Baltic Legal
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Final Study Report

STUDY OF THE SYSTEM OF INSTITUTIONS ENFORCING THE MARKET SURVEILLANCE POLICY

Study by Lawyers' Professional Partnership Baltic Legal Solutions Lietuva

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List of abbreviations:

Abbreviation	Definition
EPA	Environmental Protection Agency
EPA Regulations	Order No D1-385 of the Minister for the Environment of the Republic of Lithuania of 14 July 2004 approving the Regulations of the Environmental Protection Agency (*Official Gazette*, 2004, No 115-4310)
Conformity Assessment Law	Law of the Republic of Lithuania on conformity assessment (*Official Gazette*, 1998, No 92-2542; 2011, No 40-1919)
Administrative Infringements Code	Code of Administrative Infringements of the Republic of Lithuania (*Government Gazette*, 1985, No 1-1)
Civil Code	Civil Code of the Republic of Lithuania (*Official Gazette*, 2000, No 74-2262)
Working Party	Working Party established by Decree No 160 of Prime Minister of the Republic of Lithuania of 29 April 2009 establishing the Working Party to conduct an analysis of the functioning of the market surveillance system of the Republic of Lithuania and to submit proposals how to improve it
Directive	Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety
EU	European Union
EC	European Commission
EC report on the implementation of the Regulation	Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee of 13 February 2013 on the implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93
Guidelines	Guidelines for import controls in the area of product safety and compliance published by the European Commission and Directorate-General for Taxation and Customs Union
Constitutional Court	Constitutional Court of the Republic of Lithuania
LMI	Lithuanian Metrology Inspectorate
LMI Regulations	Order No 4-264 of the Minister for the Economy of the Republic of Lithuania of 27 April 2011 approving the Regulations of the Lithuanian Metrology Inspectorate (*Official Gazette*, 2011, No 53-2557)
Lithuania	Republic of Lithuania
Government	Government of the Republic of Lithuania
LMSA	Lithuanian Maritime Safety Administration
LMSA Regulations	Order No 3-318 of the Minister for Transport and Communications of the Republic of Lithuania of 25 June 2002 approving the Regulations of the budgetary institution the Lithuanian Maritime Safety Administration (*Official Gazette*, 2002, No 68-2803; 2008, No 143-5755)

CD	Customs Department under the Ministry of Finance of the Republic of Lithuania
CD Regulations	Order No 171 of the Minister for Finance of the Republic of Lithuania of 10 July 1998 approving the Regulations of the Customs Department under the Ministry of Finance of the Republic of Lithuania (*Official Gazette*, 1998, No 64-1861; 2004, No 98-3652)
Services Law	Law of the Republic of Lithuania on services (*Official Gazette*, 2009, No 153-6901)
Product Safety Law	Law of the Republic of Lithuania on product safety (*Official Gazette*, 1999, No 52-1673; 2001, No 64-2324)
Rules for the application of restrictions on marketing of products	Resolution No 439 of the Government of the Republic of Lithuania of 2 April 2002 approving the procedure for the application of restrictions on marketing of products (approving the rules for the application of restrictions on marketing of products) (*Official Gazette*, 2002, No 35-1307; 2004, No 177-6547) (as amended by Resolution No 927 of the Government of the Republic of Lithuania of 21 September 2006 (*Official Gazette*, 2006, No 102-3951) and Resolution No 585 of 23 May 2012 (*Official Gazette*, 2012, No 61-3074))
Regulation	Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93
Proposal for a Regulation on market surveillance of products	Proposal for a Regulation of the European Parliament and of the Council on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC and 2011/65/EU, Regulation (EU) No 305/2011, Regulation (EC) No 764/2008 and Regulation (EC) No 765/2008 of the European Parliament and of the Council
Proposal for a Regulation on consumer product safety	Proposal for a Regulation of the European Parliament and of the Council on consumer product safety and repealing Council Directive 87/357/EEC and Directive 2001/95/EC
RRT	Communications Regulatory Authority of the Republic of Lithuania
RRT Regulations	Resolution No 1029 of the Government of the Republic of Lithuania of 19 August 2004 approving the Regulations of the Communications Regulatory Authority of the Republic of Lithuania (*Official Gazette*, 2004, No 131-4734)
RSC	Radiation Protection Centre
RSC Regulations	Order No V-612 of the Minister for Health of the Republic of Lithuania of 22 July 2005 approving the Regulations of the Radiation Protection Centre (*Official Gazette*, 2005, No 94-3516; 2011, No 128-6073)
Study	Study of the system of institutions enforcing the market

	surveillance policy
VASPVT	State Healthcare Accreditation Agency under the Ministry of Health
VASPVT Regulations	Order No V-839 of the Minister for Health of the Republic of Lithuania of 7 September 2011 approving the reorganisation and the conditions for the reorganisation of the State Medical Audit Inspectorate under the Ministry of Health and the Regulations of the State Healthcare Accreditation Agency under the Ministry of Health (*Official Gazette*, 2011, No 112-5279)
SLI	State Labour Inspectorate under the Ministry of Social Security and Labour of the Republic of Lithuania
SLI Regulations	Order No A1-316 of the Minister for Social Security and Labour of the Republic of Lithuania of 12 May 2009 approving the Regulations of the State Labour Inspectorate under the Ministry of Social Security and Labour of the Republic of Lithuania (*Official Gazette*, 2009, No 58-2262)
VKTI	State Road Transport Inspectorate under the Ministry of Transport and Communications
VKTI Regulations	Order No 304 of the Minister for Transport and Communications of the Republic of Lithuania of 26 September 1996 approving the Regulations of the State Road Transport Inspectorate under the Ministry of Transport and Communications (*Official Gazette*, 1996, No 102-2333; 1996, No 102-2334)
VNMPI	State Non Food Products Inspectorate under the Ministry of the Economy
VNMPI Regulations	Order No 4-693 of the Minister for the Economy of the Republic of Lithuania of 16 September 2010 approving the Regulations of the State Non Food Products Inspectorate under the Ministry of the Economy (*Official Gazette*, 2010, No 111-5666; 2012, No 87-4527)
PHCs	Public health centres in counties
PHC Regulations	Order No V-144 of the Minister for Health of the Republic of Lithuania of 27 February 2012 approving the Regulations of public health centres in counties (*Official Gazette*, 2012, No 25-1190)
Consumer Protection Law	Law of the Republic of Lithuania on consumer protection (*Official Gazette*, 1994, No 94-1833; 2000, No 85-2581; 2007, No 12-488)
SMCA	State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania
SMCA Regulations	Order No V-27 of the Minister for Health of the Republic of Lithuania of 13 January 2011 approving the Regulations of the State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania (*Official Gazette*, 2011, No 9-401)
VVTAT	State Consumer Rights Protection Authority under the Ministry of Justice
VVTAT Regulations	Resolution No 359 of the Government of the Republic of Lithuania of 11 April 2007 changing the name of the National Consumer Rights Protection Council under the Ministry of

	Justice and approving the Regulations of the State Consumer Rights Protection Authority (*Official Gazette*, 2007, No 44-1680)

EXECUTIVE SUMMARY

The purpose of this study of the system of institutions implementing market surveillance policy is to analyse a specific area, namely the functioning of the market surveillance system and to evaluate whether the provisions of Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 ('the Regulation') have been properly implemented in national law, and to come up with recommendations for possible ways of improving the regulations. In order not to duplicate a recent study commissioned by the Ministry of the Economy with a view to drafting a plan for consolidating the activities of business supervisory institutions, this study did not include an analysis of the actual functions of the market surveillance authorities. As part of the study, national and EU regulations were analysed, public information on the internet evaluated and information provided by the Ministry of the Economy taken into account. This study also ignores the material aspect of product safety (product safety requirements).

EU legislation establishes a different legal regulation for non-food and food products and their safety. Service safety at EU level is generally not regulated. The General Product Safety Directive ('the Directive') applies only to the area of consumer non-food products. The Regulation applies to all non-food products covered by EU harmonisation legislation. This segmentation has led to the fragementation and overlap of EU regulations which it is hope will be rectified once the proposals for the regulation on the market surveillance of products and the regulation on consumer product safety have been adopted. Lithuania's regulations on the market surveillance system will thus have to be brought into line with these changes.

The study ascertained that the Lithuanian regulations basically implement the Regulation, though it also established some shortcomings in the regulations.

Firstly, the market surveillance system identified in this study is not centralized and definite in Lithuania. No definitive list of market surveillance authorities is given. Instead, the study identifies the market surveillance authorities with reference to the concept and remit of market surveillance consolidated under EU law. In order to determine the effectiveness of the implementation of Regulation in Lithuania, the activities of the market surveillance authorities in the Republic of Lithuania are examined in terms of the functions assigned to the Member States in the Regulation and the Directive, firstly by structured and grouped systematic functions (related to general policy-making in the field of market surveillance) and secondly by market-specific functions (associated with specific market surveillance application and geared to the market surveillance authorities). It was not possible to apply this study method to services, as neither the Regulation nor the Directive applies to the provision of services. However, by analogy with the definition of product market surveillance, a preliminary list was drawn up of market surveillance authorities for services. The need was underlined for clearly defined criteria, enabling the identification of specific market surveillance authorities for services (with regard not only to ongoing market surveillance functions, but also, and more specifically, to service safety requirements, which primarily determine the need for a supervisory authority for the safety of services and the scope of market surveillance) and, secondly, the need to incorporate the market surveillance of services and products into the common market surveillance system and to establish a model for coordinating such a market surveillance system.

The study discusses models for coordinating the market surveillance system – basically an institutionalized model on the one hand and a non-institutionalized model on the other. It also looks at the field of regulation in terms of a model for the coordination of market surveillance for non-food products only, and in terms of a joint system for the market surveillance of food and non-food products where the coordinating function is shared between the Ministry of the Economy or the Ministry of Justice (non-food) on the one hand and the Ministry of Agriculture (food products) on the other. When deciding on the model of coordination it is very important to note that the non-institutionalized model can operate successfully only by if it is effectively and consistently implemented.

Secondly, the study pays particular attention to the Law on Product Safety of the Republic of Lithuania as an "umbrella" law on consumer product safety. The criteria applicable to market surveillance authorities and a definitive list of institutions could be provided in the "umbrella" Law on Product Safety (with a clear indication of how this relates to specific laws regulating the product safety). As Law on Product Safety only applies to consumer products, non-consumer product safety is regulated separately by special laws or, where there are none, in the absence of which non-consumer product safety in general may remain unregulated. While coordination of the implementation of product safety laws are assigned by the Law on Product Safety to the competence of the State Consumer Rights Protection Authority, market surveillance must be considered just one of many other functions of this authority, which is responsible for coordinating the consumer protection system in Lithuania. Therefore, practically, the State Non Food Products Inspectorate is considered an "umbrella" authority for market surveillance in the field of consumer products, but in the absence of an "umbrella" market surveillance authority for non-consumer (professional) products, the surveillance of the safety of certain products in the Republic of Lithuania may remain unregulated. Considering this, it is proposed to provide the State Non Food Products Inspectorate with respective powers in the area of non-consumer (professional) products as well. This course of action would prove particularly apposite if it were decided to entrust the systematic functions of the market surveillance system to the Ministry of the Economy, rather than the Ministry of Justice.

Thirdly, after an analysis of market surveillance mechanisms, the regulation of the specific functions of institutions and their interactions, it was established that existing regulations are not entirely sufficient and should be improved. The performance of systematic market surveillance system functions is not assigned directly by law to any particular public authority, although in reality a number of systemic functions are performed by the Ministry of the Economy. In a bid to ensure legal clarity, the study suggests that specific market surveillance authorities be made clearly responsible for imposing sanctions and performing other market surveillance activities under the relevant laws, with definitive lists of such authorities and their specific functions being provided. In addition, the study makes proposals for more effective implementation of the functions assigned to the Member States under the Regulation (e.g. it proposed introducing a statutory obligation to cooperate and an obligation to build up scientific and technical know-how; to make it a clearer obligation for market surveillance authorities to monitor accidents and harm to health and to inspect products and, with a view to more detailed regulation, in suggests that the relevant rules and procedures be approved).

I. INTRODUCTION

Market surveillance is one of the areas of public governance. It must be noted that the concept of market surveillance is defined only in Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 ('**the Regulation**') whereas the national legislation regulating market surveillance does not define the concept of market surveillance[1]. As discussed in detail in this Study, the scope of the EU law and the national legislation of Lithuania regulating product safety and market surveillance is different. Both the Regulation and other EU legislation on product safety and market surveillance regulate only non-food products (EU law does not uniformly regulate the market surveillance of either foodstuffs or services).

It should be noted that after the adoption of the Regulation the Lithuanian legislation pertaining to market surveillance requirements has not been revised. So there is a need to evaluate whether the national legislation properly regulates the functions of institutions implementing the market surveillance policy set out in the Regulation. The need for evaluating the existing system also arises from the fact that the EU institutions are examining the proposal for a Regulation on market surveillance of products and the proposal for a Regulation on consumer product safety revising the *acquis communautaire* in the field of product safety and market surveillance. Therefore, if the said documents were adopted, they would have to be implemented in the national law, inter alia by granting relevant competences to certain national market surveillance authorities. An analysis of the functions of the existing national market surveillance system will make it possible to prepare for the implementation of the said EU legislation in a more appropriate and efficient manner, at the same time in a systematic and coherent way deciding on improvements to the complementary legal framework in the area of market surveillance.

The subject matter of the contract of 13 December 2012 concluded by Lawyers' Professional Partnership Baltic Legal Solutions Lietuva ('**BLS Lietuva**') and the Ministry of the Economy for the services of conducting a study on the system of institutions enforcing the market surveillance policy ('**the Contract**') is services of conducting a study on the system of institutions enforcing the market surveillance policy. The key purpose of the Study (as agreed at the inception meeting of BLS and the Ministry of the Economy) is to evaluate whether the national legislation properly implements the provisions of the Regulation relating to the functions of the system of institutions enforcing the market surveillance policy. As mentioned above, the Regulation and other EU legislation do not regulate either foodstuffs or services, which is why this Study mainly aims at analysing the legal framework relating namely to market surveillance authorities operating in the area of non-food products. However, it must be stressed that the area of non-food products covers both consumer and professional products.

The period of implementation of the Contract is 120 days. The Contract is concluded within the framework of the project "Coordination of the optimization of surveillance functions conducted by business control authorities" (project No VP1-4.3-VRM-02-V-07-001) financed under Measure VP1-4.3-VRM-02-V "Promoting public policy reforms" of Priority 4 "Administrative capacity building and increasing the efficiency of public administration" of the Operational Programme for the Development of Human Resources for 2007-2013. It should be noted that

[1] Except that the concept of market surveillance is defined in the context of regulating metrological relations in the Law on metrology.

within the same project the Ministry of the Economy also procured services of drafting a consolidation plan for the activities of institutions supervising economic entities, inter alia focusing on the following objectives: to evaluate the efficiency of functions conducted by supervisory authorities; to evaluate the relevance of the purpose of each supervisory authority for the area of surveillance and the individual nature and independence of its functions to establish functional links with other supervisory authorities discussing and evaluating opportunities for the supervision of economic entities together with other supervisory authorities; to analyse cases of cooperation of supervisory authorities with other institutions for the purpose of surveillance (e.g. joint checks, investigations conducted, conclusions delivered in respect of checks or performance of functions, information exchange, etc.) and cooperation opportunities; to evaluate the efficiency of the organisational structure and distribution of functions of supervisory authorities among the areas of surveillance identified by the supplier; to analyse the surveillance functions and processes conducted by supervisory authorities, etc.

This Study does not duplicate the aforementioned study commissioned by the Ministry of the Economy as this Study, first and foremost, seeks to analyse the functions in a specific area, i.e. market surveillance, and second, it aims at evaluating whether the national legislation properly implements the provisions of the Regulation and offering suggestions on possible regulatory improvements. It should be noted that this Study does not therefore cover an analysis of how the actual functions of market surveillance authorities are performed, which, in our opinion, should have been covered by the aforesaid study. However it is worth stressing that with a view to additionally identifying and properly justifying shortcomings and/or imperfections of the legal framework, this Study has assessed information publicly accessible online. Moreover, in some cases, to make a final decision on the need to introduce regulatory improvements, the Study suggests a consistent and systematic analysis of the actual situation relating to the application and implementation of legal provisions on product safety and market surveillance, i.e. with a view to deciding whether there is a need for improving the regulation of economic sanctions (particularly deciding on their proportionality or an appropriate proportion of sanctions regulated by the Administrative Infringements Code and the Product Safety Law).

This Study is the final report on the implementation of the Contract, inter alia, offering suggestions and recommendations on how to improve the system of institutions enforcing the market surveillance policy. This Study consists of five key parts.

Chapter II "An overview of the legal framework of product safety and market surveillance" of the Study discusses (i) the current *acquis communautaire* in the area of product safety and market surveillance focusing on crucial aspects of legal regulation and identifying the scope and fields regulated. At the same time, this Part identifies and defines systematic and specific market surveillance functions of the market surveillance system, and a detailed analysis of this legal framework is presented in Section 3.2 of the Study; (ii) general key aspects of the national legal framework in the area of product safety and market surveillance and general shortcomings of the legal framework identified; (iii) key aspects of the *acquis communautaire* in the area of product safety and market surveillance to be changed and their possible impact on the national legal framework in the field of market surveillance. It should be noted that this Study does not aim at giving suggestions as to how the provisions of the proposal for a Regulation on market surveillance of products and of the proposal for a Regulation on consumer product safety should be implemented in the national law. This Study only offers a preliminary evaluation of the possible effect of the said Regulations on the national law and in general identifies the key aspects to influence the national market surveillance system. Moreover, suggestions offered in respect of improvements to the market surveillance system, inter alia, include an evaluation of

the provisions of the said Regulations to ensure that the suggestions presented do not contradict the provisions of the proposals for the Regulations.

Chapter III "An evaluation of the efficiency of the Lithuanian market surveillance system" of the Study, first and foremost, discusses the area of market surveillance of products and separately focuses on the surveillance of services. In the area of market surveillance of products, what is identified first is the national public authorities operating in the field of market surveillance, and second, there is an analysis of the implementation of the functions of the market surveillance system set out in the current *acquis communautaire* in the area of product safety and market surveillance in the national legal framework identifying any shortcomings of the legal framework and prospective areas for improvement. Given the list of systematic market surveillance functions and specific market surveillance functions of the market surveillance system presented in Chapter I of the Study, Chapter II of the Study offers an analysis of each of these functions (its regulation in EU law, i.e. in the Regulation and the Directive, an analysis of the essence of the function, an analysis of its implementation in national law also identifying the public authority responsible for a specific function). It should be noted that an overview of the implementation of the functions of the market surveillance system in the national legal framework is presented in Annex I "An overview of the systematic functions of the market surveillance system" to the Study (presenting overall deliverables of the systematic functions of the market surveillance system) and in Annex II "An overview of the specific functions of the market surveillance system" (presenting overall deliverables of the specific functions of the market surveillance system).

The above method (based on the concept of market surveillance defined in the Regulation) could not have applied to market surveillance of services as neither the Regulation nor the Directive applies to services. Still, to draw on a comparison with the definition of market surveillance of products, a preliminary list of authorities responsible for market surveillance of services has been compiled, first, stressing the need for a clear definition of criteria that make it possible to identify specific institutions responsible for market surveillance of services (taking into account not only market surveillance functions performed but also, in particular, safety requirements to services that are key in determining the need for a market surveillance institution for services and the scope of market surveillance), and second, the need for consolidating market surveillance of services and products into a common system and setting up a coordination model for such a market surveillance system.

Chapter IV "An overview of market surveillance systems of other EU Member States" of the Study evaluates regulatory practices of four selected Member States of the European Union (Finland, the Netherlands, Poland and Sweden[2]) in the area of the functions of the market surveillance system. The purpose of this analysis is to identify good practices in the EU Member States and export them to Lithuania when reforming the market surveillance system in the future. Good practices of other countries can be used both if a new coordination model is developed in Lithuania for market surveillance and if the national legislation is amended and/or supplemented. Descriptions of practices in the EU Member States focus mainly on the legal framework regulating market surveillance in the said EU Member States, their institutional framework and an analysis of measures ensuring cooperation between the institutions. Furthermore, detailed information that can be obtained about practices of the EU Member States is used to review and

[2] It should be noted that three EU Member States (Finland, the Netherlands and Poland) were mentioned in the proposal of BLS Lietuva, and the inception meeting between the Ministry of the Economy and BLS Lietuva agreed to expand the Study by including Sweden.

evaluate how the said EU Member States implement the systematic and the specific market surveillance functions defined in the other chapters of the Study.

Chapter V "Key conclusions and suggestions of the Study" of the Study discusses general conclusions of the Study and offers suggestions on how to improve the system including a proposal on a prospective model for the market surveillance system.

Annexes to the Study include Annex I "An overview of the systematic functions of the market surveillance system" and Annex II "An overview of the specific functions of the market surveillance system".

This Study is drawn up in accordance with the current legislation of the EU and Lithuania unless otherwise specified in the Study proper and the objectives of the Contract. BLS Lietuva is not obliged to update the Study following any amendments to legislation after the Study is completed and presented to the Ministry of the Economy. At the same time, as mentioned above, the Study has analysed publicly available information too. All sources relied upon are properly listed in Chapter IV "List of references" of the Study.

In implementing the Contract and drawing up this Study, there was an inception meeting with representatives of the Ministry of the Economy. Moreover, to obtain the required information, there was e-mail correspondence with representatives of the Ministry of the Economy, and with a view to aligning this Study with the aforesaid other study commissioned by the Ministry of the Economy concerning the consolidation of authorities supervising the activity of economic entities, representatives of BLS Lietuva participated in an interim presentation of the Study. The submission of an interim Study report was followed by a meeting with representatives of the Ministry of the Economy that discussed observations relating to the Study report and provided complementary information to the representatives of BLS Lietuva on the actual situation concerning some of the functions described in the Study and their implementation. The complementary information was taken into consideration as much as possible when drafting the final report on this Study.

An analysis conducted in this Study is based on the following methods:

- teleological analysis;
- comparative analysis;
- analysis of documents;
- systematic and logical analysis;
- linguistic analysis.

It should be noted that the methods used were chosen in accordance with the objectives of the Contract, the reliability and quality of the methods and a possibility to properly ensure the attainment of the results envisaged in the Contract. The *teleological* method was used to analyse the goals and motives pursued when adopting the Regulation and the Directive and, in particular, certain provisions thereof to enable the researchers to establish the very essence and content of the market surveillance function. The *comparative* method was used to evaluate regulatory practices of the four selected EU Member States (Finland, the Netherlands, Poland and Sweden) in the area of the functions of the market surveillance system. The *systematic analysis* method was used to examine links between legal acts and provisions regulating various market surveillance institutions or methods. The *systematic analysis* method was also used to analyse

the internal links between EU legislation, laws and other legal acts. The *linguistic* method was mainly employed to explain and define concepts.

II. OVERVIEW OF THE LEGAL FRAMEWORK OF SERVICE AND PRODUCT SAFETY AND MARKET SURVEILLANCE

2.1. Overview of the EU legal framework regulating product safety and market surveillance

A systematic evaluation of the national legislation and EU law regulating product safety and market surveillance has identified three areas in which these legal provisions apply.

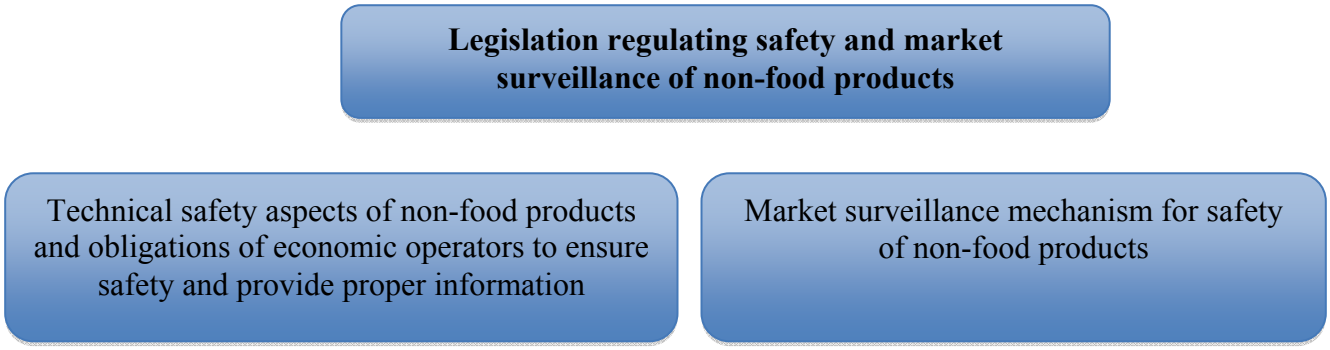
EU law regulates non-food and food products and services differently. Safety of food and non-food products is regulated by different pieces of legislation, and market surveillance aspects of these different areas are also dealt with individually. Article 15(4) of the Regulation sets out that for the purpose of the Regulation "food" is not regarded as a "product". The proposal for a Regulation on market surveillance of products provides for a still clearer unbundling of these areas. Recital 8 thereof stipulates that the scope of this Regulation should exclude food as food chain processes are subject to Regulation (EC) No 882/2004[3] establishing a comprehensive system of official controls and other official actions performed to ensure the verification of compliance with feed and food law, among other things[4]. Service safety or market surveillance of services on the EU level is not at all regulated in a uniform manner. It should be stressed that the main goal of Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market is to ensure free movement of services in the EU, and although it contains a few provisions relating to the assurance of economic interests of consumers (e.g. the service provider's duty to inform the consumer), matters of service safety are not tackled there.

The Directive analysed in this Study is transposed through a single law, the Product Safety Law, regulating product and service safety and stipulating liability for the failure to fulfil the

[3] Regulation No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
[4] Other major EU legislation on food safety includes Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs, Council Directive 93/99/EEC of 23 October 1993 on the subject of additional measures concerning the official control of foodstuffs, Regulation No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

requirements of the Law. Matters pertaining to the scope of the Product Safety Law in respect of non-food and food products are analysed in greater detail in Section 2.3 of the Study but the link developed by the national legislator integrating market surveillance aspects of foodstuffs and non-food products and services within the context of EU law cannot be treated as a single market surveillance mechanism as control mechanisms for non-food products, foodstuffs and services in EU law do not constitute a single system and are regulated separately (or, in the case of services, not at all regulated on the EU level and remain to be regulated nationally).

Legislation regulating safety and market surveillance of non-food products discussed in greater detail in this Chapter regulates two interrelated aspects: first, technical product safety aspects (e.g. general product safety requirements) and obligations of economic operators to market safe products or mandatory actions to be taken where there is suspicion in respect of product safety or where a product is deemed unsafe; and second, state control of the said technical safety requirements, i.e. the mechanism of market surveillance institutions as well as actions and duties of such institutions in ensuring proper market surveillance.



Given the subject of the Technical Specifications for the Study, the Study analyses the EU regulation of the market surveillance mechanism for non-food product safety and the implementation of the EU requirements in the national law. In other words, this Study does not examine product safety requirements and obligations of economic operators.

SUMMARY
• EU legislation regulates requirements to non-food products and foodstuffs and their safety in different pieces of legislation. The Regulation and the Directive examined in the Study only deal with safety and market surveillance matters for non-food products. Safety of services is not at all regulated on the EU level

2.2. Overview of the current EU legal framework regulating market surveillance

2.2.1. General overview of the current EU legal framework regulating market surveillance

The EU legal framework in the area of market surveillance of non-food products is presented in the table below[5].

Overview of the current EU legal framework in the area of safety of non-food products

[5] 2013 02 13 Commission Staff Working Document on Impact Assessment. Product Safety and Market Surveillance Package. A proposal for a Regulation of the European Parliament and of the Council on consumer product safety and a proposal for a Regulation of the European Parliament and of the Council on market surveillance of products.

Products / Areas	Area regulated by legislation not subject to Union harmonisation		Area regulated by legislation subject to Union harmonisation	
	Non-consumer	Consumer		Non-consumer
Obligations of economic operators	National rules on product safety under Articles 34 to 36 of the Treaty on the Functioning of the EU	Directive	Sector-specific legislation subject to Union harmonisation (the Directive as a "safety net")	Sector-specific legislation subject to Union harmonisation
Market surveillance in the internal market*	Regulation 764/2008[6]	Directive (only products dangerous for consumer health and safety)	Sector-specific legislation subject to Union harmonisation + Regulation + Directive	Sector-specific legislation subject to Union harmonisation + Regulation
RAPEX			Regulation referring to the Directive	Regulation referring to the Directive
Market surveillance control of products imported to the EU	Regulation			

The EU regulation of product safety and market surveillance covers the following areas:

- the areas of consumer[7] and non-consumer (professional) products;
- the areas harmonised by legislation subject to Union harmonisation and the areas regulated by legislation not subject to Union harmonisation.

Certain aspects of these areas are regulated differently as in a similar situation they may be subject to different pieces of legislation interactions of which are analysed below in this Section of the Study.

Historically, one of the first EU-level cooperation initiatives in the area of product safety was the Council Decision of 1984 on a common information system on dangers to health and safety arising from the use of products known as RAPEX[8]. The EU regulation of market surveillance and product safety has been developing by adopting various pieces of EU legislation regulating specific product safety and/or market surveillance aspects and sector-specific EU legislation applicable to individual products. The said Decision was revised in 1992 and repealed by Directive 92/59/EEC on the general safety of products[9], which in turn was repealed in 2001 by Directive 2001/95/EC.

[6] Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC.
[7] As established in EU law, a consumer is any natural person acting in pursuit of goals unrelated to their business, commerce or profession in contracts subject to a certain Directive.
[8] Council Decision No 84/133/EEC of 2 March 1984 introducing a Community system for the rapid exchange of information on dangers arising from the use of consumer products.
[9] Council Directive 92/59/EEC of 29 June 1992 on general product safety.

To complement the horizontal Framework Directive, safety of certain products is regulated vertically by EU sector-specific legislation applicable. This sector-specific legislation regulating safety of both consumer and non-consumer products is usually attributed to New Approach Directives[10] and together with the Directive forms a whole package of product safety rules and requirements.

The so-called New Legislative Framework was adopted in 2008. It includes:

- Regulation 764/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State[11];
- Regulation;
- Decision 768/2008.

The entry into force of the New Legislative Framework legislation has brought about a three-tier scheme of market surveillance rules:

A detailed graphic description of the interrelation of these legal acts is presented in the table at the beginning of this Chapter. This interrelation is not unambiguous as the scope of these instruments varies depending on the specific regulation of a product (whether it is regulated by legislation subject to Union harmonisation or not), on the purpose of products (consumer or non-consumer) and on aspects regulated by (or left out of) these legal acts (provisions relating to market surveillance rules, the application of the RAPEX system, duties of economic operators, etc.).

Below is an analysis of each of the aforesaid legal regulation mechanisms and a more detailed description of their interactions.

[10] New Approach Directives are EU directives normally adopted after 1985 that do away with the previously common 'old approach' to lay down very detailed technical requirements to various groups of products. The New Approach Directives employ a flexible technical harmonisation model by laying down few binding essential requirements in the areas of consumer health, safety and environment protection, thus not constraining the implementation of new technologies and new technical solutions. These requirements normally apply to horizontal risk factors or large groups of products, e.g. electric goods, devices, toys, lifts, medical devices, radio and telecommunications equipment, etc. For more information on the New Approach Directives see: http://ec.europa.eu/entreprise/policies/single-market-goods/documents/internal-market-for-products/new-legislative-framework/index_en.htm#h2-3.

[11] Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC.

2.2.2. Directive 2001/95/EC of the European Parliament and of the Council on general product safety

The Directive is one of the key EU legal acts horizontally regulating matters of product safety, related duties of economic operators and certain national control aspects. The purpose of the Directive is to ensure that products placed on the market are safe.

The scope of the Directive:

- like other *lex generalis* directives, this Directive applies apply insofar as there are no specific provisions with the same objective in rules of Community law governing the safety of the products concerned;
- unlike the Regulation discussed further in this Chapter, it applies to products regulated not only by harmonised EU legislation but also by non-harmonised legislation;
- as stated in the preamble of the Directive, this Directive does not cover services (but should apply to products that are supplied or made available to consumers in the context of service provision for use by them);
- the Directive lays down general safety requirements only to consumer products, i.e. any product placed on the market, or otherwise supplied or made available to consumers, intended for consumers, or likely to be used by consumers under reasonably foreseeable conditions even if not intended for them.

The Directive also regulates technical aspects of product safety (and related obligations of producers and distributors) as well as market surveillance measures necessary to ensure product safety (obligations of the Member States in the area of market surveillance). The most important provisions laid down in the Directive are reflected in the table below.

Product safety aspects		Market surveillance functions (for Member States or national authorities)
Producers' obligation to place only safe products on the market. The definition of a safe product and factors taken into account when evaluating the product's compliance with the general safety requirement		Coordination function: the monitoring of the market surveillance system, communicating with the EC notifying it about competent authorities and giving other notices and information and the drafting, updating, implementation and notification to the EC of market surveillance programmes
Principles for laying down European standards and the EC's obligation to publish references to the European standards adopted		The drafting, regular updating and implementation of market surveillance programmes and the monitoring of surveillance activities
Producers' obligation to inform consumers of risks which products might pose and to take action to avoid these risks (e.g. information on the packaging of the product, sample testing of products, withdrawal from the market or recall from consumers, etc.)		Cooperation with producers and distributors
		Application of market restriction measures
		Examination of complaints in respect of products

Distributors' obligation to act with due care to help to ensure compliance with the applicable safety requirements and to cooperate with producers and public authorities		Accumulation of scientific and technical knowledge in the area of safety Informing consumers about dangers
Obligation of producers and distributors to inform competent authorities about actions taken to protect consumers from unsafe products and to cooperate with them		Laying down and enforcing sanctions for infringements of the Regulation and the Directive
		System for rapid exchange of information and emergency interventions (RAPEX)

A detailed analysis of the functions of the market surveillance system set out in the Directive and its implementation in Lithuanian law is presented in Chapter 3.2 of this Study.

2.2.3. Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

The Member States have transposed the provisions of the Directive in their national law as they find fit, which could have caused certain differences in the transposed provisions of the Directive in various Member States. The functioning principles of the EU market surveillance system have been maximally harmonised by the Regulation applicable directly that entered into force on 1 January 2010 and by the common framework adopted together with the Regulation (Decision 768/2008).

The adoption of the Regulation and Decision 768/2008 was brought about by the events of the summer of 2007 where large quantities of consumer products, in particular toys, with toxic substances detected in them were withdrawn from the market in the United States of America and in the EU. As those legal acts were adopted as an emergency, neither the interaction between the Directive and the Regulation nor the interaction between Decision 768/2008 and the New Approach Directives already effective then was properly defined. Interrelations between all these legal instruments are only regulated in general terms setting out that the RAPEX system provided for in the Directive also applies *mutatis mutandis* within the framework of the Regulation while "more special" market surveillance provisions in the Directive apply as *lex specialis* in respect of the Regulation provisions regulating market surveillance[12].

Specific aspects pertaining to the scope of the Regulation:

- **general legal instrument** – the Regulation (like the Directive) applies insofar as other legislation does not contain special provisions identical as to their nature, effect or purpose;
- **application to non-consumer (professional) products** – before the adoption of the Regulation the EU did not regulate market surveillance of non-consumer products by any

[12] 2013 02 13 Commission Staff Working Document on Impact Assessment. Product Safety and Market Surveillance Package. A proposal for a Regulation of the European Parliament and of the Council on consumer product safety and a proposal for a Regulation of the European Parliament and of the Council on market surveillance of products.

horizontal rules and, unlike the Directive, the Regulation applies to checks of products intended for use not only by consumers[13];
- **not applicable to non-harmonised areas** – unlike the Directive, it only applies to products that are regulated by legislation subject to Union harmonisation.

Article 2(21) of the Regulation defines EU harmonisation legislation as "*any Community legislation harmonising the conditions for the marketing of products*". Examples of such legislation could be EU legislation regulating aspects relating to toys, electric goods, cosmetic products, medical devices, recreational craft and other products, e.g.:

- Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys;
- Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits;
- Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment;
- Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products;
- Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices;
- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices;
- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices;
- Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products;
- Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC;
- Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use;
- Directive 2003/44/EC of the European Parliament and of the Council of 16 June 2003 amending Directive 94/25/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft;
- other sector-specific EU legislation.

So, the areas where the scopes of the Regulation and of the Directive do not overlap are clearly defined:

- consumer products not subject to EU harmonisation legislation are regulated by the Directive;
- the area of non-consumer (professional) products subject to EU harmonisation legislation is regulated by the Regulation;

[13] In accordance with Article 15(4) of the Regulation, a 'product' shall mean a substance, preparation or good produced through a manufacturing process other than food, feed, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction.

- non-consumer products not subject to any EU harmonisation legislation are not regulated by any of the two horizontal instruments[14]:

Directive 2001/95/EC (consumer products)		**Regulation 765/2008** (products subject to EU harmonisation legislation)	**Area not regulated by EU legislation**
Consumer products not subject to EU harmonisation legislation	Consumer products subject to EU harmonisation legislation	Non-consumer products subject to EU harmonisation legislation	Non-consumer products not subject to EU harmonisation legislation

To avoid misunderstandings as to which legal instrument should apply to consumer products subject to EU harmonisation legislation and bearing in mind the need to ensure a high level of consumer protection, Article 15(3) of the Regulation sets out that "*the application of this Regulation shall not prevent market surveillance authorities from taking* ***more specific measures*** *as provided for in Directive 2001/95/EC*". This implies that consumer products subject to EU harmonisation legislation fall under all market surveillance provisions of the Regulation, and where the Directive sets out more specific market surveillance measures than those provided for in the Regulation, the provisions of the Directive apply. Accordingly, the market surveillance provisions of the Directive where no specific measures are envisaged no longer apply after the entry into force of the Regulation.

The Regulation has expanded the content of the obligation to send notifications via the RAPEX system by including products regulated by EU harmonisation legislation including products intended for professional activity (e.g. manufacturing machinery) and products that may be detrimental to public interests unrelated to health and safety (e.g. the environment, security, fairness of commercial transactions, etc.)[15]. The primary purpose of the expanded content of the obligation is to enhance the protection of employees and the environment. The inclusion of a reference to the RAPEX system in the Regulation has become an acknowledgement of the importance of this mechanism for information exchange for market surveillance in the single market and the links between this mechanism and EU legislation regulating specific products. To adjust the information system to the broader scope, the GRAS-RAPEX system was developed for sending RAPEX notifications (replacing in 2012 the RAPEX-REIS system).

Article 23 of the Regulation obliges the EC to develop and maintain a general archiving and exchange of information system relating to market surveillance activities.

The Regulation lays down obligations of the Member States and national authorities in charge of market surveillance (performing the functions of the market surveillance system) and regulates matters relating to the accreditation system and CE marking. They are presented in a systematic manner in the table below.

Functions of the market surveillance system		**Other provisions**
Functions relating to market surveillance policy making: • monitoring of the market surveillance system • drafting, updating, implementation and		Principles of the accreditation system: • appointment of, requirements to and

[14] 2010 03 03 European Commission Directorate-General for Enterprise and Industry and Directorate-General for Health and Consumers General Working paper on the relationship between the General Product Safety Directive 2001/95/EC and the market surveillance provisions of Regulation (EC) No 765/2008.
[15] EC report on the implementation of the Regulation.

notification to the EC of the general market surveillance programme • public awareness raising/education on market surveillance authorities and their functions • communicating with the EC notifying it of competent authorities and providing other notifications and information • establishing a cooperation mechanism between national market surveillance authorities and between national market surveillance authorities and authorities in charge of external border control		mutual cooperation of national accreditation authorities • verification of the competence of conformity assessment authorities • cross-border accreditation • European accreditation infrastructure
Development, regular updating and implementation of sector-specific market surveillance programmes, monitoring of surveillance activities and participation in developing the national programme		General CE marking requirements
Cooperation: • between market surveillance authorities and authorities in charge of external border control • with market surveillance authorities of the Member States and with market surveillance authorities of third countries		Matters of EU financing
Application of market restriction measures		
Examination of complaints concerning products		
Monitoring of accidents and damage to health relating to products		
Checks of products		
Informing consumers about dangers		
Accumulation of scientific and technical knowledge on safety		
Checking of the product, documents and CE marking (including checks of authorities in charge of external border control) and sanctions for the failure to meet requirements		
Imposing and enforcing sanctions for the failure to observe the provisions of the Regulation		
Ensuring the proper administration of RAPEX and provision of data and information to the general information support system		

Along with the Regulation, Decision 768/2008 was also adopted within the New Legislative Framework. As laid down in the preamble of the Regulation, the Regulation should be seen as complementary to **Decision No 768/2008** while the purpose of Decision 768/2008 is to make the regulation of products as clear and consistent as possible.

As Decision 768/2008 lays down a system of general principles and reference provisions for the drawing up of Community legislation harmonising the conditions for the marketing of products, this instrument is useful for the technical harmonisation and appropriation of general aspects relating to the regulation of products. Annexes to Decision 768/2008 contain definitions,

obligations of manufacturers, authorised representatives, importers and distributors and details of conformity assessment procedures. Although Community harmonisation legislation is based on general principles laid down in the Decision, given specific aspects of certain sectors and the existing regulation, certain Community instruments may depart from those general principles and reference provisions.

So, as far as the regulation of the market surveillance system is concerned, the market surveillance mechanism created by the Regulation and the Directive lays down certain functions of the Member States (which the Member States then delegate to national market surveillance authorities) relating to the functioning of the market surveillance system in each Member State and the proper assurance of the performance of these functions. The Regulation stipulates that market surveillance means the activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Community harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection.

In general, market surveillance is an essential tool helping to protect consumers and other users from unsafe products failing to meet conformity requirements and ensuring that all economic entities observe the rules. On the one hand, the market surveillance mechanism is established by the Member States proper while on the other hand, the Directive and the Regulation lay down specific minimal criteria for market surveillance systems of the Member States, such as sufficient capacity and resources to perform implementing activities. They also stipulate a minimal set of measures to be taken by the Member States in respect of dangerous products and the obligation for all Member States to have one liaison authority for RAPEX, etc.[16]

The functions of the market surveillance system laid down by the mechanism in the Regulation and the Directive may be divided into two groups by nature of these functions: (i) system functions, which are general functions relating to general policy making in the area of market surveillance; (ii) market surveillance functions, which are functions relating to the application of specific market surveillance measures and intended for market surveillance authorities. Chapter 3.2 of the Study offers a detailed analysis of the implementation of each of the functions in the table below in national law.

