

NATIONAL MARKET SURVEILLANCE PROGRAMME

2016

Romania

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1. GENERAL MARKET SURVEILLANCE ORGANISATION AND INFRASTRUCTURE

1.1. Identification and responsibilities of the national market surveillance authorities

In accordance with Government Order No 20/2010 on the establishment of certain measures for the uniform application of European Union legislation aimed at the harmonisation of the marketing conditions of products, the competent authorities (ministries) appoint market surveillance authorities and define their relevant areas of competence. Market surveillance authorities shall have the necessary resources and authority for exercising market surveillance activities, to ensure professional competence and integrity of their staff and to act independently and in a non-discriminatory manner.

Market surveillance authorities have responsibilities in each partly regulated field. The responsibility of the concerned authorities is presented in the below table.

No	Market surveillance authority	Area of competence
1	Romanian Office for Legal Metrology – Directorate for Market Inspection and Surveillance (BRML)	Non-automatic weighing instruments and prepacked products and units of measurement; Measuring instruments
2	Labour Inspection (IM)	Personal protective equipment; Machinery; Noise emitted by outdoor equipment; Equipment and protective systems intended for use in potentially explosive atmospheres; Pyrotechnic products; Explosives for civil uses; Non-road mobile machinery; Electrical appliances and equipment under LVD
3	National Authority for Consumer Protection (ANPC)	Toys, Labelling of cosmetic products, General product safety, Low voltage, Textiles
4	National Authority for Control of Boilers, Pressure Vessels and Hoisting Equipment (ISCIR)	Aerosol dispensers; Simple pressure vessels; Pressure equipment; Transportable pressure equipment; Lifts; Cableways; Appliances burning gaseous fuels; Efficiency requirements for hot-boilers fired with liquid or gaseous fuels
5	National Agency of Medicines and Medical Devices (ANMDM)	Medical devices (including <i>in vitro</i> diagnostic medical devices and Active implantable medical devices)
6	National Authority for Management and Regulation in Communications of Romania (ANCOM)	Electrical equipment under EMC; Radio equipment and telecommunications terminal equipment
7	Romanian Regulatory Authority for Energy (ANRE)	Eco-design; Energy labelling
8	State Inspection in Construction (ISC)	Construction products (except fixed fire-fighting equipment – fixed fire alarm/detecting equipment, fire-extinguishing installations, fire and smoke control and explosion protection systems)
10	Ministry of Agriculture and Rural Development	Fertilisers

	(MADR)	
11	National Environmental Guard	Electrical and electronic equipment under RoHS and WEEE and batteries; Chemicals covered by the REACH Regulation and legislation on classification and labelling; Other chemicals (Detergents, Paints, Persistent Organic Pollutants, Fluorinated greenhouse gases, Ozone Depleting Substances, etc.); biocides
12	Ministry of Health	Cosmetics; Biocides
13	“Romanian Automotive Registry” Autonomous Regie (RAR)	Motor vehicles and tractors
14	Romanian Naval Authority (ANR)	Recreational crafts; Marine equipment

The resources of the market surveillance authorities are presented in the below table:

<i>Market authority</i>	<i>surveillance</i>	<i>Staff</i>	<i>Budget (EUROS)</i>
<i>BRML</i>		4	<i>n/a</i>
<i>ANCOM</i>		8	<i>n/a</i>
<i>ANDMN</i>		5	246 233
<i>ANPC</i>			7 186 687
<i>IM</i>		20	<i>n/a</i>
<i>ISC</i>		22	514 067
<i>ISCIR</i>		8	<i>n/a</i>
<i>GNM</i>		10	<i>n/a</i>
<i>ANRE</i>		22	<i>n/a</i>

<i>ANR</i>	3	<i>n/a</i>
<i>RAR</i>	14	<i>n/a</i>
<i>MADR</i>	42	327 273

1.2. Coordination and cooperation mechanisms between national market surveillance authorities

In accordance with Government Decision No 306/2011, the Ministry of Economy, Commerce and Relations with the Business Environment (MECRMA) coordinates the market surveillance activities as provided for by Regulation (EC) No 765/2008. To that end, the Market Surveillance Coordination Committee for the surveillance of products covered by EU harmonisation legislation was established under MECRMA.

The Committee discusses issues most frequently faced by market surveillance authorities. The Committee uses email to inform market surveillance authorities about the evolution of discussions held at EU level and to consult to them on various community documents in order to substantiate Romania's position.

In addition, some market surveillance authorities cooperate bilaterally. For example, a number of them have concluded cooperation agreements with the National Customs Authority and ANPC. Moreover, taking into account the overlaps existing between the responsibilities specific to the field subject to checks, cooperation agreements have been signed with the authorities concerned as well.

MECRMA is responsible for the management of the ICSMS at national level.

ANPC is the contact point for RAPEX and at the same time is responsible for the application of Directive 2001/95/EC.

1.3. Cooperation between national market surveillance authorities and customs

Bilateral cooperation between the customs authority and market surveillance authorities can take the following forms, as appropriate:

1. Data/information exchange;
2. Organisation of training programmes in various regulated areas (For example, in 2015 a training session was organised in the field regulated by ANCOM, held by 2 representatives of ANCOM for 20 staff members of the customs authority);
3. Mutual information with regard to the legislation covering their respective competences.

Furthermore, in practice there are various ad-hoc contacts regarding matters on which the customs authority needs an urgent opinion from market surveillance authorities.

On the other hand, in July 2015 a Protocol was signed between the National Customs Authority (DGV) and ANCOM, intended to streamline cooperation between these two institutions in order to ensure that products covered by EU legislation entering the single market and declared for release for free circulation comply with all essential requirements.

Moreover, during the support visit of representatives of the European Commission (DG TAXUD) in Romania on 25 November 2015 to assess the implementation at national level of the Guidelines for import controls in the area of product safety and compliance, three market surveillance authorities, namely ANCOM, ISCIR and ANPC, held presentations on the activities carried out in the field of market surveillance, with a special focus on their cooperation with the customs authority concerning the application of Regulation (EC) No 765/2008.

1.4. Rapid information exchange system – RAPEX

ANPC is the national contact point in Romania for the RAPEX system, which is a rapid alert system for dangerous non-food products. ANPC warns users concerning dangerous non-food products, notified through the RAPEX alert system at <http://www.anpc.gov.ro/categorie/41/rapex>, but also regarding voluntary product withdrawals by economic operators at <http://www.anpc.gov.ro/categorie/44/retrageri-voluntare-de-produse>.

In 2015, ANPC issued 26 such notifications concerning dangerous non-food products (toys, textiles, cosmetic products and electrical equipment) and 10 replies to the notifications.

1.5. ICSMS information system

MECRMA is responsible for the management of the ICSMS at national level. Also the representatives of market surveillance authorities participate in the IMP-ICSMS workgroup of the European Commission.

Since 2013 market surveillance authorities have been participating at training sessions concerning the use of the ICSMS system, and currently some of these authorities are actually using ICSMS.

The ICSMS portal is available for all market surveillance authorities.

1.6. General description of market surveillance activities and relevant procedures

Market surveillance is usually carried out in accordance with the provisions of Regulation (EC) No 765/2008 and with those of Government Decision No 306/2011 on certain market surveillance measures of products covered by EU legislation harmonising the marketing conditions thereof.

Market surveillance is both a proactive and a reactive activity. Proactive controls are organised either based on risk assessments, or in the form of controlling campaigns for

different previously established products, being aware of the fact that the concerned products should generate major sales during specific national holidays.

