to think that the Ukrainian Government will decide about the form and the content of data to be entered into the RAPEX system?

Conclusions

The draft law puts the focus on enterprises more than on products. As the result the concept of market surveillance developed in the draft law has no equivalence in the EU Member States.

Actually the draft law adds a new layer of obligation to facilitate official controls. It is completely overlooked that market surveillance is mostly a mean to control products for which certain risks fall outside regulated areas or fall outside regulated areas where are set out essential safety requirement developed through the application of voluntary standards.

Furthermore, the level of centralization of market surveillance authorities is unknown in the EU. As a general rule, market surveillance authorities in the EU Member States are **coordinated** by a central body – which sometimes carries out itself a number of market surveillance activities on specific categories of products, but line institutions keep their responsibilities within their sphere of competences.

During an transitional period – the time necessary to better organize the co-ordination of Government activities in Ukraine – this excessive centralization is preferable to the absence of co-ordination.

The draft law suffers as well from an insufficient understanding of the principle of proportionality and the lack of emphasis put on the voluntary actions from economic operators.

A considerable and simple step forward would be:

- First, to introduce in the definitions of the Article 1 the criteria for the evaluation of the safety of products as they are laid down under the second paragraph of the article 3 of the GPSD.
- Second, to stick to this definition throughout the text of the draft law and to remove consequently the current references made to the compliance with the technical regulations.