Functions of the market surveillance system		
System functions		**Market surveillance functions**
Public awareness raising/education on market surveillance authorities and their functions	Drafting the sector-specific market surveillance programme and/or participation in drafting the national market surveillance programme	Cooperation between market surveillance authorities and authorities in charge of external border control
Communication with the EC (notification of authorities and provision of other notifications and information)	Cooperation with market surveillance authorities of the Member States and third countries	Cooperation with manufacturers and distributors
Monitoring of the market	Application of market	Examination of complaints

[16] 2013 02 13 Commission Staff Working Document on Impact Assessment. Product Safety and Market Surveillance Package. A proposal for a Regulation of the European Parliament and of the Council on consumer product safety and a proposal for a Regulation of the European Parliament and of the Council on market surveillance of products.

surveillance system	restriction measures	concerning products
Establishing a cooperation mechanism between national market surveillance authorities	Monitoring of accidents and damage to health relating to products	Accumulation of scientific and technical knowledge on safety
Drafting, updating, implementation and notification to the EC of national or sector-specific market surveillance programmes	Imposing and enforcing sanctions for violations of the provisions of the Regulation and the Directive	Notifying consumers about dangers
	Checks of the product, documents and CE marking performed by authorities in charge of external border control	Imposing sanctions for the misuse of CE marking
	Provision of data and information to the general information support system	Proper assurance of RAPEX administration
	Verification of products	

SUMMARY

- The Directive regulates only non-food consumer products while the Regulation applies to all non-food products subject to EU harmonisation legislation. Where the Directive provides for "more specific" market surveillance functions, the provisions of the Directive apply
- The area of non-consumer products not regulated by EU harmonisation legislation is not at all regulated on the EU level
- Such overlapping of EU legislation creates a lack of clarity both for economic operators and public authorities
- The functions of the market surveillance system created by the Directive and the Regulation can be divided into two groups depending on their nature:
  - system functions: general functions relating to general policy making in the area of market surveillance;
  - specific market surveillance functions: functions relating to the application of specific market surveillance measures and intended for market surveillance authorities

2.3. An overview of the existing Lithuanian legal framework regulating market surveillance

2.3.1. A general overview of the existing Lithuanian legal framework regulating market surveillance

The market surveillance mechanism effective in Lithuania in the area of product safety is often defined by EU legislation. An overview of the legal framework for market surveillance in Lithuania is presented in the diagram below.

Regulation of market surveillance					
General law	Special laws		By-laws		
Product Safety Law	Metrology	Standardisation	General	Laying down specific requirements on the basis of special laws	Technical regulations and medical regulations
	Electronic communications	State Labour Inspectorate	Rules on the application of measures to restrict the placing on the market of products		
	Consumer protection	Road Transport Code	RAPEX procedure approved by the VVTAT		
	Radiation protection	Environment protection	Institutional regulations		
	Chemical substances and preparations	Pharmaceuticals	Procedure for the examination of complaints		
	Radiation protection	Customs			

Below this Study goes on to discuss each of the legal regulation groups individually.

General regulation

As mentioned in the Study, the provisions of the Directive are transposed in the Lithuanian law by the Product Safety Law. Even though in this Study the EU legislation only regulates product safety and does not at all cover the safety of foodstuffs or services, when transposing the Directive to the Product Safety Law, the Lithuanian legislator chose to expand the scope of safety requirements. Thus, in this respect, the Product Safety Law is to be deemed a general, or an 'umbrella' legal instrument regulating market surveillance.

The Product Safety Law defines 'product' as a product or service, so this Law applies not only to products (as the Directive or the Regulation) but also to services. However, the scope of the Product Safety Law in respect of foodstuffs is unclear as shows a systematic examination of the Product Safety Law and other legal provisions related:

- the definition of the scope of the Product Safety Law does not provide for any exception that the Law does not apply to foodstuffs. Moreover, Article 2(2) of the Product Safety Law sets out that "*where another legal instrument lays down certain safety requirements to a specific product, the requirements of that legal instrument shall apply while this Law shall apply insofar as the other legislation regulating safety of a specific product does not contain respective provisions*". This may imply that the Product Safety Law applies to foodstuffs insofar as food safety is not regulated by special food laws but Article 3(3)

of the Product Safety Law defining the concept of 'product' does not explicitly state whether 'products' cover only non-food products or whether they also include foodstuffs;

- Article 12 of the Product Safety Law stipulates that the fulfilment of the requirement that only safe products are placed on the market is controlled by "*authorities established by the Government to be in charge of the control of safety of foodstuffs and non-food products*". This implies that the Product Safety law also regulates the safety of foodstuffs. The State Food and Veterinary Service as an authorised institution is also referred to in Resolution No 438 of the Government of the Republic of Lithuania of 2 April 2002 on granting powers in implementing the Law amending the Law of the Republic of Lithuania on product safety (*Official Gazette*, 2002, No 35-1306);
- in their rulings concerning violations of the Product Safety Law the courts of the Republic of Lithuania do not express procedural doubts whether the safety requirements laid down in the Product Safety Law apply to both types of products (non-food and food) or whether food safety is only regulated by the Law on food while the Product Safety Law only provides for the procedure for the imposition of sanctions for violations of the Food Law. An analysis of court judgments shows that the courts do not question the legality of the procedure used by public authorities where the sanctions provided for in the Product Safety Law are imposed for violations of the Food Law but it is not always that they see strict limits distinguishing between the food safety requirements in the Product Safety Law and the Food Law. For instance, they rule that "*given that relations relating to food safety and handling are regulated by the Product Safety Law laying down liability for violations of safety, quality and processing requirements laid down in this and other legal acts where there are data showing possible violations of the requirements of the Food Law, the Authority is tasked with handling the matter of liability under the Product Safety Law*"[17].
- the Food Law offers a separate definition of 'food' and in Article 7 refers to the Product Safety Law setting out that "*producers, sellers or service providers having violated the requirements of this Law or other legislation shall be liable in accordance with the procedure laid down in the Product Safety Law and other laws*". This implies that food safety requirements are only laid down in the Food Law while the liability for violations of the Food Law is provided for in the Product Safety Law;
- VVTAT Regulations include as separate annexes (Annex 1 and Annex 2) a report on violations of the Product Safety Law and a report on violations of the Food Law subject to liability under the Product Safety Law.

A systematic evaluation of all of the above explicitly demonstrates that the relation between the Product Safety Law and the Food Law and, in general, the scope of the Product Safety Law in respect of foodstuffs are not clearly defined in the legal instruments. Given that, necessary amendments need to be introduced in the Product Safety Law unambiguously and consistently stating the scope of application of that Law to food safety.

The Product Safety Law regulates: (i) aspects of product safety; and (ii) aspects of market surveillance. These aspects regulated by the Product Safety Law are presented visually in the diagram below.

PRODUCT SAFETY LAW

[17] Judgment of Vilnius Regional Administrative Court of 17 December 2012, Administrative Case No I-3330-281/2012.

State regulation and control functions in the area of product safety		Aspects of product safety
State regulation of product safety	Provision of information to the EC and other countries	General product safety requirements
State control of product safety	Market restriction measures	Obligations of producers, distributors and service providers to ensure product safety
Matters of state regulatory assessment of product safety	Regulation of liability for violations of the Product Safety Law	

To be more specific, the Product Safety Law *inter alia* sets out:

State regulation and control functions in the area of product safety		**Aspects of product safety**
State regulation of product safety: • binding product safety and labelling requirements are set by the Government and other authorities within their remit • the implementation of legislation regulating product safety is coordinated by the VVTAT • information on dangerous products is supplied by the EC and/or other countries in accordance with the procedure laid down by the Government or an authority authorised thereby		• General product safety requirements • Obligations of producers, distributors and service providers to ensure product safety
State control of product safety: • the fulfilment of the requirement that only safe products are placed on the market is controlled by control authorities in the area of food and non-food product safety established by the Government • the content of product safety control (direct control including checks, controls of product withdrawal and destruction, analysis and submission of control data to the VVTAT; indirect control including processing and analysis of statistics) • rights and obligations of control authorities • making information available to the public		
• Market restriction measures (the requirement to proper labelling of products with warnings of possible risks, a provisional ban on the supply of the product (while an investigation is ongoing), a prohibition to market the product, an order to withdraw the product immediately, recall it from consumers and/or destroy it)		
• Matters of state regulatory assessment of product safety		

• Regulation of liability for violations of the Product Safety Law		

To sum up, the provisions of the Product Safety Law relating to market surveillance are of three types:

- laying down a control system for consumer products,
- laying down market restriction measures and a mechanism for its application,
- laying down the imposition of liability for violations of product safety requirements.

Special laws

Apart from the Product Safety Law, certain aspects of market surveillance of non-food products in Lithuania are regulated by other laws covering certain areas of market surveillance of products or related aspects. The table below lists areas falling under special laws in the field of market surveillance.

Special law	Aspects regulated in the field of market surveillance
Law on metrology	• Definition of market surveillance (Article 2(27)) • Obligation to notify the EC and other authorities of Member States of market restriction measures imposed (Article 9(4)) • Competence to check products (Articles 19, 22(1) and 22(2)) • Competent to impose market restriction measures (Article 22(2)) • Cooperation with other EU Member States (without specifying that it relates to product safety) (Article 9(3)(3))
Law on the State Labour Inspectorate	• Market restriction measures (Article 8(2)(7)) • Obligation to examine complaints (without specifying that they relate to product safety) (Article 6(15)) • Obligation to collect and analyse information relating to accidents at work and drafting proposals to improve the situation (without specifying that these are in relation to product safety) (Articles 6(11) and 6(14)) • Competence to check products (work equipment used) (Article 6(3)) • Obligation to inform about a possible threat of an accident (Article 8(1)(6))
Law on electronic communications	• Competence to check products (Articles 10(1)(1) and 10(1)(2)) • Liability (Article 74)
Law on radiation protection	• Obligation to control the compliance of products with safety requirements (Article 11(2))
Law on pharmaceuticals	• Imposition of market restriction measures (Article 67) • Obligation to ensure that complaints concerning the quality of a medicinal product are properly responded to (Articles 34(2)(4) and 40(2)(3))

	• Obligation to cooperate with other public authorities (without specifying that it relates to product safety) (Article 69(1))
Road Transport Code	• Checks of products (Articles 14(2) and 14(4))
Law on customs	• Obligation to examine complaints (without specifying that they relate to product safety) (Article 6(15)) • Checks of products (Articles 27(3), 32 and 33(5)) • Obligation to cooperate with other national authorities (without specifying that it relates to product safety) (Article 13(1)) • Obligation to cooperate with other authorities of third countries (without specifying that it relates to product safety) (Article 13(2))
Law on consumer protection	• Organisation and implementation of information exchange (RAPEX system) (Article 12(1)(11))

It should be noted that as shown in the analysis in Chapter 3.2 of the Study, in many cases market surveillance provisions do not clearly regulate the link between the general law (the Product Safety Law) and the special laws. It should be noted that where an individual law regulating a specific area of management also seeks to define the functions of the market surveillance system, it should contain explicit provisions relating to the functions of the market surveillance system and an evaluation of the provisions of the Product Safety Law and establish a consistent and uniform market surveillance system. The existing regulatory framework defined in the special laws in respect of the functions of the market surveillance system is inconsistent and non-uniform, which makes it difficult to identify the provisions relating to the regulation of market surveillance.

By-laws

By-laws regulating aspects of market surveillance could be classified as follows:

- general by-laws laying down the functioning of the mechanism of the market surveillance authority (e.g. the Rules for the application of restrictions on marketing of products, Order No 1-62 of the Director of the State Consumer Rights Protection Authority of 14 May 2010 approving the Rules for rapid exchange of information on products dangerous to consumers);
- special by-laws laying down specific requirements as well as sector-specific rules and procedures (e.g. regulations of certain market surveillance authorities);
- technical regulations laying down in detail specific matters of product safety (e.g. technical regulations concerning toys, machinery or recreational craft).

By-laws relevant to the implementation of market surveillance functions are discussed in the analysis of the functions of the market surveillance system.

2.3.2. Issues relating to the existing general legal framework regulating market surveillance in Lithuania

An analysis of the legal framework regulating market surveillance in Section 2.3.2 of the Study helps to make a list of a number of issues relating to the existing general legal framework regulating market surveillance in Lithuania:

- market surveillance authorities are not analysed in detail in the Product Safety Law (the market surveillance management system is unclear);
- there is no overarching "umbrella" law regulating market surveillance of non-consumer (professional) products;
- the issue relating to the enforcement of the Regulation in the Lithuanian national law;
- the issue relating to the competence of authorities to impose market restriction measures and/or sanctions by adopting regulatory by-laws.

On the regulation of authorities in charge of market surveillance of products in the Product Safety Law

Although the Product Safety Law is the main general law regulating the safety of consumer products, the authorities involved in market surveillance of consumer products are not clear. To regulate the cornerstone of the Product Safety Law (state regulation of product safety), the Product Safety Law contains blanket provisions not even referring to other specific legislation or at least legislation drafted by specific authorities but just setting out abstract concepts. The Law in an abstract manner refers to "*authorities authorised by the Government*" or "*control authorities*" that are obliged to adopt rules creating rights and obligations of public authorities and/or economic entities controlled thereby. Such lack of concrete provisions in the Law makes it particularly difficult both for economic operators and for consumers to understand the existing system of surveillance of product safety in Lithuania.

Article 5 of the Product Safety Law stipulates that "*the Government, governmental bodies, ministries, departments under ministries and other bodies in their respective areas of public governance within their remit shall lay down binding product safety and labelling requirements aligned with the requirements of the United Nations Organisation, the European Union and the World Trade Organisation as well as a procedure for ascertaining that they meet the requirements set*". The abstract nature of this provision is partially justified by the fact that the Product Safety Law is *lex generalis*, i.e. that it applies insofar as there are no specific provisions regulating the safety of a certain product. On the other hand, the Product Safety Law does not explicitly state where and how (in what legal instrument) product safety and labelling requirements omitted in this Law and binding on producers, importers and distributors of all products or service providers should be regulated but this lack of clarity is tackled by Resolution No 1482 of the Government of the Republic of Lithuania of 27 December 1999 appointing authorities authorised to approve binding product safety requirements (*Official Gazette*, 1999, No 114-3304) stipulating which ministry of the Republic of Lithuania approves technical regulations and other binding product safety requirements in which specific product areas.

Basic interpretation problems with the Product Safety Law arise in Article 12 regulating the control of the fulfilment of product safety requirements and setting out that "*the fulfilment of requirements that only safe products are placed on the market laid down in this Law and other legislation shall be controlled by food and non-food safety control institutions established by the*

Government in accordance with the procedure laid down in the laws and other legislation of the Republic of Lithuania". The Law does not list those institutions controlling the safety of food and non-food products. What is more, the wording used in the Product Safety Law does not make it apparent at all whether in this case the Product Safety Law empowers two institutions or any market surveillance authorities. Given that the Law uses the concept "*food and non-food safety control institutions*" and the fact that following the entry into force of the Product Safety Law the State Non-Food Products Inspectorate and the State Food and Veterinary Service[18] were established in Lithuania, this may imply that the Product Safety Law only grants powers to the VVTAT (the VVTAT is directly referred to in the Product Safety Law) and these two authorities. It should be stressed that the said provision of the Product Safety Law is very important as the Product Safety Law grants broad rights to these institutions, e.g. to check the compliance with the legislation regulating product safety; to organise the required checks of product safety aspects; to receive information and documents from producers, distributors and service providers; to sample products; to request that the management of producers, distributors and service providers or their authorised representatives arrive and give oral or written explanations; to suggest to a respective authority suspending or withdrawing a licence to engage in certain economic commercial activity held by persons whose products marketed cause damage to consumers; where any violations of legal requirements to product safety are identified, to issue a warning to producers, distributors and service providers and to oblige them to eliminate the violations immediately; and on the grounds laid down in this and other laws and in accordance with the procedure set by the Government to impose market restriction measures. In other words, these authorities have significant powers in respect of third parties including powers to restrict rights of third parties. Such lack of clarity in the regulation may give rise to disputes concerning the legal basis for the powers of market surveillance authorities. It should be noted that this lack of regulatory clarity in the Product Safety Law is reinforced by a Resolution of the Government regulating the procedure for the application of restrictions on marketing of products.

The procedure for the application of restrictions on marketing of products is regulated in detailed by the Rules for the application of restrictions on marketing of products. These Rules do not contain an exhaustive list of authorities that may impose these measures either. Paragraph 3 of the Rules for the application of restrictions on marketing of products sets out that "*market restriction measures shall be imposed by the National Consumer Protection Council under the Ministry of Justice ('the Council'), the State Food and Veterinary Service (with a view to restricting the placing on the market of foodstuffs dangerous to consumer health), the State Non-Food Products Inspectorate under the Ministry of the Economy (with a view to restricting the placing on the market of non-food products dangerous to consumer health and safety), public health centres in counties (with a view to restricting the placing on the market of services dangerous to consumer health and safety within their remit) as well as other product safety control institutions established by the Government of the Republic of Lithuania within their remit*". It should be noted that an interpretation of the Product Safety Law different from the one presented above may give rise to doubts as to whether this paragraph of the Rules is compatible with Article 12 of the Product Safety Law.

[18] The VNMPI was established by Resolution No 505 of the Government of 4 May 2000 (*Official Gazette*, 2000, No 38-1064) on 1 July 2000 by reorganising the Lithuanian State Quality Inspectorate, the State Hygiene Inspectorate and the State Veterinary Service. The State Food and Veterinary Service was established in 2000 by reorganising the State Veterinary Service and veterinary bodies reporting to it, the State Hygiene Inspectorate under the Ministry of Health and the Lithuanian State Quality Inspectorate under the State Competition and Consumer Protection Service.

Given the above, this method of legal regulation where both the law and the related Governmental resolution give a generalised reference to yet other legal instruments is defective, which is why the legal framework in this area needs to be revised.

It should also be noted that market restriction measures relating to a product that is possibly dangerous or alternatively is already known as dangerous cover a requirement to properly label the product with warnings of possible risks, a provisional ban to market the product (while an investigation is ongoing), a prohibition to market the product, immediate withdrawal of the product, its recall from consumers and/or its destruction. Such market restriction measures may have drastic consequences for any economic entity involved in the production or the import of products or providing services. However in this case there is no legal certainty ensured for economic entities as to which authorities may impose such measures on them and what their competences are. It should be pointed out that the Constitutional Court has stated on numerous occasions that "*legal clarity and legal certainty are integral elements of the constitutional principle of the rule of law. The legal framework established in laws and other legislation must be clear and legal wordings must be precise to enable parties to legal relations to guide their actions so as to meet legal requirements*" (*Ruling of the Constitutional Court of 13 December 2004; Ruling of the Constitutional Court of 16 January 2006; Ruling of the Constitutional Court of 6 January 2011*). As mentioned above, the regulatory framework established in the Product Safety Law and the Rules for the application of restrictions on marketing of products lacks clarity and precision.

What is more, setting amounts of fines for violations of the Law, the Product Safety Law does not even specify which authorities are involved in the process of investigating and imposing fines for violations of the Law. Article 27 of the Law sets out that fines are imposed by the VVTAT and goes on to stipulate that a report based on which the fine is imposed is drawn up by a representative of *a control authority* who also participates in examining the case of the violation of the Product Safety Law. This provision of the Product Safety Law could be corrected taking into account Article 259[1] of the Code of Administrative Infringements of the Republic of Lithuania regulating similar relations and listing persons authorised to draw up reports on administrative infringements.

The above leads to a conclusion that such lack of clarity in the Product Safety Law (where it does not explicitly stipulate the system of market surveillance institutions in the Law proper and it is impossible to identify the functions assigned to these institutions) should be eliminated by setting out in detail in the Product Safety Law specific market surveillance authorities and their functions[19]. Given the above, there is a need to revise the existing hierarchy of product safety

[19] In its case-law the Constitutional Court has held that the constitutional principle of legitimate expectations is part to the constitutional principle of the rule of law and, in turn, includes the principle of legal security. The imperative of legal security implies certain binding requirements to the legal framework proper. It must be clear and consistent and legal wordings must be precise (*Ruling of the Constitutional Court of 12 July 2001*[19]). The Constitutional Court has held that the legal regulatory framework must ensure the consistency and internal sustainability of the legal system and that "*legal provisions must be worded precisely and without ambiguity*" (*Ruling of the Constitutional Court of 26 January 2004*[19]). The Constitutional Court has also expressed itself on the imposition of restrictions and sanctions on economic activity: "*certain economic relations may only be regulated by laws while others – by Governmental resolutions, and others still – by lower-level by-laws. Within the context of the constitutional justice case at hand it should be stressed that in accordance with the Constitution the key conditions, prohibitions and restrictions of economic activity having major effects on economic activity as well as various sanctions for violations of the law (inter alia, the so-called economic sanctions attributable to the institute of administrative liability and creating prerequisites for adverse effects on the economic status of economic entities held liable (Ruling of the Constitutional Court of 3 November 2005)) may only be stipulated by law. So it is only by law that is possible to set also economic measures that may have major effects on economic activity and that must apply where obligations are not fulfilled or are fulfilled unduly*" (*Ruling of the Constitutional Court of 31 May 2006*).

legislation in the Republic of Lithuania clearly establishing which authorities are deemed market surveillance authorities of the Republic of Lithuania and how they participate in market surveillance processes, the safety of which products they control and what rights and powers they have in the process of controlling these products. *The right* of each market surveillance authority to impose specific market restriction measures and/or sanctions should be enshrined in a law with clear references to which other laws set amounts of sanctions and the procedure for the application of market restriction measures (unless they are envisaged in the same law that gives the authority to impose sanctions or market restriction measures).

To avoid fragmentation where powers to specific market surveillance authorities are granted by different laws, the general market surveillance principles in the Republic of Lithuania, criteria pertaining to market surveillance authorities and an exhaustive list of market surveillance authorities of the Republic of Lithuania could be included in an "umbrella" law of the Republic of Lithuania on product safety, i.e. the Product Safety Law (at the same time clearly defining the link of this Law with special legal acts regulating product safety).

On market surveillance of the safety of non-consumer (professional) products in the Republic of Lithuania

Article 2(1) of the Product Safety Law sets out the scope as follows: "*this Law shall apply to legal and natural persons placing on the market consumer products*". This means that, like the Directive, the Product Safety Law applies only to consumer products. Although the Product Safety Law is the only law of the Republic of Lithuania regulating matters of product safety in a systematic manner, it still cannot be regarded as an umbrella or generalised regulatory ground for product safety as it does not regulate the market of non-consumer products (i.e. products intended for professional use).

The Product Safety Law as *lex generalis* applies in respect of legislation regulating only consumer products where the Lithuanian legislation does not contain provisions regulating the safety of a specific consumer product or insofar as there are no respective provisions in the legislation regulating the safety of a specific consumer product. At the same time, the market of non-consumer (professional) products is regulated only by special legislation regulating individual non-consumer products, their safety or their placing on the market. Such regulation may be linked with at least a few problems:

- **it is highly probable that certain non-consumer (professional) products will not fall within the scope of market surveillance**. Maximum regulation of absolutely all products or product types produced, otherwise created in or introduced to a free-economy country by individual legal acts (specifically stipulating sanctions for violations) is hardly imaginable. Therefore, it may be possible that without an umbrella law (*lex generalis*) regulating the safety of non-consumer products, the safety of certain non-consumer products is not regulated at all in the Republic of Lithuania, or where it is regulated, there is possibly no control;
- **regulation will become too fragmented and it may be difficult to understand the system of regulation**. Moreover, this would mean that each individual law would have to reiterate market surveillance measures and sanctions to be imposed for violations of safety requirements;
- **regulation also implies that there is no single "umbrella" institution competent to impose market surveillance measures in respect of non-consumer (professional)**

products where such competence is not given to individual institutions (performing specific functions). It should be noted that as will be shown further, the VNMPI is only competent to control consumer products.

It has to be stressed that although the Regulation is a legal instrument applicable directly, it cannot empower a specific national authority. So, to ensure that the Regulation is duly implemented in the national law in accordance with the hierarchy rules existing in the national law, relevant competences must be granted to public authorities. Furthermore, where a non-consumer (professional) product produced or distributed in the Republic of Lithuania is not subject to EU harmonisation legislation, the market surveillance provisions of the Regulation do not cover it at all. As matters of controlling the safety of such a product cannot be dealt with in the Product Safety Law applicable to consumer products either, the legal basis for controlling the safety of such a product is non-existent if there is no special national regulation.

On the implementation of the Regulation in Lithuania

An systematic analysis of the Lithuanian legislation regulating product safety or related aspects poses questions pertaining to the *de jure* implementation of the Regulation. As provided for in the EU law, regulations are binding in their entirety and directly applicable in all EU Member States that must ensure the effectiveness of regulations and in some cases adopt implementing national legislation.

In accordance with Article 12^{1}(1)(1) of the Law of the Republic of Lithuania on the procedure for drafting laws and other regulatory legislation effective at the moment of the entry into force of the Regulation, "*references to European Union legislation in accordance with the requirements of this Article shall be given where a legal act or specific provisions of a legal act harmonise and implement European Union legislation*". As provided for in paragraph 4.1 of the Recommendations on giving references to European Union legislation in laws and other legislation, references to EU law must be provided where EU legislation implemented contains any provisions setting out that EU Member States must implement it (by harmonising its legislation or adopting implementing legal acts) or where the content of EU legislation implemented shows that such legislation is to be harmonised or adopted. Given the nature of the Regulation and obligations imposed by it on the Member States, one may a draw a conclusion that to ensure the proper functioning of the Regulation, there is a need to adopt complementary national legislation, at least some provisions that would indicate which public authorities of the Republic of Lithuania are tasked with the performance of the functions provided for in the Regulation.

The conclusions of the Working Party of 11 September 2009 state that "*having examined market surveillance legislation of the Republic of Lithuania and the functions of market surveillance authorities of the Republic of Lithuania, the Working Party has established that the existing legal and institutional framework does not create major problems for the implementation of the Goods Package and does not require actions complementing the measures provided for in the Plan of the Government of the Republic of Lithuania for the transposition and implementation of European Union law (Measure (EC) No 765/2008_01.001/01.002, Measure (EC) No 768/2008/EC_01.001/01.002/01.003/01.004/01.005 and Measure (EC) No 764/2008_01.008/01.009)*". Still, the Working Party has stated that the definitions given in the Product Safety Law, the Consumer Protection Law and other legislation referred to in the conclusions of the Working Party differ from the definitions given in the Regulation and suggested that they be made uniform. Given the conclusions of the Working Party, the

definitions in the Product Safety Law as the main law regulating product safety in Lithuania are still not aligned with the definitions in the Regulation.

The scope of the Regulation may imply that one of the legal instruments implementing the Regulation is the Product Safety Law but the annex to the Law does not contain a reference to the Regulation. A search in the official database of the legislation of the Republic of Lithuania at www.lrs.lt returned hits of amendments to only two national laws referring in their annexes to the Regulation as the EU instrument being implemented. These are the Law amending the Law of the Republic of Lithuania on conformity assessment[20] and the Law amending Articles 1, 2, 4, 5, 6, 8, 10, 11, 12, 16, 18, 18(1), 29, 36, 39, 40, 41, 43(1) and 47 of and Annex 2 to the Law of the Republic of Lithuania on construction[21].

Moreover, in implementing the Regulation by orders of the Minister for the Economy, two technical regulations were approved including a recast of the Technical Regulation on the safety of toys and a new Technical Regulation on portable pressurised equipment[22] as well as complementary by-laws (e.g. orders of the Minister for the Economy and of the Head of the VNMPI).

Still, the sole fact that the Regulation is practically not referred to in the Lithuanian legislation relating to product safety and market surveillance as the EU instrument implemented by these legal acts is not a sufficient basis to claim that in the Republic of Lithuania the Regulation is not at all implemented or is implemented unduly. In other words, the said shortcoming in the implementation of the Regulation in itself does not imply the inappropriate implementation of the Regulation. The implementation of the mechanism of the market surveillance system created by the Regulation and the Directive in the national law is analysed in greater detail in Chapter 3.2 of the Study.

Still, given the legislative rules, legislation implementing the Regulation should contain a reference to the Regulation as such a reference *inter alia* plays an information role. Both those who apply the legislation and economic entities and the public are better informed about the existing legal framework.

On the competence of authorities to impose sanctions or market restriction measures

Special product safety requirements usually transposed from EU harmonisation legislation are laid down by relevant orders of competent ministers in approved technical regulations, medical and hygiene regulations. As the analysis of safety requirements to technical products or obligations of economic operators is not the purpose of this Study, the content of technical regulations is not analysed in detail in this Study. Still, a general analysis of the legal system for product safety in Lithuania has established that when transposing EU harmonisation legislation laying down specific product safety aspects, the by-laws adopted stipulated not only safety requirements to individual products but also powers of competent market surveillance authorities to impose market restriction measures or even sanctions for violations. Such legal techniques

[20] Law amending the Law of the Republic of Lithuania on conformity assessment (*Official Gazette*, 2011, No 40-1919).
[21] Law amending Articles 1, 2, 4, 5, 6, 8, 10, 11, 12, 16, 18, 18-1, 29, 36, 39, 40, 41, 43-1 and 47 of and Annex 2 to the Law of the Republic of Lithuania on construction (*Official Gazette*, 2013, No 68-3415).
[22] Order No 4-174 of the Minister for the Economy of the Republic of Lithuania of 1 April 2011 approving the Technical Regulation on the safety of toys (*Official Gazette*, 2011, No 40-1928); Order No 4-472 of the Minister for the Economy of the Republic of Lithuania of 7 July 2011 approving the Technical Regulation on portable pressurised machinery (*Official Gazette*, 2011, No 88-4224).

where market restriction measures or sanctions are provided for in by-laws rather than a law are defective[23].

For example:

Legal framework	Competence of institutions to impose market restriction measures or sanctions	Legal comments
Technical Regulation on the safety of machinery[24]	**Paragraph 8:** within their remit the SLI and the VNMPI are to take all measures necessary to ensure that machinery can be placed on the market and/or commissioned only if it is in line with the applicable provisions of the Machinery Directive 2006/42/EC and does not endanger human health and safety and, in certain cases, pets and property, if it is properly installed and maintained and used for the purpose intended or under circumstances that can reasonably be envisaged (the SLI is in charge of ensuring that machinery intended for use only by professional operators is in line with the provisions of this paragraph while the VNMPI ensures that machinery that may be used by non-professional operators, i.e. consumers too, meets the provisions of this paragraph) **Paragraph 60:** sanctions applicable for violations of the provisions of this Regulation are set in the Civil Code of the Republic of Lithuania. Volume Six. Law of obligations and the Product Safety Law.	As the Product Safety Law only applies to consumer products and the Regulation sets out that machinery used by consumers is under the control of the VNMPI, this leads to a conclusion that sanctions for violations of the Regulation under the Product Safety Law are imposed only by the VNMPI. For the SLI, the basis for imposing sanctions concerning machinery used by professional operators is not stipulated at all. Volume Six "Law of obligations" of the Civil Code of the Republic of Lithuania does not provide for any sanctions for violations of technical legislation, which is why it cannot be treated as the basis for the imposition of such sanctions.
Technical Regulation on recreational craft[25]	**Paragraph 25:** market surveillance of products listed in paragraph 2 of the Regulation is carried out by the Lithuanian Maritime Safety Administration. **Paragraph 25:** should it be established that products listed in paragraph 2 of the Regulation and labelled with the CE mark, even if properly designed, constructed, installed, maintained and	By-laws do not establish either complementary market restriction measures or complementary sanctions.

[23] The issue of the link between sanctions for violations of the Product Safety Law and for violations of special laws is analysed in greater detail in Chapter 3.2 of the Study.
[24] Order No 28 of the Minister for Social Security and Labour of the Republic of Lithuania of 6 March 2000 approving the Technical Regulation on the safety of machinery (*Official Gazette*, 2000, No 23-601).
[25] Order No 3-352 of the Minister for Transport and Communications of the Republic of Lithuania of 15 June 2004 approving the Technical Regulation on the design, construction, placing on the market and commissioning of recreational craft (*Official Gazette*, 2004, No 98-3654).

	used for the purpose intended, may endanger human safety and health, property or the environment, all necessary provisional measures should be taken to withdraw them from the market or to ban or restrict their placing on the market and/or commissioning. The Ministry of Transport and Communications shall immediately notify the EC of any such measure specifying the reason for its decision <…>. **Paragraph 26:** persons violating the requirements of this Regulation shall be liable in accordance with the statutory procedure.	

It should be noted that the analysis here only covers some of the regulatory examples relating to the provisions of technical regulations (and only to the extent relating to the regulation of market restriction measures and/or sanctions). It should be stressed that a comprehensive regulatory analysis of the regulations in respect of product safety has not been conducted. To compile an exhaustive list of such regulations and to evaluate the admissibility of their provisions in respect of product safety, a separate study would be needed. However, it still needs to be pointed out that the aforesaid legal regulatory problems of technical regulations, in particular, taking into account that they are adopted by different institutions, also imply differing legal regulatory practices and legal techniques in respect of those technical regulations. This may lead to a conclusion that where the coordination functions set in the Regulation are assigned to one authority, this authority having evaluated the content of all technical regulations, the practices of their adoption and other important circumstances could approve model (or standardised) general provisions of such a regulation to implement a uniform practice of drafting and approving such regulations and to create their standardised content.

Given the above, the aforesaid legal techniques should not apply to market restriction measures and sanctions. It should be noted that given the case-law of the Constitutional Court analysed above, the key conditions, restrictions or prohibitions relating to economic activity should only been laid down in laws.

SUMMARY

- In Lithuania market surveillance of products is regulated by the Product Safety Law and special laws setting safety and market surveillance requirements to specific products.
- The market surveillance mechanism established in the Product Safety Law is not clear as the Law does not provide an exhaustive list of authorities in charge of safety and market surveillance of products.
- The market surveillance system in Lithuania could be defined in the Product Safety Law as the "umbrella" law on product safety by establishing criteria of market surveillance authorities and compiling an exhaustive list of market surveillance authorities of the Republic of Lithuania (together explicitly defining the link between this Law and special legislation regulating product safety).
- As the Product Safety Law applies only to consumer products, if there are no special laws, there may emerge gaps in the regulation of non-consumer products.
- Although the Regulation sets out the basic provisions on the market surveillance

mechanism for products and is implemented in Lithuania, it is not referred to in market surveillance legislation of the Republic of Lithuania as EU legislation implemented thereby.

- Legal techniques where by-laws establish the right of institutions to impose market restriction measures or sanctions are defective.

2.4. An overview of proposed EU legislative amendments in the area of market surveillance

As mentioned in the Executive Summary of the Impact Assessment drafted by the EC for the Product Safety and Market Surveillance Package[26], market surveillance should enable unsafe, or otherwise harmful, products to be identified and kept or taken off the market and allow for the imposition of sanctions for violations of requirements, and market surveillance proper should also act as a powerful deterrent. In the single EU market covering a huge area in which products circulate freely, market surveillance needs to be highly coordinated. However, the author of the said document (the EC) states that market surveillance has not kept pace with developments in the Union's regulatory framework. Advances have been made over the last decade with the implementation of the Directive in the national provisions of the Member States, with the Regulation coming into application later. "*These legal instruments, together with market surveillance rules for certain sector-specific Union harmonisation legislation, provide today an EU legal basis for the market surveillance of all consumer products (both harmonised and non-harmonised) and for all harmonised products (for consumers and professional users). However, the market surveillance rules are fragmented and spread over different pieces of Union legislation (Regulation 765/2008, the General Product Safety Directive and sector-specific Union harmonisation legislation) which creates confusion on the part of both operators and national authorities*"[27]. As the system has been criticised on numerous occasions as misleading, inconsistent and creating confusion on the internal market, the EC has been urged to create a uniform single market surveillance system for all products based on one piece of legislation[28].

The above Impact Assessment of the Product Safety and Market Surveillance Package drafted by the EC is one of the documents included in the Product Safety and Market Surveillance Package published by the EC on 13 February 2013. Apart from other documents, the Package also includes EU legislative proposals for market reforms of market surveillance, i.e. the proposal for a Regulation on market surveillance of products and the proposal for a Regulation on consumer product safety.

Proposal for a Regulation on market surveillance of products

The proposal for a Regulation on market surveillance of products absorbs all rules relating to market surveillance, thus creating a single-tier system covering as many rules applicable to all products as possible and minimising the need to attribute products to individual categories. This new piece of legislation would apply to market surveillance of both consumer and professional products.

[26] Commission Staff Working Document Executive Summary of the Impact Assessment of 13 February 2013 to the Product Safety and Market Surveillance Package.
[27] Commission Staff Working Document Executive Summary of the Impact Assessment of 13 February 2013 to the Product Safety and Market Surveillance Package.
[28] Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee "More Product Safety and Better Market Surveillance in the Single Market for Products" of 13 February 2013.

The Regulation on market surveillance of products defines the entire market surveillance mechanism in a consistent and systematic manner:

<table>
<tr><td colspan="3">Product control inside the EU</td></tr>
<tr><td>Key requirements to sanctions for violations of the Regulation</td><td>EU market surveillance system</td><td>Control of products introduced to the EU</td></tr>
<tr><td colspan="2">Cooperation principles</td><td>Unambiguous information exchange system</td></tr>
</table>

- **the EU market surveillance system is regulated** by setting out that the Member State must establish or appoint market surveillance authorities and define their functions and by defining general obligations of such authorities and the obligation of the Member States to draw up general market strategies;

- **product control is established inside the EU** by defining products posing risks and the obligation of authorities to take necessary measures; an evaluation of EU-controlled products subject to harmonisation legislation; EU actions against products posing high risks;

- **control of products introduced to the EU is established** by regulating checks and the possibilities for suspending the release of products in free circulation in the EU as well as cases where the release of products posing risks in free circulation is refused; an evaluation of EU-controlled products subject to harmonisation legislation;

- **an unambiguous information exchange system is clearly established** by providing for the RAPEX and the general information support system (ICSMS) and international exchange of confidential information;

- **cooperation principles are established** by providing for mutual assistance between surveillance authorities and cooperation with authorities of third countries as well as a European Market Surveillance Forum to be established;

- **key requirements to sanctions for violations of the Regulation are established** by stipulating that sanctions to be established by the Member State are effective, proportionate and dissuasive.

Along with the proposal for a Regulation on market surveillance of products within the whole package, the EC also published the proposal for a Regulation on consumer product safety, so these legislative proposals are completely compatible with each other.

Proposal for a Regulation on consumer product safety

The very title of the Regulation on consumer product safety makes it obvious that this legal instrument will only apply to consumer products. Moreover, like the Directive, it will not apply to services. The new piece of legislation:

- **maintains the general product safety requirement enshrined in the Directive**, and it will be easier to apply as it will be linked with sector-specific legislation, i.e. where a consumer product is deemed as meeting the general safety requirement under sector-

specific Union legislation (and where there is none, under respective European standards or, where there are none of these, national legislation), the product is deemed safe also under the proposed Regulation on consumer product safety;

- **lays down the key obligations of economic operators (producers, importers and distributors).** These obligations are based on model provisions of Decision 768/2008 and relate to labelling, identification of products, corrective actions, etc. where they are not subject to specific requirements under sector-specific EU harmonisation legislation;

- **solves the matter of the link between this Regulation and sector-specific EU harmonisation legislation** by setting out that the scopes must be clearly separated and whilst "*the general product safety requirement and related provisions should be applicable to all consumer products, the obligations of economic operators should not apply where Union harmonisation legislation includes equivalent obligations, such as Union legislation on cosmetics, toys, electrical appliances or construction products*" (recital 9);

- **streamlines the process of identifying European standards;**

- as market surveillance rules including RAPEX rules, as mentioned before, are laid down in the proposal for a Regulation on market surveillance of products that would also apply to products identified in the Regulation on consumer product safety, this Regulation **does not contain any provisions directly relating to RAPEX or market surveillance**.

The newly proposed EU market surveillance scheme is visualised in the table[29]:

<table>
<tr><th colspan="4">Overview of the proposed EU legal framework in the Product Safety and Market Surveillance Package</th></tr>
<tr><td>Products

Areas</td><td colspan="2">Area regulated by legislation not subject to Union harmonisation
Non-consumer</td><td colspan="2">Area regulated by legislation subject to Union harmonisation
Consumer / Non-consumer</td></tr>
<tr><td>Obligations of economic operators</td><td></td><td>Regulation on consumer product safety</td><td colspan="2">Sector-specific legislation subject to Union harmonisation</td></tr>
<tr><td>Market surveillance in the internal market</td><td>Regulation 764/2008</td><td colspan="3" rowspan="3">Regulation on market surveillance</td></tr>
<tr><td>RAPEX</td><td rowspan="2"></td></tr>
<tr><td>Market surveillance control of products imported to the EU</td></tr>
</table>

Should the proposed market surveillance and product safety framework be approved and enter into force, it would inevitably affect the legislation regulating the Lithuanian market surveillance

[29] 2013 02 13 Commission Staff Working Document on Impact Assessment. Product Safety and Market Surveillance Package. A proposal for a Regulation of the European Parliament and of the Council on consumer product safety and a proposal for a Regulation of the European Parliament and of the Council on market surveillance of products.

system and the functions of market surveillance authorities. As the purpose of this Study does not cover the submission of proposals on the basis of the new proposed regulation of the EU market for products regarding possible changes in the Lithuanian legal framework, a broader analysis of the new regulatory framework and its effect on the national regulation could be covered by another study but:

- given that regulations are directly applicable items of EU legislation, this would bring about a revision and even repealing of the Product Safety Law, replacing it with a law regulating the following key provisions:
  - a clear system of market surveillance authorities and the required functions assigned to specific authorities by regulations;
  - a uniform system of sanctions;
  - a procedure for drafting market surveillance programmes;
  - principles of mutual cooperation between authorities and cooperation with the EC and authorities of other countries;
- there would be a need to revise all legislation regulating product safety, market regulation measures and principles of product control;
- there would be a need to adjust the existing RAPEX procedure and ensure the exchange of information on dangerous non-consumer products;
- there would be a need to revise the functions of the Customs Office when conducting checks of product imports and the very system of checks of products introduced from third countries;
- to ensure the participation of Lithuanian authorities in the ICSMS system and in the activities of the new European Market Surveillance Forum.

SUMMARY

- Proposals for a Regulation on market surveillance of products and a Regulation on consumer product safety aim at streamlining the current fragmented system of product safety and market surveillance.
- The new system would provide for a clear market surveillance mechanism, a clearer product control system and an unambiguous information exchange system.
- Following the entry into force of the new framework, there will be a need to revise Lithuanian legislation relating to market surveillance of products and introduce regulatory changes.

III. EVALUATION OF THE EFFICIENCY OF THE LITHUANIAN MARKET SURVEILLANCE SYSTEM

3.1. System of market surveillance authorities

To conduct a proper analysis of the Lithuania market surveillance system, there is a need to identify public authorities performing market surveillance functions. An exhaustive list of Lithuanian market surveillance authorities is not compiled and approved by any legal act. As indicated in Chapter 3.2 of the Study, the regulation of market surveillance authorities in Lithuanian law causes problems including problems with the compatibility of this framework with the Constitution. Moreover, Lithuania does not have any legislation providing for a system of market surveillance authorities or at least offering a definition of 'market surveillance'[30].

This definition is given in Regulation 765/2008 where market surveillance means "*the activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Community harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection*".

As stated in the EC's Communication "20 actions for safer and compliant products for Europe: a multi-annual action plan for the surveillance of products in the EU"[31], "*the core of market surveillance is a chain of interdependent processes such as inspections, sampling, laboratory testing, interpretation of results, risk assessment, decision making, intervention and ensuing legal procedures which may involve corrective measures or even sanctions*".

In other words, if an authority is to be deemed a market surveillance authority, it must have powers in respect of the product, i.e. be authorised to check product safety, conduct laboratory tests, assess risks and impose market restriction measures or sanctions.

It should be noted that there are currently as many as three lists of market surveillance authorities.

First, there is a list of supervision groupings of public administration bodies supervising activities of economic entities approved by Resolution No 511 of the Government of 4 May 2010 on the optimisation of functions performed by authorities (*Official Gazette*, 2010, No 53-2613; 2011, No 92-4374; 2012, No 89-4657) listing 59 authorities supervising economic entities and divided into 8 groups (the list is also published on the website of the Ministry of the Economy under Business Environment).

[30] Article 2(27) of the Law on metrology gives a definition of 'market surveillance' in the context of regulating metrological relations. It is defined as "*control of the compliance with legal metrological requirements to metrological equipment, pre-packaged merchandise and metrological vessels placed on the market or kept before their placing on the market and attributable to legal metrology. Such control shall cover actions preventing the placing on the market of incompliant metrological equipment, pre-packaged merchandise and metrological vessels*".