Reactive controls usually take place as a result of complaints received from consumers, following accidents or based on information received through the RAPEX and ICSMS systems.

The checks carried out by the market surveillance authorities may be formal ones (verification of the presence and way of affixing of the CE marking, the availability of the declaration of conformity, technical documentation or the correct choice by the manufacturer of the procedure for the assessment of conformity, applicable to the product) or general ones (verification of the conformity of the product with the essential requirements).

Where non-conforming products are identified, administrative measures are applied (warnings, prohibition of marketing, obligation of the economic operator to withdraw or to recall the concerned product from the market), and where these measures do not result in the conformity of the product, sanctions are applied. The price of the products/samples collected for checking conformity is borne by the economic operators in the event that as a result of the tests it turns out that the respective products are non-conforming.

With a few exceptions, market surveillance authorities do not have their own laboratories, so they commission various accredited laboratories in order to perform the testing.

1.7. General framework of cooperation with other Member States and non-member states

Market surveillance authorities cooperate with the other authorities from the SM under the ADCO groups. Moreover, part of the authorities cooperate with the authorities of neighbouring third countries for spot checks.

One of the authorities participates in the INTAS project under the Horizon 2020 programme in order to ensure the transfer of the know-how required.

1.8. Evaluation of Market surveillance actions and reporting

There is no overall methodology for the assessment of market surveillance activities at national level. Each authority prepares an annual report on the activity performed but not all of these reports are published on their respective websites.

1.9. Horizontal activities planned for the relevant period

Market surveillance authorities shall continue to take part at the ADCO and IMP-MSG workgroups. Part of them will take part in trainings on the use of the ICSMS system.

Special attention shall be paid to products marketed online.

The main products to undergo such controls are toys, cosmetic products, construction products, medical devices, explosives for civil uses, pressure vessels and equipment, appliances burning gaseous fuels, lifts, personal protective equipment, measuring

instruments, prepacked products, non-automatic weighing instruments, electrical equipment (including electromagnetic compatibility), and motor vehicles.

2. MARKET SURVEILLANCE IN SPECIFIC SECTORS

2.1. Sector: Medical Devices

2.1.1. Authority responsible and contact details

In the field of medical devices the national market surveillance authority is National Agency of Medicines and Medical Devices (ANMDM), with the following contact details:

National Agency of Medicines and Medical Devices

Bucharest, Șos. Nicolae Titulescu, nr. 58, sector 1

www.anm.ro

e-mail: mdevice@anm.ro

Tel: +4 021 2228652

Fax: +4 021 2228683

By the market surveillance activity carried out, ANMDM controls whether medical devices comply with the applicable technical requirements and whether economic operators act according to their obligations in order for non-conforming products to be brought into line with the requirements of the applicable technical regulations.

In performing their market surveillance duties, ANMDM hires 5 persons, employees of the Market Surveillance Service.

In cases where specific expertise is required in a certain field, employees of the following units may be involved in groups:

- Regulatory and Authorisation Service (5 employees) or;
- Laboratories Technical Department (20 employees) or;
- Department for the Assessment of Medical Engineering units (7 employees).

ANMDM has its own laboratory for testing and verifying medical devices where it can test medical devices from the perspective of electrosecurity and perform certain mechanical tests. For tests that cannot be performed in-house, ANMDM uses the services of laboratories accredited for the relevant test type.

The allocated budget for market surveillance activities for the year 2016 is of EUR 246 233.

Market surveillance procedures and strategy

In its market surveillance activities, the specialised structure under ANMDM goes through the following steps:

- a) monitoring of medical devices placed on the market and/or put into service, as well as of those presented at fairs, exhibitions, demonstrations and the like;
- b) establishing the measures that need to be taken by the economic operator, as appropriate, in order to ensure the conformity of the products;
- c) monitoring the way of applying the measures established.

In its market surveillance activities the specialised structure under ANMDM carries out the following formal and substantive checks.

By formal verifications the following are assessed: the presence and the manner in which the CE marking and/or other specific markings set out in the applicable legislation are applied, the availability of the declaration of conformity, technical documentation, information accompanying medical device and/or the correct choice by the manufacturer of the conformity assessment procedures applied to the medical device.

Substantive checks entail the verification of the conformity of the medical device with the essential requirements established by the applicable technical regulations.

In the event that a medical device is not in accordance with the provisions of the applicable technical regulations, the specialised structure under ANMDM analyses and decides whether the non-conformities ascertained are minor or major ones, and in accordance with the principle of proportionality notifies the economic operator requesting it to bring it into line with the relevant requirements.

In the event that the initial measures do not lead to the expected results or the obtained results are deemed insufficient, ANMDM takes measures to restrict or prohibit the placing on the market and/or putting into service of the product in question or ensure that it is withdrawn and/or recalled from the market.

Restricting or prohibiting the placing on the market and/or putting into service of a medical device may be a temporary measure at first, limited in duration, in order to allow the specialised directorate under ANMDM to obtain sufficient evidence with regard to the risk or to another major on-conformity of the product.

In the event that the adopted measures extend beyond national territory, ANMDM informs the European Commission and the other EU member states regarding the outcomes of the assessment of conformity and the actions required from the economic operator in order to ensure conformity.

When the grounds for initiating this measure have been eliminated, the specialised structure of ANMDM withdraws the communication and takes the necessary measures for re-establishing of the free circulation of the medical device.

Throughout the year, ANMDM performs both proactive and reactive controls. All of these controls are documented in the Operational procedure on the performance of the market surveillance activity of the specialised structure under ANMDM for medical devices, code: PO-SP01 ed. 1 rev.1 of 20 January 2015.

The same procedure focuses on the manner in which the handling of the complaints is monitored. For this purpose there is a so-called Complaint register (incidents/complaints) – code SP –S 01 ed. 1 rev. 0/2015 managed by the Market Surveillance Service. The register maintains the history of each referral/complaint from the first entry to the assessment of the actions taken and up until the termination of the situation concerned.

The website of the institution – http://www.anm.ro/anmdm/dm_reglementare_vigilenta.html – informs manufacturers/distributors/users with regard to the reporting of any incident relating to medical devices, in accordance with the relevant legal provisions.

Furthermore, ANMDM warns users concerning dangerous or possibly dangerous products and the measures taken when such situations are reported on the following link: http://www.anm.ro/anmdm/dm_reglementare_supraveghere_piata.html.

On http://www.anm.ro/anmdm/dm_reglementare_supraveghere_piata.html, ANMDM calls on all stakeholders: healthcare professionals, patients, the general public and mass-media to inform ANMDM concerning the entry in the market of non-conforming medical devices, lacking the CE marking or the operation of which may endanger the life and health of patients. Such referrals and information requests regarding various medical

devices placed on the market or being in service, or regarding the accompanying documents thereof. ANMDM replies promptly precisely to encourage such referrals. During the course of this year, ANMDM is focusing on the provision of medical devices online and through ad-hoc presentations held in hotels. These two arrangements for the distribution of medical devices are ways of placing on the market medical devices of uncertain provenance and quality, and which are possibly counterfeit. In such situations the support of ANPC is required. It is difficult to linearly monitor and solve such situations given their intermittent nature, the location and unknown circumstances of these activities.

2.1.3 Report on activities carried out under the previous planning period

During 2015 a total number of 181 announced controls (both proactive and reactive) were conducted at dealers (78), medical device manufacturers (18) and at health facilities (85) concerning compliance with the legal provisions on medical devices placed on the market.