[31] Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee of 13 February 2013 "20 actions for safer and compliant products for Europe: a multi-annual action plan for the surveillance of products in the EU".

A definition of the supervision of activities of economic entities is also offered by the Law on public administration. Its Article 36[1] sets out that "*supervision of activities of economic entities shall mean activities of public administration bodies aiming at providing methodological assistance to economic entities, supervising how economic entities fulfil the requirements laid down in laws and other legislation, controlling whether they properly perform those requirements and implementing other measures ensuring the due fulfilment of legal requirements and minimising the number of possible violations; the supervision of activities of economic entities shall also cover counseling of economic entities and other preventive actions, checks of their activities, evaluation of information on them and application of enforcement measures*".

An examination of both of the above wordings makes it obvious that the supervision of economic entities and market surveillance are not synonyms, which is why not all authorities supervising economic entities can be treated as market surveillance authorities. Market surveillance is undoubtedly part to the system of supervision of economic entities, which means that market surveillance, apart from other things, is also subject to legislation regulating the supervision of economic entities in general.

It should be noted that this Study has been based on a presumption that the list of authorities supervising activities of economic entities in the aforementioned Resolution of the Government is exhaustive, i.e. that the list contains all Lithuanian authorities conducting the supervision of activities of economic entities, i.e. the list has not been revised. Therefore, when establishing which authorities perform market surveillance functions, account was taken only of supervisory authorities listed. An evaluation of the competence of the authorities and whether the authority is attributable to market surveillance authorities was based on the above definition of market surveillance given in the Regulation. Thus, where by legal acts the authority is tasked only with the function of issuing permits/licences or setting certain requirements, etc., such an authority has not been deemed a market surveillance authority. Moreover, it should be stressed that the list of authorities supervising activities of economic entities given in the Resolution of the Government identifies a separate seventh group of authorities for product safety covering 16 authorities. The documents examined below that identify market surveillance authorities in the area of product safety mention only 5 of 16 authorities listed while the other institutions are not referred to in the documents in question. This gives rise to questions on what grounds and based on what criteria the said Resolution of the Government includes in the group on product safety, for example, the Gaming Control Authority under the Ministry of Finance of the Republic of Lithuania, the State Data Protection Inspectorate, the State Tourism Department under the Ministry of Agriculture, etc. What is more, some market surveillance authorities fall within groups other than those covering institutions attributed to the product safety group in the said Resolution of the Government. Therefore, market surveillance authorities were identified without taking into consideration the distribution of the authorities in the said Resolution of the Government.

Second, a list of market surveillance authorities is also given in Annex 1 to the conclusions of the Working Party of 11 September 2009 offering a list of Lithuanian market surveillance authorities covering 19 market surveillance authorities and 2 institutions (the VVTAT and the CD) not directly involved in market surveillance but participating in the market surveillance system.

Third, on 30 December 2009 the EC was notified[32] that Lithuania then had 11 market surveillance authorities relating to the implementation of the Regulation. The VVTAT and the CD were mentioned as authorities indirectly participating in the market surveillance system, and 6 other market surveillance authorities were listed as not relating to product safety. Any attempts to find public information that after 2009 Lithuania notified to the EC an updated list of market authorities relating to the implementation of the Regulation were unsuccessful. Given that the then effective system of 11 authorities has meanwhile changed, there is a need to consider notifying to the EC an updated list of market surveillance authorities.

Even more confusion is created by the fact that various legal acts or public information also fail to provide a clear list of market surveillance authorities. For instance, the CD's website contains a presentation of import restrictions and bans that states that in implementing the Regulation the Customs Office of the Republic of Lithuania cooperates with four market surveillance authorities[33].

The above information clearly demonstrates that there is no final consensus on which authorities should and which should not be included in the list of market surveillance institutions.

A systematic representation of information on institutions supervising activities of economic entities and on market surveillance authorities for products is given in the table below. To structure the information of three different documents drafted at different moments in one table, account was taken of structural changes within the institutional system of supervision of economic entities and of changes in the names of market surveillance authorities (e.g. that the State Plant Protection Service, the State Seeds and Grains Service and the State Plant Breed Research Centre were all united in one State Plant Service, the State Inland Navigation Inspectorate was merged with the Lithuanian Maritime Safety Administration, the State Environment Protection Inspectorate was merged with the Environment Protection Agency, etc.).

[32] Document notifying Lithuanian market surveillance authorities of 30 December 2009 [accessed on 6 January 2014]. Available online at http://ec.europa.eu/enterprise/policies/single-market-goods/files/market_surveillance/lt_art_17_lithuanian_market_surveillance_institutions_en.pdf.

[33] Website of the Customs Department of the Republic of Lithuania [accessed on 7 January 2014]. Available online at: http://www.cust.lt/web/guest/strukturakontaktai/departamentas/bendrainformacija.

	Authorities supervising activities of economic entities listed in Resolution No 511 of the Government of the Republic of Lithuania of 4 May 2010	**Market surveillance authorities referred to in the conclusions of the Working Party**	**Market surveillance authorities notified to the EC on 30 December 2009 as implementing Regulation 765/2008**
1.	State Non-Food Products Inspectorate under the Ministry of the Economy		
2.	State Healthcare Accreditation Agency under the Ministry of Health		
3.	Lithuanian Maritime Safety Administration		The authorities notified were also the State Inland Navigation Inspectorate which was later merged with the Lithuanian Maritime Safety Administration and the Lithuanian Maritime Safety Administration proper
4.	Communications Regulatory Authority of the Republic of Lithuania		
5.	State Road Transport Inspectorate under the Ministry of Transport and Communications		
6.	State Medicines Control Agency under the Ministry of Health		
7.	Lithuanian Metrology Inspectorate		
8.	Radiation Protection Centre		
9.	State Labour Inspectorate under the Ministry of Social Security and Labour		
10.	Environment Protection Agency		The authority notified was the State Environment Protection Inspectorate later merged with the Environment Protection Agency
11.	State Food and Veterinary Service		A market surveillance authority but not implementing Regulation 765/2008
12.	State Plant Service under the Ministry of Agriculture		A market surveillance authority but not implementing Regulation 765/2008
13.	State Railway Inspectorate under the Ministry of Transport and Communications		A market surveillance authority but not implementing Regulation 765/2008
14.	Weaponry Fund of the Republic of Lithuania under the Ministry of the Interior		A market surveillance authority but not implementing Regulation 765/2008
15.	Ministry of Health and public health centres in counties	Reference was made to the State Public Health Service under the Ministry of Health	The State Public Health Service under the Ministry of Health was notified as a market surveillance authority not implementing Regulation 765/2008
16.	State Consumer Rights Protection Authority	As indicated in the conclusions of the Working Party and in the notification, it is involved in market surveillance processes indirectly	
17.	Customs Department under the Ministry of	As indicated in the conclusions of the Working Party	

	Finance	and in the notification, it is involved in market surveillance processes indirectly	
18.	Ministry of the Environment (Waste Department, Nature Protection Department and General Affairs Division of the Ministry of the Environment)		
19.	Regional environment protection departments of the Ministry of the Environment		
20.	Directorate General of State Forests under the Ministry of the Environment		
21.	Lithuanian Geological Survey under the Ministry of the Environment		
22.	Lithuanian Hydrometeorological Service under the Ministry of the Environment		
23.	State enterprises forest directorates		
24.	National Land Service under the Ministry of Agriculture		
25.	State Forest Service		
26.	Competition Council of the Republic of Lithuania		
27.	Public Procurement Office		
28.	State Energy Inspectorate under the Ministry of Energy		
29.	National Control Commission for Prices and Energy		
30.	Cultural Heritage Department under the Ministry of Culture		
31.	Ministry of Education and Science		
32.	State Language Inspectorate		
33.	Office of the Inspector of Journalist Ethics		
34.	Radio and Television Commission of Lithuania		
35.	State Tax Inspectorate under the Ministry of Finance		
36.	Board of the State Social Insurance Fund under the Ministry of Social Security and Labour		
37.	Bank of Lithuania		
38.	Lithuanian Bioethics Committee		
39.	National Transplant Bureau		
40.	Drug, Tobacco and Alcohol Control Department		
41.	Health Emergency Situations Centre of the Ministry of Health		
42.	National Health Insurance Fund under the Ministry of Health		
43.	Construction Products Certification Centre		
44.	Service of Technological Security of State Documents under the Ministry of Finance		
45.	State enterprise Assay Office of Lithuania		
46.	State Healthcare Accreditation Agency under the Ministry of Health (function of the conformity assessment of medical devices)		
47.	State Data Protection Inspectorate		
48.	State Animal Breeding Supervision Service under the Ministry of Agriculture		
49.	Gaming Control Authority under the Ministry of Finance of the Republic of Lithuania		
50.	State Metrology Service		
51.	State Tourism Department under the Ministry of the Economy		
52.	Fisheries Service under the Ministry of Agriculture		
53.	Civil Aviation Administration		

54.	Lithuanian Labour Exchange under the Ministry of Social Security and Labour		
55.	Fire and Rescue Department under the Ministry of the Interior		
56.	Department of Supervision of Social Services under the Ministry of Social Security and Labour		
57.	Civil Service Department under the Ministry of the Interior		
58.	State Nuclear Power Safety Inspectorate		
59.	State Territorial Planning and Construction Inspectorate under the Ministry of the Environment		

An examination of the areas of activity of all authorities listed that supervise activities of economic entities as regulated in Lithuanian regulatory legislation and an interpretation of the results of that examination in a systematic manner together with the data of previous studies of Lithuanian authorities relating to market surveillance institutions of the Republic of Lithuania lead to a conclusion that Lithuania currently has 10 market surveillance authorities implementing the Regulation and 2 institutions participating in its implementation.

LIST OF MARKET SURVEILLANCE AUTHORITIES FOR PRODUCTS[34]
1. VNMPI
2. VASPVT
3. LMSA
4. RRT
5. VKTI
6. SMCA
7. LMI
8. RSC
9. SLI
10. EPA
11. (VVTAT)
CD participating in the market surveillance system

The conclusions of the Working Party and the notification of market surveillance authorities to the EC list the VVTAT and the CD not as market surveillance authorities but as institutions indirectly participating in the market surveillance system. The Product Safety Law authorises the VVTAT to impose both market restriction measures and sanctions. Although this main consumer protection authority does not conduct checks, safety evaluations or other specific market surveillance actions, in the area of product safety it should be treated as a market surveillance authority with a special status as, among other things, it also coordinates the implementation of product safety laws. The CD however should not be treated as a "pure" market surveillance

[34] An analysis of the market surveillance mechanism implemented under the Product Safety Law has established that the services market is supervised by the VNMPI and public health centres which after the elimination of the State Public Health Service under the Ministry of Health in 2012 were delegated the functions of that authority relating to control, supervision, issuance of permits, etc. The functions of public health centres in the area of market surveillance are analysed in greater detail in Chapter 3.3 of this Study.

authority as it imposes restrictions on products not on the basis of the Product Safety Law or other legislation regulating product safety but on the basis of specific legislation regulating external border control. Moreover, in legal provisions on "cooperation between market surveillance authorities" cooperation with the authority in charge of external border control is identified separately, so emphasising that the authority in charge of external border control does not engage in "pure" market surveillance but rather participates in market surveillance processes.

An examination of the listed market surveillance authorities identified on the basis of the above criteria (powers in respect of the product in controlling its safety (checks, laboratory testing, risk assessment, market restriction measures and sanctions)) gives rise to questions how these functions are implemented, for example, by the Lithuanian Standards Board ('the LST'). The Law on standardisation defining the competence of the LST in the area of standardisation sets out that, among other things, this institution provides information on technical regulations, standards and conformity assessment procedures of the Republic of Lithuania, plans and coordinates standardisation work in all areas of activity, provides methodological guidance in these areas, improves and develops standardisation in the Republic of Lithuania and organises the drafting of legislation in this area, etc. Neither this Law nor the LST Regulations provides for the LST's powers to check specific products and impose restriction measures or sanctions for violations of product safety requirements. This leads to a conclusion that the LST should not be treated as a market surveillance authority in the direct sense but is important and integral to the proper functioning of the mechanism of product safety and market surveillance authorities (the functions of this institution are more related with the regulation of product safety requirements rather than the regulation of the market surveillance mechanism proper).

Documents regulating activities of other institutions listed provide for their powers to control the market for products, to conduct checks and take measures in respect of unsafe or incompliant products. Given that, Chapter 3.2 of the Study analysis in detail how the market surveillance functions of these institutions laid down in the Regulation and the Directive are stipulated in the national legislation including the regulations of the institutions proper.

It should be noted that by Letter No 1.11-2.1421 of 9 May 2014, following a presentation of the Study at the Ministry of the Economy of the Republic of Lithuania on 6 May 2014, the Radiation Protection Centre stated that the RSC should not be treated as an institution implementing the market surveillance policy for products as the RSC is an authority supervising activities (services) of economic entities involving ionising radiation sources, and the services of the RSC are not subject to either the Regulation or the Directive. The RSC should not be treated as an institution implementing the said Union legislation. When performing the functions of conducting radiation protection supervision of activities of economic entities involving ionising radiation sources, the RSC does not create a greater effect on the market than other institutions supervising activities of economic entities but not treated as market surveillance authorities. As stated by the RSC, laws and other legislation do not explicitly stipulate the RSC's competence in respect of products (there are no explicit authorisation to check the safety of products and impose market restriction measures; the Centre does not implement market surveillance programmes, etc.).

A decision concerning this institution's status and competence as a market surveillance authority needs to be taken after additional consideration as the wording on the RSC's competence given in legislation implies that the RSC conducts market surveillance also by controlling product

safety[35]. Given that, there is a need to conduct an additional factual analysis of the performance of functions and an actual market survey as to how many products to be controlled in terms of radiation protection there are on the market. Should it turn out that the RSC does not conduct any market surveillance for products, a decision would need to be made on a market surveillance authority competent in this area, or, where such market surveillance is in general not possible due to the specific nature of these products, there may be a need to additionally revise the provisions of the Law on radiation protection and, on the basis of the factual analysis outcomes, update the list of market surveillance authorities of the Republic of Lithuania.

Given that the said institution in all of the above lists of market surveillance authorities was mentioned as a market surveillance authority and in 2009 even notified to the European Commission as an institution implementing the Regulation and the laws authorise the RSC to control product safety, further in this Study the RSC is analysed together with other market surveillance authorities identified. Still, bearing in mind that the RSC's competence in controlling product safety is unclear, as has been mentioned, there is a need for a more detailed factual analysis in respect of the attribution of this institution to market surveillance authorities for products and/or services and its inclusion in the list of market surveillance authorities.

Below is a table listing laws regulating market surveillance authorities and their activity.

Market surveillance authority for products	Laws
1. VNMPI	Product Safety Law
2. VASPVT	Law on the health system (market surveillance of medical devices is broader regulated by medical regulations relating to medical devices[36])
3. LMSA	Law on maritime safety
4. RRT	Law on electronic communications
5. VKTI	Road Transport Code
6. SMCA	Law on pharmaceuticals
7. LMI	Law on metrology
8. RSC	Law on radiation protection
9. SLI	Law on the State Labour Inspectorate
10. EPA	• Law on environment protection • Law on chemical substances and preparations
(11. VVTAT)	• Law on consumer rights protection (*not directly regulating market surveillance matters*)

[35] Article 11(2) of the Law of the Republic of Lithuania on radiation protection sets out that "the compliance of ionising radiation sources, radiation protection equipment and other devices and materials that may have effect on additional exposure of humans to radiation as well as ***products*** with ionising radiation sources with radiation protection requirements, except when engaging in nuclear energy activities involving ionising radiation sources, shall be controlled by the Radiation Protection Centre".

[36] Order No V-18 of the Minister for Health of the Republic of Lithuania of 19 January 2009 approving the Medical Regulation of Lithuania MN 4:2009 Technical Regulation on the safety of medical devices and the Medical Regulation MN 100:2009 Technical Regulation on the safety of active implantable medical devices and Order No V-679 of the Minister for Health of 29 December 2001 approving the Medical Regulation of Lithuania MN 102:2001 Technical Regulation on the safety of in vitro diagnostic medical devices and amending Order No 176 of the Minister for Health of 15 March 2001 approving the transitional procedure for the approval of medical devices.

	• Product Safety Law
CD participating in the market surveillance system	Customs Code

So, given the legal framework, the Lithuanian market surveillance authorities for products may conditionally be divided into two groups:

- General market surveillance authorities for products:
  - General authorities **for all consumer products** (products and services) are the VVTAT and the VNMPI (except where the relevant product falls within the competence of a specific institution);
  - No general authority is provided for non-consumer (professional) products[37];

- Special market surveillance authorities for products:
  - authorised only in respect of specific products falling within their competence: the remaining 8 market surveillance authorities for products;
  - authorised only in a specific area, in respect of all products that can be measured: the Metrology Inspectorate.

In this system a particularly important role is given to the VVTAT and the VNMPI. The VVTAT's role as a general market surveillance authority is analysed in Chapter 3.2 of the Study. An examination of Article 12 of the Product Safety Law setting out that product safety is controlled by "*food and non-food products safety control authorities established by the Government*" may lead to a conclusion that the VNMPI as the authority supervising the largest share of the market for non-food consumer products should be treated as an "umbrella" market surveillance authority for non-food consumer products (similarly as the State Food and Veterinary Service is treated as an "umbrella" authority for food safety control). However some confusion is created by paragraph 9.1 of the VNMPI Regulations stipulating that this authority "*shall supervise whether non-food products placed on the market which the Inspectorate is tasked with supervising by laws or other legislation meet safety, quality and labelling requirements to non-food products, independently choosing entities to be checked and determining the scale of checks*". However, it must be noted that paragraph 3 of the Rules for the application of restrictions on marketing of products stipulates that "*market restriction measures shall be imposed by the National Consumer Rights Protection Council under the Ministry of Justice ('the Council'), the State Food and Veterinary Service (with a view to restricting the placing on the market of foodstuffs dangerous to consumer health),* ***the State Non-Food Products Inspectorate under the Ministry of the Economy (with a view to restricting the placing on the market of non-food products dangerous to consumer health and safety)***[38]*, public health centres in counties (with a view to restricting the placing on the market of services dangerous to consumer health and safety within their remit) as well as other product safety control institutions established by the Government of the Republic of Lithuania within their remit*". This paragraph implies that the VNMPI is an "umbrella" market surveillance authority for non-food consumer products.

[37] It should be noted that certain powers in respect of non-consumer (professional) products are held by the SLI supervising the safety of lifts (on the basis of Order No 106 of the Minister for Social Security and Labour of the Republic of Lithuania of 28 December 1999 approving the Technical Regulation on lifts as later amended) and the safety of machinery intended for professional users (on the basis of Order No 28 of the Minister for Social Security and Labour of the Republic of Lithuania of 6 March 2000 approving the Technical Regulation on the safety of machinery as later amended).

[38] Stressed by the authors of the Study.

This opinion is confirmed by Article 2(2) of the Product Safety Law setting out that "this Law shall apply insofar as the legislation of the Republic of Lithuania ('**the legislation**') contains no provisions regulating the safety of a specific product. Where another legal instrument lays down certain safety requirements to a specific product, the requirements of that legal instrument shall apply while this Law shall apply insofar as the other legislation regulating safety of a specific product does not contain respective provisions". Although this provision is intrinsically linked with the establishment of product safety requirements, this may still lead to a conclusion that where a special law does not provide for competences of a specific authority (within its area of management) to supervise a certain non-food product, such supervision is to be conducted by the VNMPI in accordance with Article 12 of the Product Safety Law. Thus, the VNMPI should be seen as an "umbrella" market surveillance authority for non-food consumer products. Thus, where there is an "umbrella" market surveillance authority for non-food consumer products, there can be no "grey area" meaning that not a single institution is in charge of market surveillance of non-food consumer products. As indicated in this Study, the actual implementation of legislation is not covered by this Study, which is why it is not known whether this is actually how institutions interpret legal provisions and implement their competences. Therefore, to take into account all circumstances, there is a need to examine the actual implementation of the functions of this authority. Should an examination of the actual implementation of the function reveal that the provision of Article 12 of the Product Safety Law is interpreted otherwise, there would be a need to deal with the matter of revising that provision. Moreover, it should be noted that should it become clear that there are products which the VNMPI for some reason cannot control, the coordination function in respect of the implementation of product safety legislation assigned to the VVTAT by Article 6 of the Product Safety Law should ensure that the matter is handled separately and that amendments are proposed to the respective legislation, the matter of assuring the required funding for the VNMPI is handled or the problem at hand is tackled otherwise.

Furthermore, as mentioned in Chapter 2.3 of the Study, the market for non-consumer (professional) products is not covered by any *lex generalis*, or an "umbrella" law regulating safety that would apply where there is not special legislation regulating the safety of a specific product. Also, as has been mentioned above, the area of non-consumer (professional) products does not have a general authority tasked with market surveillance of all non-consumer (professional) products. Therefore, there is no "umbrella" market surveillance authority covering these products. Without an "umbrella" market surveillance authority for products that would control the so-called "grey areas", i.e. the safety of products not assigned to any specific institution, there is a risk that the safety of such products is out of control at all. Given the above, there is a need to consider expanding the competence of a respective market surveillance authority (the one most suitable in terms of its functions would be the VNMPI) to cover market surveillance of the safety of non-consumer (professional) products by stipulating that this authority supervises the safety of non-consumer products the control of which is not assigned to another institution.

SUMMARY

- There is no valid and exhaustive list of market surveillance authorities approved in any piece of legislation.
- Given the definition of market surveillance in the Regulation and the provisions of the Lithuanian legal framework, 11 market surveillance institutions are to be identified for these products:
  - VNMPI

- VASPVT
- LMSA
- RRT
- VKTI
- LMI
- RSC
- SLI
- EPA
- VVTAT
- CD as participating in the market surveillance system.

- In accordance with the legal framework provisions, in the area of non-food consumer products the VNMPI is to be treated as an "umbrella" market surveillance authority for products (except for non-food products the market surveillance of which is assigned to another institution), which ensures that there should be no "grey areas" where non-food consumer products are out of control by any market surveillance authority. However, to avoid doubts concerning the treatment of the VNMPI as an "umbrella" market surveillance authority for non-food products, there is a need to regulate the VNMPI's competence by law.
- There is no general or "umbrella" legal framework in respect of non-food non-consumer products and there is accordingly no "umbrella" institution tasked with market surveillance of all non-consumer (professional) non-food products (except for products the market surveillance of which is assigned to a specific authority), which is why there is a need to consider assigning the role of an "umbrella" market surveillance authority for non-consumer (professional) products too to the VNMPI.

3.2. Analysis of the functions of the market surveillance system and the effectiveness of the market surveillance system

As indicated in Chapter 2 of the Study, the functions of the market surveillance system laid down in the Regulation and the Directive may be divided into systematic market surveillance functions and specific market surveillance functions. As mentioned above, the systematic market surveillance functions relate more to the shaping of the market surveillance policy, the coordination of the functioning of the entire market surveillance system and the improvement of the market surveillance system proper.

It should be noted that requirements to certain products (e.g. medical devices, recreational craft, medicinal products, etc.) and specific safety control and market surveillance requirements to them are laid down in special EU harmonisation legislation. Certain provisions of this EU legislation are respectively transposed both to specific national laws (e.g. market surveillance aspects pertaining to medicinal products – to the Law on pharmaceuticals) and by-laws (e.g. aspects of the safety of medical devices and recreational craft – to the medical regulations previously referred to in this Study that lay down requirements to medical devices or the technical regulation on recreational craft). As mentioned above in this Study, the Product Safety Law only applies to special products in part, i.e. insofar as other legislation of the Republic of Lithuania does not contain provisions regulating the safety of a specific product; where another legal instrument lays down certain safety requirements to a specific product, the requirements of that legal instrument apply while the Product Safety Law applies insofar as the other legislation regulating safety of a specific product does not contain respective provisions.

Special EU legislation and its provisions transposed to the national law in certain cases lay down special, complementary or other principles of market surveillance of specific products or market surveillance actions (that are different from the general regulatory framework and general market surveillance functions laid down in the Regulation, the Directive and the Product Safety Law). Given the above, institutions conducting market surveillance of certain products and implementing special Union legislation or its provisions transposed to the national law are not subject to all provisions of the Regulation and the Directive and market surveillance functions laid down therein (or are subject to them only in part)[39].

Still, an analysis of the effectiveness of the system of market surveillance functions established in the Regulation and the Directive (coordination and specific market surveillance functions) does not bring forward any special functions of market surveillance authorities for specific products (laid down in special legislation) and/or the admissibility of their regulation and implementation is not additionally checked on an individual basis. All market surveillance authorities identified and their functions are analysed within the framework of the system of market surveillance functions created by the Regulation and the Directive.

However differences in market surveillance of specific products are to be borne in mind when making decisions concerning the stipulation of the market surveillance system and principles and a list of institutions in an "umbrella" market surveillance instrument.

3.2.1. Systematic market surveillance functions

As mentioned in Chapter 2 of the Study, the Product Safety Law stipulates the state regulation of product safety. Article 6(1) of the Product Safety Law sets out that the implementation of the Law and other legislation regulating product safety is coordinated by the National Consumer Rights Protection Council (i.e. the VVTAT). Given that the Product Safety Law defines a product both as a product and a service, this means that the VVTAT is tasked with coordinating the implementation of legislation regulating the safety of both products[40] and services. However it should also be noted that the VVTAT's competence only covers consumer products.

It should be pointed out that the provision in Article 6 of the Product Safety Law does not reflect the change in the VVTAT's institutional status following the adoption of the Law on consumer protection[41]. Although Article 2(2) of the Law amending the Law of the Republic of Lithuania on consumer protection set out that the functions of the National Consumer Rights Protection Council laid down in laws and other legislation were to be performed by the State Consumer Rights Protection Authority, some provisions of the Product Safety Law were amended in 2012, which was why the provisions of this Law relating to the title and status of the National Consumer Rights Protection Council could also have been revised.

The legal regulation of the coordination function poses several issues:

[39] RAPEX system also excludes notifications of products subject to special and equivalent notification mechanisms laid down in other EU legislation (e.g. medicinal products or medical devices).
[40] As indicated in Chapter 2.3 of the Study, the application of the Product Safety Law to food products creates some confusion.
[41] Law amending the Law of the Republic of Lithuania on consumer protection (*Official Gazette*, 2007, No 12-488) effective as of 1 March 2007.

- lack of clarity as to which minister (ministry) is tasked with the function of coordinating the area of product safety and market surveillance;
- which public authority is specifically tasked with the function of coordinating product safety and market surveillance and what the content of that function is.

Lack of clarity as to which minister (ministry) is tasked with the competence to coordinate the implementation in the area of product safety and market surveillance

In accordance with Article 98(1) of the Constitution, a minister is head of the ministry handling matters falling within the competence of the ministry and performing other statutory functions. This constitutional provision implies that a minister is to be tasked with taking care of the respective area of public governance. Specific areas of public governance are normally assigned to ministers (ministries) by laws and described in greater detail in the regulations of the ministry.

On the legislative level as will be presented in detail below, either the Ministry of Justice or the Ministry of the Economy is not tasked with the coordination functions in implementing the product safety and market surveillance system. The functions of the said Ministries, the VVTAT and the VNMPI relating to the coordination of the product safety and market surveillance system are shown in the chart below.

Shaping the national policy in the area of consumer protection	Ministry of Justice	Ministry of the Economy	Coordinates market surveillance of non-food products
	VVTAT	VNMPI	
	Coordination of the implementation of the Product Safety Law and other laws regulating product safety	Implementation of the market surveillance policy for non-food products and services	

An analysis of the Regulations of the Ministry of Justice of the Republic of Lithuania[42] approved by Resolution No 851 of the Government of the Republic of Lithuania of 9 July 1998 shows that the Ministry of Justice does not have any functions relating to market surveillance of product safety, and there is only one of the objectives of the activities of the Ministry of Justice that is the shaping of the national policy in the area of consumer protection (paragraph 7 of the Regulations).

Paragraph 8.45 of the Regulations of the Ministry of the Economy of the Republic of Lithuania approved by Resolution No 921 of the Government of the Republic of Lithuania of 23 July 1998 sets out that "<…> *pursuing the objective of its activities set in paragraph 7.1*[43]*, the Ministry of*

[42] Resolution No 851 of the Government of the Republic of Lithuania of 9 July 1998 approving the Regulations of the Ministry of Justice of the Republic of Lithuania (*Official Gazette*, 1998, No 63-1816).

[43] Paragraph 7.1 of the Regulations of the Ministry of the Economy of the Republic of Lithuania: "*to shape the national economic policy: in the areas of the general economic (macroeconomic) policy, competition, European Union internal market, public procurement, state and municipal property privatisation, company law, insolvency, better regulation, internal trade, advertising, metrology, standardisation, accreditation and human resources and to organise, coordinate and control its implementation*".

the Economy shall <…> coordinate market surveillance of non-food products". The fact that the Minister for the Economy has in their remit the participation in the shaping of the market surveillance policy for non-food products is likely to be linked with the fact that the VNMPI falls within the competence of the Ministry of the Economy[44]. The Ministry of the Economy of the Republic of Lithuania also has the function of participating in the shaping of the consumer protection policy[45].

The main purpose of the VVTAT set in paragraph 2 of the VVTAT Regulations approved by Resolution No 359 of the Government of the Republic of Lithuania of 11 April 2007 is "<…> *to implement the national policy in the area of consumer protection and to ensure consumer protection*" while paragraph 10.1.1 sets out that the VVTAT "<…> *coordinates the activities of consumer protection authorities in charge of the regulation of a specific area of consumption, the activities in the area of consumer protection (analysing information collected and regularly received from state and municipal authorities and bodies on consumer protection and submitting proposals on the improvement of consumer protection)*". As mentioned above, Article 6(1) of the Product Safety Law sets out that the implementation of the Product Safety Law and other legislation regulating product safety is coordinated by the VVTAT. At the same time, paragraph 8.1 of the VNMPI Regulations approved by Order No 4-693 of the Minister for the Economy of the Republic of Lithuania of 16 September 2010 stipulates that one of the objectives of the VNMPI's activities is to "*implement the market surveillance policy for non-food products and services ('non-food products')*", and in pursuit of this objective the VNMPI "*supervises whether non-food products placed on the market which the Inspectorate is tasked with supervising by laws or other legislation meet safety, quality and labelling requirements to non-food products, independently choosing entities to be checked and determining the scale of checks*" (paragraph 9.1). It should be noted that the definition of "non-food products" used by the VNMPI covers both non-food products and services. So, this concept is in line with the definition of the product given in the Product Safety Law.

The Regulations of the said Ministries may lead to a conclusion that the coordination functions in implementing the non-food product safety (non-food products and services) and market surveillance system are assigned to the Ministry of the Economy. It must be stressed that none of the institutions is tasked by law with coordinating the area of non-consumer (professional) products. However, an examination of the provisions of the Product Safety Law and the competence laid down in the Regulations of the Ministry of the Economy, i.e. to coordinate market surveillance of non-food products, first, either implies that the function is duplicated, or second, makes it obvious that there is a certain lack of clarity as to which of the Ministers (the Minister for Justice or the Minister for the Economy) is in charge of the coordination of the market surveillance system, especially in the area of non-food products. This lack of clarity becomes especially relevant given that the VVTAT as an institution reports to the Ministry of Justice[46] while the VNMPI – to the Ministry of the Economy[47]. What is more, as pointed out during the meeting with the Ministry of the Economy, *de facto* some of the systematic functions of market surveillance of non-food products are performed by the Ministry of the Economy. Taking that into account, the distribution of the functions between the VVTAT and the Ministry of the Economy *de jure* and *de facto* in coordinating the implementation of product safety

[44] Resolution No 505 of the Government of the Republic of Lithuania of 4 May 2000 on the reorganisation of market surveillance institutions (*Official Gazette*, 2000, No 38-1064).
[45] Paragraph 8.46 of the Regulations of the Ministry of the Economy.
[46] Paragraph 6 of the VVTAT Regulations.
[47] Resolution No 505 of the Government of the Republic of Lithuania of 4 May 2000 on the reorganisation of market surveillance institutions (*Official Gazette*, 2000, No 38-1064).

legislation and market surveillance of product safety is unclear. Moreover, it should also be noted that the effective legislation contain no provisions defining how the said authorities should mutually coordinate their activities, thus ensuring the proper management of the product safety and market surveillance system.

Hence, the current regulation should be improved, at the same time deciding which of the institutions should be tasked with the coordination function concerning the implementation of the product safety and market surveillance system. At the same time, it should be pointed out that the attribution of this function should also mean, first of all, the attribution of the systematic functions described further in this Study and, second, the proper balance of other functions in this area, i.e. representation of Lithuania's interests in the EU institutions, communicating with the institutions, etc. should be properly balanced.

Moreover, a decision on the coordination function should also cover a decision what areas the coordination function should include. As mentioned in Chapter 2 of the Study, the market surveillance system in Lithuania covers the implementation of safety requirements to products, services and food products but the Product Safety Law only regulates safety requirements to products (and only consumer products) and services[48]. This means that the regulation of the functions of the authorities as described above implies that legislation does not set out any uniform coordination of the market surveillance system in all areas. Still, bearing in mind that various areas are covered by safety regulation of products, services and food products and, in particular, the specific area of food safety, this gives rise to a question whether such a uniform coordination of the market surveillance system in all areas is needed. Also, this Study has not examined whether the absence of such uniform coordination of the surveillance system raises serious practical concerns. It should be noted that only an analysis of the actual implementation of the activities of the institutions in charge of the safety of food products and other market surveillance areas could lead to conclusions about existing problems and the need to have common coordination covering all market surveillance areas.

Lack of clarity as to which of the national market surveillance authorities is specifically tasked with the coordination function relating to product safety and market surveillance and what the content of that function is

Setting the VVTAT's function to coordinate the implementation of the Product Safety Law and other legislation regulating product safety, the Product Safety Law does not define and present a concept of this function and specify what rights and obligations are given to the VVTAT implementing this function. The Law on consumer protection adopted[49] also defined the VVTAT's functions. That Law provided for the VVTAT's coordination function in the area of consumer protection and offered its definition (Article 12(1)(2) of the Law set out that the VVTAT coordinates the activities of consumer protection authorities in charge of the regulation of a specific area of consumption in the field of consumer protection (analysing consumer protection information collected and regularly received from state and municipal authorities and submitting proposals on the improvement of consumer protection)). However, the said Law did not contain any specific provisions in respect of the product safety and market surveillance system. So, the legal framework in question implies that the VVTAT in fact performs the coordination function in the area of market surveillance insofar as market surveillance (or

[48] As indicated in Chapter 2.3 of the Study, the application of the Product Safety Law to food products remains unclear.
[49] Law amending the Law of the Republic of Lithuania on consumer protection (*Official Gazette*, 2007, No 12-488) effective as of 1 March 2007.

product safety) relates to the regulation of consumer protection. This creates some confusion about the link between the provisions of the Product Safety law and the Law on consumer protection as far as the implementation of market surveillance functions is concerned. However, as will be shown below, this link is somewhat elaborated on in the procedure approved by the Government.

As already said, Article 12(1)(2) of the Law on consumer protection provided for and defined the VVTAT's coordination function. The same coordination obligation is also laid down in paragraph 10.1.1 of the VVTAT Regulations. It should be mentioned that for the purpose of implementing the VVTAT's coordination function, Resolution No 61 of the Government of 23 January 2008 approved the Procedure for the submission of consumer protection information to the State Consumer Rights Protection Authority[50] ('the Procedure') obliging state and municipal authorities to supply information to the VVTAT and setting out the procedure for the supply of such information. The said Procedure describes in detail what information is to be supplied by each authority to the VVTAT. Paragraph 5 of the Procedure stipulates that the VNMPI provides the VVTAT with the following information relating to product safety:

- number of products incompliant with safety requirements (by product group and nature of incompliance);
- number and nature of market restriction measures imposed (by product group and enforcement measures);
- number of investigations of violations of the Product Safety Law;
- number of consumer applications (reports and complaints) (including the number of justified ones) and their analysis (by product group, causes and enforcement measures imposed);
- number of products having damaged consumer health or caused consumer death (by product group and nature of damage).

In accordance with paragraph 11 of the Procedure, along with the information listed in paragraphs 5 to 10 of the Procedure, state and municipal authorities in charge of their respective area of management relating to consumer protection also submit a free description of product safety and/or consumer protection issues and problems to be dealt with and proposed solutions as well as proposals of amendments to legislation in the area of consumer protection. So, the said Procedure may lead to a conclusion that the coordination function in the area of consumer protection envisaged in the Law on consumer protection also covers the coordination of product safety (including products and services). However, as pointed out in Chapter 2 of the Study, this coordination function only covers consumer products and does not cover non-consumer (professional) products.

It should be noted that in accordance with the Product Safety Law, the VVTAT is granted numerous powers in the area of market surveillance (product safety):

- coordination of the implementation of legislation regulating product safety;
- imposition of market restriction measures;
- examination of cases and imposition of fines as provided for in the Product Safety Law.

[50] Resolution No 61 of the Government of the Republic of Lithuania of 23 January 2008 approving the Procedure for the submission of consumer protection information to the State Consumer Rights Protection Authority (*Official Gazette*, 2008, No 13-442).

However, given the lack of clarity in the wordings of the legal provisions and their mutual links, it is still not fully clear what specifically the VVTAT is to do and does when performing the coordination function concerning the implementation of product safety and market surveillance legislation. This lack of clarity is also reflected in the actual implementation of institutional functions. It should be stressed that the coordination of the implementation of product safety legislation or integrated action taken to implement this function is not mentioned in the VVTAT's activity reports for 2012 and 2013[51] either. True, these reports present some statistics relating to the number of violations of the Product Safety Law investigated by the VVTAT, fines imposed for violations of the Product Safety Law, categories of unsafe products, etc. At the same time, there is a need to underline that the VVTAT's website publishes general information relating to consumer rights upon purchasing unsafe or dangerous products, the operative parts of cases of violations of the Product Safety Law and annual RAPEX reports but it does not show, for instance, any systematic information relating to the general product safety and market surveillance system, EU legislation regulating product safety, new EU legislative proposals or methodological recommendations. As mentioned previously, it is unclear which institution (the Ministry of Justice or the Ministry of the Economy) is in charge of market surveillance of product safety. It should be noted that the websites of either the Ministry of Justice or the Ministry of the Economy do not provide any systematic information on product safety market surveillance, except only for a general list of surveillance authorities published on the website of the Ministry of the Economy.

As indicated above, paragraph 8.45 of the Regulations of the Ministry of the Economy of the Republic of Lithuania approved by Resolution No 921 of the Government of the Republic of Lithuania of 23 July 1998 sets out that "<…> *pursuing the objective of its activities set in paragraph 7.1*[52]*, the Ministry of the Economy shall <…> coordinate market surveillance of non-food products*". In the Ministry of the Economy the implementation of this function is delegated to the Industrial Policy Division of the Industry and Trade Department. One of the areas of activity of the Industrial Policy Division is to participate in shaping the market surveillance policy of non-food products and one of the objectives of this Division is to coordinate market surveillance of non-food products[53]. As mentioned previously, paragraph 8.1 of the VNMPI Regulations sets out that one of the objectives of the VNMPI's activity is "*to implement the market surveillance policy for non-food products and services ('non-food products')*" and in pursuit of this objective, the VNMPI "*supervises whether non-food products placed on the market which the Inspectorate is tasked with supervising by laws or other legislation meet safety, quality and labelling requirements to non-food products, independently choosing entities to be checked and determining the scale of checks*" (paragraph 9.1). As mentioned above, the Product Safety Law and the Law on consumer protection oblige the VVTAT to coordinate the activity of consumer protection institutions in charge of regulating a certain area of consumption in the field of consumer protection. This leads to a situation where the coordination function is assigned to

[51] VVTAT activity reports. Website of the VVTAT [accessed on 21 January 2014]. Available online at http://vvtat.lt/index.php?3482342445

[52] Paragraph 7.1 of the Regulations of the Ministry of the Economy of the Republic of Lithuania: "*to shape the national economic policy: in the areas of the general economic (macroeconomic) policy, competition, European Union internal market, public procurement, state and municipal property privatisation, company law, insolvency, better regulation, internal trade, advertising, metrology, standardisation, accreditation and human resources and to organise, coordinate and control its implementation*".

[53] Areas of activity of the Industrial Policy Division of the Industry and Trade Department (functions). Website of the Ministry of the Economy [accessed on 21 January 2014]. Available online at http://www.ukmin.lt/web/lt/pramones_paslaugu_ir_prekybos_departamento_pramones_politikos_skyriaus_veiklos_sritys_funkcijos.

two public authorities of different levels (the Ministry of the Economy and the VVTAT), thus making it unclear whether the coordination is ensured by the authority on the policy-making level or by the implementing authority.

To sum up the above, one could draw a conclusion that the existing regulatory framework in respect of the coordination function relating to the product safety and market surveillance system is defective, which is why it needs to be improved by clearly defining and aligning the powers of both ministries and market surveillance authorities in implementing the coordination function of the product safety and market surveillance system.

As indicated in Chapter 2 of the Study, the regulatory framework of the functions of the market surveillance system established in the Regulation and the Directive implies several systematic functions. Therefore, this Study presents a detailed analysis of the admissibility of systematic market surveillance functions and their implementation in Lithuanian legislation. A summary of the implementation of systematic functions is presented in Annex I.

3.2.1.1. Monitoring of the market surveillance system

Article 18(6) of the Regulation lays down an obligation to the Member States to periodically (at least once every four years) review and assess the functioning of their surveillance activities. The Regulation also stipulates that the results of such reviews and assessments are to be communicated to the other Member States and the Commission and be made available to the public, by way of electronic communication and, where appropriate, by other means.

Article 9(1)(c) of the Directive sets out that in order to ensure effective market surveillance, aimed at guaranteeing a high level of consumer health and safety protection, which entails cooperation between their competent authorities, Member States shall ensure that approaches employing appropriate means and procedures are put in place, which may include *inter alia* periodical review and assessment of the functioning of the control activities and their effectiveness and, if necessary, revision of the surveillance approach and organisation put in place.

The Regulation and the Directive essentially lay down a similar function consisting of three key obligations:

- to ensure the monitoring of the market surveillance system;
- to make available to the public information on the monitoring results;
- to notify the results to the EC.

It should also be noted that the monitoring function of the market surveillance system must result in ensuring that any shortcomings of the market surveillance system identified are eliminated and the system is improved accordingly. It should be stressed that neither the Regulation nor the Directive specify how this monitoring function is to be performed.

In accordance with the additional information supplied by representatives of the Ministry of the Economy, after the entry into force of the Regulation the aforementioned Article 18(6) of the Regulation has not been employed in any of the Member States. The Ministry of the Economy has also informed that this year the EC launched an assessment of the market surveillance system of the Member States and drew up a system assessment template to which the Member

States are to send in their comments by 7 March of this year. The Ministry of the Economy has said that after the approval of the said template, it will initiate the collection of data from market surveillance authorities and ensure the notification of the aggregated results to the EC.

Article 10(2) of the Law on public administration stipulates that the main method of quality management in public administration is the monitoring of public administration entities and their activities.

By Resolution No 1097 of 17 October 2007 the Government of the Republic of Lithuania approved the Procedure for the monitoring of public administration entities and their activities[54]. Its paragraph 6 sets out that "<…> *the monitoring of public administration on the national level shall be organised by the Ministry of the Interior*". In accordance with the procedure approved by that Resolution, public administration entities are obliged to supply information in certain form to the Ministry of the Interior which then structures and analyses it and draws conclusions. It is unclear how detailed the analysis (monitoring) by the Ministry of the Interior is in a specific field of product safety and market surveillance.

Neither the Product Safety Law nor other legislation regulating the activity of market surveillance authorities regulates the matters of monitoring of the market surveillance system. The Regulations of individual market surveillance authorities do not provide for an obligation to monitor the market surveillance system either.

As has been mentioned, the concept and content of the market surveillance coordination function are not specifically defined and it is not clear which specific authority on the policy-making level and on the implementation level is responsible for the coordination of product safety and market surveillance, and it is thus unclear which of them should perform the market surveillance monitoring function. It should be noted that the monitoring function is not specifically mentioned in the Law on consumer protection, which sets out the content of the coordination function, either. Hence, it is not even known whether the market surveillance coordination function also includes the market surveillance monitoring function. Still, one may conclude that these functions are closely interlinked as the monitoring of a management area is obviously a tool for making and managing a certain policy area. Therefore, without the monitoring of the product safety and market surveillance system, it would be impossible to coordinate it, i.e. to make it possible to coordinate the system proper, it first needs to be continuously monitored. Given the above, one may conclude that legislative provisions should lay down an obligation for a specific public authority to perform the product safety and market surveillance monitoring function (which could be envisaged as part of the system coordination function). Moreover, it needs to be stressed that the proper performance of this function is undoubtedly linked with a certain need for budgetary funds for the performance of this function, which is why when empowering a certain authority to perform the monitoring function, this institution needs to be provided with sufficient budget appropriations for the performance of this function, which, as we gather from the conclusions of the Working Party, has not been done previously.

3.2.1.2. Drafting, updating, implementation and notification to the EC of national or sector-specific market surveillance programmes

[54] Resolution No 1097 of the Government of the Republic of Lithuania of 17 October 2007 approving the Procedure for the monitoring of public administration entities and their activities (*Official Gazette*, 2007, No 110-4499).

Article 18(5) of the Regulation obliges the Member States to establish, implement and periodically update their market surveillance programmes. The Regulation enables the Member States to draw up a general market surveillance programme or sector-specific programmes, covering the sectors in which they conduct market surveillance. In other words, the Regulation does not specifically set out which programme needs to be drafted and whether the national general programme must be drawn up. The Regulation also stipulates that these programmes are to be communicated to the other Member States and the Commission and made available to the public, by way of electronic communication and/or by other means. The Regulation does not specify what is meant by periodic updating, and so it does not set a period for which such a market surveillance programme should be drawn up. This is left up to each Member State to decide. Article 16(3) of the Regulation sets out that national market surveillance infrastructures and programmes ensure that enforcement measures can be taken in relation to any product category subject to Community harmonisation legislation.

Article 9(1)(a) of the Directive stipulates that in order to ensure effective market surveillance, aimed at guaranteeing a high level of consumer health and safety protection, which entails cooperation between their competent authorities, Member States shall ensure that approaches employing appropriate means and procedures are put in place, which may include *inter alia* establishment, periodical updating and implementation of sectoral surveillance programmes by categories of products or risks and the monitoring of surveillance activities, findings and results.

The EC report on the implementation of the Regulation[55] states that the purpose of these programmes is to allow the other countries' authorities, as well as citizens in general, to understand how, when, where and in which areas market surveillance is carried out. To help the Member States to implement the provisions of the Regulation, the EC has proposed a general template for presenting sector-specific programmes but it is not published on the EC's website. An examination of the purpose of these market surveillance programmes identified in the EC report makes it obvious that they are important to:

- consumers insofar as they relate to the protection of their rights in the area of product safety;
- business entities insofar as they relate to the protection of their rights, e.g. during their checks conducted by a market surveillance authority.

Laws regulating the activities of Lithuanian market surveillance authorities do not stipulate an obligation relating to the drawing up and/or adoption and notification to the EC and Lithuanian market surveillance authorities of a general or a sector-specific programme. No such obligation is set in the Regulations of the Ministry of the Economy either. The Regulations of individual market surveillance authorities do not oblige market surveillance authorities to draft and/or adopt and communicate to the EC sector-specific market surveillance programmes either. An examination of strategic plans of several market surveillance authorities (the VVTAT, the RRT and the VNMPI) leads to a conclusion that therein the authorities do not provide for an obligation to draw up and communicate to the EC sector-specific market surveillance programmes either.

During the Study, following additional consultations with representatives of the Ministry of the Economy, it was established that the coordination of the implementation of the Regulation and the submission of information on the implementation of the Regulation is the responsibility of

[55] EC report on the implementation of the Regulation.

the Ministry of the Economy. It was also established that the basis for the coordination function was the provision in the Regulations of the EU Internal Market Coordination Division of the EU Affairs Department of the Ministry of the Economy setting out that the Division "*coordinates the implementation of the provisions of horizontal Union legislation regulating free movement of goods and coordinates the implementation of the principle of mutual recognition in Lithuania*".

It should be noted that in this case it is important that actions provided for in those market surveillance programmes match and are compatible with the general national policy in the area of the business surveillance system. It should be stressed that the handbook on the reorganisation of business surveillance[56] initiated by the Ministry of Justice and the Ministry of the Economy back in 2009 set out that reorganisation is reorganisation of economic entities and their functions for the sake of improved efficiency and purposefulness with a view to reducing the burden on the entities checked. So, one of the objectives of the reorganisation of the business surveillance system is to reduce the burden on economic entities checked. So, the monitoring activities envisaged in market surveillance programmes such as routine and non-routine checks, sampling and desk audits must be in line with the general principle relating to the objective of reducing the burden on the entities checked, i.e. market surveillance authorities must align their market surveillance programmes with certain requirements of the business surveillance system, and relating to the objective to perform efficient surveillance to ensure public security interests.

The information published on the website of the EC includes some general and/or sector-specific market surveillance programmes submitted by individual Member States[57]. It should be noted that the EC's website only publishes the most up-to-date market surveillance programmes of the Member States, which is why we cannot draw conclusions as to how often the Member States update them. Still, market surveillance programmes usually specify that the measures envisaged therein are to apply during a period of one year, which is certain programming of annual updates of such a programme. Representatives of the Ministry of the Economy have mentioned that Lithuanian market surveillance authorities are annually reminded about the drafting of sector-specific programmes. Sector-specific programmes drafted are communicated to the other Member States and the Commission. However as there is no final agreement on the EU level in respect of the scope of sector-specific programmes, the matter of making these programmes available to the public is not settled either.

It should be noted that some EU Member States have communicated both general and sector-specific market surveillance programmes (e.g. Finland, the Netherlands, Romania, Sweden and the United Kingdom). Some other Member States have submitted either the general programme or sector-specific market surveillance programmes. It should be stressed that Sweden has submitted a particularly comprehensive general market surveillance programme for 2014 where, apart from general information on market surveillance, it also presents a detailed action plan for the year and a list of responsible authorities. Sweden has also submitted sector-specific market surveillance programmes. The same is true about Finnish and Dutch market surveillance programmes while Poland has only submitted the general market surveillance programme. A detailed analysis of the market surveillance system of these four countries is given in Chapter IV of the Study.

[56] Reorganisation of business surveillance authorities. Website of the Ministry of the Economy [accessed on 21 January 2014]. Available online at http://www.ukmin.lt/web/lt/verslo_aplinka/verslo-prieziuros-reforma.

[57] *Market surveillance*. Commission's website [accessed on 17 January 2014]. Available online at http://ec.europa.eu/enterprise/policies/single-market-goods/internal-market-for-products/market-surveillance/index_en.htm#h2-3.

Among the programmes published on the EC's website was the Lithuanian programme for 2012 but it was only a sector-specific one providing for market surveillance measures of the SLI. The SLI's sector-specific programme for 2012 was focused on the surveillance of lifts and machinery and mechanisms. The programme contained the following information:

- a specific product;
- product control type (e.g. checks by own initiative);
- control activity (e.g. desk audit, visual checks, etc.);
- the start date of the control exercise;
- control interfaces;
- control results.

During the Study the Commission published on its website the most up-to-date programmes drawn up by certain authorities for 2014 including the RRT, the VASPVT, the SLI, the LMSA and the LMI.

Some other sector-specific national market surveillance programmes are also available online but not published on the EC's website:

- Market surveillance programme of the LMI for metrological equipment and pre-packaged merchandise in legal metrology of 27 December 2012;
- Market surveillance programme of the LMI for metrological equipment and pre-packaged merchandise in legal metrology of 27 December 2013;
- Sector-specific national market surveillance programme of the VNMPI for 2013 (although the programme is entitled as national, it only focuses on non-food areas coordinated by the VNMPI).

These programmes presented in the form of tables all offer similar information. The programme drawn up by the VNMPI covers numerous areas of non-food products and, apart from elements of the SLI's programme mentioned previously, offers a detailed description of the expected results or future initiatives. The latest programme drawn up by the LMI, apart from elements of the SLI's programme mentioned previously, also gives a detailed description of programme implementing measures, lists completed projects and in the form of a table presents a market surveillance action plan.

During the additional consultations representatives of the Ministry of the Economy said that sector-specific programmes were drawn up by the State Non-Food Products Inspectorate, the Lithuanian Maritime Safety Administration, the State Healthcare Accreditation Agency and the State Labour Inspectorate.

It should also be noted that, as mentioned above, the EU legal framework does not set out for what period of time national and/or sector-specific market surveillance programmes are to be drawn up. Given that, it is important that along with the obligation to draw up such programmes, national legislation specifically sets a period for which such a programme needs to be drafted.

The proper drafting and subsequent efficient implementation of market surveillance programmes are closely related to sufficient funding. Article 18(3) of the Regulation obliges the Member States to entrust market surveillance authorities with the powers, resources and knowledge necessary for the proper performance of their tasks. It is of particular importance that market

surveillance authorities have sufficient funds for properly implementing actions envisaged in programmes.

An examination of market surveillance programmes submitted by Lithuania and some other Member States may lead to a number of conclusions:

- there is no standard content of the programmes;
- not all Member States in their programmes provide the same level of information.

Normally, general market surveillance programmes provide information on the limits of responsibility of market surveillance authorities in the Member State, working methods of market surveillance authorities, mutual cooperation between national market surveillance authorities and their cooperation with stakeholders as well as methods to exchange information while sector-specific market surveillance programmes are often rather concise and in the form of a table present information on specific measures to be taken in a certain sector or in respect of certain products. However, even though, as mentioned above, the EC in its report on the implementation of the Regulation has stated that the use of a single template for presenting sector-specific programme would facilitate the comparability of national information on special products or legislation and enable market surveillance authorities to plan for cross-border cooperation in those areas where their interests coincide, still a look at the content of the programmes submitted (information presented therein) makes it obvious that there is currently no uniform report form used by all EU Member States. A note of the Commission's Directorate-General for Enterprises and Industry to the Market Surveillance Group[58] presented a uniform template for sector-specific programmes to be used for drafting all sector-specific programmes. Still, it should be noted that an examination of programmes drawn up by individual market surveillance authorities in Lithuania presented by the Ministry of the Economy shows that not all of them are drawn up using the said form.

To sum up the situation with the drafting of market surveillance programmes in Lithuania as discussed above, the following drawbacks can be identified:

- laws do not empower authorities to draft market surveillance programmes;
- laws and other legislation do not define which programmes need to be drafted (national and/or sector-specific ones) and the link between these programmes and do not regulate the content and period of implementation of these programmes;
- varying practices in market surveillance authorities reveal that best practices in drawing up such programmes are not shared;
- the implementation of such programmes is not evaluated.

It should be noted that, as mentioned above, the Regulation does not specifically set out and oblige the Member States to draw up both the general and sector-specific programmes, and still the most comprehensive presentation of the market surveillance system can be ensured by drafting both the general and sector-specific market surveillance programmes. Therefore, Lithuanian legislation should envisage the drafting of both programmes also specifying their mutual links. However, what is needed first is that such an obligation of market surveillance authorities is stipulated in laws also providing for a specific period of time for which the programme is to be drawn up. Then the general programme would lay down the key principles

[58] European Commission's Directorate-General for Enterprises and Industry, General Note to the Senior Officials' Group for standardisation and conformity assessment policy – Market Surveillance Group (SOGS-MSG).

of the functioning of the market surveillance system while sector-specific programmes would give a detailed description of specific activities to be taken by market surveillance authorities in their respective areas of competence. When drafting sector-specific programmes (should a decision be made to draw them up), it is important to ensure that they are drafted in all sectors (these sectors are to be identified and institutions in charge of the drafting of the respective sector-specific programme are to be specified). In other words, the same principle needs to be enforced in respect of all market surveillance authorities.

When drafting sector-specific and general market surveillance programmes, there is a need to align their content, i.e. to draw up and apply the same requirements to all market surveillance authorities in respect of the scope and nature of information included in the market surveillance programme, and to ensure uniform practices in implementing these programmes where such practices are standardised to the extent possible in accordance with the best practices. Therefore, a regulatory framework for the function of programme drafting needs to provide for the respective coordination of the function. At the same time, there is a need to clearly define how this information is to be communicated to the EC: through centralised channels or via a specific market surveillance authority.

It should be noted that the drafting and implementation of market surveillance programmes undoubtedly help to consolidate the entire market surveillance system. Before drafting a programme, market surveillance authorities first need to examine the current situation and to evaluate the monitoring results concerning the market surveillance system, which requires mutual cooperation between market surveillance authorities.

The above leads to a conclusion that although this function is actually being implemented, its regulation can be improved.

3.2.1.3. Public awareness raising/education on market surveillance authorities and their functions

The Regulation lays down obligations for the Member States relating to the publication of market surveillance information and public awareness raising about market surveillance authorities, their system and functions. Article 17(2) of the Regulation obliges the Member States to ensure that the public is aware of the existence, responsibilities and identity of national market surveillance authorities, and of how those authorities may be contacted. So, the function of public awareness raising and education laid down in the Regulation is perceived as a general systematic function covering public education about the general market surveillance system in the Member State (market surveillance authorities proper, their functions and ways to contact them).

It should be noted that Article 16(2) of the Regulation lays down an obligation to inform the public about products which are liable to compromise the health or safety of users while Article 19(2) of the Regulation stipulates that market surveillance authorities take appropriate measures to alert users within their territories within an adequate timeframe of hazards they have identified relating to any product so as to reduce the risk of injury or other damage. Accordingly, Article 16(1) of the Directive sets out that information available to the authorities of the Member States or the Commission relating to risks to consumer health and safety posed by products shall in general be available to the public, in accordance with the requirements of transparency and without prejudice to the restrictions required for monitoring and investigation activities. The

Directive stipulates that, in particular, the public shall have access to information on product identification, the nature of the risk and the measures taken. This leads to believe that the obligation laid down in Articles 16(2) and 19(2) of the Regulation and Article 16(1) of the Directive to properly inform the public is different in content from the public information obligation laid down in Article 17(2) of the Regulation. As mentioned previously, the objective defined in Article 17(2) of the Regulation is to inform the public about a system of market surveillance authorities while the obligation defined in Article 19(2) of the Regulation and Article 16(1) of the Directive relates to the provision of information about a specific product, related risks and measures imposed in respect of that product. An analysis of this function is given in Section 3.2.2.10 of the Study.

The Regulation does not provide for specific ways or measures and specific institutions that should implement the function of public awareness raising of market surveillance authorities and their obligations. This implies that such details are left for national legislation. National legislation may provide for various ways to implement the aforementioned function including the following:

- **the function is assigned to an authority coordinating the entire market surveillance system** (this would ensure that systematic information is supplied, the relevant authority is obliged to update it and adopt decisions on appropriate ways to inform the public that may depend on the actual situation and the need for active supply of information, etc.);
- **the function is assigned to individual market surveillance authorities** (this way the provision of information to the public would be the responsibility of individual authorities in charge of a specific market surveillance area, and the function would be implemented individually by each authority representing its area of activity).

Still, it should be noted that this function of public awareness raising about authorities and their obligations is laid down in Article 12(1) of the Regulation obliging the Member States to inform the Commission of the identity of market surveillance authorities and their areas of competence. This leads to a conclusion that this provision means that information supplied in accordance with Article 17 of the Regulation must clearly imply that the public understands the entire system of market surveillance authorities and obligations (competences) of the authorities. This way such an objective would not be achieved if the function of informing the public of market surveillance authorities and their obligations were assigned individually to each market surveillance authority. This leads to a conclusion that a more appropriate way to implement Article 17(2) of the Regulation in the national legislation would be to grant respective powers to an authority coordinating the entire market surveillance system.

It should be pointed out that the Lithuanian legislation does not envisage any general obligation relating specifically to informing the public about the market surveillance system. As analysed further, legal acts provide for certain public awareness raising obligations of public authorities but none of them is not specifically related to the information of the public about the entire market surveillance system.

First, Article 3(1) of the Law on the right to obtain information from state and municipal authorities and bodies obliges institutions to provide information to applicants. Article 6(1) of that Law obliges authorities to have a website meeting requirements approved by the Government where it is to publish information about their functions and structure, an index of information relating to the provision of information and other statutory information. So, market

surveillance authorities are obliged to provide information to the public, which leads to a conclusion that the legislation implies sufficient regulation to ensure that the public is made aware of the activities and functions of those market surveillance authorities. However it must be stressed that, apart from the general requirement to supply relevant information on the authority's website, the provision of information in accordance with the Law on the right to obtain information from state and municipal authorities and bodies is envisaged only where the initiative to obtain information comes from the public, i.e. information is supplied where there is a specific request from a person. At the same time, the function laid down in the Regulation and the Directive practically implies active action to be taken by the Member State with a view to informing the public about the market surveillance system. As mentioned above, the purpose of this Study is not to examine how institutions actually implement this function or whether the information supplied to the public is *de facto* understandable and clear to the public.

Second, the Law on consumer protection (e.g. Article 10(6)) obliges public authorities to educate consumers but it does not provide for specific functions relating to the obligation to provide information specifically about the market surveillance system, market surveillance authorities and their functions.

Third, the Product Safety Law provides for an obligation to make available to the public certain information. Article 15(1) of the Product Safety Law sets out that information held by the VVTAT and control institutions (the VNMPI that is relevant to the Study) on risks posed by products to consumer health and safety should be available to the public without breaking certain restrictions applicable. The public can access information on the identification of products, the nature of related risks and measures taken. Obviously, these provisions of the Product Safety Law implement the requirements of the aforementioned Article 16(1) of the Directive and, as mentioned above, Article 16(1) of the Directive lays down information requirements different from those stipulated in Article 17(2) of the Regulation.

Fourth, certain functions relating to public awareness raising can also be found in the Regulations of individual market surveillance authorities. Information on these functions of market surveillance authorities is presented in the table below. It should be noted that the regulatory framework laid down in the Regulations does not imply that the information function specifically relates to the information on the implementation of market surveillance functions and rather covers general provisions on the supply of information to the public.

Paragraph 10.1.5 of the VVTAT Regulations	organise education of consumers, coordinate activities of other state and municipal authorities and bodies and consumer associations in organising consumer education and provide sellers and service providers with information on consumer rights
Paragraphs 9.10 and 9.11 of the VNMPI Regulations	consult natural and legal persons and provide them with information on matters falling within the VNMPI's remit examine consumer requests concerning the fulfilment of legal requirements relating to the safety, quality and labelling of non-food

	products and provision of information
Paragraphs 10.9 and 10.27 of the CD Regulations	provide information and consultations to persons as well as other methodological assistance on matters relating to the application of tax duty legislation inform the public about the activities of the Customs Department and publish information relating to the activities of the Customs Department on the website of the Customs Department
Paragraph 10.46 of the VASPVT Regulations	provide information and other services to legal and natural persons
Paragraph 8.30 of the VKTI Regulations	inform the public about its activities

An analysis of the legal framework described above leads to a conclusion that in general legislation implies the obligation of public authorities in charge of market surveillance about their functions. However these obligations do not relate to the specific function of informing the public about the market surveillance system. Given that, the function of public awareness raising/education about market surveillance authorities and their obligations envisaged in Article 17(2) of the Regulation is not very well implemented in the Lithuanian legislation, which is why the current legislative framework could be improved.

As mentioned in the comments of the Ministry of the Economy on the interim Study report, the Ministry is of the opinion that Articles 16(2) and 17(2) of the Regulation are to be implemented with the help of a public-access section on the ICSMS portal accessible without registration to all users. An actual check of what information on that portal is accessible to all users leads to a conclusion that information available to users in the Lithuanian language is very scarce. It is very difficult to find specific products deemed incompliant with safety requirements by entering key words in the field "Product search" (key words can only be entered in English) although in the field "Institution search" it is not difficult to find public authorities participating in the ICSMS system by a specific country. Moreover, system navigation is inflexible and user-unfriendly. Without clear guidance on how to use the system, it is probable that an average user (in accordance with the legal practice and where an average user is a sufficiently well-informed, careful and attentive user who is not an expert in a certain field) would find it difficult to use. There is little public information on the ICSMS portal, which is why it is probable that users are not even aware of the existence of the portal. Therefore, the ICSMS portal cannot currently be seen as a tool contributing to the implementation of the function of public information laid down in the Regulation.

3.2.1.4. Communications with the EC (notification of market surveillance authorities and their areas of competence and provision of similar notifications and information)

The Regulation obliges the Member States to notify the EC of market surveillance authorities and their areas of competence (Article 17(1)). The EC forwards this information to the other

Member States. Article 6(3) of the Directive obliges the Member States to define the tasks, powers, organisation and cooperation arrangements of the competent authorities. They keep the Commission informed, and the Commission passes on such information to the other Member States. So, both the Directive and the Regulation oblige the Member States to inform the EC about national authorities. It should be noted that although both obligations are essentially identical, because the Directive relates only to consumer products and the Regulation also applies to non-consumer (professional) products and concerns in general market surveillance authorities, this obligation had to be laid down in the Regulation too.

Article 7 of the Product Safety Law sets out that information on dangerous products and competent authorities and their powers is supplied to the EC and/or other countries in accordance with the procedure laid down by the Government of the Republic of Lithuania or an institution authorised thereby. Paragraph 22 of the Rules for the application of restrictions on marketing of products, in fact, reiterates the provision of the Product Safety Law. In accordance with Article 7 of the Product Safety Law, Order No 1-62 of the Director of the VVTAT of 14 May 2010 approved the Rules for rapid exchange of information on products dangerous to consumers[59]. However they only regulate the submission of notifications of dangerous products to the EC but not notifications of authorities constituting the market surveillance system. So, the legislation does not specifically state which specific authority is in charge of informing the Commission about market surveillance authorities in Lithuania and their competences. As Article 6(1) of the Product Safety Law sets out that the implementation of this Law and other laws regulating product safety is coordinated by the VVTAT, this leads to a conclusion that this authority is the one in charge of notifying the EC. The VVTAT Regulations stipulate that one of the functions of the VVTAT is to cooperate with other public authorities and bodies in organising information exchange (and exchanging information) with the EC and national authorities of the EU Member States.

It should be noted that Lithuania has notified the EC of market surveillance authorities in Lithuania and their competences[60]. This information was sent to the Commission in 2009, which leads to a conclusion that the function set in the Regulation and the Directive to provide information to the EC about national market surveillance authorities and their competences has been implemented at least partially although it must be noted that the EC has not been notified of an updated list of market surveillance authorities. It should be pointed out that the website of the Ministry of the Economy publishes a list of surveillance authorities[61] but there is no separate list of market surveillance authorities. That list of surveillance authorities simply identifies certain authorities in charge of product safety. The link between this list and the list of market surveillance authorities notified to the EC is analysed in Chapter 3.1 of the Study.

As mentioned previously, the Regulations of the Ministry of the Economy and of the Industrial Policy Division of the Industry and Trade Department lay down as one of the objectives the coordination function in the area of market surveillance of non-food products. Still, neither the Regulations of the Ministry of the Economy nor the documents of the Industrial Policy Division

[59] Order No 1-62 of the Director of the State Consumer Rights Protection Authority of 14 May 2010 approving the Rules for rapid exchange of information on products dangerous to consumers (*Official Gazette*, 2010, No 58-2871).
[60] *Market surveillance*. Commission's website [accessed on 17 January 2014]. Available online at http://ec.europa.eu/enterprise/policies/single-market-goods/internal-market-for-products/market-surveillance/index_en.htm#h2-3.
[61] List of surveillance authorities. Website of the Ministry of the Economy [accessed on 17 January 2014]. Available online at http://www.ukmin.lt/web/lt/verslo_aplinka/verslo-prieziuros-reforma/prieziuros_funkcijas_atliekancios_institucijos

of the Industry and Trade Department define in detail the obligation of these institutions to communicate with the EC and keep it duly informed.

In their Regulations certain market surveillance authorities often stipulate as one of their obligations communication with the Commission on matters falling within their remit:

Paragraph 10.6.9 of the EPA Regulations	in accordance with the statutory procedure draft and submit reports to the EC, other EU institutions and international organisations
Paragraph 10.1.10 of the LMSA Regulations	in accordance with the procedure laid down in the legislation of the Republic of Lithuania, provide information to the EC
Paragraph 10.3.2 of the LMI Regulations	in the statutory cases notify the EC and authorised institutions of the other EU Member States of measures imposed to prohibit the use or the placing on the market of metrological equipment, pre-packaged merchandise or metrological vessels and of the reasons for adopting these decisions
Paragraph 9.3 of the SLI Regulations	delegated by the Ministry of Social Security and Labour to represent the Ministry in meetings of the working parties and committees of the EC
Paragraph 10.2.4 of the VVTAT Regulations	together with other public authorities and bodies organise exchange of information (and exchange information) with the EC

As seen from the information presented in the table, most often the obligation to communicate with the EC laid down in the Regulations of market surveillance authorities relates to the general obligation to submit information or reports but they do not specifically stipulate the obligation to provide information on the institution proper as part to the market surveillance system and its competence in the area of market surveillance as well as the obligation to update information after it changes.

It should be noted that although information about market surveillance authorities has been supplied to the EC, with a view to defining the functions (and liability for their performance) of the authorities at the same time guaranteeing legal certainty, it is advisable to assign the performance of this obligation to a specific authority by adopting a national law.

3.2.1.5. Establishing a mechanism of cooperation between national market surveillance authorities and between national market surveillance authorities and authorities in charge of external border control

Article 18(1) of the Regulation sets out that the Member States establish appropriate communication and coordination mechanisms between their market surveillance authorities. Article 27(2) of the Regulation obliges market surveillance authorities of the Member States to cooperate with authorities in charge of external border control. On the other hand, the Directive does not provide for such a cooperation function for market surveillance authorities and authorities responsible for external border control. So, the Regulation provides for a dual need for cooperation:

- *market surveillance authority v market surveillance authority;*
- *market surveillance authority v authority responsible for external border control.*

Although the Regulation only talks about ensuring institutional cooperation as such and does not stipulate a specific duty to coordinate the performance of this function, still the aforesaid monitoring function relating to the market surveillance system implies that a coordination mechanism for such a function is also needed. This leads to a conclusion that the coordination function for institutional cooperation needs to be identified as a systematic (coordinating) function of the market surveillance system (or, in other words, this function should ensure that it results in establishing a mechanism for such cooperation and the performance of the monitoring of the mechanism). The performance of this function would, on the one hand, ensure a standardised cooperation model and a possibility of identifying the best cooperation practices on the national level and would also imply an obligation to take interest in the best cooperation practices on the EU level; on the other hand, the performance of this function would allow for the monitoring of the implementation of this function, identifying any shortcomings in its implementation and offer coordinated suggestions for the improvement of the market surveillance system. As will be further discussed in detail, the current situation relating to the performance of the cooperation function *market surveillance authority v market surveillance authority* and *market surveillance authority v authority responsible for external border control* (the problems identified below) clearly implies the need for the coordination and standardisation of the cooperation function.

Legislation regulating the activities of national market surveillance authorities does not establish a common mechanism for either of these forms of cooperation: either the cooperation *market surveillance authority v market surveillance authority* or the cooperation *market surveillance authority v authority responsible for external border control*. As the Product Safety Law was adopted with a view to implementing the Directive, like the Directive, it does not lay down the function of establishing an institutional cooperation mechanism.

Article 3(5) of the Law on public administration enshrines a principle of official assistance that means that "*public administration entities drafting administrative decisions, where appropriate, provide one another with necessary information and other assistance*"[62]. So, based on this provision, as will be discussed further, many market surveillance authorities have provided for the duty of such mutual cooperation in their Regulations. However as these functions are listed in this manner (without regulating their implementation more specifically), it is doubtful that they will be implemented properly. These doubts are reaffirmed by an analysis of the situation concerning cooperation agreements as will be shown later. It should be noted that although the actual implementation of the cooperation function has not been examined, the information analysed is already enough to demonstrate the existing issue of ensuring the proper implementation of the cooperation function.

[62] Law of the Republic of Lithuania on public administration (*Official Gazette*, 1999, No 60-1945; 2006, No 77-2975).

It should be pointed out that Article 13(1) of the Law on customs sets out that the customs office performing its functions cooperates with state and municipal authorities and bodies of the Republic of Lithuania and other bodies, businesses and organisations. However, this provision in the Law does not establish a cooperation mechanism proper, does not define principles of such cooperation and does not assign the function to any authority. What is more, this function is not reflected in the CD Regulations either.

It should be noted that the Regulations of some market surveillance authorities provide for a general duty of the market surveillance authority to cooperate with other authorities, and only the LMI and the VNMPI lay down a specific obligation to cooperate with other market surveillance authorities. It should be noted that the Regulations of authorities do not specifically lay down an obligation to cooperate with the authority responsible for external border control.

Paragraph 12. 4 of the EPA Regulations	within its remit cooperate with authorities, bodies and other natural and legal persons of the Republic of Lithuania
Paragraph 10.2.4 of the LMI Regulations	at the invitation of other surveillance authorities conduct measurements of product quantities during joint checks
Paragraph 7.7 of the RRT Regulations	in performing its functions, cooperate with competent public authorities
Paragraphs 2 and 10.6 of the RSC Regulations	coordinate actions of state and municipal authorities in the area of radiation protection within its remit cooperate with authorities and bodies of the Republic of Lithuania in the area of radiation protection and participate in activities of international organisations and European Union institutions, committees and groups
Paragraph 10.41 of the VASPVT Regulations	within its remit cooperate with all authorities controlling healthcare establishments and other state and municipal bodies
Paragraphs 8.3.9 and 9.3 of the SLI Regulations	cooperate and exchange information with state and municipal authorities and bodies, trade unions, works councils and employer organisations delegated by the Ministry of Social Security and Labour to represent the Ministry within its remit on behalf of the State Labour Inspectorate in state and municipal authorities and bodies of the Republic of Lithuania

Paragraph 10.70 of the SMCA Regulations	cooperate with institutions and organisations and medical and/or pharmaceuticals specialists in implementing its statutory functions
Paragraphs 10.1.1, 10.2.4 and 11.7 of the VVTAT Regulations	coordinate the activities of consumer protection authorities responsible for the regulation of certain areas of consumption in the field of consumer protection together with other public authorities and bodies organise exchange of information (and exchange information) with the EC and the national authorities of the European Union Member States cooperate with public authorities, bodies and consumer associations of the Republic of Lithuania
Paragraphs 9.17 and 10.5 of the VNMPI Regulations	cooperate with market surveillance and consumer protection authorities of the Republic of Lithuania, conformity assessment bodies and business and consumer associations in the area of the fulfilment of safety, quality and labelling requirements to non-food products, provision of information on non-food products and other binding requirements and in the area of consumer protection in respect of non-food products involve representatives of other state and municipal authorities and bodies, consumer and business associations, subject to agreement with their management, in handling issues at hand, establishing commissions and working parties to deal with maters of the competence of the State Non-Food Products Inspectorate

An analysis completed leads to a conclusion that market surveillance authorities implement the cooperation function established in the Regulation usually through mutual cooperation agreements ('cooperation agreements').

As mentioned before, Article 3(5) of the Law on public administration sets out the principle of official assistance, and it has also been stated that the Regulations of market surveillance authorities regulate (in general or in specific relation to market surveillance) the function of cooperation with other authorities. Both the materials of the Working Party given to us and the information available publicly (its analysis is presented below) show that the cooperation *market*

surveillance authority v market surveillance authority and *market surveillance authority v authority responsible for external border control* is ensured by signing interagency cooperation agreements.

The list of authorities ensuring market surveillance in Lithuania compiled by the Working Party contained a number of national interinstitutional cooperation agreements. The Working Party also stressed the importance of more active interinstitutional cooperation for ensuring efficient market surveillance. Still, an examination of publicly available information leads to the following conclusions:

- there is little public information on these agreements. Cooperation agreements are not published in INFOLEX database;
- only a few market surveillance authorities (the RRT and the VKTI) have published their national interinstitutional cooperation agreements with other market surveillance authorities and with the CD[63], i.e. published the content of those agreements;
- some authorities publish only lists of cooperation agreements concluded (the EPA, the CD and the VNMPI) but not their contents;
- many market surveillance authorities on their websites do not inform the public of their interinstitutional cooperation agreements at all;
- the list of authorities ensuring market surveillance in Lithuania compiled by the Working Party listed 13 interinstitutional cooperation agreements but only 4 of them could be found online;
- a random examination of annual activity reports of some[64] market surveillance authorities leads to a conclusion that they do not contain any reference to those cooperation agreements and any analysis of the situation relating to their implementation. Annual activity reports of institutions show that all market surveillance authorities tend to provide information only about international cooperation while there is nothing on cooperation on the national level;
- cooperation agreements have different contents and scopes, and some are more detailed while other are limited to very general provisions only.

So, the above conclusions prove that there is no uniform practice between authorities relating to the need to sign (conclude) cooperation agreements. An analysis of the current situation does not make it clear why some authorities decide that cooperation agreements are needed while others believe that they are not necessary and do not sign such cooperation agreements. Obviously, there is no uniform policy in respect of such cooperation agreements.

When notifying the EC of market surveillance authorities of Lithuania and their mutual cooperation, Lithuania mentioned only five national interinstitutional cooperation agreements and two agreements under consideration at the time[65] (an agreement between the LMSA and the CD and an agreement between the CD and the VASPVT). A comprehensive search for the said cooperation agreements online has returned the texts of only two cooperation agreements between the RRT and the CD and the VNMPI notified to the Commission. It should be emphasised that interagency agreements referred to in the information on the market surveillance

[63] Legal information. Website of the RRT [accessed on 17 January 2014]. Available online at http://www.rrt.lt/lt/teisine-informacija/teisine-informacija_1072/teises-aktai.html; interagency and international official agreements. Website of the VKTI [accessed on 17 January 2014]. Available online at http://www.vkti.gov.lt/go.php/lit/Tarpzinybiniai-ir-tarptautiniai-tarpzinybiniai-susitarimai/2100.
[64] VVTAT, VNMPI, RRT and SMCA.
[65] EC report on the implementation of the Regulation.

system of Lithuania notified to the EC are about ten years old, and it is unclear why the EC is not notified of other cooperation agreements mentioned on the websites of the said authorities, e.g. all cooperation agreements concluded by the VKTI or the cooperation agreement signed between the RRT and the CD. This leads to a conclusion that information notified to the EC is not duly updated and the list of national interinstitutional cooperation agreements is not exhaustive. What is more, the said agreement between the RRT and the VNMPI (mentioned also by the EC) lists specific persons designated by each of the authorities as responsible for the receipt and submission of information from and to each other indicating their names, positions and contact data. Given that the agreement was signed as long ago as on 14 November 2005, it is obvious that persons responsible for this area may have changed, which gives rise to doubts about the practice of listing specific persons responsible in the agreement proper.

Cooperation agreements should ensure smoother, more rapid and efficient cooperation between various public authorities. Interagency cooperation may take various forms including sharing of information, exchange of information, methodological assistance, consultations, participation in joint activities and joint performance of certain actions. Irrespective of the form, interinstitutional cooperation should take place without prejudice to legal requirements regulating the functions and activities of respective authorities.

An examination of the content of existing and publicly available cooperation agreements and general information about these agreements reveals two issues relating to these agreements (discussed in greater detail below):

- an unclear legal meaning of cooperation agreements;
- practices of drafting cooperation agreements are not standardised.

Legal meaning of cooperation agreements

It should be noted that the legal meaning of cooperation agreements is not clear, i.e. it is unclear:

- whether these agreements are to be treated as public agreements (*inter alia* subject to the Civil Code provisions) or whether they should rather be deemed to be legal acts, i.e. it is unclear to what extent their provisions are binding. It should also be noted that where these cooperation agreements are binding, there should not be a situation where some authorities sign such agreements while other do not, and there may be no different procedures for publishing such agreements. An example to be mentioned here is the legal meaning of consultations of economic entities provided for in the Law of the Republic of Lithuania on public administration: economic entities are authorised to follow consultative advice given in writing or published by a surveillance authority (in other words, it is binding on public administration entities);
- whether these agreements should be subject to the provisions of the Law on public administration. Having examined agreements of the Regional Health Insurance Fund with healthcare establishments[66], the Supreme Administrative Court of Lithuania has held that "<…> *these agreements must be treated as administrative agreements as legal relations based on which contractual relations arise are of administrative nature while the agreements proper are concluded by public administration entities on the grounds of imperative legal provisions with a view to protecting public interests in the area of healthcare*". So, although the Court dealt with an agreement concluded between a public

[66] Ruling of the Supreme Administrative Court of Lithuania of 6 May 2008, Administrative Case No A[261]-339/2008.

administration entity and a public service provider, the said cooperation agreements concluded by two public administration entities should all the more be treated as administrative agreements and thus be subject to the provisions of the Law on public administration. This determines the limits of discretion of the parties, the terms and conditions of the agreements established not only by consent of the parties but also on the basis of legal provisions set out in special legislation. What is more, in the aforementioned case the Court also stated that "<…> *the Regional Health Insurance Fund as a public administration entity performing the public administration function in the area of health insurance must precisely follow statutory requirements and procedures rather than create or through its practices shape procedures not provided for in the law*". So, the cooperation agreements cannot depart from legal requirements regulating public administration relations;

- what the procedure for disputing them is (whether they can at all be disputed in administrative courts);
- what legal consequences they create or can create for third parties, i.e. it is unclear whether third parties can at all rely on them in protecting their rights and whether and to what extent market surveillance authorities proper can rely on them;
- what the procedure for publishing them is and whether they are to be published at all.

It should be noted that the case-law does not offer an established position in respect of the legal meaning of such cooperation agreements either. In one administrative case the Court *inter alia* relied on a cooperation agreement concluded between institutions when adopting a decision in respect of the performance of functions and the limits of competence of one of the officers[67]. Another case is the aforesaid case of the Supreme Administrative Court of Lithuania concerning administrative agreements and related requirements. However, there is no more specific case-law proving the legal value of these agreements.

These agreements may have value *inter alia*:

- when establishing and evaluating the limits of powers of the state (and of a specific public authority), the content of the function performed and the ensuing admissibility of its performance, and they can be decisive when determining the existence of liability of the state for actions conducted by public authorities;
- when establishing and evaluating the content of duties performed by specific civil servants, and they can be decisive when determining the existence or non-existence of their liability for the performance of certain functions;
- for rights and duties of third parties.

An evaluation of the content of some cooperation agreements shows that such agreements may have effect on the rights of third parties. This is confirmed by the following provisions of the cooperation agreements:

- to share experience of examining consumer requests and, where necessary, to organise joint meetings relating to matters of examining consumer requests (the cooperation agreement between the RRT and the VVTAT);
- to exchange information on persons who violate legal requirements when placing on the market radio communications equipment and telecommunications end equipment

[67] Judgment of Vilnius Regional Administrative Court of 11 June 2012, Case No I-1886-426/2012.

suspected of being incompatible with safety and other requirements (the cooperation agreement between the RRT and the CD);
- to cooperate when checking the working and resting time of drivers (the cooperation agreement between the SLI and the VKTI).

The circumstances described above imply that the legal meaning of such cooperation agreements must be clearly defined and properly regulated (if at all deemed that the cooperation function is to be ensured from now on by concluding cooperation agreements).

Standardised practices of drafting cooperation agreements

The above analysis of the publicly available cooperation agreements has revealed that the following problems arise in the area of drafting and implementing cooperation agreements:

- there is no uniform practice of drafting cooperation agreements;
- there is no standardised content of cooperation agreements (in other words, each individual cooperation agreement is as if drafted from scratch);
- there is no uniform practice of publishing cooperation agreements;
- there is no uniform practice of analysing the implementation of cooperation agreements. At the same time, the information available publicly shows that the efficiency of the implementation of such agreements is not at all clear;
- there is no sharing of best practices of implementing cooperation agreements (such practices are non-existent as such).

The non-existence of the above standardised practices of drafting and implementing cooperation agreements raises doubts as to the proper performance of the cooperation function. Even if a factual analysis of the cooperation function performed revealed that it was actually performed properly (albeit differently by different authorities), the non-existence of such standardised practices definitely does not contribute to the transparency and clarity of the activities performed by public authorities, and what is more, this may give rise to questions concerning the criteria based on which the efficiency of the function performed is determined.

It should be noted that the need for standardising cooperation agreements is also identified in the Guidelines for import controls in the area of product safety and compliance drafted by the EC that will be discussed in greater detail in Section 3.2.2.2 of the Study.

It is also important to stress that the standardised practice of drafting cooperation agreements and the matter of the legal meaning are relevant to all authorities supervising economic entities, which is why these issues could be dealt with within the framework of the reorganisation of business surveillance authorities, at the same time handling the matter concerning the need to amend the Law on public administration.

Given the above issues relating to the regulation of the implementation of the cooperation function (and the issues relating to the legal meaning of cooperation agreements and the non-existence of standard practices), the regulatory framework of the cooperation *market surveillance authority v market surveillance authority* and *market surveillance authority v authority responsible for external border control* should be improved.

SUMMARY

- The legal framework in respect of the coordination function of the product safety and market surveillance system is defective, which is why it needs to be improved by clearly defining and mutually aligning the competence of ministries involved in the process and of market surveillance authorities, at the same time establishing a possible model of their cooperation (activity coordination) with a view to ensuring the management of the product safety and market surveillance area.
- Although the performance of certain functions reflecting systematic functions of the market surveillance system is provided for in national legislation, still the existing regulatory framework is insufficient and creates grounds for stating that the systematic market surveillance functions laid down in the Regulation are not fully implemented in national legislation, which is why the existing legal framework should be improved.
- The performance of systematic functions of the market surveillance system is not directly assigned by legislation to a specific public authority although the Ministry of the Economy actually performs certain systematic functions.
- The lack of clarity in EU legislation creates confusion or causes improper implementation of functions in national legislation.

3.2.2. An overview of specific market surveillance functions

Below is an overview of specific market surveillance functions. An aggregate summary of the overview in the form of a table is given in Annex II to the Study.

3.2.2.1. Drafting a sector-specific market surveillance programme and/or participation in drafting the national market surveillance programme

As mentioned above, Article 18(5) of the Regulation and Article 9(1)(a) of the Directive oblige the Member States to draft, implement and periodically update market surveillance programmes. A detailed analysis of this obligation of the Member States is given in Section 3.2.1.2 of the Study.

For the purpose of this Study, this function is attributable both to systematic and to market surveillance functions. In this part of the Study this function is identified as a specific obligation of market surveillance authorities to draw up a sector-specific market surveillance programme or to participate in drafting the national market surveillance programme.

3.2.2.2. Cooperation between market surveillance authorities and authorities in charge of external border control

Article 27(2) of the Regulation lays down the obligation of customs officers and officers of market surveillance authorities to cooperate. Moreover, the principles of cooperation between the Member States and the EC laid down in Article 24 of the Regulation apply, where necessary, also in respect of authorities in charge of external border controls (Article 27(5)).