Furthermore, 11 unannounced checks were carried out at dealers and medical device manufacturers to verify whether the legal provisions on medical devices placed on the market were complied with.

2.2. Sector: Cosmetics

Authority responsible and contact details

Contact details of the coordinating competent authority:

Ministry of Health, Str. Cristian Popișteanu nr. 1-3, 010024, sector 1, Bucharest
Person responsible for the sectoral plan: Conf. univ. Dr. Lucian L. INDREI – Head of Service, State Health Inspection
e-mail: lucian.indrei@ms.ro, tel. 021.307.25.56

Data concerning the resources at the disposal of the competent authority

- health inspectors of county level public health directorates
- laboratories of the National Institute of Public Health and of county level public health directorates

Contact details of the authority responsible for checking the labelling

National Authority for Consumers' Protection (ANPC)
Bucharest, B-dul Aviatorilor, nr. 72, RO-011865, sector 1
URL: www.anpc.gov.ro; E-mail: office@anpc.ro
Tel: +4 021 3121275; Fax: +4 021 3143462,

The budget allocated to market surveillance activities for the year 2016 is EUR 7 186 647, without any breakdowns per sectors from the responsibility of ANPC.

2.2.2. Market surveillance procedures and strategy

Market surveillance activities in the field of cosmetic products are carried out in accordance with the provisions of Government Decision No 147/2015 on adopting

certain measures for the creation of a framework for the application of the provisions of Regulation (EC) No 1223/2009 on cosmetic products, as well as those of Commission Regulation (EU) No 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products.

This act describes the duties of the Ministry of Health acting as coordinating competent authority and the responsibilities of ANPC.

Government Decision No 147/2015 includes the infringements and penalties applied by the state health inspectors under the Ministry of Health and by authorised persons employed by ANPC, with the observation of the confidentiality of data contained in the documents which they verified during the control actions performed, with the exception of situations where there is a risk to public health. Furthermore, the act specifies that samples may be taken from the cosmetic products in order to carry out physical and laboratory tests thereon.

Details of the strategy and procedures of the Ministry of Health

In accordance with the provisions of Order No 824/2006 approving the rules concerning the structure and operation of the State Health Inspection, as subsequently amended and supplemented, public health related inspection activities consist of official controls aimed at the characteristics of facilities, the activities and the products therein, in order to establish and impose compliance with the requirements set out in public health regulations in the field of cosmetic products.

As set out by Order No 824/2006, the state health inspection uses during its activity: inspection guides, specific rules and standards for each type of activity, specific controlling instruments and equipment for on-site measurements and sampling, as well as specific printed forms (such as reports of findings relating to the health and hygiene conditions, reports of findings concerning non-criminal offences, reports on sampling, inspection reports, forms of decisions on the suspension of activities, forms of decisions on the prohibition of activities), and other documents relating to health inspection.

The types of control performed by staff authorised to carry out state health inspections are:

(a) thematic controls – when a single type of activity or a single target, product or service is inspected;

(b) scheduled controls, when a single target is periodically inspected based on a previous scheduling, and the frequency is proportional to the risk level;

(c) controls at requests/referrals: inspections requested by citizens (following the identification thereof), institutions and central and local public administration authorities, other bodies and organisations, mass-media, ex-officio controls, as well as at the request of a competent authority from another European Union Member State;

(d) repeated controls, reinspections at the expiration of the deadline for remedying the previously identified non-conformities.

Based on the provisions of national legislation in force and taking into account Order No 824/2006, each county-level health directorate has elaborated their own operational procedures, which mainly include the following: operational procedure for inspections, operational procedure on handling complaints, operational procedure on non-criminal offences, operational procedure on the decisions of suspension of activities, as well as a complaint and referral register, contravention register and repeated control register.

2.2.3. Report from activities carried out by the Ministry of Health under the previous planning period

In 2015, the controlling activity of health inspectors within the Ministry of Health was carried out according to the Market surveillance programme, elaborated and published by

the Ministry of Health on its website, with the objectives of the thematic actions consisting of:

- Verification of the files of cosmetic products at the manufacturers and importers;
- Verification of organic creams without preservatives (notification, labelling, composition, allegations, storage, technical files, as appropriate) at manufacturers, importers, dealers, retail stores, beauty salons;
- Verification of compliance with the provisions of Regulation (EC) No 1223/2009 on cosmetic products;
- Verification of compliance with the provisions of Commission Regulation (EU) No 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products;
- Monitoring by sampling organic creams without preservatives (1 sample/county) for microbiological determination.

During the control of cosmetic products and of the conformity of organic creams without preservatives a number of 1086 cosmetic products were checked, of which approximately 89% were deemed as conforming. Furthermore, during the control action 53 cosmetic product files were verified of which 42 were compliant. During the control action it was ascertained that of the total number of 1086 cosmetic products, 51 products had not been notified on the Cosmetic Products Notification Portal of the European Commission, although this is compulsory pursuant to Regulation (EC) No 1223/2009.

The following sanctions were applied during the verification of cosmetic products:

- 33 cosmetic product items were stopped from being marketed, while 2 cosmetic product items were banned from use;
- 5 warnings;
- 2 fines in amount of EUR 358.

Furthermore, for the non-conformities identified at the cosmetic product files, a number of 5 warnings were issued.

Moreover, in 2015, health inspectors of the county-level public health directorates permanently conducted control actions based on complaints, RAPEX notifications or incidents relating to the adverse effects of cosmetic products.

The outcomes of the control actions performed at national level in the field of cosmetic products, grouped into specific information categories, are published on the website of the Ministry of Health.

Details on the strategy and procedures of ANPC

In the field of cosmetics, ANPC verifies whether the provisions of Regulation (EC) No 1223/2009 on the labelling of cosmetic products were observed, checks the declarations relating to the product, label contents, checks the access of the public to the information's relating to the cosmetic product concerned, which should be made available by an appointed person, applies appropriate measures, including corrective actions in order to ensure that the provisions of Regulation (EC) No 1223/2009 and those of Commission Regulation (EU) No 655/2013 are complied with.

2.2.3 Report on the control activities carried out by ANPC in 2015

The control actions were carried out at the distributors, and a total of 745 irregularities were found at economic operators, with the amount of the products with irregularities of EUR 904 428.

The controls revealed irregularities with regard to: labelling/inscriptions on the packaging/recipients with the data/information provided for by Regulation (EC) No 1223/2009, the lack of translation into Romanian of these information, failure to comply with the DMD (products with the date of minimum durability passed).

Actions taken for the solution of non-conformities

- 508 fines were applied for non-criminal offences, in amount of EUR 360 127.
- 377 measures were taken for the temporary interruption of marketing due to the failure to comply with labelling requirements, amounting to EUR 51 272 and 48 measures were taken for the definitive cessation of marketing for cosmetic products with exceeded DMD (expired products).
- At request, economic operators were offered counselling services.

2.3. Sector: Toys

Authority responsible and contact details

In the field of toys, the national market surveillance authority is the National Authority for Consumers' Protection (ANPC), whose contact details are:

National Authority for Consumers' Protection (ANPC)
Bucharest, B-dul Aviatorilor, nr. 72, RO-011865, sector 1
URL: www.anpc.gov.ro; E-mail: office@anpc.ro
Tel: +4 021 3121275; Fax: +4 021 3143462

The budget allocated for market surveillance activities for the year 2016 is EUR 7 186 647.