It should be noted that this function is analysed in detail in Section 3.2.1.5 of the Study. It should also be noted that in order to help customs authorities and market surveillance authorities to

properly implement the Regulation, the Commission drafted the Guidelines. Apart from other matters, the Guidelines also discuss the key principles of cooperation between customs authorities and market surveillance authorities. One of the objectives of the Guidelines is to ensure proper cooperation between customs and market surveillance authorities and/or to improve it so that the entire system of import controls in the area of product safety and compliance applies in a consistent and uniformly rigid manner throughout the EU. The Guidelines state that cooperation between Customs and market surveillance authorities should be based on formal agreements that cover all necessary aspects and elements to ensure that the control process will be carried out in an appropriate manner. The Guidelines also set out that the agreed elements, described in the Guidelines, should be implemented in a uniform manner at national level. The uniform implementation of the requirements laid down in the Guidelines is an important element of common safety and compliance control activities. The Guidelines also set out which elements are to be included in national cooperation agreements:

- contact list of the responsible officers of the authorities;
- setting out the agreed roles and responsibilities on controls to be undertaken;
- the exchange of information and intelligence;
- proper exchange of information concerning the granting of simplified customs procedure authorisation;
- the establishment of regular meetings between officers of the authorities;
- proper account taken by market surveillance authorities of the needs of the customs authorities when establishing their national market surveillance programmes;
- terms for an efficient and effective cooperation;
- appropriate dealing with new and unplanned products and processes;
- planning of future meetings;
- training of responsible officers;
- common training sessions;
- methods, processes, procedures and elements of cooperation;
- early communication between both authorities concerning upcoming legislative proposals with impact on both authorities;
- elaboration of clear rules for seized goods.

It is important to stress that Lithuania has not drafted and adopted any piece of legislation that would evaluate and take into account the aforementioned provisions of the Guidelines. Given the above criticism concerning cooperation agreements, there is a need, first and foremost, to decide whether the model proposed by the EC where interinstitutional cooperation agreements are signed is at all suitable given the specificities of the national system, and second, should it be decided that there is a need and benefit in implementing the cooperation function through cooperation agreements, a standard agreement between customs and market surveillance authorities duly taking account of the recommendations offered in the Guidelines should be drawn up not only to clearly regulate the legal meaning of such an agreement but also to standardise the cooperation function.

Given the issues identified in Section 3.2.1.5 of the Study relating to cooperation agreements and the recommendations given in the Guidelines, the regulatory framework on the cooperation between market surveillance and customs authorities is to be improved.

3.2.2.3. Cooperation with market surveillance authorities of the Member States and market surveillance authorities of third countries

Article 24(1) of the Regulation sets out that the Member States ensure efficient cooperation and exchange of information between their market surveillance authorities and those of the other Member States and between their own authorities and the Commission and the relevant Commission agencies regarding their market surveillance programmes and all issues relating to products presenting risks. Article 24(2) of the Regulation describes in detail the cooperation between market surveillance authorities of the Member States setting out that the market surveillance authorities of one Member State give the market surveillance authorities of other Member States assistance on an adequate scale by supplying information or documentation, by carrying out appropriate investigations or any other appropriate measure and by participating in investigations initiated in other Member States. Article 26(1) of the Regulation stipulates that national market surveillance authorities may cooperate with the competent authorities of third countries with a view to exchanging information and technical support, promoting and facilitating access to European systems and promoting activities relating to conformity assessment, market surveillance and accreditation.

In analysing the cooperation of market surveillance authorities with other market surveillance authorities of the EU Member States, it is also important to refer to Article 25 of the Regulation setting out that market surveillance initiatives designed to share resources and expertise between the competent authorities of the Member States may be set up by the Commission or the Member States concerned. Such initiatives are coordinated by the Commission.

It should be noted that Regulation (EC) No 2006/2004 of the European Parliament and of the Council of 27 October 2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws does not apply in this case as this Regulation only applies to relations regulated by legislation listed in the annex to the Regulation and that annex does not refer to either the Regulation or the Directive.

The diagram below shows the system of cooperation:

Cooperation inside the EU			**Cooperation with third countries**
Level I EU level	EU Member State	EU Member State	
			Third country
Level II National level	EU Member State	EU Member State	
			Third country

It should be noted that cooperation between market surveillance authorities of the EU may take place as if on two levels:

Level I. EU level

- EU efforts. This may be manifested in specific legislation adopted by the EU directly regulating the principles and procedure of mutual cooperation between the EU Member States.
- EU efforts. In this case cooperation is ensured rather from the organisational viewpoint where the EC establishes certain procedural rules, measures and methods as to how the authorities of the Member States could cooperate.

Level II. National level

These are national efforts of each country to ensure proper cooperation with other market surveillance authorities of the EU. In this case cooperation takes place on bilateral basis and is possible by various methods:

- sharing of experience between certain market surveillance authorities;
- coordination of specific actions and organisation of joint performance thereof;
- other forms of cooperation.

Cooperation with market surveillance authorities of third countries may also take place on two levels:

Level I. EU level

This is general EU legislation harmonising certain efforts of the Member States to cooperate with third countries. Article 26(2) of the Regulation sets out that cooperation with the competent authorities of third countries takes the form of, inter alia, the activities referred to in Article 25(2). Article 25(2) of the Regulation, in turn, lays down the coordinating actions organised by the Commission to support and promote cooperation:

- develop and organise training programmes and exchanges of national officials;
- develop, organise and set up programmes for the exchange of experience, information and best practice, programmes and actions for common projects, information campaigns, joint visit programmes and the consequent sharing of resources.

Level II. Cooperation on the national level

Cooperation takes place on the grounds of international agreements as well as interinstitutional cooperation agreements.

No doubt, both cooperation between market surveillance authorities of the EU Member States and cooperation of market surveillance authorities with third countries depends also on the Commission's initiatives. In the aforementioned EC report on the implementation of the Regulation, the Commission refers to working parties consisting of experts from the Member States. So the Member States first are obliged to ensure the participation of these experts in various working parties depending on their competence.

Some laws regulating the activity of market surveillance authorities oblige a specific market surveillance authority to cooperate with respective authorities in the other Member States.

Article 9(3)(3) of the Law on metrology sets out that the State Metrology Service exchanges information with the competent authorities of the other EU Member States on matters of calibration of metrological equipment and activities of notified bodies.

The Law on pharmaceuticals obliges the SMCA to cooperate and exchange information with the EU institutions, authorised institutions of the other EEA Member States and the World Health Organisation (Article 69(1)). To that end, the SMCA must inter alia notify the other Member States of all information necessary to ensure the quality and safety of homeopathic preparations produced and placed on the Community market (Article 69(2)(8)).

Article 13(2) of the Law on customs lays down an obligation to cooperate not only with other EU institutions but also with responsible authorities of third countries.

Below is some information on the obligation set in the Regulations of market surveillance authorities to cooperate both with market surveillance authorities of the other EU Member States and market surveillance authorities of third countries.

Paragraphs 10.4.5 and 12.4 of the EPA Regulations	within its remit cooperate with international organisations, institutions and bodies of other countries and other natural and legal persons; cooperate with the European Commission, the European Union Member States and national competent or responsible authorities of non-EU countries
Paragraphs 10.1.10 and 11.5 of the LMSA Regulations	within its remit cooperate with foreign institutions and international organisations; within its remit cooperate with institutions and bodies of other countries and international organisations
Paragraph 10.20 of the CD Regulations	within its remit cooperate with authorities of other countries, the EU institutions and international organisations
Paragraph 10.1.2 of the LMI Regulations	cooperate with the authorities of the EU Member States and international organisations and participate in the work of international legal metrology organisations
Paragraph 8.23 of the RRT Regulations	cooperate with the EU institutions, the Member States and their authorities in accordance with EU legislation and mutual agreements as well as foreign authorities regulating electronic communications activities and post activities, within its remit participate in the activities of international organisations and the EU

	institutions, committees and groups the activity of which relates to electronic communications (telecommunications), radio communications and end equipment, electromagnetic compatibility and/or radio wave range management
Paragraph 10.41 of the VASPVT Regulations	within its remit cooperate with all authorities controlling healthcare establishments, international organisations and competent authorities of other countries
Paragraphs 8.1.21 and 8.3.9 of the SLI Regulations	where necessary, cooperate and exchange information with the competent authorities of the other Member States on the observance of working conditions and guarantees of posted workers; cooperate and exchange information with state and municipal authorities and bodies, trade unions, works councils, employer organisations and respective services of other countries
Paragraph 8.29 of the VKTI Regulations	keep in touch with international organisations and respective control authorities of other countries representing the Republic of Lithuania within its remit or as assigned by the Government of the Republic of Lithuania or the Minister for Transport and Communications
Paragraphs 9.2, 10.2.4 and 11.7 of the VVTAT Regulations	cooperate with foreign authorities and international organisations in the area of consumer protection; together with other public authorities and bodies organise exchange of information (and exchange information) with the national authorities of the European Union Member States; cooperate with consumer protection authorities and organisations of other countries implementing consumer protection
Paragraph 10.7 of the VNMPI Regulations	within its remit keep in touch and develop relations, exchange experience and good practices, implement joint projects in the area

	of market surveillance of non-food products with international organisations, market surveillance authorities of the EU Member States and conformity assessment bodies

So, taking into account statutory obligations of market surveillance authorities as well as their Regulations, one may draw a conclusion that the existing legal framework in Lithuania could be improved with a view to, first, clearly establishing in legislation the functions of market surveillance authorities in the area of cooperation.

3.2.2.4. Cooperation with producers and distributors

Article 5(4) of the Directive sets out that producers and distributors shall, within the limits of their respective activities, cooperate with the competent authorities, at the request of the latter, on action taken to avoid the risks posed by products which they supply or have supplied. The Directive also stipulates that procedures for such cooperation, including procedures for dialogue with the producers and distributors concerned on issues related to product safety, shall be established by the competent authorities.

Article 8(6) of the Product Safety Law sets out the producer's obligation to cooperate with control authorities to avoid risks presented by products placed or available on the market. Article 9(4) of the Product Safety Law lays down the distributor's obligation to cooperate with control authorities and producers to avoid risks to consumers presented by products supplied. Article 14(3) of the Product Safety Law stipulates the right of control authorities to receive information and documents from product producers and distributors necessary for investigating violations of the Product Safety Law and other laws.

The Regulations of individual market surveillance authorities do not provide for a specific obligation of these authorities to cooperate with producers and distributors. It should be noted that the above provisions of the Product Safety Law imply that the obligation to cooperate is set for producers and distributors rather than market surveillance authorities, i.e. market surveillance authorities are not obliged to take action to cooperate. The above and initiatives to improve activities of business surveillance entities lead to a conclusion that this is how the Directive provisions are in fact implemented but the regulatory framework could be improved.

3.2.2.5. Imposition of market restriction measures

Article 16(2) of the Regulation lays down the obligation to impose market restriction measures, i.e. it sets out that market surveillance shall ensure that products covered by Community harmonisation legislation which, when used in accordance with their intended purpose or under conditions which can be reasonably foreseen and when properly installed and maintained, are liable to compromise the health or safety of users, or which otherwise do not conform to applicable requirements set out in Community harmonisation legislation are withdrawn or their being made available on the market is prohibited or restricted and that the public, the Commission and the other Member States are informed accordingly. Article 20(1) of the Regulation obliges the Member States to ensure that market restriction measures apply to products which present a serious risk. Article 21 of the Regulation dedicated to restrictive

measures sets out that these measures are proportionate and that the exact grounds on which they are based are stated and defines the procedure for imposing restrictive measures. Article 29(2) of the Regulation sets out an obligation that where the Member States find that a product does not comply with Community harmonisation legislation, they shall take appropriate action, which may, if necessary, include prohibiting the product's being placed on the market. Article 18(2)(c) of the Regulation stipulates that the Member States establish adequate procedures in order to verify inter alia that corrective action has been taken.

Market restriction measures set in the Regulation	Market restriction measures set in the Directive
• to prohibit the product's being made available on the market • to restrict the product's being made available on the market • to withdraw the product from the market • to recall the product from the market	• to organise checks • to require all necessary information • to take samples of products and subject them to safety checks • to require that products are marked suitably • to make the product's marketing subject to prior conditions so as to make it safe • to order that persons concerned be given warning of the risk presented by the product in good time and in an appropriate form • temporarily to ban the product's supply, the offer to supply it or its display • to ban the product's marketing • to withdraw the product from the market • to recall the product from consumers and destruct it in suitable conditions

An examination of restrictive measures set in the Regulation and the Directive shows that the Directive contains a broader list of market restriction measures than the Regulation. However it must be noted that the Regulation regulates almost all restrictive measures set in the Directive, except for the setting of prior conditions to the marketing of products. Still, the Regulation attributes some of the market restriction measures listed in the Directive not to restrictive measures but rather regulates them separately as individual functions of market surveillance authorities. So, this leads to a conclusion that the Regulation and the Directive in fact set the following market restriction measures:

- to prohibit the product's being made available on the market;
- to restrict the product's being made available on the market;
- to withdraw the product from the market;
- to recall the product.

Accordingly, the table below shows restrictive measures laid down in the laws regulating activities of the Lithuanian market surveillance authorities.

Article 17(1) of the Product Safety Law	Article 22(2) of the Law on metrology	Article 8(2)(7) of the Law on the State Labour Inspectorate	Article 67 of the Law on pharmaceuticals
• to prohibit the product's being made available on the market; • to restrict the product's being made available on the market; • to withdraw the product from the market; • to recall the product; • to require that products are marked suitably; • to order that persons concerned be given warning of the risk presented by the product in good time and in an appropriate form	• to give a written warning and set a deadline for eliminating the violation; • to prohibit the use and the making available on the market of metrological equipment, pre-packaged merchandise or metrological vessels where the violation is not eliminated in due time	• to prohibit the use of working and personal protective equipment where they fail to meet occupational safety and health regulations	• to prohibit the medicinal product's being made available on the market • to recall the medicinal product from the market • to suspend the production or import of medicinal products Articles 34(2)(5) and 40(2)(4) oblige managers of pharmaceutical activities and managers of pharmaceutical activities of pharmacies to ensure that a system for recalling medicinal preparations from the market is set up and functions properly

An overview of the restrictive measures stipulated in the Lithuanian laws leads to a conclusion that the Product Safety Law and individual laws compile different lists of market restriction measures. The list of restrictive measures compiled in the Product Safety Law matches the one in the Regulation and the Directive. On the other hand, special laws compile a narrower list of applicable restrictive measures. It should also be noted that these special laws do not contain a reference to the Product Safety Law, which leads to a conclusion that they do not ensure a sufficient implementation of the Regulation as far as restrictive measures are concerned.

The Rules for the application of restrictions on marketing of products elaborate on the procedure for the imposition of restrictive measures listed in Article 17 of the Product Safety Law. As discussed in Chapter 2.3 of the Study, these Rules expand the range of institutions authorised to impose restrictive measures under the Product Safety law (presuming that the Product Safety Law only covers three authorities): "*market restriction measures shall be imposed by the*

National Consumer Protection Council under the Ministry of Justice ('the Council'), the State Food and Veterinary Service (with a view to restricting the placing on the market of foodstuffs dangerous to consumer health), the State Non-Food Products Inspectorate under the Ministry of the Economy (with a view to restricting the placing on the market of non-food products dangerous to consumer health and safety), public health centres in counties (with a view to restricting the placing on the market of services dangerous to consumer health and safety within their remit) as well as other product safety control institutions established by the Government of the Republic of Lithuania within their remit ('control authorities')" (paragraph 3). However as the Product Safety Law directly authorises only the VVTAT and control authorities (control authorities established by the Government in the area of food and non-food product safety) to impose restrictive measures (Article 17(1)), the expansion of the range of the authorities by by-laws (a resolution of the Government) is impossible. This raises a question which market surveillance authorities and on what legal grounds are authorised to apply market restriction measures.

It should also be noted that some provisions in the Rules for the application of restrictions on marketing of products should be regulated by a higher-level piece of legislation (a law) rather than a Government resolution: distribution of competences of the Council and other control authorities in respect of the application of market restriction measures; cases of setting prior conditions to the marketing of products; a temporary ban on the supply, offers to supply and demonstrations of products where the said provisions of the Rules relate to restrictions of third parties' rights. Given the above, one needs to conduct a general examination of the need for regulating the imposition of restrictive measures by by-laws (except for provisions relating to the supply of information on restrictive measures imposed).

Some market surveillance authorities in their Regulations authorise market surveillance authorities to impose restrictive measures:

Paragraph 10.3.2 of the LMI Regulations	in statutory cases notify the EC and the authorised institutions of the other EU Member States of measures imposed seeking to prohibit the use or the placing on the market of metrological equipment, pre-packaged merchandise or metrological vessels and the reasons for adopting the decision; prohibit the use or the placing on the market of metrological equipment, pre-packaged merchandise or metrological vessels where the violation is not eliminated in due time
Paragraphs 10.31.3 and 11.8 of the VASPVT Regulations	take all necessary measures to restrict, prohibit or withdraw unsafe medical devices from the Lithuanian market; [authorised] by a reasoned decision to suspend or prohibit the placing on the market of medical devices, to suspend or prohibit the distribution and use of medical devices and to

	order to withdraw unsafe medical devices from the Lithuanian market
Paragraph 26 of the SLI Regulations	The SLI inspector shall immediately suspend works where inter alia working and personal protective equipment does not meet occupational safety and health and other regulatory legal requirements and in other cases
Paragraphs 10.15, 11.9, 11.27, 11.28 and 11.29 of the SMCA Regulations	in the cases stipulated in the Law on pharmaceuticals, prohibit the placing on the market of medicinal preparations and/or recall them from the market; by a reasoned decision prohibit the placing on the market of series of medicinal preparations raising doubts under circumstances defined in Article 67(1) of the Law on pharmaceuticals and impose the full or partial recall of the medicinal preparation; The SMCA shall be authorised: • to prohibit the use of precursors, interim products and unpacked products and/or the placing on the market of medicinal preparations by sealing them; • to prohibit the production and/or control by sealing production and/or control equipment; • to prohibit the distribution of medicinal preparations by sealing equipment, installations or premises
Paragraph 10.1.9 of the VVTAT Regulations	apply statutory enforcement measures
Paragraphs 9.2, 9.3 and 9.9 of the VNMPI Regulations	in statutory cases impose administrative penalties and restrictive measures; supervise the withdrawal of dangerous non-food products from the market; in accordance with the procedure laid down by the Government, publish dangerous non-food products banned by the VNMPI from placing on the market that are produced in Lithuania or introduced from the EU Member States or other countries on the VNMPI's website

Given such legal regulation, it should be noted that the majority of laws regulating activities of market surveillance authorities and analysed in this Study do not envisage possibilities for applying market restriction measures and do not contain a reference to the Product Safety Law while the aforementioned special laws (the Law on metrology, the Law on the State Labour Inspectorate and the Law on pharmaceuticals), as mentioned above, only present a limited list of market restriction measures and do not refer to the Product Safety Law either, which leads to a conclusion that laws regulating activities of market surveillance authorities fail to fully implement the Regulation, and in order to improve the legal framework, laws need to clearly authorise market surveillance authorities to impose restrictive measures and present a specific list of market restriction measures which the authorities are authorised to impose.

3.2.2.6. Examination of complaints concerning products

The Regulation obliges the Member States to follow up complaints or reports on issues relating to risks arising in connection with products subject to Union harmonisation legislation (Article 18(2)(a)). Article 9(2) of the Directive stipulates that Member States shall ensure that consumers and other interested parties are given an opportunity to submit complaints to the competent authorities on product safety and on surveillance and control activities and that these complaints are followed up as appropriate. The Directive also sets out that Member States shall actively inform consumers and other interested parties of the procedures established to that end.

It should be noted that this function of the examination of complaints concerning products is understood specifically as the submission of complaints to a market surveillance authority, following which market surveillance authorities exercising their powers take appropriate action to examine the complaint. In other words, this function is not understood as a preliminary extrajudicial examination of disputes and cannot be identified with it.

Article 14(1) of the Law on public administration sets out that public administration entities examine requests of persons in accordance with the procedure approved by the Government. The said provision of the Law is implemented by the Government Resolution approving the Rules for the examination of requests of persons and their service in public administration authorities, bodies and other public administration entities[68]. This Resolution of the Government regulates in detail the procedure for examining requests of persons. Paragraph 3 of the Resolution sets out that the procedure of these Rules also applies to the examination of complaints filed by persons: "<…> *In accordance with the provisions of Chapter IV "Examination of requests of persons and admission of persons in accordance with the one-stop-shop principle" of the Rules, complaints and reports shall also be accepted from persons in respect of their rights or legitimate interests violated and procedural administrative decisions shall be issued*".

The Product Safety Law stipulates that market surveillance authorities must enable consumers and interested parties to file complaints concerning the safety and surveillance of products and controls and ensure the proper follow-up of those complaints. They must inform consumers and interested parties about the procedure for filing complaints (Article 17(5)). The Law on pharmaceuticals obliges the manager of pharmaceutical activities (Article 34(2)(4)) and the manager of pharmaceutical activities of a pharmacy (Article 40(2)(3)) to ensure the follow-up of consumers' complaints or reports on the quality of a medicinal preparation and/or services. So,

[68] Resolution No 875 of the Government of the Republic of Lithuania of 22 August 2007 approving the Rules for the examination of requests of persons and their service in public administration authorities, bodies and other public administration entities (*Official Gazette*, 2007, No 94-3779).

these laws specifically provide for the examination of complaints relating to product safety. On the other hand, other laws regulating activities of market surveillance authorities only lay down general provisions on the obligation to examine complaints of applicants or to set rules for the examination of such complaints but do not specify that they refer to the examination of complaints concerning product safety:

- the Law on the State Labour Inspectorate lays down the SLI's obligation to examine applications and complaints within the competence of the SLI and to ensure the confidentiality of applicants (Article 6(15));
- Article 94 of the Law on customs sets out that Director General of the CD sets up a procedure for submitting complaints to the CD and examining them in the Department.

Below is some information about obligations to examine complaints laid down in the Regulations of market surveillance authorities. It should be noted that although the majority of these authorities provide for the obligation to examine complaints, it is only the VNMPI Regulations that specify that the authority is competent to examine specifically complaints relating to product safety while the Regulations of the other authorities do not make this precision.

Paragraph 9.11 of the VNMPI Regulations	examine consumer requests concerning the safety, quality and labelling of non-food products and the observance of statutory requirements on the provision of information
Paragraph 11.11 of the EPA Regulations	within its remit in accordance with the established procedure examine complaints, reports and requests of legal and natural persons
Paragraph 17.13 of the LMSA Regulations	in accordance with the statutory procedure organise the examination of reports (complaints) filed by employees and the population and control their implementation
Paragraph 10.10 of the CD Regulations	examine requests and complaints of persons concerning decisions of customs authorities or their failure to adopt decisions and actions of customs officers and take action to eliminate drawbacks and violations established or penalising the guilty officers
Paragraph 10.11 of the RSC Regulations	in accordance with the statutory procedure examine requests, complaints and reports of persons and within its remit take action to solve issues raised thereby
Paragraph 10.47 of the VASPVT Regulations	within its remit examine requests, reports and complaints of legal and natural persons

Paragraphs 8.3.1 and 32.11 of the SLI Regulations	examine applications and complaints on matters within the SLI's competence and ensure the confidentiality of applicants; examine requests and complaints of the population and persons on the legality of the SLI's actions and decisions adopted
Paragraph 8.28 of the VKTI Regulations	in accordance with the established procedure examine applications, complaints and suggestions of the population and economic entities and within its remit take necessary steps to solve issues raised
Paragraph 10.65 of the SMCA Regulations	examine reports and complaints on the quality of medicinal preparations and pharmaceutical activity

It should be noted that almost all market surveillance authorities have adopted internal procedures for the examination of personal complaints and requests. The table below presents information on the procedures for the examination of complaints approved by market surveillance authorities.

Authority	Legislation
VNMPI	Rules for the examination of requests and service of persons by the State Non-Food Products Inspectorate under the Ministry of the Economy approved by Order No 1R-105 of the Head of the VNMPI of 12 August 2008
EPA	Order No AV-263 of the Director of the EPA of 30 December 2010 approving the Procedure for the examination of personal complaints and reports by the Environment Protection Agency
LMI	Rules for the examination of personal requests and service of persons by the Lithuanian Metrology Inspectorate approved by Order No 11V-36 of the Head of the LMI of 25 June 2008
LMSA	Order No V-46 of the Director of the LMSA of 31 January 2008 on the examination of personal complaints and service of persons by the Lithuanian Maritime Safety Authority
RRT	There is no special procedure, and personal complaints and requests are examined in accordance with the above Resolution No 875 of the Government of the Republic of Lithuania of 22 August 2007 approving the Rules for the examination of requests of persons and their service in public administration authorities, bodies and other public administration entities
VASPVT	Order No T1-137 of the Director of the VASPVT under the Ministry of Health of 6 February 2013 approving the procedure for the examination of patients' complaints by the State Healthcare Accreditation Agency under the Ministry of Health
SLI	Order No V-168 of the Chief State Labour Inspector of the Republic of Lithuania of 29 July 2011 approving the recast of the Rules for the

	examination of personal requests and service of persons by the State Labour Inspectorate of the Republic of Lithuania
SMCA	Order No 1A-1303 of the Head of the SMCA of 25 November 2008 approving the Rules for the service of persons and examination of their requests and complaints by the State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania
VKTI	Order No 2B-217 of the Head of the VKTI of 4 June 2009 approving the Rules for the examination of personal requests and service of persons by the State Road Transport Inspectorate under the Ministry of Transport and Communications
VVTAT	Order No 1-141 of the Director of the VVTAT of 1 October 2009 approving the procedure for the examination of personal requests and service of persons by the State Consumer Rights Protection Service
CD	Order No 1B-540 of the Director General of the CD of 19 May 2004 approving the Regulations for the examination of complaints by the Customs of the Republic of Lithuania

The legal framework leads to a conclusion that market surveillance authorities have procedures for the examination of complaints, so this function is implemented properly. Still, to evaluate whether no special rules are indeed needed in respect of the examination of complaints and/or requests relating to product safety, there is a need for an analysis of the actual institutional activities relating to the examination of complaints. The results of that analysis should serve as grounds to decide whether the related legislation needs to be improved.

3.2.2.7. Monitoring of accidents and harm to health caused by products

Article 18(2)(b) of the Regulation obliges the Member States to establish adequate procedure inter alia to monitor accidents and harm to health which are suspected to have been caused by products. However the Regulation does not offer broader regulation of the content of the monitoring function proper.

Given such legal framework in the EU, the model for the monitoring of accidents and harm to health caused by products should be set up on the national level. It should be noted that the performance of this function undoubtedly can affect the rights and legitimate interests of third parties. The proper performance of this function could possibly create certain additional burden on business entities which would be obliged to collect statistics on accidents and harm to health, notify a market surveillance authority responsible for the proper implementation of this function, etc. Therefore, it is very important that legislation clearly defines the content of this function and its monitoring methods and measures.

The Communication from the Commission of 13 February 2013 states that "*data related to accidents and injuries caused by unsafe products should feed into the market surveillance efforts. Although Regulation 765/2008 (Article 18) obliges Member States to monitor accidents, little has happened in practice, considering the many practical difficulties to establish a reporting system that could be helpful for all authorities and economic operators*"[69].

[69] Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee of 13 February 2013 "20 actions for safer and compliant products for Europe: a multi-annual action plan for the surveillance of products in the EU", p. 4.

The Commission Staff Working Document of 13 February 2013[70] says that a more efficient market surveillance system needs monitoring and collecting of information relating to accidents and harm to health caused by unsafe products. The EC recognises that this is easiest to implement by setting up a database of accidents and harm to health. The so-called European Injury Database was set up to that end but it only is used by 13 Member States and it is too difficult to gain access to this database and find detailed information in it. The EC admits that Europe needs to develop and improve a standard system necessary for ensuring the safety of products. It is very important to collect reliable, consistent and permanent data on accidents and harm to health caused by products in order to protect consumers. This information would provide useful statistical knowledge both to consumers and to market surveillance authorities and would be instrumental in developing the legal framework aiming at minimising the scale of harm to health and the number of accidents[71].

The Product Safety Law does not oblige market surveillance authorities to monitor accidents and harm to health caused by products.

It should be noted that by Resolution No 790 of 22 July 2009 the Government of the Republic of Lithuania approved the Rules for exchange of information on dangerous products and related accidents[72]. In accordance with those Rules, information on dangerous products and related injuries is to be notified to the VVTAT by the Fire and Rescue Department, the VNMPI and public health centres in counties. However, in accordance with the activity report of the VVTAT for 2013, these Rules are not effective as the said authorities do not provide such information to the VVTAT and the key authorities usually holding such information (healthcare institutions) are not obliged to submit it to the VVTAT. It should be noted that at the proposal of the Ministry of Health the VVTAT filed its suggestion to the Institute of Hygiene to include additional provisions for collecting information on dangerous products and relating accidents in implementing the project "Setting up of the monitoring system for injuries and accidents". The monitoring is to start as of 1 November 2014.

The said Resolution of the Government obliges the VVTAT to enter the information received about accidents caused by a product and information received by competent authorities on dangerous products and related accidents in the Database of domestic or leisure accidents within 20 working days. The Database of domestic or leisure accidents contains information on products failing to meet general product safety requirements and having caused accidents, which is public. The VVTAT on its website announces that public information will allow for a better consumer protection and for the prevention of possible accidents. Moreover, such information on products and services having caused harm to consumers may also be useful to producers and service providers to ensure a still better product safety. This information is also important when setting up injury prevention programmes and for market surveillance.

Article 6 of the Law on the State Labour Inspectorate tasks the SLI with functions including the obligation to register serious or fatal accidents at work, to collect information on minor accidents

[70] 2013 02 13 Commission Staff Working Document on Impact Assessment. Product Safety and Market Surveillance Package. A proposal for a Regulation of the European Parliament and of the Council on consumer product safety and a proposal for a Regulation of the European Parliament and of the Council on market surveillance of products, p. 33 and 34.
[71] 2013 02 13 Commission Staff Working Document on Impact Assessment. Product Safety and Market Surveillance Package. A proposal for a Regulation of the European Parliament and of the Council on consumer product safety and a proposal for a Regulation of the European Parliament and of the Council on market surveillance of products, p. 53.
[72] Resolution No 790 of the Government of the Republic of Lithuania of 22 July 2009 approving the Rules for exchange of information on dangerous products and related accidents (*Official Gazette*, 2009, No 90-3860).

at work received from employers and in accordance with the established procedure to store reports on investigations of causes of accidents at work and occupational diseases (Article 6(11)) and the obligation to analyse the circumstances and causes of accidents at work, occupational diseases and emergencies as well as violations of occupational safety and health requirements and to draft proposals with a view to improving occupational safety and health situation in the country (Article 6(14)). In this case the obligation set is a general obligation relating to any accidents irrespective of what has caused them but it is obvious that such a general obligation also covers the obligation to monitor accidents and harm to health caused specifically by products.

The Regulations of market surveillance authorities do not provide for such an obligation of market surveillance authorities.

The above analysis of the legal framework leads to a conclusion that certain efforts to establish obligations relating to the performance of this function are in place but the legal framework in Lithuania still needs to be improved in order to ensure the proper and efficient implementation of the function.

3.2.2.8. Collection of scientific and technical knowledge concerning safety issues

Article 18(2)(d) of the Regulation obliges the Member States to establish adequate procedures inter alia in order to follow up scientific and technical knowledge concerning safety issues. Article 9(1)(b) of the Directive sets out that in order to ensure effective market surveillance, aimed at guaranteeing a high level of consumer health and safety protection, which entails cooperation between their competent authorities, Member States ensure that approaches employing appropriate means and procedures are put in place, which may inter alia include in particular follow-up and updating of scientific and technical knowledge concerning the safety of products.

It should be noted that the purpose of this function stipulated in the Regulation and the Directive should be construed not only as accumulation of scientific and technical knowledge for the sake of it but, in particular, as an effort to modify and update methods applicable to ensure product safety based on the information collected. Accumulation of scientific and technical knowledge allows for an analysis of information relevant to product safety and using it for improving surveillance activities, thus ensuring public safety. The function can be implemented properly by:

- setting up a procedure for accumulating scientific and technical knowledge;
- interinstitutional cooperation.

This leads to believe that there is a need to approve a general Procedure for the accumulation of scientific and technical knowledge (obliging by law a certain institution to approve such a procedure). It should set out which specific information the market surveillance authority needs to accumulate, what methods it needs to employ to structure and store the information and who is responsible for the accumulation of such information. Active cooperation between market surveillance authorities would be useful, in particular, in terms of information sharing and in respect of the procedure for the accumulation of information. Some authorities could have a joint system for collecting scientific and technical knowledge and/or coordinate the collection of such information among themselves.

It should be noted that the implementation of this function is closely related to the provision of additional funds to market surveillance authorities. As mentioned previously, Article 18(3) of the Regulation obliges the Member States to entrust market surveillance authorities with the powers, resources and knowledge necessary for the proper performance of their tasks. The matter of providing additional funds is particularly relevant where a market surveillance authority needs to commission a study relating to the improvement of the market surveillance system. It is specifically because of the possible need for additional funds that this function needs focus on the legislative level.

Article 13(2) of the Product Safety Law sets out that indirect product safety control includes the collection, accumulation, processing and analysis of statistics on the production, import and marketing of dangerous products as well as information on any factors that may be decisive for the augmentation or reduction of consumer risks.

Other laws regulating activities of market surveillance authorities do not provide for an obligation of market surveillance authorities to collect scientific and technical knowledge concerning the safety of products and the follow up and update it. These laws do not refer to the Product Safety Law either, which leads to a conclusion that in respect of non-consumer (professional) products the obligation to collect scientific and technical knowledge set out in the Regulation is not properly implemented. It is doubtful whether this function is properly implemented in respect of consumer products too as the Product Safety Law elaborates more on the collection of statistics rather than scientific and technical knowledge, and there is no approved procedure for the accumulation and use of such knowledge.

The Regulations of some market surveillance authorities lay down obligations of market surveillance authorities relating to the collection and structuring of certain scientific information on products within their remit:

Paragraph 10.3.8 of the RSC Regulations	initiate and coordinate research and tests relating to radiation protection necessary to improve radiation protection
Paragraph 10.52 of the SMCA Regulations	register and collect data on undesirable phenomena identified in the course of clinical tests of medicinal preparations in a database and analyse these data
Paragraph 9.19 of the VNMPI Regulations	submit proposals to research institutions and research tasks relating to safety and quality issues of non-food products

It should be noted that the procedure for the function set for the SMCA to register and collect data is laid down in the Procedure for the notification of undesirable phenomena and undesirable response to medicinal preparations tested established in the course of clinical tests of medicinal

preparations approved by Head of the SMCA [73] that elaborates on the procedure for the registration and accumulation of data on undesirable events and lays down the procedure for notifying these events to the VVTAT.

Still, having in mind that on the legislative level this obligation is not established for market surveillance authorities and only a few have it in their Regulations, this leads to a conclusion that this function is not fully implemented in Lithuania, and in order to ensure its proper implementation, it should first be established on the legislative level and elaborated upon in by-laws in terms of its implementation procedure.

3.2.2.9. Checks of products

Article 19(1) of the Regulation as one of market surveillance measures refers to the obligation of market surveillance authorities to perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples. In order for this function of market surveillance authorities to be implemented properly, the Regulation sets out the rights of market surveillance authorities, i.e. the right to require that economic operators make such documentation and information available as appear to them to be necessary for the purpose of carrying out their activities; the right, where it is necessary and justified, to enter the premises of economic operators and take the necessary samples of products.

It should be noted that this obligation to check products is undoubtedly linked with third parties who may be affected by its performance, and, in particular, it affects the rights and duties of such third parties relating to the performance of such product checks. So that this function is properly implemented in national law, there is a need for:

- defining the powers of authorities relating to checks of products on the legislative level;
- establishing a clear procedure both for product sampling and checking. The key principles of this procedure may be stipulated in the law proper while procedural matters could be regulated in a separate procedure adopted by a market surveillance authority. It should be noted that the Constitutional Court has also held that "*certain economic relations may only be regulated by laws while others – by Governmental resolutions, and others still – by lower-level by-laws. In accordance with the Constitution, <...> the key conditions, prohibitions and restrictions of economic activity having major effects on economic activity <...> may only be stipulated by law. So it is only by law that is possible to set also economic measures that may have major effects on economic activity and that must apply where obligations are not fulfilled or are fulfilled unduly*"[74];
- clearly defining in the procedure adopted the rights and duties of third parties.

Article 14(1)(1) of the Product Safety Law authorised control institutions (the VVTAT and the VNMPI) to organise necessary checks of product safety characteristics even after the product is already placed on the market and deemed safe while Article 14(1)(4) of the Product Safety Law authorises control institutions (the VVTAT and the VNMPI) to sample products and check their safety. What is more, Article 14(1)(3) of the Product Safety Law provides for the right of market

[73] Order No 1A-633 of the Head of the SMCA of 30 October 2006 approving the Procedure for the notification of undesirable phenomena and undesirable response to medicinal preparations tested established in the course of clinical tests of medicinal preparations (*Official Gazette*, 2006, No 120-4579).
[74] Ruling of the Constitutional Court of the Republic of Lithuania of 31 May 2006.

surveillance authorities to receive from producers, distributors and service providers any information and documentation necessary to investigate violations of this and other laws.

Article 21(2) of the Law on metrology sets out that metrological surveillance inter alia covers the surveillance of metrological equipment, pre-packaged merchandise and metrological vessels. Article 2(27) of the Law on metrology defines market surveillance as control of the compliance with legal metrological requirements to metrological equipment, pre-packaged merchandise and metrological vessels placed on the market or kept before their placing on the market and attributable to legal metrology. Such control shall cover actions preventing the placing on the market of incompliant metrological equipment, pre-packaged merchandise and metrological vessels. Article 19 of the Law on metrology regulates metrological checks of metrological equipment setting out the need for initial, periodic, extraordinary and random checks of products. Paragraph 1 of that Article stipulates that initial checks are conducted on all newly produced or repaired used metrological equipment. Article 22(1)(2) of the Law on metrology sets out that the LMI officers conducting legal metrological surveillance are authorised to take metrological equipment, pre-packaged merchandise or metrological vessels for checking in accordance with the procedure laid down by the Government in order to establish their compliance.

The Law on electronic communications authorises the RRT to evaluate whether equipment and installations, radio communications and end equipment meet binding requirements and/or standards and to conduct measurements and other actions to evaluate whether the technical parameters of equipment and installations, radio communications and end equipment are in line with binding requirements (Articles 10(1)(1) and 10(1)(2)).

Article 6(3) of the Law on the State Labour Inspectorate sets out that within its area of competence the SLI checks whether working tools used are in line with statutory and other regulatory requirements and controls the observance of the procedure and deadlines for checking the technical condition of potentially dangerous installations.

The Road Transport Code authorises the VKTI officers to pull over heavy and passenger road transport and check their measurements, appearance, technical condition, regularity of completing the mandatory roadworthiness tests, documents of the crew and documents necessary for the transport of passengers, baggage and cargoes (Articles 14(2) and 14(4)).

In accordance with Article 14(1)(4) of the Product Safety Law and Article 22(1)(2) of the Law on metrology, by Resolution No 1103 of 13 September 2001 the Government of the Republic of Lithuania approved the Procedure for taking and paying for product samples[75]. This Procedure regulates the taking of and payment for product samples but does not lay down a procedure for checking the product.

Article 36^4 of the Law on public administration regulates checks of activities of economic entities. Articles $36^4(2)(1)$ and $36^4(2)(2)$ of that Law set out that the manager of the surveillance entity, a person authorised thereby or a collegial body of the surveillance entity inter alia approve the procedure for conducting routine checks and the rules setting their duration as well as the procedure for conducting non-routine checks and the rules setting their duration.

[75] Resolution No 1103 of the Government of the Republic of Lithuania of 13 September 2001 approving the Procedure for taking and paying for product samples (*Official Gazette*, 2006, No 136-5175).

Some market surveillance authorities lay down their obligation to check products in their Regulations:

Paragraphs 10.4.6 and 11.4 of the LMI Regulations	supervise whether checks of metrological equipment are conducted by designated or notified bodies; in accordance with the procedure laid down by the Government, take for checking metrological equipment, pre-packaged merchandise or metrological vessels to establish their metrological compliance
Paragraph 10.31.1 of the VASPVT Regulations	check medical devices in places of their production, distribution and use
Paragraph 10.2 of the VNMPI Regulations	receive from state and municipal authorities and bodies, producers, importers, distributors (sellers) and service providers and other legal and natural persons information and documentation necessary for investigating violations of statutory requirements on the safety, quality and labelling of non-food products, to access technical documentation used by producers, importers, distributors (sellers) and service providers being checked, applicable standards and other documents and to take photographs where this is necessary for the performance of the functions

As mentioned above, the Law on public administration obliges economic entities to have rules for routine and non-routine checks. On the other hand, special laws regulating activities of market surveillance authorities only in certain cases (the Law on radiation protection, the Law on potentially dangerous installations) lay down a specific or conditional obligation for authorities to adopt special product checking rules. In some cases the ground for adopting such rules is the Law on public administration (the rules of the VNMPI) or the ground is not at all specified (the rules of the LMI). It should be noted that, for example, the rules adopted by the CD cite as the grounds the Law on customs but they do not elaborate on the specific provision obliging the authority to draw up such internal rules. The table below presents information on the internal procedures drawn up by market surveillance authorities.

Authority	Grounds	Legislation
VNMPI	Article 36^4 of the Law on public administration	Order No 1R-115 of the Head of the State Non-Food Products Inspectorate of 29 October 2010 approving the Procedure for conducting checks
LMI	Not specified	Order No 11V-54 of the Head of the Lithuanian Metrology Inspectorate of 30 December 2010

		approving the Procedure for conducting legal metrological surveillance Order No 11V-61 of the Director of the State Metrology Service of 17 June 2009 approving the Procedure for provisional registration of checks of metrological equipment based on calibration results
RSC	Article 11(2) of the Law on radiation protection	Order No 146 of the Minister for Health of the Republic of Lithuania of 31 March 1999 approving the Procedure for the control of compliance with radiation protection requirements Order No 74V of the Director of the Radiation Protection Centre of 28 October 2011 approving the Procedure for establishing compliance with radiation protection requirements at the radiation protection centre
SLI	Article 5(1)(5) of the Law on potentially dangerous installations	Order No A1-289 of the Minister for Social Security and Labour of the Republic of Lithuania of 27 December 2004 approving the Procedure for checking technical documentation of new and used imported potentially dangerous installations and the recognition of these installations as fit for use in the Republic of Lithuania
CD	Law on customs Not specified	Order No 1B-407 of the Director General of the Customs Department under the Ministry of Finance of the Republic of Lithuania of 11 June 2008 approving the Rules for conducting customs checks Order No 1-869 of the Director General of the Customs Department under the Ministry of Finance of the Republic of Lithuania of 17 December 2013 approving the Rules for taking product samples during random checks of vehicles and their cargo in the customs territory of the Republic of Lithuania and for processing samples

An examination of the legal framework leads to a conclusion that there is currently no consistent legal framework relating to the regulation of product checks. As mentioned previously, only some laws regulating activities of market surveillance authorities lay down the obligation of market surveillance authorities to conduct checks. In rare cases a special law directly stipulates the right of market surveillance authorities to set a detailed procedures on checks in by-laws. True, this right is laid down, as mentioned above, by the Law on public administration. In spite of that, some market surveillance authorities have adopted such procedures by orders of the head of the authority without specifying on what grounds the procedure is approved or as grounds

citing the entire special law rather than its specific provision. So, for the sake of consistency and clarity, the legal framework should be improved.