In accordance with the provisions of Government Decision No 700/2012 on the structure and operation of the National Authority for Consumers' Protection (ANPC), the central institution has under its authority 8 Regional Commissariats for Consumers' Protection, which include 41 County Commissariats for Consumers' Protection and the Commissariat for Consumers' Protection in Bucharest, employing specialists in the area of non-food products.

Market surveillance procedures and strategy

By means of the market surveillance activity carried out, ANPC checks whether toys comply with the applicable technical requirements, and whether economic operators act according to their corresponding obligations so that non-conforming toys are brought into line with the applicable technical regulations.

To test toys, ANPC uses accredited laboratories for the required type of testing. In its market surveillance activities, ANPC performs formal and substantive verifications.

Formal verifications involve the following: existence of the manufacturer's coordinates, existence of the unique identification number of the toy, the existence and way of affixing of the CE marking, availability of the declaration of conformity and its compliance with the requirements of Directive 2009/28, technical documentation, the

information accompanying the toy and the correct choice by the manufacturer of the conformity assessment procedures applied.

Substantive checks entail the verification of the conformity of the toy with the essential requirements established by the applicable technical regulations.

Where a toy is not in accordance with the provisions of the applicable technical regulations, the representatives of ANPC analyse and decide whether the ascertained non-conformities are minor or major ones, and in line with the principle of proportionality, they notify the economic operator requesting it to bring that product into conformity.

In the event that requests do not lead to the expected results or if the results obtained are deemed insufficient, ANPC takes measures to prohibit the placement on the market and/or making available on the market of non-conforming toys or to withdraw them from the market and/or recall them from consumers.

In the event that the measures adopted extend beyond national territory, ANPC communicates to the European Commission and to the other Member States of the European Union the results of the assessment of conformity and the actions required from the economic operator concerned.

When the grounds for initiating this measure have been eliminated, ANPC withdraws the communication and takes the necessary measures to re-establish the free circulation of the toy.

Report on activities carried out under the previous planning period

Checks were performed at manufacturers, importers, distributors, and retailers, with irregularities identified at 1242 economic operators, in the amount of EUR 225 063.

Analysis of non-conformities identified during the control activity

The checks revealed irregularities with regard to the application of the legal provisions concerning the safety of toys (Government Decision No 74/2011 on the safety of toys, as subsequently amended and supplemented), as well as regarding the application of legislation regulating the course of promotions and the display of prices.

According to the provisions of Government Decision No 74/2011 on the safety of toys, as subsequently amended and supplemented), infringements were ascertained regarding: the inscription of the name, the manufacturer's and/or importer's registered trade name or trademark, the address at which these can be contacted; mentioning/inscription of the unique identification number of the toy; the affixing of the CE marking; the absence of general warnings (regarding age), of specific warnings and indications concerning the precautions for use for certain toy categories, as well as the instructions for use or the absence of a translation into Romanian of all aspects mentioned above; irregularities regarding the declaration of conformity (its absence or the failure to issue it according to the template provided in Annex No 3 to the Government Decision); irregularities concerning the technical documentation (failure to issue it or the absence of certain documents from the file).

Actions taken to rectify non-conformities

- 836 fines were applied for non-criminal offences, in the amount of EUR 610 165.
- 837 measures were taken to temporarily suspend marketing for failure to comply with labelling requirements, 35 measures were taken for the definitive cessation of marketing for failure to observe the essential safety requirements and 6 remedial measures (correcting or providing additional information on advertising sites where irregularities had been found), for online sales.
- On request, economic operators were offered counselling services.

2.4. Sector: Personal protective equipment

Authority responsible and contact details

Responsible authority: Labour Inspection

Contact details: Labour Inspection
Strada Matei Voievod nr. 14, sector 2, Bucharest
E-mail: daniel.stoicescu@inspectiamuncii.ro;
cristian.nedu@inspectiamuncii.ro
Tel. 0040213027031 / Fax. 0040212520097

Resources: The activity of market surveillance is coordinated at central level by a specific structure, and within each territorial labour inspections there are two labour inspectors having also market surveillance-related responsibilities. Overall, there are 42 territorial labour inspections, organised in each county and in the capital city of Bucharest. The institution does not have its own laboratories for product testing.

Market surveillance procedures and strategy

Labour Inspection carries out controls, both proactive controls generally focusing on the products included in the sectoral programme of the institution, and reactive controls as a result of the referrals received, or at the request of other institutions with competences in the field, such as custom institutions, as well as a result of the decisions of the European Commission referring to the application of safeguard clauses.

Following these controls, labour inspectors may ascertain cases of irregularities, may apply remedial measures, may apply sanctions for non-criminal offences, as well as measures for the restriction of the marketing or for the recall from the market of non-conforming products.

The products from this category included in the annual sectoral programme are established taking into account the information collected in the previous period, other member states' concerns in this field, the impact of the respective products on safety and on the health of users (high number of users, risk level), or other criteria.

Report on activities carried out under the previous planning period

In 2015, 2470 products were controlled from the personal protective equipment category, of which 2351 were identified as being considered conforming to the legal provisions in force, and non-conformities were identified for 119 products.

As a result of the non-conformities ascertained, measures for bringing into conformity, as well as sanctions for non-criminal offences (fine or warnings) and restrictive measures (prohibition of the placement on the market, prohibition of marketing) were taken, as appropriate.

2.5. Sector: Construction products

2.5.1. Authority responsible and contact details

State Inspection in Construction (ISC) is appointed by Government Decision No 1236/2012, as an authority for the surveillance of the market of construction products, except fixed fire-fighting equipment – fixed fire alarm/detecting equipment, fire-extinguishing installations, fire and smoke control and explosion protection systems.

Contact details of the authority:

State Inspection in Construction

Address: Str. C.F. Robescu, nr. 23, sector 3, Bucharest, Romania

Tel: +40 21 318 17 00; Fax: +40 21 318 17 19; e-mail: isc@isc-web.ro

Data concerning the resources at the disposal of the authority (estimate for the year 2016):

2016 budget for market surveillance activities (EUR)	Number of staff (full-time equivalent)
514 067	22

ISC does not have its own laboratories

Market surveillance procedures and strategy

ISC organises scheduled, thematic, unannounced and spot inspections (and based on referrals) at the involved economic operators (manufacturers, authorised representatives, importers, distributors), as well as at the locations where these are used (construction sites), in order to check whether these comply with the provisions of the legislation of the European Union, with the implementing acts thereof and with other provisions of national technical acts.

Report on activities carried out under the previous planning period

In the Sectoral market surveillance programme for construction products for the year 2015, ISC, by its territorial structures carried out inspections at economic operators (manufacturers, authorised representatives, importers and distributors) and users in

semester I for “Masonry units of category I” and in semester II for “Thermal insulating products for buildings”.

On the two product families a total of 449 controls were carried out, 34 of which at the manufacturers, 4 at importers, 1 at authorised dealers, 351 at distributors and 59 at users (construction sites).

For the family products “Masonry units of category I” a total of 15 controls were carried out at manufacturers, 4 at importers, 201 at distributors and 31 at users (construction sites).

The main non-conformities found during the inspections were the failure to enclose to the products all the documents set out by the legislation in force or the incomplete information accompanying the products.

During the controls conducted at the economic operators placing on the market imported products the absence of the identification details of the importers was found. For these non-conformities a set of corrective measures were ordered.

For the family products “Thermal insulating products for buildings” a total of 19 controls were carried out at manufacturers, 1 at authorised dealers, 150 at distributors and 28 at users (construction sites).