3.2.2.10. Alerting users of hazards

Article 19(2) of the Regulation obliges market surveillance authorities to take appropriate measures to alert users within their territories within an adequate timeframe of hazards they have identified relating to any product so as to reduce the risk of injury or other damage. Article 19(5) of the Regulation sets out that market surveillance authorities observe confidentiality where necessary in order to protect commercial secrets or to preserve personal data pursuant to national legislation, subject to the requirement that information be made public under this Regulation to the fullest extent necessary in order to protect the interests of users in the Union.

It should be noted that this obligation set for market surveillance authorities cannot be equalled with the obligation of public awareness raising and education analysed in Section 3.2.1.1 of the Study. The obligation to inform users of hazards is a specific obligation as it, first, implies the supply of specific information to users and, second, usually the need to communicate that information to users arises unexpectedly and it is highly probable that the information needs to reach the user as quickly as possible. Such content of the obligation implies a special procedure for the supply of information and a specific method of publishing it, i.e. information via public means of information such as radio, television and the internet. Also, this may undoubtedly affect the amount of funding allocated to market surveillance authorities. Ensuring the adequate financing of market surveillance authorities as provided for in Article 18(3) of the Regulation is necessary for the proper performance of functions of market surveillance authorities.

Given the content of this function and with a view to ensuring the proper implementation of this function, there is a need to set up a clear procedure for alerting users and the mechanism of financing the sending of such alerts to users. At the same time, there is a need to evaluate the actual situation relating to the provision of this information and establish which information channels and procedures are the most efficient.

Article 9(3) of the Product Safety Law sets out the obligation for distributors, as soon as they become aware that a product is dangerous, to immediately discontinue the placing on the market of the product, to inform the producer, consumers, the VVTAT and the relevant control authority and take other actions necessary to eliminate risks for consumers.

Paragraph 13.2 of the Rules for the application of restrictions on marketing of products sets out that the VVTAT and other market surveillance authorities using the materials on safety assessments, checks and controls and conclusions of state expert evaluations of safety are authorised to order that risks presented by any product be communicated in due time and in an appropriate form (including the publishing of special alerts). Paragraph 21 of the Rules stipulates that the VVTAT and/or other market surveillance authorities notify their decisions to withdraw products from the market to distributors supplying products of the same type to the market and public consumer protection organisations to encourage them to contribute to the implementation of these decisions. They inform consumers via public means of information.

Where legislation regulating activities of market surveillance authorities do not oblige market surveillance authorities to alert users of hazards and do not refer to the Product Safety Law, this leads to a conclusion that the duty to notify users of hazards presented by non-consumer products laid down in the Regulation is not properly implemented.

Paragraph 9.9 of the VNMPI Regulations	in accordance with the procedure laid down by the Government of the Republic of Lithuania publish information on dangerous non-food products banned from being placed on the market by the Inspectorate that are produced in the Republic of Lithuania or introduced from the EU Member States or other countries on the Inspectorate's website

An examination of the legal framework leads to a conclusion that the Rules for the application of restrictions on marketing of products lay down the rules for alerting users of hazards, which is why the function to alert users of hazards stipulated in the Regulation is properly implemented in the national legislation. However, on the other hand, an analysis of the actual situation shows that there is a need to consider improving the regulation of this function.

3.2.2.11. Checks of the product and its documentation and CE marking by authorities responsible for external border controls

Articles 27 to 29 of the Regulation regulate controls of products entering the Community market (in particular, Article 27(1) of the Regulation obliges the authorities of the Member States in charge of the control of products entering the Community market to carry out appropriate checks on the characteristics of those products). These checks are the responsibility of the authorities in charge of external border controls which perform their tasks in the area of market surveillance in cooperation with national market surveillance authorities. A product check covers checks not only of the product proper but also its documentation and CE marking.

The authorities in charge of external border controls and market surveillance authorities cooperate when checking products. The aforementioned Guidelines of the Commission, even though they are not binding, are a supporting document for applying the Regulation, and the Regulation sets out the following competences of the customs authorities:

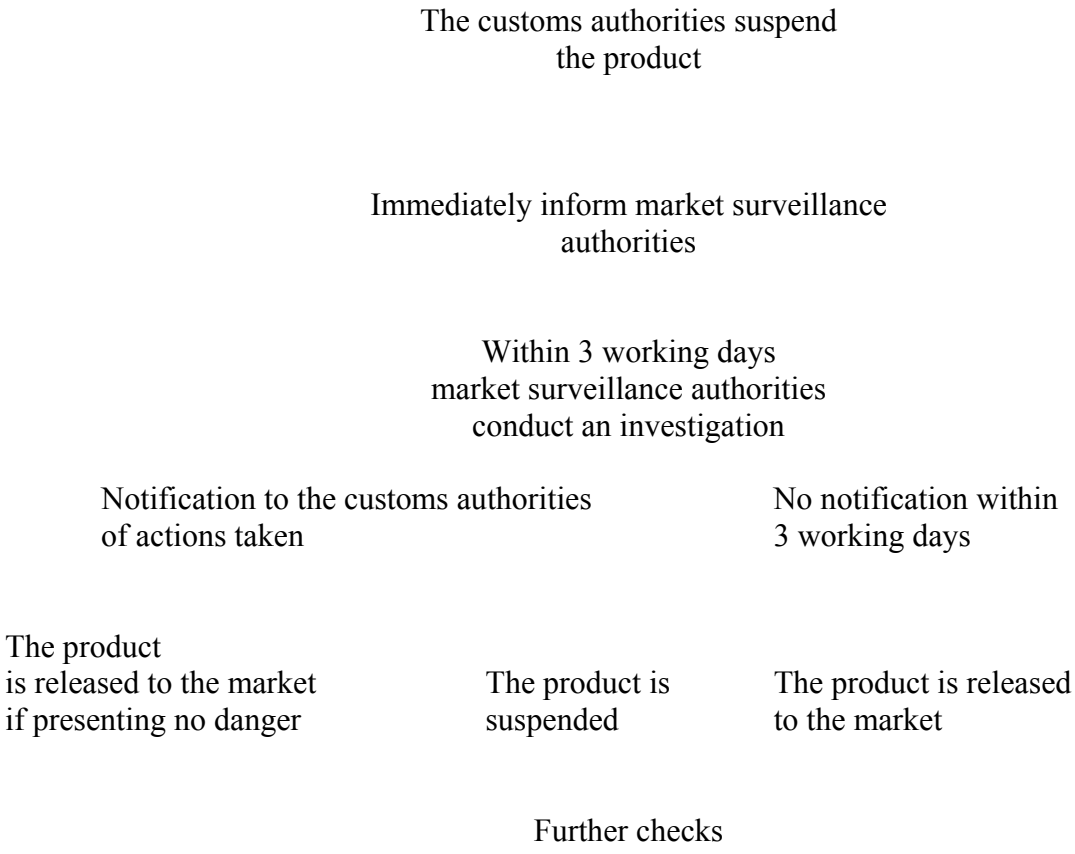
- to suspend release of a product for free circulation on the Community market where:
  - the product presents a serious risk to health, safety, the environment or any other public interest;
  - the product is not accompanied by the written or electronic documentation;
  - the CE marking has been affixed to the product in a false or misleading manner;
- to prohibit the product from being placed on the market where the product presents a serious risk or is in breach of Community harmonisation legislation;
- to release the product in free circulation on the Community market if it is compatible with Community harmonisation legislation.

Having suspended release of the product for free circulation, the authority responsible for external border controls immediately notifies market surveillance authorities of such suspension. In this case market surveillance authorities are to conduct a preliminary assessment of the product and adopt one of the following decisions within 3 working days:

- the product is released if it is found not to present a serious risk to health and safety;

- the product is suspended if it is found that further checks are needed to establish its safety and compliance.

The procedure for suspending and checking the product is visualised in the chart below:



The distribution of functions between the market surveillance authorities and the authorities in charge of external border controls in accordance with the Regulation implies that the release or suspension of the product is the responsibility of the authorities in charge of external border controls but market surveillance authorities are obliged to evaluate whether products are in line with statutory requirements and in due time inform the authorities in charge of external border controls.

The Law on customs lays down certain conditions relating to checks of products. In accordance with Article 27(3) of the Law, a customs officer is authorised to demand that persons declare and submit for customs clearance any goods imported to, exported from or in transit in the Community Customs Area, related transportation documents and other information and explanations necessary for customs checks. Article 32 of the Law on customs lays down requirements to persons relating to the storage of information and accounts and obliges persons relating to import (including actions sanctioned by the customs authorities with the imported goods) and/or export transactions at the request of the customs authorities to supply documents and information in their possession for customs checks. Article 33(5) of the Law on customs sets out that at the request of the customs authorities persons are to transport the goods to places of their checks and sampling and to properly prepare them for such checks or sampling.

The CD Regulations authorise the Customs Department to receive documents relating to imported goods:

Paragraph 11.5 of the CD Regulations	receive from persons relating to goods import, export, transit and removal and introduction transactions or further marketing transactions with these goods any information and documents available

Checks performed by the customs authorities are regulated in detail by Resolution No 1253 of the Government of the Republic of Lithuania of 9 October 2003 on checks of imported goods with a view to establishing whether they meet safety requirements[76]. That Resolution assigned the CD and the VNMPI to implement the provisions of the procedure approved. The Government Resolution actually reiterates the procedure laid down in the Regulation in respect of goods checks and sets up the same procedure. It should only be noted that the Regulation obliges the CD to cooperate with all market surveillance authorities in conducting checks of products while the said Government Resolution only refers to the VNMPI and its powers.

Checks conducted by the CD are also regulated by Order No 1B-407 of the Director General of the Customs Department of 11 June 2008 approving the Rules for conducting customs checks[77].

It should be noted that for the sake of clear regulation properly implementing the Regulation, legislation regulating the CD must clearly state the obligations of market surveillance authorities as well as the rights of economic entities checked and the procedure for disputing decisions adopted or conclusions presented by the CD and/or market surveillance authorities.

Given the legal framework, it should be noted that legislation regulates in detail checks of products, documents and CE marking conducted by the CD. However, as mentioned above, the Regulation obliges all market surveillance authorities to cooperate with the CD helping it to properly implement this function while the national framework only sets this obligation to the VNMPI. Given that, the national framework is to be improved.

3.2.2.12. Imposing sanctions for the improper use of the CE marking

Article 30(6) of the Regulation sets out that the Member States ensure the correct implementation of the regime governing the CE marking and take appropriate action in the event of improper use of the marking. The Regulation also obliges the Member States to provide for penalties for infringements, which may include criminal sanctions for serious infringements. The Regulation also sets out that those penalties are proportionate to the seriousness of the offence and constitute an effective deterrent against improper use of the marking.

Specific requirements to the use of the CE marking on products are laid down in sector-specific legislation, e.g. technical regulations.

[76] Resolution No 1253 of the Government of the Republic of Lithuania of 9 October 2003 on checks of imported goods with a view to establishing whether they meet safety requirements (*Official Gazette*, 2003, No 97-4346).
[77] Order No 1B-407 of the Director General of the Customs Department under the Ministry of Finance of 11 June 2008 approving the Rules for conducting customs checks (*Official Gazette*, 2008, No 68-2617).

Articles 152^4, 152^{11}, 163, 167^3 and 43^{10} of the Administrative Infringements Code provide for liability for infringements of the legislation directly setting requirements to the CE marking.

The Product Safety Law lays down the conditions relating to the liability for infringements of the Law while Article 8 of the Product Safety Law obliges the producer to properly mark products. Although the Product Safety Law does not directly regulate the CE marking, there is a need to consider whether the requirement laid down in Article 8 of the Product Safety Law to properly mark products does not cover the CE marking too. This would make it possible to hold that the improper use of the CE marking should be subject to sanctions laid down in the Product Safety Law. However, still there is no case-law confirming this position although in accordance with the opinion presented by representatives of the Ministry of the Economy, the CE marking is covered by the scope of Article 8 of the Product Safety Law.

Other legislation regulating activities of market surveillance authorities does not provide for the requirement concerning the CE marking and liability for the improper use of the marking.

It should be noted that Article 163^{13} of the Administrative Infringements Code laying down liability for administrative infringements sets out liability for the placing on the market of unmarked products and the provision of false information about the product: "*the placing on the market of the Republic of Lithuania of goods unmarked in accordance with the statutory procedure, making them available on the market and marketing them on the domestic market of the Republic of Lithuania shall be subject to a warning or fine imposed on natural persons engaging in individual business activity in the amount between LTL 50 and LTL 150, a fine imposed on employees of enterprises in the amount between LTL 200 and LTL 500 and on officials in the amount between LTL 700 and LTL 1 000. <...> The provision of false information about the product when marking products shall be subject to a warning or fine imposed on natural persons engaging in individual business activity in the amount between LTL 50 and LTL 100, a fine imposed on employees of enterprises in the amount between LTL 200 and LTL 500 and on officials in the amount between LTL 700 and LTL 1 200*".

Given this legal framework, there is a need to consider whether the liability for the improper use of the CE marking provided for in the Administrative Infringements Code and the Product Safety Law is not duplicated and the link between the liability provisions in those two legal instruments. It should be noted that fines set in the Product Safety Law for infringements of the Law are significantly higher than those set in the Administrative Infringements Code. What is more, this raises a question of the admissibility of the person liable. In accordance with the Administrative Infringements Code, fines are only imposed on natural persons while it is normally economic entities producing or distributing the product that would probably be liable for the improper use of the marking.

Still, to be able to evaluate whether the current system of liability for the improper use of the CE marking is sufficiently efficient and does not create any confusion for economic entities and market surveillance authorities, there is a need to evaluate the current situation: how many fines are imposed in accordance with the said Article of the Administrative Infringements Code, what entities are penalised, which market surveillance authorities apply liability provisions under this Article, whether the regulatory regime attains its preventive goal, etc. To sum up, one may conclude that the national law contains certain provisions regulating liability for the improper use of the CE marking but it is not clear whether they are "proportionate to the seriousness of the offence and constitute an effective deterrent against improper use of the marking" as provided for in the Regulation.

3.2.2.13. Imposing and enforcing sanctions for infringements of the provisions of the Regulation and the Directive

Article 41 of the Regulation lays down certain requirements to sanctions to be imposed for infringements of the provisions of the Regulation. The Regulation obliges the Member States to lay down rules on penalties for economic operators and take all measures necessary to ensure that they are implemented. The Regulation also stipulates that the penalties provided for are effective, proportionate and dissuasive and may be increased if the relevant economic operator has previously committed a similar infringement of the provisions of the Regulation. The Regulation also stipulates until when the Member States are to notify the Commission of those provisions.

Article 7 of the Directive lays down the same obligation for the Member States relating to the establishing of rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and the taking of all measures necessary to ensure that they are implemented.

It should be noted that neither the Regulation nor the Directive sets specific sanctions and lays down any rules on sanctions but, as is common in the case of other consumer protection directives, they only provide for criteria of these sanctions. They must be effective, proportionate and dissuasive. This means that the Member State proper can choose the regulation to ensure that the sanctions provided for are compatible with the said criteria. No doubt, the established criteria relating to sanctions also imply that the regulation of sanctions needs to be analysed and monitored constantly and revised, where necessary.

A general scheme of liability for infringements of product safety requirements is given below.

	Liability		
Product Safety Law	Special laws	Administrative Infringements Code	Criminal Code
	Administrative Infringements Code		

An examination of the legislation regulating product safety and market surveillance in Lithuania leads to a conclusion that the Product Safety Law (Article 27(1)) regulates certain provisions relating to the application of sanctions for infringements of the Product Safety Law:

- the VVTAT examines cases referred to in the Product Safety Law and imposes the fines envisaged;
- fines envisaged for infringements of the Product Safety Law (Article 23 of the Product Safety Law);
- the possibility to increase fines is envisaged for repeated offences;
- indemnity and mitigating and aggravating circumstances are provided for (Article 24 of the Product Safety Law);
- deadlines for imposing fines are set (Article 25 of the Product Safety Law);

- the VVTAT is authorised to examine cases referred to in the Product Safety Law and to impose the fines envisaged. The procedure for preparing and examining cases and for imposing fines is laid down in this Law and the VVTAT Regulations and approved by the Government of the Republic of Lithuania and the regulation adopted by the VVTAT (Article 27(1) of the Product Safety Law);
- the VNMPI staff is authorised to draw up a report on infringements of the Product Safety Law and together with necessary evidence to pass it on to the VVTAT no later than within 3 working days (Article 27(2) of the Product Safety Law).

So, the Product Safety Law essentially authorised one market surveillance authority (the VVTAT) in Lithuania to impose penalties for infringements of the Product Safety Law. It should be noted that the procedure for preparing and examining cases and imposing fines can also be laid down by a legal instrument of a lower level than a law (a Resolution of the Government or an order of the Director of the VVTAT). This is not seen as good regulation as these rules should be set on the legislative level. Still, to be able to evaluate whether the sanctions set in the Product Safety Law are sufficiently effective, proportionate and dissuasive, there is a need to examine the actual situation surrounding the imposition of the sanctions. Given that the Product Safety Law is adopted a long time ago and the actual situation, the legal framework relating to sanctions could be revised including the amounts of sanctions, the rules for imposing sanctions, etc.

The table below shows the liability provisions contained in laws regulating activities of market surveillance authorities.

Authority	Legal provision on liability
EPA	Article 34 of the Law on environment protection. **Legal liability and procedure for examining and resolving disputes relating to environment protection matters:** Persons having infringed on environment protection requirements shall be liable in accordance with the laws of the Republic of Lithuania.
LMI	Article 26 of the Law on metrology. **Liability for infringements of the Law** Legal and natural persons having infringed on the requirements of this Law shall be liable in accordance with the laws of the Republic of Lithuania.
LMSA	Article 51 of the Law on maritime safety. **Liability for non-fulfilment of maritime safety requirements** Persons guilty of the non-fulfilment of maritime safety requirements shall be liable in accordance with the laws of the Republic of Lithuania.
RSC	Article 23 of the Law on radiation protection. **Liability for infringements of legislation regulating radiation protection requirements** Natural and legal persons, other organisations and branches of legal persons and other organisations having infringed on the legislation

	regulating radiation protection shall be liable in accordance with the laws of the Republic of Lithuania.
RRT	Article 74 of the Law on electronic communications. **Economic sanctions** The Communications Regulatory Authority shall be authorised to penalise an economic entity who <…> fails to fulfil the technical regulation on radio communications installations and telecommunications end installations or the technical regulation on electromagnetic compatibility by imposing a fine of up to 3% of the total annual income from activity relating to electronic communications and where the annual scale of such activities is difficult or impossible to assess – up to LTL 300 000.
SMCA	Article 75 of the Law on pharmaceuticals. **Liability for infringements** Natural and legal persons shall be liable for infringements of activities with pharmaceutical products and veterinary pharmaceuticals and unlawful activities in accordance with the procedure laid down in the legislation of the Republic of Lithuania.
VKTI	The Road Transport Code does not regulate liability for infringements on market surveillance requirements
VVTAT	The Law on consumer protection provides for liability only for infringements on the procedure for providing financial services
CD	The Law on customs does not provide for liability for infringements on market surveillance requirements

An analysis of the special legal provisions leads to a conclusion that most often this legislation does not regulate liability and rather makes references to other legal instruments. These laws do not contain a reference to the Product Safety Law either, which means that liability provided for in the Product Safety Law cannot apply where these laws are infringed upon. In such a case the concept "in accordance with the statutory procedure" could be construed as a reference to the Administrative Infringements Code but as the special laws do not directly refer to the Administrative Infringements Code, it is not fully clear whether these laws make references specifically to the application of liability under the Administrative Infringements Code. It should be noted that e.g. the LMI's activity report for Quarter III of 2013 simply stated how many infringements were identified and indicated the total amount of fines imposed but did not directly mention that the fines were imposed under the Administrative Infringements Code.

Individual Articles of the Administrative Infringements Code regulate liability applied by certain marker surveillance authorities: the VKTI – Article 232[1]; the SLI – Article 233; the RSC – Article 239[2]; the VNMPI – Article 241[1]; the LMI – Article 241[2]; environment protection bodies (the EPA) – Article 242; and the RRT – Article 246. It should be noted that most often these

Articles of the Administrative Infringements Code regulate liability applied by these market surveillance authorities not for actions relating to the application of market surveillance measures. However, still some Articles of the Administrative Infringements Code directly provide for liability specifically for violations relating to product safety:

Article	Authority applying liability	Disposition and sanction
Article 189 of the Administrative Infringements Code. **Infringements on quality requirements to goods, services and raw materials**	RSC VNMPI	"*The placing on the market, making available on the market, sale and marketing of goods, services and raw materials whose quality, operational properties, composition, complexity and packaging do not meet binding quality requirements laid down in technical regulations, recipes, technical specifications (conditions), standards and other documents declared as well as legislation including construction products not matching their operational properties declared; the placing on the market, making available on the market and sale of goods, provision of services and marketing of raw materials without required documentation certifying their quality and safety and mounting, installation, assembly or use guides, the failure to keep these documents and supply them to the market surveillance authority in due time, except for the cases listed in paragraph 7 shall be subject to a warning or a fine imposed on employees of enterprises as well as natural persons engaging in individual business activity in the amount between LTL 50 and LTL 500 and on officers – between LTL 1 000 and LTL 2 000*".
Article 189[7] of the Administrative Infringements Code. **Infringements on legal metrology requirements**	LMI	"<…> the production, repairs, placing on the market, renting and use of metrological equipment the incompliance of which with legal requirements and/or technical documentation of the producer is established in the course of legal metrological surveillance as well as the production and placing on the market of metrological vessels and pre-packaged merchandise; <…> shall be subject to a fine imposed on natural persons in the amount between LTL 100 and LTL 1 000, on legal persons or managers of foreign company branches in the Republic of Lithuania or persons authorised thereby – between LTL 300 and LTL 2 000".

The above shows that the performance of this function raises certain concerns:

- **Issue of the link between the Administrative Infringements Code and economic sanctions.** It should be noted that in practice there is an issue with the link of the Administrative Infringements Code with the laws regulating economic sanctions. This problem should be dealt with in a systematic manner, taking into account suggestions on how to improve the general sanction regulatory regime. It should be stressed that to tackle problems relating the application of enforcement measures imposed on economic entities, by its Resolution of 24 October 2012 the Government of the Republic of Lithuania approved the Concept of the key provisions on the application of enforcement measures to economic entities[78] ('**the Concept**'.) For the purpose of the Concept, enforcement measures are construed as sanctions imposed on economic entities for violations of the legislation regulating their activity. The concept of "enforcement measures" is synonymous to the one of "economic measures". The Concept analyses the matters of the current system of application of enforcement measures and suggests creating a new regulatory framework by adding new provisions to the Law on public administration laying down the key provisions on the application of enforcement measures to economic entities. The current Law on public administration has not yet been amended as proposed in the Concept but, as far as we understand, public authorities still are to revise the existing regulation in respect of economic sanctions in individual laws (including the Product Safety Law);
- **the system for setting sanctions is not clear**. Given the current situation where some sanctions applicable by market surveillance authorities are laid down in the Product Safety Law while the others – in the Administrative Infringements Code, the very system of imposing sanctions is unclear, i.e. it is unclear what determines that in some cases liability imposed by the Administrative Infringements Code alone is enough;
- **there are significant differences in the amount of fines**. It should be noted that the fines set in the Product Safety Law for perpetrators are much higher than those laid down in the Administrative Infringements Code;
- **different persons held liable**. It should be noted that the Administrative Infringements Code imposes liability on natural persons while liability provided for in the Product Safety Law can also cover economic entities, i.e. legal persons.

The above leads to a conclusion that Lithuania does not have a clear procedure for regulating and imposing sanctions for violations of the Regulation and the Directive. The system of sanctions is confusing and unclear, which is why for the sake of transparency and clarity, the regulatory framework should be improved accordingly.

3.2.2.14. Ensuring the proper administration of RAPEX

Article 11 of the Directive sets out that where a Member State takes measures which restrict the placing on the market of products, it must inform the Commission about those measures (to the extent that such notification is not required under Article 12 or any other Union legislation) specifying its reasons for adopting them. Where the Member State considers that the effects of the risk do not or cannot go beyond its territory, it notifies the measures concerned insofar as they involve information likely to be of interest to Member States from the product safety standpoint, and in particular if they are in response to a new risk which has not yet been reported

[78] Resolution No 1304 of the Government of the Republic of Lithuania of 24 October 2012 approving the Concept of the key provisions on the application of enforcement measures to economic entities (*Official Gazette*, 2012, No 127-6403).

in other notifications. The Commission forwards the notification to the other Member States where the measures comply with EU law.

Article 12 of the Directive establishes the RAPEX mechanism: where a Member State adopts or decides to adopt, recommend or agree with producers and distributors, whether on a compulsory or voluntary basis, restrictive measures for products by reason of a serious risk, it immediately notifies the Commission thereof through RAPEX. On receiving such notifications, the Commission checks whether they comply with the Directive and with the requirements applicable to the functioning of RAPEX and forwards them to the other Member States, which, in turn, immediately inform the Commission of any measures adopted.

The Regulation, which, unlike the Directive, also applies to non-consumer products, also regulates exchange of information. In accordance with Article 22 of the Regulation, where a Member State takes or intends to take a measure in respect of a product presenting a serious risk and considers that the reasons which prompted the measure or the effects of the measure go beyond its territory, it immediately notifies the Commission of that measure. This notification is sent using the RAPEX mechanism established by the Directive while the Directive provisions regulating this mechanism apply *mutatis mutandis*[79].

The administration of the RAPEX system in Lithuania is the responsibility of the VVTAT which back in 2002 was obliged by the Government[80] to draw up the Rules for rapid exchange of information on products dangerous to consumers[81].

Paragraph 4 of the current Rules for rapid exchange of information on products dangerous to consumers gives a non-exhaustive list of authorities cooperating through RAPEX:

- VVTAT (RAPEX liaison authority);
- VNMPI;
- VKTI;
- Ministry of Transport and Communications;
- LMSA;
- Weaponry Fund of the Republic of Lithuania under the Ministry of the Interior;
- Police Department under the Ministry of the Interior;
- other authorities responsible for the monitoring and market surveillance of consumer product safety;
- CD listed not as a market surveillance authority but as an authority in charge of the EU external border controls.

Out of 10 market surveillance authorities covered by the Study, this list only includes 3 (the VNMPI, the LMSA and the VKTI) while the other 7 (the VASPVT, the RRT, the SMCA, the LMI, the SLI, the EPA and the RSC) are not listed. This is partially explained by two reasons. First, RAPEX inter alia does not apply to notifications concerning medicinal products and

[79] The RAPEX mechanism is presented in detail in Commission Decision 2010/15/EU of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive).
[80] Resolution No 438 of the Government of the Republic of Lithuania of 2 April 2002 on granting powers in implementing the Law amending the Law of the Republic of Lithuania on product safety (*Official Gazette*, 2002, No 35-1306).
[81] The rules currently in force are the Rules for rapid exchange of information of products dangerous to consumers approved by Order No 1-62 of the Director of the VVTAT of 14 May 2010 (*Official Gazette*, 2010, No 58-2871) as amended by Order No 1-1 of the Director of the VVTAT of 2 January 2014.

medical devices; second, the Procedure for rapid exchange of information on products dangerous to consumers approved by the VVTAT only applies to consumer products.

The Regulations of none of the market surveillance authorities analysed in this Study directly set out an obligation to provide information specifically through RAPEX. However, for example, Article 9(4) of the Law on metrology stipulates that the Lithuanian Metrology Inspectorate carries out legal metrological surveillance and in statutory cases notifies the Commission and the authorised institutions of the other Member States of measures imposed to prohibit the use or placing on the market of metrological equipment, pre-packaged merchandise or metrological vessels and reasons for adopting such decisions. The Procedure of the VNMPI for conducting checks[82] sets out that checks verify where dangerous products announced through RAPEX are not marketed, and following the imposition of restrictive measures, the VNMPI inspector is obliged to notify this information to the RAPEX liaison authority.

Some other market surveillance authorities publish information on RAPEX on their websites, e.g. the VKTI publishes the latest information received through RAPEX from the VVTAT about vehicles recalled while the VNMPI provides general information on the RAPEX system and dangerous products identified in Lithuania.

The VVTAT activity report for 2013[83] mentions the number of notifications sent to other authorities of the Republic of Lithuania in 2013:

- the VNMPI – 2 207 notifications;
- authorised representatives of car manufacturers in Lithuania – 124 notifications;
- the Police Department under the Ministry of the Interior – 47 notifications on unsafe pyrotechnical products;
- the LMSA – 4 notifications;
- the Weaponry Fund of Lithuania – 17 notifications.

As specified in the VVTAT activity report for 2013, in 2013 the VVTAT proper received from the VNMPI and sent to the EC 48 notifications and 1 reply concerning products dangerous to consumer health detected in the Lithuanian market. The RAPEX report for 2012[84] presenting statistics on how many RAPEX notifications received were sent to market surveillance authorities in Lithuania lists the same authorities: the VNMPI (2 149 notifications), the VKTI and representatives of car manufacturers in Lithuania (120 notifications), the Police Department under the Ministry of the Interior (26 notifications), the LMSA (4 notifications) and the Weaponry Fund of Lithuania (1 notification). It should be noted that the largest number of RAPEX notifications is annually received by the VNMPI, and this authority is the only one drawing up notifications that the VVTAT then passes on to the Commission.

The RAPEX report for 2012 also sets out that "*the functioning of the system for rapid exchange of information on products dangerous to consumers has been impeded by the withdrawal of the State Road Transport Inspectorate under the Ministry of Transport and Communications from the RAPEX system. All information given in a RAPEX notification is passed on to authorised*

[82] Order No 1R-115 of the Head of the VNMPI of 29 October 2010 approving the Procedure for conducting checks of the State Non-Food Products Inspectorate under the Ministry of the Economy.
[83] Activity report on the State Consumer Rights Protection Authority for 2013 approved by Order No 2-1 of the Director of the VVTAT of 27 January 2014.
[84] Report of the VVTAT of 10 January 2013 on rapid exchange of information on products dangerous to consumer health for 2012.

representatives of car manufacturers but there are notifications on unsafe vehicles the manufacturers of which are not represented in Lithuania"[85].

So the RAPEX liaison authority (the VVTAT) proper identifies an issue: the non-involvement or improper involvement of the Lithuanian market surveillance authorities in the System for rapid exchange of information on products dangerous to consumers creates difficulties as where other countries identify a dangerous product, the VVTAT as the RAPEX liaison authority just does not have anyone to notify that a responsible authority would take action to protect Lithuanian consumers from unsafe products (where there are authorised representatives of the product in Lithuania, at least they are notified). Given the above and in order to ensure the efficient exchange of information between market surveillance authorities, there is a need to ensure their participation in the RAPEX system by obliging market surveillance authorities to do so in the legislation regulating their activities.

As mentioned above, the Procedure for rapid exchange of information on products dangerous to consumers approved by the VVTAT applies only when exchanging information on consumer products. This system functions so the requirement laid down in Article 12 of the Directive is formally implemented. However, the Regulation expands the scope of the RAPEX system envisaged in the Directive, i.e. imposes an obligation to exchange information through RAPEX on dangerous non-consumer (professional) products subject to Union harmonisation legislation. Unfortunately, no public information showing that this obligation laid down in the Regulation is fulfilled in Lithuania has been found in public access. As specified in the Commission's report on the implementation of Regulation 765/2008, during the first several years of implementing the Regulation the total number of such new notifications was low but during the recent years they become more and more numerous. The RAPEX report for 2013 [86] drafted by the Commission mentions Lithuania as one of the Member States that has not sent such notifications during the recent years.

Given that Lithuania does not ensure exchange of information on dangerous non-consumer products, there is a need to correct the scope of RAPEX in Lithuania by amending the Lithuanian legislation ensuring that it also covers non-consumer (professional) products. This is possible in two ways:

(1) by expanding the competence of the VVTAT in the area of RAPEX and accordingly laying down that the VVTAT is the RAPEX liaison authority passing on notifications not only on consumer products but also on non-consumer products;
(2) by delegating the functions of the RAPEX liaison authority to the VNMPI as given the above statistics, this authority receives a disproportionately large number of RAPEX notifications (as compared to other authorities) from other countries, and the VNMPI is the only institution issuing such notifications. In that case the VNMPI's competence should also be expanded accordingly:

- by enabling it to participate in market surveillance of non-consumer products based solely on RAPEX;

[85] The VVTAT activity report for 2013 specifies that public authorities finally agreed that as of 2014 RAPEX notifications are to sent to the VKTI again.
[86] European Commission. Keeping European consumers safe. 2012 Annual Report on the operation of the Rapid Alert System for non-food dangerous products RAPEX [accessed on 10 February 2014]. Available online at http://ec.europa.eu/consumers/safety/rapex/docs/2012_rapex_report_en.pdf.

- taking into account the suggestion given at the end of Chapter 3.1 of the Study, by expanding the competence of the VNMPI to cover also the "grey areas" of non-consumer products, i.e. areas and products not controlled by any specific authority in Lithuania.

3.2.2.15. Provision of data and information to the general information support system

Article 23 of the Regulation sets out that the Commission *develops and maintains a general archiving and exchange of information system, using electronic means, on issues relating to market surveillance activities, programmes and related information on non-compliance with Community harmonisation legislation. The system shall appropriately reflect notifications and information provided under Article 22.*

To that end, a decision was made to create the ICSMS (the Information and Communications System on Market Surveillance), which is now the only such system available. The ICSMS enables all market surveillance authorities to exchange all necessary information. The system enables its users to quickly and efficiently exchange information on test results, identification data of products, photographs, information on economic operators, risk assessment data including hazards and information on accidents and measures imposed by market surveillance authorities. Still, as mentioned by the EC, *it is still too early to evaluate the ICSMS agreement as it was signed in November 2011 and the implementation of the system in the EU Member States that had not used it just started*[87].

In accordance with the data of February 2013, the ICSMS contained 47 500 product testing results and more than 650 authorities from all EEA countries under more than 45 directives, and the number of users was 3 600[88]. No public information has been found on how the Lithuanian market surveillance authorities use this system. As the Ministry of the Economy has informed, Lithuania started to use the ICSMS system in September 2012, and in accordance with the data of July 2013 the Lithuanian market surveillance authorities made over 200 queries in this system and uploaded about 100 notifications on products presenting risks but still the market surveillance authorities use the system scarcely. Unfortunately, no public information is announced on the use of the ICSMS among the Lithuanian authorities.

The public section of the ICSMS e-portal accessible to all users offers a list of the Lithuanian authorities participating in the system:

- VNMPI
- CD
- SLI
- RRT
- the State Inland Navigation Inspectorate (merged with the LMSA)
- the Public Health Service (Ministry of Health) (specifying that the Service was reorganised and its functions were delegated to the Ministry of Health and PHCs in counties)
- LMI

[87] EC report on the implementation of the Regulation.
[88] EC report on the implementation of the Regulation.

- the State Veterinary Preparations Inspectorate (which back in 2008 together with the National Veterinary Laboratory was reorganised by establishing a new National Food and Veterinary Risk Assessment Institute)
- the State Plant Service under the Ministry of Agriculture
- the Ministry of the Economy
- the State Environment Protection Inspectorate (merged with the EPA)
- the State Weaponry Fund
- LMSA
- VASPVT (Ministry of Health)
- Vilnius PHC (although PHCs are active in all the 10 counties)

Given that some of the authorities listed on the said ICSMS portal are no longer existent, the smoother use of the ICSMS system by the Lithuanian authorities would be made possible inter alia by compiling an exhaustive list of the authorities that must participate in the ICSMS system and, second, the setting out of the obligation to participate in the system in the legislation regulating activities of competent authorities.

SUMMARY

- The Regulation is largely implemented in the Lithuanian law. However, there are some drawbacks in the legal regulation identified.
- Some specific functions of the market surveillance system established by the Regulation (relating to the examination of complaints in respect of products; alerting users of hazards) are properly implemented in the national law.
- In respect of other specific functions of the market surveillance system established by the Regulation, the following drawbacks in the legal regulations have been identified:
  - in some cases certain provisions can be stipulated on the legislative level (on the obligation to cooperate, the obligation to accumulate scientific and technical knowledge, the right to impose restrictive measures);
  - in some cases there is a need for clearer regulation of the obligation of market surveillance authorities to perform certain functions (monitoring of accidents and harm to health, checks of products)
  - in some case there is a lack of more detailed regulation (there is a need to adopt relevant procedures and rules)
- In respect of certain specific functions of the market surveillance system established by the Regulation (on the imposition of sanctions for the improper use of the CE marking; examination of complaints concerning products; alerting users of hazards; imposition of restrictive measures; sanctions for violations of product safety requirements) there is a need to conduct a comprehensive analysis of the actual situation and procedures to establish whether a certain market surveillance function is properly implemented in the national law.
- Although the RAPEX liaison authority is the VVTAT, the most notifications through this system are addressed to the VNMPI, and the participation of the countries in the RAPEX system is rather fragmented. Information on the participation of the Lithuanian authorities in the RAPEX system is not published and the list of Lithuanian authorities published on the ICSMS e-portal that is to contribute to public awareness raising is not up-to-date.

3.3. Lithuanian market surveillance system for services and its efficiency

As mentioned on numerous occasions in this Study, EU legislation applies different legal regimes to products and services. The principal EU legal instrument regulating services is the Services Directive 2006/123/EC[89]. The purpose of this Directive is to facilitate the exercise of the freedom of establishment for service providers and the free movement of services, while maintaining a high quality of services. While providing for the principle of the freedom of establishment for service providers and the principles for streamlining procedures for exercising the right to engage in services, the Directive does not regulate matters relating to physical security (i.e. protection from danger to health or other interests). However the Services Directive

[89] Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market seeks to ensure free movement of services in the EU while matters of service safety are not regulated therein.

2006/123/EC indirectly ensures the protection of economic interests of consumers, for instance, from unfair commercial practices.

Article 20 of the Directive analysed in the Study sets out that Commission *shall identify the needs, possibilities and priorities for Community action on the safety of services and submit to the European Parliament and the Council, before 1 January 2003, a report, accompanied by proposals on the subject as appropriate*.

On that basis, on 6 June 2003 the Commission published the Report on consumer services[90]. In the report the EC stated that at EU level there is no horizontal legislation on service safety but a number of existing instruments in various policy areas contribute indirectly to the safety of certain services, in particular, legislation regulating the technical rules for certain products. As stated in that document, the safety of services is regulated in the EU only in the transport sector while the EU regulation of certain individual aspects of services, in particular, seeks to ensure the principle of free movement of services. The Commission mentions that all Member States have adopted legislation and administrative measures relating to service safety but these are different. Analysing measures adopted by the Member States in various sectors, the EC has drawn a conclusion that the analysis of the actual situation has shown that the Member States do not have much general systematic information available on service safety. Taking this into account, the Commission has submitted a proposal to create a general information system which would be used for exchanging information on the safety regulation of services in the Member States and cases of unsafe services.

In response to the said provision of Article 20 of the Directive, on 1 December 2003 the EU Council published its Resolution on safety of services for consumers[91] specifying that in order to decide what action needs to be taken, there is a need to conduct a more detailed analysis of types of services that may present a risk and mentioning that safety aspects of services are regulated individually in all Member States, so the regulation and policy on the safety of services in the Member States vary. Given that, the EU Council proposed to the Commission to cooperate with the Member States and conduct an analysis and identify priorities in regulating service safety and possible ways to exchange information on the safety of services. It also invited the Member States to take active part in this process.

However the recent decades have not seen any major changes in the safety of services on the EU level. The website of the European Commission's Directorate-General for Health and Consumer Protection[92] announces that in 2013 the EC plans to launch consultations on specific aspects of services for consumers. The Commission's website does not yet offer any more specific data on these consultations or the results of the consultations.

To identify the Lithuanian market surveillance authorities for services, there is a need to define the concept of market surveillance of services. Such a definition of market surveillance of *services* is not given either in the Lithuanian legislation or in other documents. As mentioned above in other Chapters of the Study, the Regulation which, as has been said more than one, applies only to products, stipulates that market surveillance means "*the activities carried out and*

[90] 2003 06 06 Commission of the European Communities. Report from the Commission to the European Parliament and the Council on the safety of services for consumers [accessed on 2014 02 11]. Available online at http://ec.europa.eu/consumers/safety/serv_background/index_en.htm.
[91] Council Resolution of 1 December 2003 on safety of services for consumers (2003/C 299/01).
[92] EC's website [accessed on 2014 01 21]. Available online at http://ec.europa.eu/consumers/safety/serv_background/index_en.htm.

measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection" while the Commission's Communication "20 actions for safer and compliant products for Europe: a multi-annual action plan for the surveillance of products in the EU"[93] specifies that "*the core of market surveillance is a chain of interdependent processes such as inspections, sampling, laboratory testing, interpretation of results, risk assessment, decision making, intervention and ensuing legal procedures which may involve corrective measures or even sanctions*". So, as mentioned in Chapter 3.1 of the Study, when identifying the market surveillance authorities for products, checks were conducted to verify whether a specific authority had actual powers in respect of a specific product, i.e. was authorised to check the safety of products, conduct laboratory tests, assess risks and impose market restriction measures or sanctions.

In order to identify public authorities conducting market surveillance of services in Lithuania, a similar method has been employed: checks whether an authority[94] can perform checks, assess risks and impose enforcement measures where services provided by an economic entity are not compatible with the safety requirements laid down in legislation.

It should be noted that both in the case of products and in the case of market surveillance of services, it is very important when identifying market surveillance authorities to evaluate not only the powers granted to market surveillance authorities but also safety requirements (in particular, those regulated for specific types of products or services). However, this Study does not focus on the evaluation of the system of safety requirements. This is thought to be a separate object worth studying.

Given the specific nature of activities and the functions performed, the safety of services provided to consumers in terms of certain aspects thereof is ensured by the following authorities:

Authority	Function
VNMPI	Service safety surveillance on the grounds of the Product Safety Law
Public health centres in counties	(*competences are discussed in greater detail in this Chapter of the Study below*)
Lithuanian Maritime Safety Administration	State control of navigation safety in coastal navigation areas and inland waters
State Railway Inspectorate under the Ministry of Transport and Communications	Ensuring a high level of railway traffic safety
State Road Transport Inspectorate under the Ministry of Transport and Communications	Control of safety of passenger vehicles carrying passengers to long distances and on international routes
Civil Aviation Administration	Control of safety in aviation including air carriage of passengers

[93] Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee of 13 February 2013 "20 actions for safer and compliant products for Europe: a multi-annual action plan for the surveillance of products in the EU".

[94] The analysis only covered the authorities included in the list of supervision groupings of public administration bodies supervising activities of economic entities approved by Resolution No 511 of the Government of 4 May 2010 on the optimisation of functions performed by authorities (*Official Gazette*, 2010, No 53-2613; 2011, No 92-4374; 2012, No 89-4657).

Functions of other authorities in ensuring the safety of services provided to consumers or professional users are integral to the safety control of products or the safety control of work/production processes performed by these authorities. Still, one may conclude that in certain aspects the safety of services or processes relating to the provision of services is supervised, for example, by:

- the Radiation Protection Centre;
- the VASPVT;
- the State Energy Inspectorate under the Ministry of Energy (technical safety of energy installations);
- the State Territorial Planning and Construction Inspectorate under the Ministry of the Environment (state surveillance of construction).

So, while there is a certain system of authorities in the area of market surveillance of products based on the system established by the Directive and the Regulation and the surveillance mechanism under the Product Safety Law, market surveillance of services in Lithuania is not centralised. There is no legislation defining market surveillance of services and compiling a list of authorities or criteria based on which authorities should or could be treated as market surveillance authorities for services. Moreover, it is often the case that when analysing the functions of a specific authority, it is difficult to formally separate the controls performed by the authority in respect of products from the controls performed in respect of services as service controls are conducted through the controls of products used in the process of providing services (e.g. surveillance of safe passenger carried conducted by the VKTI). Given the above, although artificial separation of the control mechanisms for products and for services is not useful, still a definition of "market surveillance for services" and a list of authorities conducting such surveillance should be put in place clearly identifying the authorities falling within the system of surveillance of services.

As mentioned previously in other Chapters of the Study, when analysing the mechanism of the functioning of the Product Safety Law, the Lithuanian legislator expanding the scope of market surveillance of products regulated in the EU specified that the national "umbrella" legislation for market surveillance of consumer product safety (the Product Safety Law) also applies to the surveillance of safety of consumer services. The Rules for the application of restrictions on marketing of products[95] specified the authorities authorised to impose restrictive measures but there is no exhaustive list of authorities authorised to impose those measures. However the VNMPI (as the authority in control of non-food products (products and services)) and public health centres in counties controlling services within their remit are listed as institutions empowered to control market surveillance of services dangerous to consumer health and safety. So, it is important to stress that an evaluation of the legal framework leads to a conclusion that of the authorities listed in the above preliminary list of service surveillance authorities, the activity of only two institutions (the VNMPI and public health centres in counties) is in one way or another based on the umbrella law (the Product Safety Law). Regulated activities of the other authorities do not have any links to the Product Safety Law. This obviously raises concerns in respect of the clarity of the very institutional system of service surveillance and its regulation.

[95] Paragraph 3 of the Rules for the application of restrictions on marketing of products sets out that "*market restriction measures shall be imposed by the National Consumer Protection Council under the Ministry of Justice ('the Council'), the State Food and Veterinary Service (with a view to restricting the placing on the market of foodstuffs dangerous to consumer health), the State Non-Food Products Inspectorate under the Ministry of the Economy (with a view to restricting the placing on the market of non-food products dangerous to consumer health and safety), public health centres in counties (with a view to restricting the placing on the market of services dangerous to consumer health and safety within their remit) as well as other product safety control institutions established by the Government of the Republic of Lithuania within their remit*".

On service safety surveillance by the VNMPI

As mentioned previously in Chapter 3.2 of the Study, paragraph 8.1 of the VNMPI Regulations sets out that one of the objectives of the VNMPI's activity is "*to implement the market surveillance policy for non-food products and services ('non-food products')*", and in pursuit of this objective the VNMPI "*supervises whether non-food products placed on the market which the Inspectorate is tasked with supervising by laws or other legislation meet safety, quality and labelling requirements to non-food products, independently choosing entities to be checked and determining the scale of checks*" (paragraph 9.1). As already mentioned, a respective provision is also laid down in the Rules for the application of restrictions on marketing of products. This legal framework implies that the VNMPI is responsible for the entire service safety market surveillance, except where service safety surveillance is assigned to the competence of a specific authority (but as indicated above, such assignment is clear, in fact, in respect of only one authority, i.e. public health centres in counties). It should be noted that the legislation does not specify in detail and identify a specific area of service market surveillance falling under the responsibility of the VNMPI (or not falling within its area of competence). This leads to a conclusion that the VNMPI is an "umbrella" authority for service market surveillance. Therefore, in the area of service marker surveillance there should not be a situation where a certain area of services is out of control. However, despite that, as mentioned before, the legislation does not establish a very clear and unambiguous system of service market surveillance, which is why the legal framework needs to be improved. This would be especially important if the legislation referred to above is construed otherwise than proposed in this Study.

On service safety surveillance by public health centres in counties

Lithuania currently has ten public health centres active in Alytus, Kaunas, Klaipėda, Marijampolė, Panevėžys, Šiauliai, Tauragė, Telšiai, Utena and Vilnius. The Law of the Republic of Lithuania on public health and the PHC Regulations (which are different for each PHC but approved by a single Order of the Minister for Health of the Republic of Lithuania) set out that the PHCs inter alia conduct state control of public health safety in the areas of *personal healthcare, education, inpatient care institutions, internet cafes and clubs, passenger carriage by trains, vessels and ferries along inland routes, police detention centres and places of imprisonment and services provided by legal persons, state enterprises, municipal enterprises, public bodies and foreign legal persons or branches of other organisations producing cosmetic products, hairdressing and tattoo salons, beauty salons, tanning salons, swimming pools, laundry services, public baths, saunas and gyms as well as accommodation services*, etc.

As provided, for example, in paragraph 10.1.7 of the Vilnius PHC Regulations, the PHC *imposes restrictive measures provided for in the Law of the Republic of Lithuania on product safety and enforces decisions adopted in respect of the application of restrictive measures* but it does not specify in detail that PHC's role where the VVTAT imposes sanctions for violations of the Product Safety Law.

Still, a systematic examination of publicly available information shows that, like in those cases where based on the checks conducted by the VNMPI or the State Food and Veterinary Service and the procedure laid down in Article 27 of the Product Safety Law, the VVTAT imposes sanctions for violations of the Product Safety Law in the areas of non-food products and food products respectively, in the same way, on the basis of check reports drawn up by the PHC for violations of the Product Safety Law the VVTAT imposes sanctions in respect of the provision

of services to consumers that are not compatible with safety requirements. Although the VVTAT's resolutions on violations of the Product Safety Law are not published (in accordance with the established procedure, only the operative part of these resolutions is published), the role of check reports drawn up by the PHC for the imposition of sanctions for violations of the Product Safety Law by the VVTAT is also referred to in the case-law (e.g. Ruling of the Supreme Administrative Court of Lithuania of 19 March 2012, Administrative Case No A[662]-377/2012; Judgment of Vilnius Regional Administrative Court of 29 December 2011, Administrative Case No I-3728-629/2011).

In accordance with the annual analyses of the report on direct state safety controls of services of hairdressers, cosmetics and tattoo salons, beauty salons, tanning salons, swimming pools, laundry services, public baths, saunas, gyms and accommodation services conducted by the PHCs in counties that are published on the VVTAT's website, in performing their functions the centres usually apply administrative penalties (e.g. in 2013 the PHCs imposed 595 fines, and in 2012 – 574 administrative penalties (including 4 warnings and 570 fines))[96]. As all PHCs in counties have their own websites, information on the reports on violations of the Product Safety Law drawn up by the PHCs during the year is not published in a centralised manner but an examination of the publicised[97] operative parts of the VVTAT's resolutions on violations of the Product Safety Law and other information published leads to a conclusion that the number of resolutions on violations of the Product Safety Law adopted on the grounds of the reports drafted by the PHCs is very small (in 2011, 2012 and 2013 – 2 resolutions each year). In order to establish clear reasons underlying such a situation with the application of the Product Safety Law, there is a need to analyse the actual situation and conduct a fact-finding investigation of the application of the Product Safety Law and the Administrative Infringements Code in this area by examining all decisions to impose penalties by respective authorities.

In accordance with the market surveillance functions defined in the Regulation and the Directive, Chapter 3.2 of the Study analyses the efficiency of the Lithuanian system of authorities in charge of product market surveillance checking how these authorities implement their systematic and specific surveillance functions. Service market surveillance is not regulated on the EU level, and the Regulation and the Directive do not at all apply to the control of service safety (and thus do not establish any functions relating to the specific market surveillance mechanism for services). Moreover, the Lithuanian law does not set any criteria based on which one could compile a specific exhaustive list of market surveillance authorities for services, and Lithuanian service market surveillance authorities are not analysed separately in this Study either from the standpoint of their systematic functions or in terms of their specific functions.

SUMMARY
• Service market surveillance is not essentially regulated on the EU level, except for certain aspects of transport safety, leaving this area solely to national regulation. • A system of Lithuanian service market surveillance authorities is not structured; there is no definition of the very concept of service market surveillance or list of respective authorities, or criteria defining which authorities should be treated as market surveillance authorities. Moreover, in many cases it is difficult to make a formal distinction between service safety market surveillance and product safety

[96] Information from the VVTAT's website, section "Market surveillance analysis" available at http://www.vvtat.lt/index.php?2967465971.
[97] VVTAT's website, section "Unsafe non-food products" available at http://www.vvtat.lt/index.php?2109348192.

controls, which is why separating them artificially is not useful either.

- An examination of the legal framework of service market surveillance established by the Product Safety law and implementing legislation leads to a conclusion that the activity of only two authorities (the VNMPI and public health centres in counties) is in one way or another based on this Law while regulated activities of the other authorities (that may be seen as service market surveillance authorities) do not have any links to the Product Safety Law. This obviously raises concerns in respect of the clarity of the very institutional system of service surveillance and its regulation. Moreover, the existing regulatory framework implies that the VNMPI is an "umbrella" service market surveillance authority. However, the legislation still does not establish a very clear and unambiguous system of service market surveillance, which is why the legal framework needs to be improved.

IV. AN OVERVIEW OF MARKET SURVEILLANCE SYSTEMS OF OTHER EU MEMBER STATES

4.1. Finland

Structure of market surveillance authorities

Overall, market surveillance in Finland is organised in individual sectors. There are administrative bodies of various ministries responsible for the implementation of market surveillance in each sector[98].

The following authorities active in various sectors are in charge of market surveillance in Finland:

Market surveillance authorities in Finland	
Authority	**Coordinating ministry**
• Finland's Food Safety Authority (Evira)	Ministry of Agriculture and Forestry
• Finland's Transport Safety Agency (TraFi)	Ministry of Transport and Communications
• National Police Board	Ministry of the Interior
• National Supervisory Authority for Welfare and Health (Valvira)	Ministry of Social Affairs and Health
• Occupational Safety and Health Department and regional public administration bodies in charge of occupational safety and health	Ministry of Social Affairs and Health
• Radiation and Nuclear Safety Authority (STUK)	Ministry of Social Affairs and Health
• Finland's Safety and Chemicals Agency (Tukes)	Ministry of Labour and the Economy, Ministry of Social Affairs and Health, Ministry of the Environment, Ministry of Agriculture and Forestry, Ministry of Finance and Ministry of Transport and Communications
• Finland's Communications Regulatory Authority (FICORA)	Ministry of Transport and Communications
• Finland's Institute of the Environment (SYKE)	Ministry of the Environment
• Customs	Ministry of Finance

[98] Website of the Finnish Ministry of Labour and the Economy [accessed on 24 February 2014]. Available online at http://www.tem.fi/en/consumers_and_the_market/free_movement_of_goods_and_services/market_surveillance/market_surveillance_authorities.

In Finland the coordination function of the market surveillance system and the supervision of the implementation of the Regulation are the responsibility of the Ministry of Labour and the Economy. The Advisory Committee for Conformity Assessment reports to that Ministry and practically assists the Ministry in performing all its tasks relating to the coordination of the market surveillance system and the implementation of the Regulation. The Committee consists of representatives of market surveillance authorities and business associations, and one of the key functions is exchange of information between business and market surveillance institutions.

Apart from the above market surveillance authorities listed in Finland's General Market Surveillance Programme for 2013[99], Finland also has the Finnish Consumer Agency. On 1 January 2013 this authority was merged with the Finnish Competition Authority and is now known as the Finnish Competition and Consumer Authority[100]. This authority is not deemed a market surveillance authority but is involved in the market surveillance system.

Following the adoption of the Regulation, cooperation and coordination mechanisms between market surveillance authorities in Finland were established as follows[101]:

- by establishing a working party (the NWP – the National Working Party)
- by adopting the Act on exchange of market surveillance information (No 1197/2009)
- by improving (modifying) the Market Surveillance Information Exchange Network

In order to ensure centralised coordination of market surveillance on the national level, in the future Finland plans to establish an umbrella authority the key function of which will be the coordination of the market surveillance system. What is more, given the new regulatory framework on market surveillance in the EU, some preparations are made for respective amendments to the national regulatory framework.

Legal framework for the market surveillance system

It should be noted that Finland does not have a single legal instrument regulating market surveillance in all sectors (as there is no single market surveillance authority on the national level). Separate groups of products are subject to different special laws covering only that specific group. Additionally, areas relating to consumer products may also be subject to general consumer protection laws, e.g. where sector-specific regulation does not contain sufficient provisions relating to measures ensuring market surveillance[102].

In implementing the Regulation, Finland has adopted amendments to national law. The powers of market surveillance authorities were enhanced by adopting paragraph 36 of the Consumer Protection Act regulating the CE marking. The same Act also sets sanctions to be imposed on

[99] General Market Surveillance Programme for 2013, Finland [accessed on 24 February 2014]. Available online at http://ec.europa.eu/enterprise/policies/single-market- goods/files/market_surveillance/nmsp/fi_nmsp_2013_en.pdf.
[100] Website of Finland's Competition and Consumer Authority [accessed on 24 February 2014]. Available online at http://www.kkv.fi/Page/71661344-b9e9-49f2-bdc0-c533afea001a.aspx.
[101] 2013 02 13 Commission staff working document accompanying the report from the Commission to the European Parliament, the Council and the European economic and social Committee on the implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EC) No 339/93. Guidance papers on accreditation.
[102] General Market Surveillance Programme 2014, Finland, p. 4 (6) [accessed on 24 February 2014]. Available online at http://ec.europa.eu/DocsRoom/documents/161/attachments/1/translations/en/renditions/native.

economic operators for the improper use of the CE marking[103]. These sanctions are also regulated in the legal instrument on violations relating to the CE marking.

Market surveillance programmes

With a view to implementing the provisions of the Regulation and ensuring the effective functioning of the market surveillance system, the Finnish Ministry of Labour and the Economy drew up the first General Market Surveillance Programme for 2013. Before that this Member State had only had sector-specific market surveillance programmes (Finland has been drafting sector-specific programmes since the entry into force of the Regulation in 2010[104]). This is due to the practice of sector-specific market surveillance established in Finland. The General Programme complements and endorses the sector-specific market surveillance programmes.

The General Market Surveillance Programme of Finland describes the organisation and coordination of market surveillance in the Member State, the key market surveillance authorities, the planning and procedures of market surveillance, interinstitutional cooperation and the information exchange systems RAPEX and ICSMS. The General Market Surveillance Programme submitted by Finland in 2013 and the one submitted in 2014 differ little but the 2014 Programme contains an additional section describing the EU reform of the legal framework in the area of product safety and market surveillance.

The first General Market Surveillance Programme of Finland for 2013 sets out that the Commission has particularly explicitly expressed its wish that the Member States not only submit their sector-specific programmes but also general market surveillance programmes. In Finland's General Market Surveillance Programme for 2014 the market surveillance system is discussed insofar as it falls within the scope of the Regulation and the Directive. The Programme does not discuss, for example, the surveillance of foodstuffs as it is outside of the scope of the Regulation. The General Market Surveillance Programme also omits the surveillance of the safety of services as it is regulated exclusively by national law[105].

Cooperation

Finland's national market surveillance authorities actively cooperate both among themselves and with the authorities of the other EU Member States. Cooperation is bilateral and multilateral inter alia including joint market surveillance projects and exchanges of information. In its reports Finland also stresses cooperation of the authorities of the EU Member States within sector-specific Administration Cooperation Groups (ADCOs).

The Nordic countries have been cooperating among themselves in the area of market surveillance for a long time. Various cooperation programmes such as the Nordic Forum and the Nordic Project are promoted and supported by the Nordic Council of Ministers. This

[103] 2013 02 13 Commission staff working document accompanying the report from the Commission to the European Parliament, the Council and the European economic and social Committee on the implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EC) No 339/93. Guidance papers on accreditation.

[104] General Market Surveillance Programme 2014, Finland [accessed on 24 February 2014]. Available online at http://ec.europa.eu/DocsRoom/documents/161/attachments/1/translations/en/renditions/native.

[105] General Market Surveillance Programme 2014, Finland [accessed on 24 February 2014]. Available online at http://ec.europa.eu/DocsRoom/documents/161/attachments/1/translations/en/renditions/native.

organisation (also represented in Lithuania[106]) plays a crucial role in supporting also market surveillance projects dedicated to specific products in the Nordic countries. The purpose of the said programmes and projects is to exchange market surveillance and other information between the Nordic countries (Finland, Sweden, Denmark, Norway and Iceland) and to provide one another with any assistance necessary.

4.2. Netherlands

Market surveillance authorities of the Netherlands

The Dutch market surveillance system includes five main market surveillance authorities[107]. These authorities closely cooperate among themselves and with the customs authorities. The customs authorities in this country play a rather important role. The Kingdom of the Netherlands on a daily basis receives large quantities of imported goods not only from the EU Member States but also from other continents (e.g. Asia), which demands undivided attention to ensure the safety of products. For that reason the main focus in the Netherlands is on the maintenance and efficiency of continuous cooperation between market surveillance authorities proper and with the customs authorities, rapid exchange of information (e.g. RAPEX) and liaising with importers from third countries.

To implement these objectives, the Netherlands have the Alliance Working Group on product market surveillance and external border control. This formation does not enjoy an institutional status. It is a national coordination forum involving representatives of all market surveillance authorities and customs authorities[108]. The key objectives of the forum is to improve the dissemination of information, to share market surveillance strategies, tactics and knowledge and the actual practical cooperation between market surveillance and customs authorities.

As indicated in the Dutch General Market Surveillance Programme, the Netherlands have five market surveillance authorities[109]:

Dutch market surveillance authorities	
Authority	**Category of products under surveillance**
• Dutch Food and Consumer Products Authority (*Nederlandse Voedsel en Waren Autoriteit*)	General product safety, consumer goods, technical equipment, toys and cosmetic products
• Metrology Inspectorate (*Verispect*)	Metrological equipment
• Radio Communications Authority (*Agentschap Telecom*)	Radio equipment and electromagnetic compatibility
• Environment and Transport	Navigation equipment, recreational craft and

[106] Website of the Office of the Nordic Council of Ministers in Lithuania [accessed on 24 February 2014]. Available online at http://www.norden.lt/.
[107] National Product Market Surveillance Plan for 2013 and 2014, Netherlands [accessed on 25 February 2014]. Available online at http://ec.europa.eu/enterprise/policies/single-market-goods/files/market_surveillance/nmsp/nl- nmsp-2013-2014_en.pdf.
[108] 2013 02 13 Commission staff working document accompanying the report from the Commission to the European Parliament, the Council and the European economic and social Committee on the implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (ECC) No 339/93. Guidance papers on accreditation.
[109] National Product Market Surveillance Plan for 2013 and 2014, Netherlands [accessed on 25 February 2014]. Available online at http://ec.europa.eu/enterprise/policies/single-market-goods/files/market_surveillance/nmsp/nl- nmsp-2013-2014_en.pdf.

Inspectorate (*Inspectie Leefomgeving en Transport*)	railways
• Social Affairs and Labour Inspectorate (*Inspectie Sociale Zaken en Werkgelegenheid*)	Occupational safety equipment

In accordance with Article 17 of the Regulation, the Netherlands notified the Commission of eight market surveillance authorities[110]:

- Radio Communications Authority (Agentschap Telecom)
- Labour Inspectorate (Arbeidsinspectie)
- Health Inspectorate (Inspectie voor de Gezondheidszorg)
- Transport and Water Management Inspectorate (Inspectie Verkeer en Waterstaat)
- Food and Consumer Products Authority (Voedsel en Waren Autoriteit)
- Housing, Spatial Planning and Environment Inspectorate (VROM-Inspectie)
- National Road Authority (*Rijksdienst voor het wegverkeer*)

The above lists of the Dutch market surveillance authorities are presented in this Study as reference lists as the lists of market surveillance authorities officially published and notified to the Commission by the Netherlands and indicated in the General Market Surveillance Programme are obviously different.

Legal framework

The Netherlands do not have a single legal instrument regulating market surveillance. Product safety in this country is regulated by the Law on goods (*Warenwet*). The majority of the EU Directives regulating product safety is implemented by the Decree supported by the Law on goods (*Warenwetbesluit*). The Directive analysed in this Study is implemented by the Law on goods and the Decree on the general product safety[111].

A systematic examination of the Dutch General Market Surveillance Programmes for 2013 and 2014[112] shows that in the Netherlands the concept of product market surveillance only covers the market for non-food products as these instruments only refer to product market surveillance excluding foodstuffs, animal feeds, live plants or animals, products of human origin or plant and animal products relating to their subsequent reproduction. Product safety in the Netherlands is regulated by the Law on goods and goods solely refer to products and not services. As for the imports of goods, only producers and importers are referred to as their suppliers. All this leads to a conclusion that centralised market surveillance in the Netherlands includes only product market surveillance.

Cooperation

[110] Article 17 notification The Netherlands [accessed on 25 February 2014]. Available online at http://ec.europa.eu/enterprise/policies/single-market-goods/files/market_surveillance/nl_art_17_overzicht_markttoezichthouders_en.pdf.

[111] PROSAFE Information Publication "Who is who" in PROSAFE and EMARS [accessed on 27 February 2014]. Available online at http://www.prosafe.org/read_write/file/WHOS-WHO/The%20Netherlands.pdf.

[112] National Product Market surveillance Plan for 2013 and 2014, Netherlands [accessed on 25 February 2014]. Available online at http://ec.europa.eu/enterprise/policies/single-market-goods/files/market_surveillance/nmsp/nl- nmsp-2013-2014_en.pdf.

Wherever possible, the Dutch market surveillance authorities cooperate among themselves to reduce the burden on economic entities when performing surveillance functions. Economic operators explicitly attempting to improve their compliance can hope to be subject to reduced-intensity surveillance. In this case there are official agreements concluded between market surveillance authorities and economic entities stipulating partnership relations in ensuring the compliance of products with regulatory requirements[113].

The Netherlands specifically focus on the cooperation of market surveillance authorities with customs authorities. During the external border control checks, this cooperation takes many different forms depending on the nature and commercial volumes of products. The customs authorities notify market surveillance authorities of products to be imported that match risk criteria pre-set by surveillance authorities. This way the authorities can check products before they are placed on the national market. Questions relevant to imports of products are also discussed by market surveillance and customs authorities at the national discussions forum. This forum also ensures the continuous application of the Regulation on the national level. For example, it was that forum that examined and discussed the possibility of additional cooperation opportunities and joint projects between market surveillance authorities and authorities responsible for external border controls.

Because of large volumes of imports to the Netherlands, much attention is given in this country to its cooperation with third countries and their market surveillance authorities. The Netherlands maintain especially close relations with the Chinese market surveillance authorities to form a closed chain of the safety and surveillance of consumer products produced in China and exported to the EU. There is also an ongoing study of whether the online tool "Trade Route Asia" intended for supplying information to the EU importers developing business relations with China that imported consumer products must be compatible with the European Union legal requirements can also be used in other sectors of the market surveillance system[114].

Programmes

The Dutch Cabinet of Ministers has developed a national policy framework for the entire public governance supervision known as the Framework for Surveillance II. This vision also covering other market surveillance authorities lays down 6 key principles indispensable in the work of all surveillance authorities: selection, efficiency, cooperation, independence, transparency and professionalism. Market surveillance is based on risk assessment and seeks to affect the behaviour of a participant in the market surveillance system so as to encourage them to comply with legal requirements.

The Netherlands notified the EC of 6 sector-specific market surveillance programmes for 2014 and the general national market surveillance programme and plan for 2013 and 2014. The general programme offers an overview of the Dutch market surveillance system identifying specific authorities in charge of market surveillance and devotes much attention to a description of cooperation links with other authorities, customs and third countries.

[113] National Product Market Surveillance Plan for 2013 and 2014, Netherlands [accessed on 25 February 2014]. Available online at http://ec.europa.eu/enterprise/policies/single-market-goods/files/market_surveillance/nmsp/nl- nmsp-2013-2014_en.pdf.
[114] National Product Market Surveillance Plan for 2013 and 2014, Netherlands [accessed on 25 February 2014]. Available online at http://ec.europa.eu/enterprise/policies/single-market-goods/files/market_surveillance/nmsp/nl- nmsp-2013-2014_en.pdf.

4.3. Poland

Structure of market surveillance authorities

The national market surveillance system in Poland covers the performance of product controls and administrative procedures in respect of incompliant products subject to important, essential, specific and other requirements. On the national level the coordination of the market surveillance system is the responsibility of the Competition and Consumer Protection Authority. This Authority has the Advisory Committee for Market Surveillance involving representatives of market surveillance authorities and the Government.

The Competition and Consumer Protection Authority may be considered an umbrella market surveillance authority in Poland. The President of the Authority supported by the Market Surveillance Department is responsible for the national coordination of market surveillance authorities[115]. Apart from the Competition and Consumer Protection Authority, the following authorities[116] implement market surveillance in Poland:

Structure of the Polish market surveillance authorities		
Coordinating authority – Competition and Consumer Protection Authority (President and Market Surveillance Department)		
Other authorities	**Responsible officers/divisions**	**Categories of products under surveillance**
• Trade Inspectorate	Regional inspectors	
• Labour Inspectorate	National labour inspection authorities	Occupational safety, low voltage, pressurised equipment, lifts, etc.
• Electronic Communications Authority	President of the Authority	Radio communications and equipment compliance
• Environment Protection Inspectorate	Environment protection inspection authorities	Waste packaging and noise level in the environment
• Railway Transport Inspectorate	President of the Authority	Railway network, pressurised equipment, etc.
• Construction Surveillance Authority	Construction surveillance authorities	Construction products
• National Mining Authority	President of the Authority	Metrological equipment, machinery, protective equipment, etc.
• Independent Maritime Authority	Directors of maritime management authorities	Recreational craft, maritime installations
• Road Transport Inspectorate	Regional road transport inspectors	Portable pressurised equipment

[115] National Market Surveillance Programme for 2013 – General part, Poland [accessed on 27 February 2014]. Available online at www.uokik.gov.pl/download.php?plik=12738.

[116] List of contact details of market surveillance authorities (New Approach Directives) in Poland [accessed on 27 February 2014]. Available online at http://ec.europa.eu/enterprise/policies/single-market-goods/files/market_surveillance/pl_ms_authorities_art_17_en.pdf.

The role of the President of the Competition and Consumer Protection Authority in the Polish market surveillance system is central. He or she is responsible for the implementation of the following market surveillance functions[117]:

- Monitor and coordinate the market surveillance system (draw up reports) and cooperate with national market surveillance authorities and customs authorities
- Cooperate with the European Commission (e.g. when drafting national market surveillance programmes, participating in meetings of Administration Cooperation Groups (ADCOs) and other joint projects)
- Organise administrative procedures concerning unsafe (under Directive No 2001/95/EU) and incompliant (under the 12 New Approach Directives) products
- Draw up the market surveillance action (inspection) plan for the Trade Inspectorate
- Manage the national register of unsafe and incompliant products
- Act as a contact person for the exchange of information through RAPEX

As far as the functions of the Polish market surveillance system are concerned, the area of competence of the Trade Inspectorate is the broadest. The Trade Inspectorate in Poland is responsible not only for surveillance of non-food products but also supervises the market for food products and services[118]. The Trade Inspectorate performs market surveillance through regional voivodship inspectorates, and the Competition and Consumer Protection Authority controls and supervises all their activities.

To ensure efficient cooperation between market surveillance authorities, Poland established a special advisory consultative body, the Steering Committee for Market Surveillance. The Steering Committee for Market Surveillance consists not only of representatives of the above authorities but also the Minister for Finance (representing the customs authorities) and the Minister for the Economy (responsible for legislative issues relating to product safety)[119]. The main function of the Steering Committee for Market Surveillance is the exchange of information and tackling problems in the field of market surveillance.

Legal framework for the market surveillance system

The market surveillance system of Poland is defined by the Law on the conformity assessment system of 2002 and implementing by-laws. The implementation of these legal instruments is ensured by the President of the Competition and Consumer Protection Authority responsible for the control of market surveillance authorities. Moreover, product control and safety fall within the scope of the Law on product safety of 2003 applicable both to consumer and non-consumer products.

Cooperation

Regulation No 765/2008 lays down the objective of the cooperation of customs and market surveillance authorities, which, as claimed by the Polish Competition and Consumer Protection

[117] Market surveillance system of non-food products in Poland [accessed on 27 February 2014]. Available online at http://www.zapotrosace.rs/CMS/study-visit-to-poland/UOKiK_market_survaillance_ENG.ppt.
[118] Market surveillance and product safety. Activity report 2012 [accessed on 28 February 2014]. Available online at http://www.uokik.gov.pl/download.php?plik=13213.
[119] National Market Surveillance Programme for 2013 – General part, Poland [accessed on 27 February 2014]. Available online at www.uokik.gov.pl/download.php?plik=12738.

Authority in its 2012 activity report, is implemented by employing the following methods of cooperation[120]:

- The customs authorities contact certain sector-specific market surveillance authorities where they suspect that goods subject to customs procedures before their release for free circulation are incompatible with certain legal requirements
- Within 3 working days national market surveillance authorities are obliged to provide consultations (their opinion) to the customs authorities whether goods suspended from being released on the market meet legal requirements
- Where the said consultations are not provided, this means that the goods may be released for free circulation under the condition that they meet all related import requirements
- Should market surveillance authorities establish that products are incompliant, the customs authorities, where possible, seek that economic operators voluntarily eliminate those drawbacks in accordance with the existing legal regulation. However where a market surveillance authority establishes that in certain cases corrective actions cannot be taken, the customs authorities suspend the release of such products for free circulation
- In accordance with the national law the customs authorities are to inform the Competition and Consumer Protection Authority about actions taken by the customs authorities in respect of incompliant products
- The Polish customs authorities follow a risk-based approach when conducting market surveillance checks. Customs officers have a unique opportunity to access documents relating to imports from third countries. Data contained in customs declarations and accompanying documents are structured to enable purposeful checks of those groups of products, in particular, that present the greatest threat to consumers.

In fact, this procedure employed by the Polish customs authorities matches the procedure used by the Lithuanian customs authorities that is based on communications with market surveillance authorities to find out as quickly as possible whether certain goods are compatible with legal requirements and may be released. Upon receipt of the corresponding conclusion/consultation from market surveillance authorities, both Polish and Lithuanian customs authorities are authorised to take identical actions laid down: to release products or to suspend their release.

All regional customs offices have appointed so-called "coordinators for product safety". The key duties of these customs officers include the provision of assistance to officers conducting customs inspections, support to the central managing authority (the Ministry of Finance), risk analysis or helping to conduct risk analysis and help in coordinating actions of customs authorities and training customs officers. There is a noticeable systematic increase in the number of actions performed by customs authorities in the area of market surveillance and in the efficiency of these actions, which is confirmed by a significantly higher number of negative opinions issued by market surveillance authorities[121].

Programmes

[120] 2013 02 13 Commission staff working document accompanying the report from the Commission to the European Parliament, the Council and the European economic and social Committee on the implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EC) No 339/93. Guidance papers on accreditation.

[121] 2013 02 13 Commission staff working document accompanying the report from the Commission to the European Parliament, the Council and the European economic and social Committee on the Implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (ECC) No 339/93. Guidance papers on accreditation.

In 2013 and 2014 the Polish general market surveillance programmes[122] were drawn up in accordance with sector-specific control plans and priority areas identified by market surveillance authorities. The 2014 Programme mainly discusses the functioning of the non-food products control system (market surveillance system) relating to Community harmonisation legislation on the CE marking[123]. Like Finland, Poland's general market surveillance programmes for 2013 and 2014 are almost identical. In 2013 Poland notified its general market surveillance programme to the Commission in the Polish language. In 2014 it submitted the programme in English.

So, the Polish model of the market surveillance system is institutionalised. Poland has one authority coordinating market surveillance and one overarching national legal instrument regulating the market surveillance system. A special role in the market surveillance system is attributed to the President of the Competition and Consumer Protection Authority who is in charge of the performance of the majority of market surveillance functions.

4.4. Sweden

System of market surveillance authorities

The Swedish market surveillance system is unique in the sense that this country has a single specific umbrella authority in charge of the functioning, coordination and organisation of the market surveillance system. The main authority coordinating Sweden's market surveillance system is the Swedish Board for Accreditation and Conformity Assessment (SWEDAC reporting to the Ministry of Foreign Affairs and the Ministry of Enterprises, Energy and Communications). SWEDAC represents Sweden in meetings of the Commission's expert working parties dealing with market surveillance issues. This authority is also in charge of the presidency and secretarial functions in the Market Surveillance Council. The Market Surveillance Council consists of 15 representatives of market surveillance authorities and authorised representatives of the customs authorities and the National Chamber of Commerce.

In total, the Swedish market surveillance system covers about 20 public authorities and 290 municipalities[124]. Surveillance authorities have distributed their shared responsibility in the area of market surveillance by types and properties of products. The Decree on product market surveillance specifically identifies 15 public authorities directly responsible for market surveillance and reporting to nine ministries. These authorities and their areas of competence are presented in the table below:

Sweden's system of market surveillance authorities	
Coordinating authority – SWEDAC	
Other authorities	**Categories of products under surveillance**
• Swedish Authority for Work Environment	Personal protective equipment (intended for professional use), machinery and pressurised equipment

[122] National Market Surveillance Programme for 2013 – General part, Poland [accessed on 27 February 2014]. Available online at www.uokik.gov.pl/download.php?plik=12738.
[123] National Market Surveillance Programme for 2014 – General part, Poland [accessed on 27 February 2014]. Available online at http://ec.europa.eu/DocsRoom/documents/4432/attachments/3/translations/ns/renditions/native.
[124] Swedish Market Surveillance Plan, 2014 [accessed on 24 February 2014]. Available online at http://ec.europa.eu/enterprise/policies/single-market-goods/files/market_surveillance/nmsp/se-nmsp- 2014_en.pdf

• Swedish National Board for Housing, Construction and Planning	Construction products, observance of new efficiency requirements of hot water boilers, lifts
• National Board for Electric Safety	Electric equipment
• Swedish Energy Agency	Energy-related products
• Swedish Chemistry Agency	Hazardous substances and preparations, plant protection products and chemical products
• Swedish Consumer Agency	Toys, personal protective equipment (for personal use) and consumer products
• Medicinal Products Agency	Medical devices and cosmetics
• Swedish Environment Protection Agency	Waste electric and electronic equipment and elements
• Swedish Post and Telecommunications Authority	Radio and telecommunications equipment
• Swedish Radio and Television Authority	Electronic communications networks and services
• Swedish Civil Protection Agency	Explosives and gas equipment
• Swedish National Board for Health and Welfare	Medical devices
• Swedish Tax Agency	Cash registers
• Swedish Board for Accreditation and Conformity Assessment	Metrological equipment
• Swedish Transport Agency	Navigation equipment, farming and forestry tractors, trailers, systems, components and separate technical units

Apart from the above market surveillance authorities[125], Sweden also has the Swedish Consumer Agency in charge of the implementation of the Law (Act) on product safety which together with the Decree on product safety implements Directive No 2001/95/EC. The Swedish Consumer Agency is tasked with consumer protection covering market surveillance of consumer products unless a certain category of products is assigned to another market surveillance authority[126]. The Agency's area of competence also includes market surveillance not only of consumer products but also services in Sweden. The Swedish Consumer Agency is also the contact authority for the information exchange system RAPEX and conducts the coordination function for other market surveillance authorities connected to the RAPEX network.

The Swedish Board for Accreditation and Conformity Assessment (SWEDAC) and the Swedish Consumer Agency together participate in the activity of the Product Safety Forum (PROSAFE). The Swedish customs authorities and SWEDAC together participate in the activity of the Commission's expert working parties dealing with cooperation between customs and market surveillance authorities. SWEDAC and the National Chamber of Commerce together participate in the UN Working Party on Market Surveillance.

Legal framework for the market surveillance system

[125] Article 17 notification, Sweden. List of Swedish authorities with responsibility for market surveillance (Regulation 765/2008, article 17) [accessed on 28 February 2014]. Available online at http://ec.europa.eu/enterprise/policies/single-market-goods/files/market_surveillance/sw_article_17_notification_sweden_en.pdf

[126] PROSAFE Information Publication "Who is who" in PROSAFE and EMARS [accessed on 28 February 2014]. Available online at http://www.prosafe.org/read_write/file/WHOS-WHO/Sweden.pdf

The main legal instrument regulating the market surveillance system in Sweden is the Decree on product market surveillance. This Decree lists all authorities in Sweden in charge of market surveillance, the competence and functions of the Market Surveillance Council and transposes numerous provisions of the Regulation relating to the efficient enforcement of the functioning of the market surveillance system.

The market surveillance system in Sweden is also regulated by the Law (Act) on product safety and the Decree on product safety. These two legal instruments together transpose the provisions of Directive No 2001/95/EC on general product safety.

The adoption of the Regulation in Sweden triggered some amendments to legislation relating to the regulation of market surveillance. Market surveillance authorities and their responsibilities are defined in the Regulation on accreditation and the CE marking and the Law under the same title. In some sectors there was a need to approximate the Swedish law with the Regulation provisions. This resulted in amending legislation regulating market surveillance in certain sectors.

Sweden still is in the process of adjusting and approximating national legislation with the Regulation provisions. National legislation is updated, and at the same time the powers of market surveillance authorities are expanded. In the future the plan is to update the entire legal framework regulating the market surveillance system in Sweden to avoid any duplication or conflicts between national law and the Regulation[127].

Market surveillance programmes

In accordance with the Decree on product market surveillance, Sweden annually draws up general market surveillance programmes (plans). As set out in Sweden's General Market Surveillance Programme for 2013[128], those general programmes by no means affect sector-specific market surveillance programmes and reports to be submitted by market surveillance authorities in accordance with the Regulation, the Swedish Decree on product safety or as specially directed by the Swedish Government. Apart from the general programme, Sweden has notified to the Commission 12 sector-specific market surveillance programmes.

Sweden's annual general market surveillance programmes are comprehensive and adapted to significant shifts in the area of market surveillance. These programmes offer more than a generalised description of the country's market surveillance system. They also give an overview of the implementation of all market surveillance functions set in the Regulation. Sweden's general programmes identify topical issues and propose possible solutions.

Cooperation

Together with other Baltic States, Sweden belongs to the Baltic Sea Market Surveillance Network the purpose of which is to develop cross-border cooperation and information exchange

[127] 2013 02 13 Commission staff working document accompanying the report from the Commission to the European Parliament, the Council and the European economic and social Committee on the Implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EC) No 339/93. Guidance papers on accreditation.

[128] General Market Surveillance Programme 2013, Sweden [accessed on 24 February 2014]. Available online at http://www.marknadskontroll.se/sites/default/files/General%20Market%20Surveillance%20Plan%202013% 20final_0.pdf.

in the area of market surveillance of non-food products. The members of this Network are Sweden, Finland, Denmark, Lithuania, Latvia, Estonia, Poland and three federal lands in Germany bordering the Baltic Sea (Hamburg, Mecklenburg-Western Pomerania and Schleswig-Holstein). This cooperation network is supported by the Nordic Council of Ministers. Efficient cooperation and rapid information exchange between institutions should prevent imports of unsafe products. This would not only enhance consumer safety but also help to protect the closely interrelated economies of the Baltic States from distorted competition[129].

As of 2010 the Swedish Market Surveillance Council has an internal system used for information exchange between authorities and for joint management of documents and projects. This internal information exchange system is managed by SWEDAC.

Sweden stands out in the sense that it has a single specific authority actively coordinating national market surveillance authorities and promoting interinstitutional cooperation and exchange of information. The Council established in Sweden specifically for the purpose of market surveillance organises various seminars and courses in the area of market surveillance which are very popular among representatives of various authorities.

SUMMARY

- The countries examined in this Chapter of the Study (Finland, the Netherlands, Poland and Sweden) have different market surveillance systems both in terms of the market surveillance model and by number of market surveillance authorities:
  - Finland's market surveillance system is explicitly sector-specific where individual authorities are in charge of market surveillance in each sector;
  - the Netherlands have five market surveillance authorities;
  - Poland has one coordinating market surveillance authority;
  - Sweden has a specific authority in charge of the functioning, coordination and organisation of the market surveillance system as well as the Council established for the purpose of market surveillance.

- As far as coordination is concerned, there are two main models in these countries:

1. Institutionalised model where there is one main authority coordinating market surveillance;
2. Non-institutionalised model where fora, committees, commissions or councils are established for the coordination of market surveillance. The institutionalised model is in place in Poland and Sweden while Finland and the Netherlands employ the non-institutionalised market surveillance model.

- All the four EU Member States described in the Study draw up and notify to the Commission their general national market surveillance programmes. Three countries, except for Poland, have also notified sector-specific market surveillance programmes.

- These countries specifically focus on the implementation of cooperation functions both nationally and internationally. For example, the Nordic

[129] Cooperating with the Baltic Sea States on consumer safety [accessed on 24 February 2014]. Available online at http://www.hamburg.de/baltic-sea-network/125334/ostsee-netzwerk-englisch.html.

countries have the Nordic Forum supported by the Nordic Council of Ministers, and these states also belong to the Baltic Sea Market Surveillance Network. In the Netherlands market surveillance authorities cooperate with customs authorities, and there are official agreements concluded between market surveillance authorities and economic entities establishing partnership relations for the purpose of ensuring the compliance of products with legal requirements. A special advisory consultative committee was established in Poland in order to ensure efficient cooperation between market surveillance authorities on the national level.

V. KEY CONCLUSIONS AND SUGGESTIONS

5.1. Key conclusions

CONCLUSIONS

- EU legal requirements to non-food and food products and their safety are regulated by a number of legal instruments. The Regulation and the Directive analysed by the Study only regulate matters relating to safety and market surveillance of non-food products. Service safety is not at all regulated on the EU level. The Directive only applies to non-food consumer products while the Regulation applies to all non-food products subject to Union harmonisation legislation. Where the Directive sets out "more specific" market surveillance functions, the provisions of the Directive apply. The area of non-consumer (professional) products not subject to Union harmonisation legislation is not at all regulated on the EU level.

- Such duplication and fragmentation of EU legislation create confusion both to economic operators and to public authorities. Proposals for a Regulation on market surveillance of products and a Regulation on consumer product safety seek to streamline the existing fragmented market surveillance system for product safety. The new framework would provide for a clear market surveillance mechanism, a clearer product control system and an unambiguous system for the exchange of information. Following the entry into force of the new framework, there will be a need to revise Lithuanian legislation relating to product market surveillance and introduce regulatory amendments.

- The functions of the market surveillance system listed in the Directive and the Regulation can be divided into two groups by the nature of those functions:
  - systematic functions, i.e. more general functions relating to general policy-making in the area of market surveillance;
  - specific market surveillance functions, i.e. functions relating to the application of specific market surveillance measures and oriented towards market surveillance authorities.

- In Lithuania market surveillance of non-food products is regulated by the Product Safety Law and special laws laying down specific product safety and market surveillance requirements. The mechanism established in the Product Safety Law is not sufficiently clear as the Law does not define market surveillance and

does not present an exhaustive list of authorities carrying out market surveillance of product safety. As the Product Safety Law only applies to consumer products, where no special laws are in place, the safety of certain non-consumer products may stay out of control. Such legal techniques where authorities are authorised to apply market restriction measures or sanctions by by-laws are defective. Although the Regulation lays down basic provisions pertaining to the product market surveillance mechanism and is implemented in Lithuania, it is not referred to in the market surveillance legislation of Lithuania as the EU legislation implemented thereby.

- Legislation does not contain an approved and exhaustive list of market surveillance authorities. Individual laws do not list specific authorities as market surveillance authorities either. Given the concept of market surveillance defined in the Regulation and the provisions of the Lithuanian legal framework, the following authorities are identified in Lithuania as market surveillance authorities for non-food products:
  - State Non-Food Products Inspectorate under the Ministry of the Economy
  - State Healthcare Accreditation Agency under the Ministry of Health
  - Lithuanian Maritime Safety Administration
  - Communications Regulatory Authority of Lithuania
  - State Road Transport Inspectorate under the Ministry of Transport and Communications
  - Lithuanian Metrology Inspectorate
  - Radiation Protection Centre
  - State Labour Inspectorate of Lithuania under the Ministry of Social Security and Labour
  - Environment Protection Agency
  - State Consumer Rights Protection Authority
  - Customs Department under the Ministry of Finance of Lithuania participating in the market surveillance system (although it is not deemed a market surveillance institution).