The main non-conformities found during the inspections are: the information accompanying the products were incomplete or there were inconsistencies between the information in the declaration of performance and those accompanying the CE marking and the failure to observe the provisions of the legislation in force on the labelling of these products.

For the substantive check of the products, ISC took samples from the distributors from the batches placed on the market by 3 manufacturers, which were tested in an accredited laboratory. Following the laboratory tests discrepancies were identified between the declared and the obtained characteristics. The manufacturers cooperated, and pursuant to Article 11 of Regulation (EU) No 305/2011, they withdrew from the market the concerned batches in order to bring them into conformity. Until the products concerned were brought into conformity, ISC ordered the temporary prohibition of their placement on the market.

2.6. Sector: Aerosol dispensers

Authority responsible and contact details

National Authority for Control of Boilers, Pressure Vessels and Hoisting Equipment (ISCIR), Inspection, Market Surveillance and Regulatory Directorate, Market Surveillance Service

Address: Bucharest, Str. Sf. Elefterie nr. 47-49, Sector 5

Telephone/Fax: 004021.411.97.60; 004021.411.97.61 / 004021.410.00.19

E-mail: iscir@iscir.ro

Resources of the Market Surveillance Service under ISCIR:

- 8 full-time staff members;

- available budget: the funding of the activity of ISCIR is fully ensured from the state budget, by the Ministry of Economy, Commerce and Relations with the Business Environment as the Market Surveillance Service does not have a separate budget.

Market surveillance procedures and strategy

The activity of the Market Surveillance Service is carried out on the basis of the annual sectoral programme and on the monthly control programme approved by the Chief State Inspector of ISCIR to be conducted at economic operators (importers, distributors, authorised representatives and others) on the products/equipment in the field regulated by ISCIR.

Inspections are conducted at economic operators for the verification of the products (visual check of the marking and labelling, as well as the verification of the documents attesting the assessment of the conformity of the products with the essential safety requirements set out in European directives).

In cases where non-conformities are found in the products, economic operators are offered a period of no less than 10 days to take the required corrective actions.

In the event that economic operators fail to bring the products into conformity, they are sanctioned with a fine and/or complementary measures (withdrawal from the market prohibition of marketing, etc.)

Report on activities carried out under the previous planning period

During the course of 2015, ISCIR carried out 9 proactive inspections. Out of these there were 7 findings of conformity and 2 findings of non-conformity.

Furthermore, 1 corrective action was taken by an economic operator and 1 restrictive measure was adopted by the market surveillance authority.

2.7. Sector: (a) Pressure equipment

Authority responsible and contact details

National Authority for Control of Boilers, Pressure Vessels and Hoisting Equipment (ISCIR), Inspection, Market Surveillance and Regulatory Directorate, Market Surveillance Service

Address: Bucharest, Str. Sf. Elefterie nr. 47-49, Sector 5

Telephone/Fax: 004021.411.97.60; 004021.411.97.61 /004 021.410.00.19

E-mail: iscir@iscir.ro

Resources of the Market Surveillance Service under ISCIR:

- 8 full-time staff members;

- available budget: the funding of the activity of ISCIR is fully ensured from the state budget, by the Ministry of Economy, Commerce and Relations with the Business Environment as the Market Surveillance Service does not have a separate budget.

Market surveillance procedures and strategy

The activity of the Market Surveillance Service is carried out on the basis of the annual sectoral programme and on the monthly control programme approved by the Chief State Inspector of ISCIR to be conducted at economic operators (importers, distributors, authorised representatives and others) on the products/equipment in the field regulated by ISCIR.

Inspections are conducted at economic operators for the verification of the products (visual check of the marking and labelling, as well as the verification of the documents attesting the assessment of the conformity of the products with the essential safety requirements set out in European directives).

In cases where non-conformities are found in the products, economic operators are offered a period of no less than 10 days to take the required corrective actions.

In the event that economic operators fail to bring the products into conformity, they are sanctioned with a fine and/or complementary measures (withdrawal from the market prohibition of marketing, etc.).

Report on activities carried out under the previous planning period

During the course of 2015, ISCIR carried out 4 proactive inspections. Out of these there were 3 findings of conformity and 1 finding of non-conformity.

Furthermore, 1 corrective action was taken by an operator.

2.7. Sector: (b) Pressure equipment

Authority responsible and contact details

National Authority for Control of Boilers, Pressure Vessels and Hoisting Equipment (ISCIR), Inspection, Market Surveillance and Regulatory Directorate, Market Surveillance Service.

Address: Bucharest, Str. Sf. Elefterie nr. 47-49, Sector 5

Telephone/Fax: 004021.411.97.60; 004021.411.97.61 / 004021.410.00.19

E-mail: iscir@iscir.ro

Resources of the Market Surveillance Service under ISCIR:

- 8 full-time staff members;

- available budget: the funding of the activity of ISCIR is fully ensured from the state budget, by the Ministry of Economy, Commerce and Relations with the Business Environment as the Market Surveillance Service does not have a separate budget.

Market surveillance procedures and strategy

The activity of the Market Surveillance Service is carried out on the basis of the annual sectoral programme and on the monthly control programme approved by the Chief State Inspector of ISCIR to be conducted at economic operators (importers, distributors, authorised representatives and others) on the products/equipment in the field regulated by ISCIR.

Inspections are conducted at economic operators for the verification of the products (visual check of the marking and labelling, as well as the verification of the documents attesting the assessment of the conformity of the products with the essential safety requirements set out in European directives).

In cases where non-conformities are found in the products, economic operators are offered a period of no less than 10 days to take the required corrective actions.

In the event that economic operators fail to bring the products into conformity, they are sanctioned with a fine and/or complementary measures (withdrawal from the market prohibition of marketing, etc.).

Report on activities carried out under the previous planning period

During the course of 2015, ISCIR carried 48 inspections, of which 47 were proactive inspections and 1 was initiated by the customs authorities.

Altogether there were 18 findings of conformity and 30 findings of non-conformity.

Moreover, a number of 21 corrective actions were taken by economic operators and a number of 9 restrictive measures were adopted.

2.8. Sector: Transportable pressure equipment

Competent authority and contact details

National Authority for Control of Boilers, Pressure Vessels and Hoisting Equipment (ISCIR), Inspection, Market Surveillance and Regulatory Directorate, Market Surveillance Service.

Address: Bucharest, Str. Sf. Elefterie nr. 47-49, Sector 5

Telephone/Fax: 021.411.97.60; 021.411.97.61 / 021.410.00.19

E-mail: iscir@iscir.ro

Resources of the Market Surveillance Service under ISCIR:

- 8 full-time staff members;

- available budget: the funding of the activity of ISCIR is fully ensured from the state budget, by the Ministry of Economy, Commerce and Relations with the Business Environment as the Market Surveillance Service does not have a separate budget.

Market surveillance procedures and strategy

The activity of the Market Surveillance Service is carried out on the basis of the annual sectoral programme and on the monthly control programme approved by the Chief State Inspector of ISCIR to be conducted at economic operators (importers, distributors, authorised representatives and others) on the products/equipment in the field regulated by ISCIR.

Inspections are conducted at economic operators for the verification of the products (visual check of the marking and labelling, as well as the verification of the documents attesting the assessment of the conformity of the products with the essential safety requirements set out in European directives).

In cases where non-conformities are found in the products, economic operators are offered a period of no less than 10 days to take the required corrective actions.

In the event that economic operators fail to bring the products into conformity, they are sanctioned with a fine and/or complementary measures (withdrawal from the market prohibition of marketing, etc.).

Report on activities carried out under the previous planning period

During the course of 2015, ISCIR carried 3 inspections, with no non-conformities found.

2.9. Sector: Technical equipment (machines)

Authority responsible and contact details

Responsible authority: Labour Inspection

Contact details: Labour Inspection
Strada Matei Voievod nr. 14, sector 2, Bucharest
E-mail: daniel.stoicescu@inspectiamuncii.ro;
cristian.nedu@inspectiamuncii.ro
Tel. 0040213027031 / Fax. 0040212520097

Resources: The activity of market surveillance is coordinated at central level by a specific structure, and within each territorial labour inspections there are two labour inspectors having also market surveillance-related responsibilities. Overall, there are 42 territorial labour inspections, organised in each county and in the capital city of Bucharest. The institution does not have its own laboratories for product testing.

Market surveillance procedures and strategy

Labour Inspection carries out controls, both proactive controls generally focusing on the products included in the sectoral programme of the institution, and reactive controls as a result of the referrals received, or at the request of other institutions with competences in the field, such as custom institutions, as well as a result of the decisions of the European Commission referring to the application of safeguard clauses.

Following these controls, labour inspectors may ascertain cases of irregularities, may apply remedial measures, may apply sanctions for non-criminal offences, as well as measures for the restriction of the marketing or for the recall from the market of non-conforming products.

The products from this category included in the annual sectoral programme are established taking into account the information collected in the previous period, other member states' concerns in this field, the impact of the respective products on safety and on the health of users (high number of users, risk level), or other criteria. Labour Inspection has signed, in this field, a cooperation protocol with the National Authority for Control of Boilers, Pressure Vessels and Hoisting Equipment – ISCIR, taking into consideration the interference between the specific duties covered by these two institutions.

Report on activities carried out under the previous planning period

During the course of 2015, 8022 products were controlled from the category of machines, 7088 of which were identified as compliant with the legal provisions in force, while non-conformities were identified in the case of 214 products.

As a result of the non-conformities ascertained, measures for bringing into conformity, as well as sanctions for non-criminal offences (fine or warnings) and restrictive measures (prohibition of the placement on the market, prohibition of marketing) were taken, as appropriate.

2.10. Sector: Lifts

Authority responsible and contact details

National Authority for Control of Boilers, Pressure Vessels and Hoisting Equipment (ISCIR), Inspection, Market Surveillance and Regulatory Directorate, Market Surveillance Service.

Address: Bucharest, Str. Sf. Elefterie nr. 47-49, Sector 5

Telephone/Fax: 004021.411.97.60; 004021.411.97.61 / 004021.410.00.19

E-mail: iscir@iscir.ro

Resources of the Market Surveillance Service under ISCIR:

- 8 full-time staff members;

- available budget: the funding of the activity of ISCIR is fully ensured from the state budget, by the Ministry of Economy, Commerce and Relations with the Business Environment as the Market Surveillance Service does not have a separate budget.

Market surveillance procedures and strategy

The activity of the Market Surveillance Service is carried out on the basis of the annual sectoral programme and on the monthly control programme approved by the Chief State Inspector of ISCIR to be conducted at economic operators (importers, distributors, authorised representatives and others) on the products/equipment in the field regulated by ISCIR.

Inspections are conducted at economic operators for the verification of the products (visual check of the marking and labelling, as well as the verification of the documents attesting the assessment of the conformity of the products with the essential safety requirements set out in European directives).

In cases where non-conformities are found in the products, economic operators are offered a period of no less than 10 days to take the required corrective actions.

In the event that economic operators fail to bring the products into conformity, they are sanctioned with a fine and/or complementary measures (withdrawal from the market prohibition of marketing, etc.).

Report on activities carried out under the previous planning period

During the course of 2015, ISCIR carried 47 inspections, of which 44 were proactive inspections and 3 were reactive one.

Altogether there were 14 findings of conformity and 33 findings of non-conformity.

Moreover, a number of 23 corrective actions were taken by economic operators and a number of 10 restrictive measures were adopted by the market surveillance authorities.

2.11. Sector: Cableways

Authority responsible and contact details

National Authority for Control of Boilers, Pressure Vessels and Hoisting Equipment (ISCIR), Inspection, Market Surveillance and Regulatory Directorate, Market Surveillance Service.

Address: Bucharest, Str. Sf. Elefterie nr. 47-49, Sector 5

Telephone/Fax: 004021.411.97.60; 004021.411.97.61 / 004021.410.00.19

E-mail: iscir@iscir.ro

Resources of the Market Surveillance Service under ISCIR:

- 8 full-time staff members;

- available budget: the funding of the activity of ISCIR is fully ensured from the state budget, by the Ministry of Economy, Commerce and Relations with the Business Environment as the Market Surveillance Service does not have a separate budget.

Market surveillance procedures and strategy

Inspections are conducted at economic operators for the verification of the products (visual check of the marking and labelling, as well as the verification of the documents attesting the assessment of the conformity of the products with the essential safety requirements set out in European directives).

In cases where non-conformities are found in the products, economic operators are offered a period of no less than 10 days to take the required corrective actions.

In the event that economic operators fail to bring the products into conformity, they are sanctioned with a fine and/or complementary measures (withdrawal from the market prohibition of marketing, etc.).

Report on activities carried out under the previous planning period

During the course of 2015 ISCIR did not conduct any inspections in this sector.

2.12. Sector: Noise emission in the environment by equipment for use outdoors

Authority responsible and contact details

Responsible authority: Labour Inspection

Contact details: Labour Inspection
Strada Matei Voievod nr. 14, sector 2, Bucharest
E-mail: daniel.stoicescu@inspectiamuncii.ro;
cristian.nedu@inspectiamuncii.ro
Tel. 0040213027031 / Fax. 0040212520097

Resources: The activity of market surveillance is coordinated at central level by a specific structure, and within each territorial labour inspections there are two labour inspectors having also market surveillance-related responsibilities. Overall, there are 42 territorial labour inspections, organised in each county and in the capital city of Bucharest. The institution does not have its own laboratories for product testing.

Market surveillance procedures and strategy

Labour Inspection carries out controls, both proactive controls generally focusing on the products included in the sectoral programme of the institution, and reactive controls as a result of the referrals received, or at the request of other institutions with competences in the field, such as custom institutions, as well as a result of the decisions of the European Commission referring to the application of safeguard clauses.

Following these controls, labour inspectors may ascertain cases of irregularities, may apply remedial measures, may apply sanctions for non-criminal offences, as well as

measures for the restriction of the marketing or for the recall from the market of non-conforming products.

The products from this category included in the annual sectoral programme are established taking into account the information collected in the previous period, other member states' concerns in this field, the impact of the respective products on safety and on the health of users (high number of users, risk level), or other criteria.

Report on activities carried out under the previous planning period

During the course of 2015, 3911 products were controlled in the category of noise emitting equipment for use outdoors, 3813 were identified as compliant with the legal provisions in force, while non-conformities were identified in the case of 98 products.

As a result of the non-conformities ascertained, measures for bringing into conformity, as well as sanctions for non-criminal offences (fine or warnings) and restrictive measures (prohibition of the placement on the market, prohibition of marketing) were taken, as appropriate.