- An examination of the legal framework of non-food product controls shows that in the area of non-food consumer products the VNMPI is to be treated as an "umbrella" market surveillance authority (except for products regulated by special legislation for which market surveillance is carried out by other authorities), which should help to avoid "grey areas", i.e. cases where the safety of non-food consumer products is not controlled by any market surveillance authority. However, to avoid doubts in respect of the treatment of the VNMPI as an "umbrella" market surveillance authority for non-food products, there is a need to ensure proper regulation of the VNMPI's competence by a law. In the area of non-consumer (professional) non-food products, there is no single or "umbrella" regulatory framework as there is no "umbrella" market surveillance authority for non-consumer products (where the safety of individual products is supervised by individual authorities within their remit).

- The legal framework laying down the coordination function of the product safety and market surveillance system is defective, which means that there is a need to improve it by clearly defining and aligning the competences of both the ministries involved in the process and market surveillance authorities, at the same time establishing a model for their prospective cooperation (activity coordination) helping to

ensure the management of the product safety and market surveillance area.

- The lacking clarity of the EU framework also creates confusion or causes the improper implementation of functions in the national law. In fact, the Regulation is properly implemented in Lithuania but there are certain drawbacks of legal regulation identified. The implementation of the systematic functions of the market surveillance system is not directly assigned by law to any public authority although certain systematic functions are performed by the Ministry of the Economy. Some specific functions of the market surveillance system laid down in the Regulation in respect of the examination of complaints concerning products and alerting users of hazards are properly implemented in the national law. Other specific functions of the market surveillance system defined in the Regulation are characterised by the following main defects in legal regulation:
  - in some cases certain provisions need to be stipulated by a law (concerning the obligation to cooperate, the obligation to accumulate scientific and technical knowledge and the right to impose restrictive measures)
  - in some cases there is a need to clearly define the obligation for market surveillance authorities to perform certain functions (monitoring of accidents and harm to health as well as checks of products)
  - in some cases there is a lack of more detailed regulation (there is a need to adopt respective procedures and rules).

- Some specific functions of the market surveillance system defined in the Regulation in respect of the imposition of sanctions for the improper use of the CE marking; in respect of the examination of complaints concerning products; alerting users of hazards; the imposition of market restriction measures and sanctions for violations of product safety requirements need a comprehensive factual and procedural analysis with a view to establishing whether a certain market surveillance function is properly implemented in the national law.

- Lithuania does not have either a list of market surveillance authorities for services or criteria as to which authorities should be deemed market surveillance authorities for services. Given that the safety control of products and services is inextricably linked, a formal separate list of market surveillance authorities for services is not needed.

5.2. Suggestions

5.2.1. Circumstances affecting suggestions

It should be noted that several significant circumstances affect the implementation of the suggestions proposed in this Section of the Study.

First, when implementing suggestions relating to the market surveillance system, it is important to take into account and examine them in the context of the recent study commissioned by the Ministry of the Economy for drafting a consolidation plan for the activities of authorities supervising the activity of economic entities. The said study was to examine the following key issues: a revision and analysis of the functions of surveillance authorities and recommendations

and the implementation plan of the consolidation model. Thus, its results will affect the proper implementation of the suggestions given in this Study as this Study relates to the competences assigned to respective public authorities which in accordance with the said study may later be merged.

However, even though one of the objects for drafting the consolidation plan for the activities of authorities supervising the activity of economic entities was recommendations on the consolidation of surveillance authorities, it should be noted that even if some surveillance authorities are merged or dissolved, the suggestions given in this Study remain relevant because this Study has focused on evaluating whether the functions defined in the Regulation for market surveillance authorities are properly implemented in the Lithuanian law. Therefore, irrespective of any changes in the system of market surveillance authorities, the functions defined in the Regulation must be implemented properly and efficiently.

Second, the proper implementation of the suggestions will also be influenced by the adoption of the proposal for a Regulation on market surveillance of products and the proposal for a Regulation on consumer products safety. Chapter 2.4 of the Study has provided a comprehensive overview of the new framework proposed and discussed a possible need for revising the national framework following the adoption and entry into force of the said proposals. It should be noted that the unclear or ever-changing legal framework in the EU also causes a certain lack of clarity in the national legislation. Obviously, when preparing amendments to legal regulation of a certain area on the EU level, it is inefficient to amend the national regulation while the new legal framework in the EU is not yet adopted. Should the said Regulations be approved, the suggestions given in the Study will have to be adjusted and aligned with the new regulatory framework. However it should be noted that if the adoption of the said proposals takes time, a revision of the national law could be considered without waiting for the adoption of the aforementioned Regulations.

5.2.2. Suggestion on the proper implementation of the coordination function of the market surveillance system

As discussed in Section 3.2.1 of the Study, the stipulation of the market surveillance coordination function in legislation and its actual implementation give rise to certain practical concerns.

First, there is a need to deal with the matter of which minister (ministry) (the Ministry of the Economy or the Ministry of Justice) is to be in charge of the policy-making and, accordingly, coordination function in the area of product safety and market surveillance.

On the other hand, consideration could also be given to the option where functions are shared between the two Ministries, and those functions are clearly and precisely defined and separated. In any case, when dealing with the matter of the assignment of the policy-making function in the field of product safety and market surveillance, there is a need to take into account that the VVTAT and the VNMPI fall within the competence areas of different Ministries (Ministers).

Second, a decision needs to be made as to the content of the coordination function and the granting of respective powers to a specific authority. This authority should also be given the systematic functions of the market surveillance system.

Third, a decision needs to be made whether all areas (products, services and food products) should be coordinated jointly, or whether such common coordination is not needed given the specific nature of these areas, and at least the safety and market surveillance of food products should be coordinated separately by the coordinating authority.

Fourth, a decision needs to be made on the clear incorporation of service market surveillance in the overall market surveillance system (and its coordination) by setting which authorities are in charge of market surveillance of the safety of products, which – of products and services and which – only of services. Although the formal separation of market surveillance authorities for products and for services is not needed, it is necessary to lay down criteria based on which an authority can be considered a service market surveillance authority.

It should be stressed that given the experience of the EU Member States examined in this Study, the coordination model for product safety and market surveillance could be dual: first, the institutionalised model where the coordination function of the market surveillance system belongs to an "umbrella" authority making the policy; second, the non-institutionalised model where the coordination function is assigned to a pro bono entity (a council, a committee, a forum established specifically for that purpose, etc.).

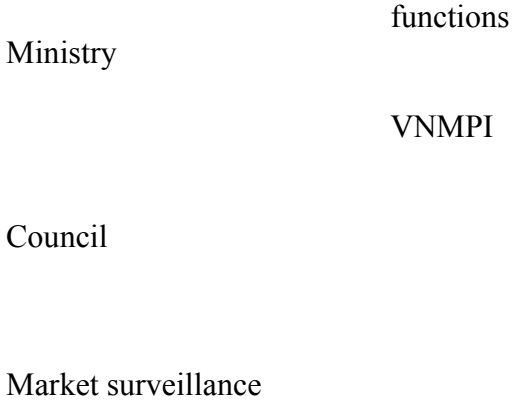
When deciding on the model, it is also important to decide whether that model will only cover the interaction of market surveillance authorities or whether the implementation of the coordination function will also involve representatives of consumer and business organisations. In this case, there may also be several options where, first, business and consumer organisations are involved in the non-institutionalised entity, or, second, where cooperation with these entities is ensured on the basis of other principles such as e.g. by signing cooperation agreements, establishing separate working parties for dealing with specific issues, coordinating matters (draft legislation) in accordance with the procedure laid down in the Rules of Procedure of the Government, etc.

It should be noted that all models are acceptable if their proper implementation is ensured. However, given that Lithuania does not have an explicit "umbrella" authority making the policy, the initial stage could be the implementation of a non-institutionalised coordination mode of the market surveillance system, later possibly followed by considering the institutionalised model.

Moreover, as mentioned before, it is necessary to decide whether the market surveillance coordination model should cover all the areas (non-food products, food products and services). Therefore, below we present two alternative suggestions: *Option I* where the overall coordination of the market surveillance system does not cover the coordination of food products safety, and *Option II* where the coordination of the market surveillance system also includes the coordination function of food products safety. No separate model is proposed for a market surveillance system for services as, given the existing situation, the non-food products system should apply to services.

Option I. *The coordination function does not cover coordination of food products safety*

Coordinating authority	Implementation of systematic



In accordance with the chart presented above, the proposal is to assign the market surveillance coordination function to one coordinating authority – a ministry (and the legislator is to decide whether these functions are to be undertaken by the Ministry of the Economy or the Ministry of Justice). Relevant provisions should be directly stipulated in a law and imply that the Ministry is in charge of the market surveillance policy making and coordinates the Lithuanian market surveillance system on the policy-making level. This would also mean that the Ministry would be charged with the implementation of the systematic market surveillance functions identified and analysed in the Study.

Accordingly, in the case of this model the authority implementing the market surveillance policy would be the VNMPI. A separate advisory body of the Ministry, the Council, would contribute to the proper implementation of the coordination function of the market surveillance system. The Council's structure, competence and rights should be stipulated in a law.

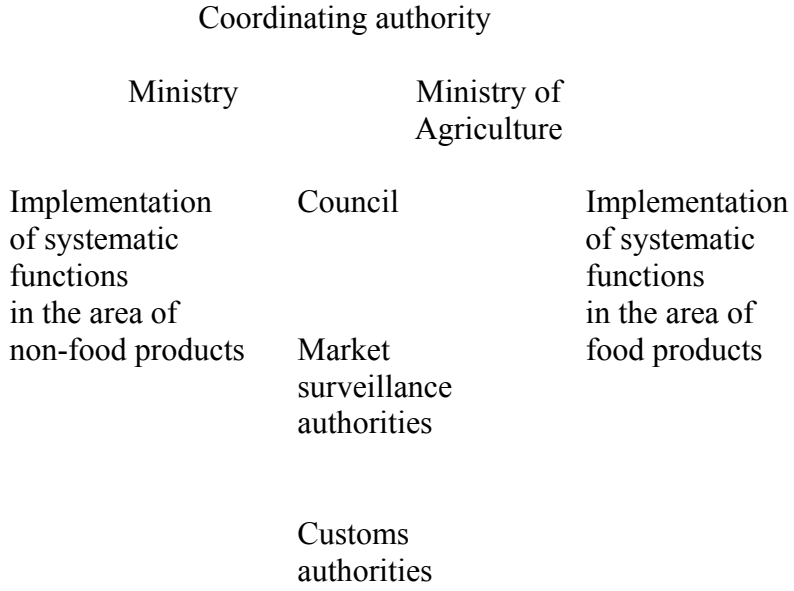
The Council could consist of representatives of certain market surveillance authorities whose main function when participating in the activity of the Council would be to advise the Ministry on various market surveillance matters. In this case it is particularly important to ensure that the Council acts in accordance with clear pre-defined rules (both stipulated in a law and those laid down in its Regulations and the Rules of Procedure), i.e. it is important that there is a specific schedule of meetings of the Council members, that meetings are duly prepared for and that the members' competence, rights and duties, the decision-making procedure and clear controls are also established. Furthermore, it is important to ensure the proper organisation of the Council's activity relating to the financing of that activity. It should be noted that if the implementation of the latter aspects is not duly ensured, the Council's activities will only be hypothetical and have no real impact. What is more, it will only be seen as an unnecessary additional encumbrance.

The Council's functions could be grouped as follows:

- to submit proposed solutions to problems facing market surveillance authorities to the Ministry;
- to submit proposals on how to improve the market surveillance system and its legal regulation to the Ministry;
- to structure and analyse information on the market surveillance system collected and regularly received from market surveillance authorities;

- to create "good practices" in the area of market surveillance and to standardise processes;
- to establish working parties and commissions for drafting specific proposals and/or tackling specific issues;
- to communicate with organisations representing interests of businesses and consumers;
- to perform other functions.

Option II. *The coordination function also includes coordination of food products safety*



This chart shows the proposed implementation model of the coordination function of the market surveillance system covering safety and market surveillance of products, services and food products. As mentioned before, if a decision is made that a part of the market surveillance system relating to the regulation of safety and market surveillance of food products should be coordinated separately, the suggestion is that two main coordinating and policy-making authorities are appointed in the field of market surveillance. In this case the Ministry of the Economy or the Ministry of Justice would be the main authority coordinating market surveillance of products and services while the Ministry of Agriculture would be the authority coordinating market surveillance of food products. Each Ministry would be accordingly in charge of their specific areas of the market surveillance system and of the implementation of the systematic functions in those areas. Although, as specified in the Study, the Regulation does not apply to market surveillance of food products, the systematic market surveillance functions established therein could also apply to market surveillance of food products ensuring as efficient a functioning of the system as possible.

It should also be noted that this model would also need an advisory body (the Council). The Council would be subject to the same requirements as those discussed under the first model. However in this case the Council would be an advisory body to both coordinating authorities (the Ministry of the Economy or the Ministry of Justice and the Ministry of Agriculture), i.e. these authorities would share the function of managing the Council and organising its activities. Such nature of the Council's activities implies that in this case the Council would consist of a much larger number of representatives of market surveillance authorities. This may raise concerns about efficient organisation of the Council's work.

As mentioned previously, in the event of both models being employed, the important coordinating role of the market surveillance system would go to the Council. In this case it should be stressed that the Council could also act on the basis of two alternative models:

Alternative I

Council

Coordinates activities
of market surveillance authorities

In this case the Council only focuses on the coordination of activities of market surveillance authorities. This means that it only deals with matters that directly affect market surveillance authorities proper.

Alternative II

Council

Coordinates activities of market surveillance authorities | Consumers | Business

In this case the Council's activity focuses not only on the activity of market surveillance authorities and its coordination but also covers certain approximation of interests in the area of market surveillance with consumers and business representatives. This model is especially important where the market surveillance system affects third parties. Still, it is obvious that in this case, should the Council's competence be expanded like this, its composition would also be much broader. This would make work organisation more difficult and may raise concerns about the efficiency of the Council's work. Therefore, in the case of this model, particular focus should be placed on the proper preparation for the Council's work.

5.2.3. Suggestions for the implementation of certain functions identified and analysed in the Study

Given the analysis of the systematic and market surveillance functions offered in the Study, below are some structured suggestions concerning the proper regulation of these functions. The suggestions are presented depending on what level (a law or by-laws) they need to be regulated.

The following needs to be regulated in a law:

- there is a need to clearly set out by compiling an exhaustive list which specific authorities are entitled to impose market restriction measures under the Product Safety Law and participate in the mechanism of sanctions established in the Product Safety Law;
- a specific public authority needs to be tasked with the monitoring function of product safety and market surveillance (which could be laid down as part to the system coordination function), also defining the content of the coordination function;
- there is a need to establish an obligation for market surveillance authorities to draw up both national and sector-specific programmes establishing also a period of time for which the programmes are drafted and their interrelations;
- the contents of sector-specific and national programmes are to be made uniform, i.e. the same requirements are to be laid down and apply to all market surveillance authorities in respect of the scope and nature of information included in the market surveillance programme; uniform implementation practices of such programmes and cooperation of market surveillance authorities when implementing the programmes also need to be ensured;
- there is a need to establish an obligation for a specific authority to inform/educate the public about market surveillance authorities and their duties;
- there is a need to establish an obligation for a specific authority to notify the EC of national market surveillance authorities and their areas of competence and to submit other notifications and information to the EC;
- there is a need to clearly defined the functions of market surveillance authorities relating to their cooperation with market surveillance authorities of the other EU Member States and third countries;
- certain market surveillance authorities are authorised to impose specific restrictive measures by stipulating this in special laws regulating activities of market surveillance authorities (unless a decision is adopted to consolidate the powers of authorities under one law on market surveillance);
- there is a need to establish by law the function of a specific authority to collect scientific and technical knowledge relating to safety (with more detailed rules for the performance of that function being laid down in by-laws);
- there is a need to directly provide for an obligation of a market surveillance authority to conduct checks of products and to enable it to set detailed procedures on checks in by-laws (where the essential rules are laid down in laws and by-laws approve specific procedures or rules for checking products);
- there is a need to clearly define obligations of market surveillance authorities in cooperating with the CD as well as rights of economic entities subjected to checks and the procedure for disputing decisions made or conclusions offered by the CD and/or market surveillance authorities;
- there is a need for clear regulation of the legal meaning and legal consequences of cooperation agreements between the customs authorities and market surveillance authorities (should the cooperation agreement model be opted for);

- there is a need for a clear system regulating sanctions applicable for violations of market surveillance legislation, also handling the matter of sanctions to be imposed under specific laws and the Administrative Infringements Code);
- there is a need to establish an obligation of market surveillance authorities to participate in the RAPEX and ICSMS systems by setting this out in detail in legislation regulating their activities.

The following needs to be regulated in by-laws:

- for the purpose of standardising the function of cooperation between the customs and market surveillance authorities, there is a need to draft a standard agreement between the customs and market surveillance authorities;
- there is a need to improve the legal framework on monitoring of accidents and harm to health relating to products setting special obligations for market surveillance authorities in rules for exchange of information on hazardous products and related accidents;
- there is a need for a detailed implementation procedure for the function of the accumulation of scientific and technical knowledge in the area of safety.

5.2.4. Individual suggestions for the implementation of certain functions or solution to certain problems identified and analysed in the Study

On a clear and exhaustive list of Lithuania's market surveillance authorities

Following a revision of the hierarchic legal system regulating product safety in Lithuania, there is a need to clearly state which authorities are to be deemed market surveillance authorities in Lithuania and how they participate in market surveillance processes, the safety of which products and services they control and what rights and powers they have in these product control processes. *The right* of any market surveillance authority to impose specific market restriction measures and/or sanctions should be enshrined in laws giving clear reference what other law sets the amount of sanctions and the procedure for the imposition of restrictive measures (unless these are set in the same law empowering authorities to impose sanctions or restrictive measures). This common list of market surveillance authorities should include market surveillance authorities for services.

Given that the list of market surveillance authorities implementing the Regulation notified to the European Commission on 30 December 2009 does not match the current situation (as some of those authorities no longer exist or are merged with other authorities), as soon as the exhaustive list of market surveillance authorities is adopted, the updated list of authorities implementing the Regulation should be notified to the European Commission.

Establishing a cooperation mechanism between national market surveillance authorities and between national market surveillance authorities and authorities in charge of external border controls

Given the two key problems discussed in the Study in relation to cooperation agreements: (i) an unclear legal value of cooperation agreements; (ii) no standard practices of drafting cooperation agreements, below are proposed solutions:

Solution 1. A law should lay down the basic principles of cooperation agreements between these authorities, and the ministry coordinating activities of market surveillance authorities (the

Ministry of Justice and/or the Economy) is obliged to approve a cooperation agreement template between authorities. A law also sets out that such interinstitutional agreements have legislative power and are disputed in accordance with the statutory procedure, i.e. by administrative proceedings.

Solution 2. To do away with the practice of concluding agreements. In this case a law should stipulate the obligation for the Government to draft and approve certain good practice rules on interinstitutional cooperation. These rules would be binding on authorities reporting to the Government. In this case authorities would not sign individual mutual cooperation agreement but rather act in accordance with the binding mutual cooperation principles laid down in the said rules, which would be binding on everyone. In this case the institution coordination the market surveillance system could establish a certain control mechanism, i.e. to oblige authorities together with their activity reports to provide the coordinating authority with reports showing how the cooperation of each authority meets the approved good practice rules on interinstitutional mutual cooperation. The coordinating authority would be able to summarise those reports and evaluate interinstitutional cooperation. This method seems to be more acceptable as it would not only tackle the issue of the standardisation of agreements but would also clarify the legal meaning of such cooperation.

Properly ensuring the administration of RAPEX and ICSMS and the VNMPI's competence

Given the information exchange problems relating to how information exchange on hazardous non-consumer products is ensured as discussed in the Study, below are alternative ways to improve the legal framework:

Solution 1. The VVTAT's competence in the area of RAPEX is expanded setting out that the VVTAT is a liaison authority for RAPEX transmitting notifications not only on consumer products but also on non-consumer products.

Solution 2. The functions of the RAPEX liaison authority are entrusted to the VNMPI as based on the statistics presented in the Study, this authority receives the disproportionately largest number of RAPEX notifications from other countries (as compared to other authorities), and, what is more, the VNMPI also issues such notifications itself. In this case the VNMPI's competence would also be expanded accordingly:

- enabling it to participate in market surveillance of non-consumer products only on the basis of RAPEX;
- given the proposal presented at the end of Chapter 3.1 of the Study, to expand the VNMPI's competence also to cover "grey areas" of non-consumer products, i.e. areas and products not falling within the control of any specific authority.

VI. LIST OF REFERENCES

6.1. National legislation

6.1.1. Laws (as amended)

1. Constitution of the Republic of Lithuania (*Lietuvos Aidas*, 1992, No 33-1014);
2. Code of Administrative Infringements of the Republic of Lithuania (*Official Gazette*, 1985, No 1-1);
3. Civil Code of the Republic of Lithuania (*Official Gazette*, 2000, No 74-2262);
4. Road Transport Code of the Republic of Lithuania (*Official Gazette*, 1996, No 119-2772);
5. Law of the Republic of Lithuania on environment protection (*Lietuvos Aidas*, 1992, No 5-75);
6. Law of the Republic of Lithuania on conformity assessment (*Official Gazette*, 1998, No 92-2542; 2011, No 40-1919);
7. Law amending the Law of the Republic of Lithuania on conformity assessment (*Official Gazette*, 2011, No 40-1919);
8. Law of the Republic of Lithuania on electronic communications (*Official Gazette*, 2004, No 69-2382);
9. Law of the Republic of Lithuania on pharmaceuticals (*Official Gazette*, 2006, No 78-3056);
10. Law of the Republic of Lithuania on food (*Official Gazette*, 2000, No 32-893);
11. Law of the Republic of Lithuania on metrology (*Official Gazette*, 1996, No 74-1768; 2006, No 77-2966);
12. Law of the Republic of Lithuania on customs (*Official Gazette*, 2004, No 73-2517);
13. Law of the Republic of Lithuania on services (*Official Gazette*, 2009, No 153-6901);
14. Law of the Republic of Lithuania on the supervision of potentially dangerous installations (*Official Gazette*, 1996, No 46-1116; 2000, No 89-2742);
15. Law of the Republic of Lithuania on product safety (*Official Gazette*, 1999, No 52-1673; 2001, 64-2324);
16. Law of the Republic of Lithuania on radiation protection (*Official Gazette*, 1999, No 11-239);
17. Law of the Republic of Lithuania on maritime safety (*Official Gazette*, 2000, No 75-2264; 2005, No 31- □974);
18. Law of the Republic of Lithuania on standardisation (*Official Gazette*, 2000, No 35-972; 2007, No 39-1435);
19. Law of the Republic of Lithuania on construction (*Official Gazette*, 1996, No 32-788; 2001, No 101-3597);
20. Law amending Articles 1, 2, 4, 5, 6, 8, 10, 11, 12, 16, 18, 18-1, 29, 36, 39, 40, 41, 43-1 and 47 of and Annex 2 to the Law of the Republic of Lithuania on construction (*Official Gazette*, 2013, No 68- □3415);
21. Law of the Republic of Lithuania on healthcare establishments (*Official Gazette*, 1996, No 66-1572; 1997, □No 62-1462; 1998, No 109-2995);
22. Law of the Republic of Lithuania on the healthcare system (*Official Gazette*, 1994, No 63-1231; 1998, No 112- □3099);
23. Law of the Republic of Lithuania on the fundamentals of the legislature (*Official Gazette*,

2012, No 110-5564);
24. Law of the Republic of Lithuania on the right to receive information from state and municipal authorities and bodies (*Official Gazette*, 2000, No 10-236; 2005, No 139-5008);
25. Law of the Republic of Lithuania on the State Labour Inspectorate (*Official Gazette*, 2003, No 102-4585);
26. Law of the Republic of Lithuania on consumer rights protection (Law of the Republic of Lithuania on consumer rights protection) (*Official Gazette*, 1994, No 94-1833; 2000, No 85-2581; 2007, No 12-488);
27. Law amending the Law of the Republic of Lithuania on consumer rights protection (*Official Gazette*, 2007, No 12-488);
28. Law of the Republic of Lithuania on public administration (*Official Gazette*, 1999, No 60-1945; 2006, No 77-2975).

6.1.2. By-laws

6.1.2.1. Resolutions of the Government

1. Resolution No 921 of the Government of the Republic of Lithuania of 23 July 1998 approving the Regulations of the Ministry of the Economy of the Republic of Lithuania (*Official Gazette*, 1998, No 67-1957);
2. Resolution No 1482 of the Government of the Republic of Lithuania of 27 December 1999 appointing institutions authorised to approve binding product safety requirements (*Official Gazette*, 1999, No 114-3304);
3. Resolution No 505 of the Government of the Republic of Lithuania of 4 May 2000 on the reorganisation of market surveillance authorities (*Official Gazette*, 2000, No 38-1064) Resolution No 1029 of the Government of the Republic of Lithuania of 19 August 2004 approving the Regulations of the Communications Regulatory Authority of the Republic of Lithuania (*Official Gazette*, 2004, No 131-4734);
4. Resolution No 744 of the Government of the Republic of Lithuania of 28 June 2000 approving the Regulations of the State Food and Veterinary Service (*Official Gazette*, 2000, No 53-1537);
5. Resolution No 1103 of the Government of the Republic of Lithuania of 13 September 2001 approving the procedure for taking and paying for product samples (*Official Gazette*, 2006, 136 -5175);
6. Resolution No 439 of the Government of the Republic of 2 April 2002 approving the procedure for the application of restrictions on marketing of products (approving the rules for the application of restrictions on marketing of products) (*Official Gazette*, 2002, No 35-1307; 2004, No 177-6547) (as amended by Resolution No 927 of 21 September 2006 (*Official Gazette*, 2006, No 102-3951) and Resolution No 585 of 23 May 2012 (*Official Gazette*, 2012, No 61-3074));
7. Resolution No 1253 of the Government of the Republic of 9 October 2003 on checks of imported goods with a view to establishing their compliance with product safety requirements (*Official Gazette*, 2003, No 97 -4346);
8. Resolution No 359 of the Government of the Republic of 11 April 2007 changing the name of the National Consumer Rights Protection Council under the Ministry of Justice and approving the Regulations of the State Consumer Rights Protection Authority (*Official Gazette*, 2007, No 44-1680);
9. Resolution No 875 of the Government of the Republic of 22 August 2007 approving the rules for the examination of personal requests and service of persons by public

administration authorities and bodies and other public administration entities (*Official Gazette*, 2007, No 94- 3779);

10. Resolution No 1097 of the Government of the Republic of 17 October 2007 approving the procedure for the monitoring of public administration entities and their activities (*Official Gazette*, 2007, No 110-4499);
11. Resolution No 61 of the Government of the Republic of 23 January 2008 approving the procedure for the provision of information on consumer protection to the State Consumer Rights Protection Authority (*Official Gazette*, 2008, No 13-442);
12. Resolution No 790 of the Government of the Republic of 22 July 2009 approving the rules for information exchange on dangerous products and related accidents (*Official Gazette*, 2009, No 90-3860);
13. Resolution No 511 of the Government of the Republic of 4 May 2010 on the optimisation of surveillance functions of authorities (*Official Gazette*, 2010, No 53-2613; 2011, No 92-4374; 2012, No 89-4657);
14. Resolution No 826 of the Government of the Republic of 21 June 2010 approving the Regulations of the Weaponry Fund of the Republic of Lithuania under the Ministry of the Interior of the Republic of Lithuania (*Official Gazette*, 2010, No 77-3920);
15. Resolution No 244 of the Government of the Republic of 23 February 2011 approving the reorganisation and the reorganisation conditions of the State Tobacco and Alcohol Control Service under the Government of the Republic of Lithuania and the Drug Control Department under the Government of the Republic of Lithuania and approving the Regulations of the Drug, Tobacco and Alcohol Control Department (*Official Gazette*, 2011, No 28-1331).

6.1.2.2. Instructions and order of Ministries and other bodies

1. Order No D1-385 of the Minister for the Environment of the Republic of Lithuania of 14 July 2004 approving the Regulations of the Environmental Protection Agency (*Official Gazette*, 2004, No 115-4310);
2. Order No 171 of the Minister for Finance of the Republic of Lithuania of 10 July 1998 approving the Regulations of the Customs Department under the Ministry of Finance of the Republic of Lithuania (*Official Gazette*, 1998, No 64-1861; 2004, No 98-3652);
3. Order No 1V-1015 of the Director of the Communications Regulatory Authority of the Republic of Lithuania of 21 October 2011 approving the rules for the examination of disputes between final service recipients and providers of electronic communications services and disputes between postal and/or courier service providers and recipients (approving the rules for the examination of disputes between final service recipients and providers of electronic communications services and disputes between users and postal service providers) (*Official Gazette*, 2011, No 130-6176);
4. Order No 28 of the Minister for Social Security and Labour of the Republic of Lithuania of 6 March 2000 approving the Technical Regulation on the safety of machinery (*Official Gazette*, 2000, No 23-601);
5. Order No A1-316 of the Minister for Social Security and Labour of the Republic of Lithuania of 12 May 2009 approving the Regulations of the State Labour Inspectorate under the Ministry of Social Security and Labour of the Republic of Lithuania (*Official Gazette*, 2009, No 58-2262);
6. Order No 3-509 of the Minister for Transport and Communications of the Republic of Lithuania of 27 December 2006 approving the Regulations of the State Railway Inspectorate under the Ministry of Transport and Communications (*Official Gazette*, 2007, No 1-40; 2010, No 88-4686; 2013, No 95-4751);

7. Order No 304 of the Minister for Transport and Communications of the Republic of Lithuania of 26 September 1996 approving the Regulations of the State Road Transport Inspectorate under the Ministry of Transport and Communications (*Official Gazette*, 1996, No 102-2333; 1996, No 102-2334);
8. Order No 3-318 of the Minister for Transport and Communications of the Republic of Lithuania of 25 June 2002 approving the Regulations of the budgetary institution the Lithuanian Maritime Safety Administration (*Official Gazette*, 2002, No 68-2803; 2008, No 143-5755);
9. Order No 3-352 of the Minister for Transport and Communications of the Republic of Lithuania of 15 June 2004 approving the Technical Regulation on the design, construction, placing on the market and commissioning of recreational craft (*Official Gazette*, 2004, No 98-3654);
10. Order No V-612 of the Minister for Health of the Republic of Lithuania of 22 July 2005 approving the Regulations of the Radiation Protection Centre (*Official Gazette*, 2005, No 94-3516; 2011, No 128-6073);
11. Order No V-27 of the Minister for Health of the Republic of Lithuania of 13 January 2011 approving the Regulations of the State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania (*Official Gazette*, 2011, No 9-401);
12. Order No V-839 of the Minister for Health of the Republic of Lithuania of 7 September 2011 approving the reorganisation and the conditions for the reorganisation of the State Medical Audit Inspectorate under the Ministry of Health and the Regulations of the State Healthcare Accreditation Agency under the Ministry of Health (*Official Gazette*, 2011, No 112-5279);
13. Order No 4-693 of the Minister for the Economy of the Republic of Lithuania of 16 September 2010 approving the Regulations of the State Non Food Products Inspectorate under the Ministry of the Economy (*Official Gazette*, 2010, No 111-5666; 2012, No 87-4527);
14. Order No 4-174 of the Minister for the Economy of the Republic of Lithuania of 1 April 2011 approving the Technical Regulation on the safety of toys (*Official Gazette*, 2011, No 40-1928);
15. Order No 4-264 of the Minister for the Economy of the Republic of Lithuania of 27 April 2011 approving the Regulations of the Lithuanian Metrology Inspectorate (*Official Gazette*, 2011, No 53-2557);
16. Order No 4-472 of the Minister for the Economy of the Republic of Lithuania of 7 July 2011 approving the Technical Regulation on portable pressurised machinery (*Official Gazette*, 2011, No 88-4224);
17. Order No V-168 of the Chief State Labour Inspector of the Republic of Lithuania of 29 July 2011 approving the recast of the Rules for the examination of personal requests and service of persons by the State Labour Inspectorate of the Republic of Lithuania (*Official Gazette*, 2011, No 100-4735);
18. Order No 3D-938 of the Minister for Agriculture of the Republic of Lithuania of 12 December 2012 amending Order No 3D-490 of the Minister for Agriculture of 24 May 2010 approving the Regulations and the administration structure of the State Plant Service under the Ministry of Agriculture (*Official Gazette*, 2012, No 149-7637);
19. Order No 1B-540 of the Director General of the Customs Department under the Ministry of Finance of 19 May 2004 approving the Regulations for the examination of complaints by the Customs of the Republic of Lithuania (*Official Gazette*, 2004, No 84-3060);
20. Order No 1B-407 of the Head of the Customs Department under the Ministry of Finance of 11 June 2008 approving the Rules for conducting customs checks (*Official Gazette*, 2008, No 68 -2617);

21. Order No T1-137 of the Director of the State Healthcare Accreditation Agency under the Ministry of Health of 6 February 2013 approving the procedure for the examination of patients' complaints by the State Healthcare Accreditation Agency under the Ministry of Health (*Official Gazette*, 2013, No 15-765);
22. Order No 2B-217 of the Head of the State Road Transport Inspectorate under the Ministry of Transport and Communications of 4 June 2009 approving the Rules for the examination of personal requests and service of persons by the State Road Transport Inspectorate under the Ministry of Transport and Communications (*Official Gazette*, 2009, No 70-2887);
23. Order No 1A-1303 of the Head of the State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania of 25 November 2008 approving the Rules for the service of persons and examination of their requests and complaints by the State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania (*Official Gazette*, 2008, No 139-5528);
24. Order No 1-141 of the Director of the State Consumer Rights Protection Service of 1 October 2009 approving the procedure for the examination of personal requests and service of persons by the State Consumer Rights Protection Service (*Official Gazette*, 2009, No 120-5189);
25. Order No 1-62 of the Director of the State Consumer Rights Protection Authority of 14 May 2010 approving the Rules for rapid exchange of information on products dangerous to consumers (*Official Gazette*, 2010, No 58-2871)

6.2. EU legislation

1. Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC;
2. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93;
3. Regulation No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;
4. Regulation No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;
5. Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs;
6. Council Directive 92/59/EEC of 29 June 1992 on general product safety;
7. Council Directive 93/99/EEC of 23 October 1993 on the subject of additional measures concerning the official control of foodstuffs;
8. Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety;
9. Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market seeks to ensure free movement of services in the EU while matters of service safety are not regulated therein;
10. Council Decision No 84/133/EEC of 2 March 1984 introducing a Community system for the rapid exchange of information on dangers arising from the use of consumer products;

11. Council Resolution of 1 December 2003 on safety of services for consumers (2003/C 299/01).

6.3. Case law

1. Resolution of the Constitutional Court of the Republic of Lithuania of 12 July 2001 on the provisions of the Law on work remuneration for judges;
2. Resolution of the Constitutional Court of the Republic of Lithuania of 26 January 2004 on the Law on alcohol control and the licencing rules for the production of alcoholic products;
3. Resolution of the Constitutional Court of the Republic of Lithuania of 3 November 2005 on the Law on tobacco control;
4. Resolution of the Constitutional Court of the Republic of Lithuania of 31 May 2006 on exports of quota sugar;
5. Ruling of the Supreme Administrative Court of Lithuania of 6 May 2008, Administrative Case No A^{261}-339/2008;
6. Judgment of Vilnius Regional Administrative Court of 11 June 2012, Case No I-1886-426/2012.

6.4. Special readings

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4. 2013 02 13 Commission staff working document accompanying the report from the Commission to the European Parliament, the Council and the European economic and social Committee on the implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (ECC) No 339/93. Guidance papers on accreditation [accessed on 7 January 2014]. Available online at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=swd:2013:0036:FIN:EN:PDF
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ANNEX I

OVERVIEW OF THE SYSTEMATIC FUNCTIONS OF THE MARKET SURVEILLANCE SYSTEM

No	Function	Legal basis of the function	Lithuanian market surveillance authority performing the function	Legal basis for the performance of the function (in national law)
1.	Monitoring of the market surveillance system	Article 18(6) of the Regulation; Article 9(1)(c) of the Directive	none	none
2.	Drafting, updating, implementation and notification to the EC of national or sector-specific market surveillance programmes	Article 18(5) of the Regulation; Article 9(1)(a) of the Directive	none	none
3.	Public awareness raising/education about market surveillance authorities and their functions	Article 17(2) of the Regulation	none	none
4.	Communicating with the EC (notification of authorities and submission of other notifications and information)	Article 17(1) of the Regulation; Article 6(3) of the Directive	VVTAT VNMPI	• Article 7 of the Product Safety Law; • paragraph 22 of the Rules for the application of restrictions on marketing of products approved by Resolution No 439 of the Government of Lithuania of 2 April

				2002
5.	Establishing a cooperation mechanism between national market surveillance authorities and between national market surveillance authorities and authorities in charge of external border controls	Article 18(1) of the Regulation	none	none

ANNEX II

OVERVIEW OF THE MARKET SURVEILLANCE FUNCTIONS

No	Function	Legal basis of the function	Lithuanian market surveillance authority performing the function	Legal basis for the performance of the function (in national law)
1.	Drafting of the sector-specific programme and/or participation in drafting the national market surveillance programme	Article 18(5) of the Regulation; Article 9(1)(a) of the Directive	none	none
2.	Cooperation between market surveillance authorities and authorities in charge of external border controls	Article 27(2) of the Regulation	none	none
3.	Cooperation with market surveillance authorities of the Member States and market surveillance authorities of third countries	Articles 24(1), 24(2) and 26(1) of the Regulation	CD LMI	• paragraph Article 13(2) of the Lithuanian Law on customs • paragraph 10.20 of the CD

			SLI SMCA EPA LMSA RRT VASPVT	Regulations • Article 9(3)(3) of the Lithuanian Law on metrology • paragraph 10.1.2 of the LMI Regulations • Article 8(2)(2) of the Lithuanian Law on the supervision of potentially dangerous installations • paragraphs 8.1.21 and 8.3.9 of the SLI Regulations • Articles 69(1) and 69(2)(8) of the Lithuanian Law on pharmaceuticals • paragraphs 10.4.5 and 12.4 of the EPA Regulations • paragraphs 10.1.10 and 11.5 of the LMSA Regulations • paragraph 8.23 of the RRT Regulations • paragraph

			VKTI VVTAT VNMPI RRC	10.41 of the VASPVT Regulations • paragraph 8.29 of the VKTI Regulations • paragraphs 9.2, 10.2.4 and 11.7 of the VVTAT Regulations • paragraph 10.7 of the VNMPI Regulations • paragraph 10.6 of the RRC Regulations
4.	Cooperation with producers and distributors	Article 5(4) of the Directive	VVTAT VNMPI	• Article 8(6), 9(4) and 14(3) of the Product Safety Law
5.	Imposition of market restriction measures	Articles 16(2), 18(2)(c), 20(1), 21 and 29 of the Regulation; Article 8 of the Directive	LMI SLI SMCA	• Article 22(2) of the Lithuanian Law on metrology • paragraph 10.3.2 of the LMI Regulations • Article 8(2)(7) of the Lithuanian Law on the State Labour Inspectorate • paragraph 26 of the SLI Regulations • Article 67 of the Lithuanian Law on pharmaceuti

			VASPVT VVTAT VNMPI	cals • paragraphs 10.15, 11.9, 11.27, 11.28 and 11.29 of the SMCA Regulations • paragraphs 10.31.3 and 11.8 of the VASPVT Regulations • paragraph 10.1.9 of the VVTAT Regulations • paragraphs 9.2, 9.3 and 9.9 of the VNMPI Regulations
6.	Examination of complaints concerning products	Article 18(2)(a) of the Regulation; Directive 9(2)	VVTAT VNMPI VASPVT	• Article 17(5) of the Product Safety Law • Articles 34(2)(4) and 40(2)(3) of the Lithuanian Law on pharmaceuticals
7.	Monitoring of accidents and harm to health caused by products	Article 18(2)(b) of the Regulation	VVTAT SLI	• paragraph 2 of the Rules for exchange of information on dangerous products and related accidents approved by Resolution No 790 of the Government of Lithuania

				of 22 July 2009 • Article 6 of the Lithuanian Law on the State Labour Inspectorate
8.	Accumulation of scientific and technical knowledge relating to safety	Article 18(2)(d) of the Regulation; Article 9(1)(b) of the Directive	VVTAT, VNMPI RSC SMCA VNMPI	• Article 13(2) of the Product Safety Law • paragraph 10.3.8 of the RSC Regulations • paragraph 10.52 of the SMCA Regulations • paragraph 9.19 of the VNMPI Regulations
9.	Checks of products	Article 19(1)	LMI VASPVT VNMPI VVTAT VNMPI SLI	• Article 19 of the Lithuanian Law on metrology • paragraphs 10.4.6 and 11.4 of the LMI Regulations • paragraph 10.31.1 of the VASPVT Regulations • paragraph 10.2 of the VNMPI Regulations • Article 14(1)(4) of the Product Safety Law • Article 3(1) of the

			VKTI	Lithuanian Law on the supervision of potentially dangerous installations • Article 6(3) of the Lithuanian Law on the State Labour Inspectorate • Articles 14(2) and 14(4) of the Lithuanian Road Transport Code
10.	Alerting users of hazards	Articles 19(2) and 19(5) of the Regulation; Article 16(1) of the Directive	VVTAT SLI VNMPI VVTAT	• Article 9(3) of the Product Safety Law • Article 8(1)(6) of the Lithuanian Law on potentially dangerous products • paragraph 9.9 of the VNMPI Regulations • paragraph 13.2 of the Rules for the application of restrictions on marketing of products [130] approved by

[130] Resolution No 439 of the Government of the Republic of 2 April 2002 approving the rules for the application of restrictions on marketing of products (as amended by Resolution No 927 of 21 September 2006 (*Official Gazette*, 2006, No 102-3951) and Resolution No 585 of 23 May 2012 (*Official Gazette*, 2012, No 61-3074)).

				the Government of Lithuania
11.	Checks of products, documents and CE marking performed by the authorities in charge of external border controls	Article 27 to 29 of the Regulation	CD CD and VNMPI	• Articles 27(3), 32 and 33(5) of the Lithuanian Law on customs • paragraph 11.5 of the CD Regulations Resolution of the Government on checks of imported goods with a view to establishing their compliance with product safety requirements
12.	Imposition of sanctions for the improper use of the CE marking	Article 30(6)		Article 163[13] of the Administrative Infringements Code
13.	Imposition and enforcement of sanctions for violations of the provisions of the Regulation and the Directive	Article 41 of the Regulation; Article 7 of the Directive	VVTAT	Article 27(1) of the Product Safety Law
14.	Ensuring the proper administration of RAPEX	Articles 22 and 23 of the Regulation; Articles 11(1) and 12 of the Directive	VVTAT VNMPI VKTI, Ministry of Transport and Communications, LMSA Weaponry Fund of Lithuania Police Department under the Ministry of the Interior other authorities in charge of product safety and market surveillance for products intended	Rules on rapid exchange of information on products dangerous to consumers

			for drivers CD	
15.	Submission of data and information to the general information support system	Articles 22 and 23 of the Regulation; Article 12 of the Directive	VNMPI CD SLI RRT LMSA LMI State Plant Service Ministry of the Economy EPA State Weaponry Fund LMSA VASPVT Vilnius PHC	

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