2.13. Sector: Equipment and protective systems intended for use in potentially explosive atmospheres

Authority responsible and contact details

Responsible authority: Labour Inspection

Contact details: Labour Inspection
Strada Matei Voievod nr. 14, sector 2, Bucharest
E-mail: daniel.stoicescu@inspectiamuncii.ro;
cristian.nedu@inspectiamuncii.ro
Tel. 0040213027031 / Fax. 0040212520097

Resources: The activity of market surveillance is coordinated at central level by a specific structure, and within each territorial labour inspections there are two labour inspectors having also market surveillance-related responsibilities. Overall, there are 42 territorial labour inspections, organised in each county and in the capital city of Bucharest. The institution does not have its own laboratories for product testing.

Market surveillance procedures and strategy

Labour Inspection carries out controls, both proactive controls generally focusing on the products included in the sectoral programme of the institution, and reactive controls as a result of the referrals received, or at the request of other institutions with competences in the field, such as custom institutions, as well as a result of the decisions of the European Commission referring to the application of safeguard clauses.

Following these controls, labour inspectors may ascertain cases of irregularities, may apply remedial measures, may apply sanctions for non-criminal offences, as well as

measures for the restriction of the marketing or for the recall from the market of non-conforming products.

The products from this category included in the annual sectoral programme are established taking into account the information collected in the previous period, other member states' concerns in this field, the impact of the respective products on safety and on the health of users (high number of users, risk level), or other criteria.

Report on activities carried out under the previous planning period

During the course of 2015, 68 products were controlled from the category of equipment and protective systems intended for use in explosive atmospheres, all of which were found to be compliant with the legal provisions in force.

2.14. Sector: Pyrotechnic products

Authority responsible and contact details

Responsible authority: Labour Inspection.

Contact details: Labour Inspection
Strada Matei Voievod nr. 14, sector 2, Bucharest
E-mail: daniel.stoicescu@inspectiamuncii.ro;
cristian.nedu@inspectiamuncii.ro
Tel. 0040213027031 / Fax. 0040212520097

Resources: The activity of market surveillance is coordinated at central level by a specific structure, and within each territorial labour inspections there are two labour inspectors having also market surveillance-related responsibilities. Overall, there are 42 territorial labour inspections, organised in each county and in the capital city of Bucharest. The institution does not have its own laboratories for product testing.

Market surveillance procedures and strategy

Labour Inspection carries out controls, both proactive controls generally focusing on the products included in the sectoral programme of the institution, and reactive controls as a result of the referrals received, or at the request of other institutions with competences in the field, such as custom institutions, as well as a result of the decisions of the European Commission referring to the application of safeguard clauses.

Following these controls, labour inspectors may ascertain cases of irregularities, may apply remedial measures, may apply sanctions for non-criminal offences, as well as measures for the restriction of the marketing or for the recall from the market of non-conforming products.

The products from this category included in the annual sectoral programme are established taking into account the information collected in the previous period, other member states' concerns in this field, the impact of the respective products on safety and on the health of users (high number of users, risk level), or other criteria.

Report on activities carried out under the previous planning period

During the course of 2015, 859 pyrotechnic products were controlled, 807 of which were found to be compliant with the legal provisions in force, while non-conformities were identified for 52 products.

As a result of the non-conformities ascertained, measures for bringing into conformity, as well as sanctions for non-criminal offences (fine or warnings) and restrictive measures (prohibition of the placement on the market, prohibition of marketing) were taken, as appropriate.

2.15. Sector: Explosives for civil uses

Authority responsible and contact details

Responsible authority: Labour Inspection.

Contact details: Labour Inspection
Strada Matei Voievod nr. 14, sector 2, Bucharest
E-mail: daniel.stoicescu@inspectiamuncii.ro;
cristian.nedu@inspectiamuncii.ro
Tel. 0040213027031 / Fax. 0040212520097

Resources: The activity of market surveillance is coordinated at central level by a specific structure, and within each territorial labour inspections there are two labour inspectors having also market surveillance-related responsibilities. Overall, there are 42 territorial labour inspections, organised in each county and in the capital city of Bucharest. The institution does not have its own laboratories for product testing.

Market surveillance procedures and strategy

Labour Inspection carries out controls, both proactive controls generally focusing on the products included in the sectoral programme of the institution, and reactive controls as a result of the referrals received, or at the request of other institutions with competences in the field, such as custom institutions, as well as a result of the decisions of the European Commission referring to the application of safeguard clauses.

Following these controls, labour inspectors may ascertain cases of irregularities, may apply remedial measures, may apply sanctions for non-criminal offences, as well as measures for the restriction of the marketing or for the recall from the market of non-conforming products.

The products from this category included in the annual sectoral programme are established taking into account the information collected in the previous period, other member states' concerns in this field, the impact of the respective products on safety and on the health of users (high number of users, risk level), or other criteria.

Report on activities carried out under the previous planning period

During the course of 2015, 100 products were controlled from the category of explosives for civil uses, all of which were found to be compliant with the legal provisions in force.

2.16. Sector: Appliances burning gaseous fuels

Authority responsible and contact details

National Authority for Control of Boilers, Pressure Vessels and Hoisting Equipment (ISCIR), Inspection, Market Surveillance and Regulatory Directorate, Market Surveillance Service.

Address: Bucharest, Str. Sf. Elefterie nr. 47-49, Sector 5

Telephone/Fax: 004021.411.97.60; 004021.411.97.61 / 004021.410.00.19

E-mail: iscir@iscir.ro

Resources of the Market Surveillance Service under ISCIR:

- 8 full-time staff members;

- available budget: the funding of the activity of ISCIR is fully ensured from the state budget, by the Ministry of Economy, Commerce and Relations with the Business Environment as the Market Surveillance Service does not have a separate budget.

Market surveillance procedures and strategy

The activity of the Market Surveillance Service is carried out on the basis of the annual sectoral programme and on the monthly control programme approved by the Chief State Inspector of ISCIR to be conducted at economic operators (importers, distributors, authorised representatives and others) on the products/equipment in the field regulated by ISCIR.

Inspections are conducted at economic operators for the verification of the products (visual check of the marking and labelling, as well as the verification of the documents attesting the assessment of the conformity of the products with the essential safety requirements set out in European directives).

In cases where non-conformities are found in the products, economic operators are offered a period of no less than 10 days to take the required corrective actions.

In the event that economic operators fail to bring the products into conformity, they are sanctioned with a fine and/or complementary measures (withdrawal from the market prohibition of marketing, etc.).

Report on activities carried out under the previous planning period

During the course of 2015, ISCIR carried 57 inspections, of which 56 were proactive inspections and 1 was initiated by the customs authorities.

Altogether there were 23 findings of conformity and 34 findings of non-conformity.

Moreover, a number of 30 corrective actions were taken by economic operators and a number of 4 restrictive measures were adopted.

2.17. Sector: Measuring instruments, non-automatic weighing instruments and prepacked products and units of measurement

Authority responsible and contact details

➤ **Authority:**

Inspection and Market Surveillance Service under the Romanian Bureau for Legal Metrology

➤ **Contact details of the authority:**

Șos. Vitan Bârzești, nr. 11, sector 4, 042122, Bucharest, Romania, tel. 0040.21 3320954, fax. 0040.21 3320615, office@brml.ro,

➤ **Data concerning the resources at the disposal of the authority:**

- does not have its own budget for income and expenses, and the expenses involved in the carrying out of market surveillance activities are fully borne by the centralised budget of the Romanian Bureau for Legal Metrology;
- is composed of 9 people, whose market surveillance-related activity is equivalent to four full-time units;
- has the required technical equipment for carrying out the market surveillance activity through formal verifications, namely 7 mobile laboratories. Where substantive inspections are required, which involve the testing of the controlled weighing instruments, the Romanian Bureau for Legal Metrology provides the market surveillance authority with the available technical and human resources.

2.17.2. Market surveillance procedures and strategy

The “Guide for the uniform application of market surveillance activity for non-automatic weighing instruments and prepacked products and units of measurement” is used in carrying out the activities related to market surveillance.

It cooperates with market surveillance authorities of its area of competence belonging to EU Member States through participating as a member at the meeting of the WELMEC group and ADCO WG5 “Metrological Supervision”, the WELMEC WG2 “Weighing Instruments” group and the WELMEC WG6 “Prepackages” group.

The market surveillance strategy includes the following elements:

- covering all types of products falling under the competence of the surveillance authority through its market surveillance activity;
- covering the entire national territory through its market surveillance activity;
- applying the best practices used at European level in carrying out this activity;
- using the available financial and human resources as efficiently as possible (using risk analysis, information exchange through access to the ICSMS and EMeTAS databases and during the meeting of the WELMEC workgroups, using the results of previous controls, etc.);

- cooperation with the staff responsible for inspection under the Romanian Bureau for Legal Metrology in issues relating to obtaining information on compliance with the technical and metrological requirements during the use of weighing instruments the placement on the market and/or the commissioning of which is the target of market surveillance in order to carry out certain possible reactive surveillance activities at the economic operators responsible for the placement on the market and commissioning thereof;
- campaigns of raising awareness and empowerment of economic operators with responsibilities concerning the placement on the market and/or commissioning of weighing instruments, carried out during proactive surveillance activities with a view to prevent the placement on the market of non-conforming weighing instruments;
- taking all lawful measures for the elimination from the market of non-conforming products, in accordance with the procedures established in the applicable legislation.

Report on activities carried out under the previous planning period

The results obtained after the market surveillance activity:

- During the course of 2015, 942 non-automatic weighing instruments were controlled at 127 economic operators and 8672 weighing instruments at 171 economic operators. 413 products were withdrawn from the market as a result of identifying non-conformities (weighing instruments and non-automatic weighing instruments)

In case of control activities on prepacked products:

- During the course of 2015, for the first three quarters a number of 636 economic operators were controlled, with a total of 1716 batches tested, 8 of which were declared “rejected” and were withdrawn from marketing.

2.18. Sector: Electrical equipment under EMC

2.18.1. Authority responsible and contact details

National Authority for Management and Regulation in Communications of Romania (ANCOM)

www.ancom.org.ro

Str. Delea Nouă, nr. 2
Sector 3, Cod 030925
Bucharest
Telephone: +40 372 845 845
Fax: +40 372 845 402

E-mail: adrian.dan@ancom.org.ro

ANCOM does not have a separate budget allocated for the surveillance of the equipment market.

Given the number of inspections with controlling duties, we estimate a number of 8 full-time equivalent units.

ANCOM owns a test laboratory.

2.18.2. Market surveillance procedures and strategy

Market surveillance entails both proactive and reactive control activities. Proactive market surveillance activities are carried out in accordance with the sectoral market surveillance programme and with market surveillance campaigns organised at European level by the administrative cooperation group EMC ADCO. Reactive market surveillance activities are performed based on the complaints coming from service providers and electronic communications networks, based on notifications received from the National Customs Authority according to the provisions of Regulation (EC) No 765/2008, based on complaints from radio amateurs and users. The applicable penalties for infringing the legislation are warnings/fines and withdrawal/recall from the market.

The sectoral market surveillance programme is developed taking into account the experience gained by ANCOM during the controls performed and following the performance of an impact assessment.

ANCOM cooperates at local level with the National Customs Authority and with the National Authority for Consumers' Protection.

At European level, ANCOM cooperates with market surveillance authorities of EU Member States within the administrative cooperation group EMC-ADCO. The controls are conducted by inspectors in the facilities where the equipment are marketed and commissioned, and at customs points through administrative controls, and as appropriate, through technical verifications done in laboratories.

During 2016, inspections of the following type of electrical equipment shall have priority: power supplies, lighting devices with LED technology and DVD players.

2.18.3. Report on activities carried out under the previous planning period

During the course of 2015, ANCOM carried out 442 controls, as a result of which 42 warnings and 9 fines were imposed.

2.19. Sector: Radio and telecom equipment under RTTE

2.19.1. Authority responsible and contact details

National Authority for Management and Regulation in Communications of Romania (ANCOM)

www.ancom.org.ro

Str. Delea Nouă, nr. 2
Sector 3, Cod 030925

Bucharest
Telephone: +40 372 845 845
Fax: +40 372 845 402

E-mail: adrian.dan@ancom.org.ro

ANCOM does not have a separate budget allocated for the surveillance of the equipment market.

Given the number of inspectors with controlling duties, we estimate a number of 8 full-time equivalent units.

ANCOM owns a test laboratory.

2.19.2. Market surveillance procedures and strategy

Market surveillance entails both proactive and reactive control activities. Proactive market surveillance activities are carried out in accordance with the sectoral market surveillance programme and with market surveillance campaigns organised at European level by the administrative cooperation group ADCO-R&TTE. Reactive market surveillance activities are performed based on the complaints coming from service providers and electronic communications networks, based on notifications received from the National Customs Authority according to the provisions of Regulation (EC) No 765/2008, based on complaints from radio amateurs and users. The applicable penalties for infringing the legislation are warnings/fines and withdrawal/recall from the market.

The sectoral market surveillance programme is developed taking into account the experience gained by ANCOM during the controls performed and following the performance of an impact assessment.

ANCOM cooperates at local level with the National Customs Authority and with the National Authority for Consumers' Protection.

At European level, ANCOM cooperates with market surveillance authorities of EU Member States within the administrative cooperation group ADCO-R&TTE. Furthermore, ANCOM cooperates with the representatives of Member States and of the European Commission within the TCAM Committee, founded on the basis of the provisions of Directive 1999/5/EC.

The controls are conducted by inspectors in the facilities where the equipment are marketed and commissioned, and at customs points through administrative controls, and as appropriate, through technical verifications done in laboratories.

During 2016, inspections of the following type of radio equipment shall have priority: drones, equipment for data transmission in frequency bands 2.4 GHz / 5GHz and GSM/3G/4G repeaters.

2.19.3. Report on activities carried out under the previous planning period

During the course of 2015, ANCOM performed 498 controls, as a result of which 88 warnings and 11 fines were imposed.

2.20. Sector: Electrical appliances and equipment under LVD

Authority responsible and contact details

Responsible authority: Labour Inspection

Contact details: Labour Inspection
Strada Matei Voievod nr. 14, sector 2, Bucharest
E-mail: daniel.stoicescu@inspectiamuncii.ro;
cristian.nedu@inspectiamuncii.ro
Tel. 0040213027031 / Fax. 0040212520097

Resources: The activity of market surveillance is coordinated at central level by a specific structure, and within each territorial labour inspections there are two labour inspectors having also market surveillance-related responsibilities. Overall, there are 42 territorial labour inspections, organised in each county and in the capital city of Bucharest. The institution does not have its own laboratories for product testing.

Market surveillance procedures and strategy

Labour Inspection carries out controls, both proactive controls generally focusing on the products included in the sectoral programme of the institution, and reactive controls as a result of the referrals received, or at the request of other institutions with competences in the field, such as custom institutions, as well as a result of the decisions of the European Commission referring to the application of safeguard clauses.

Following these controls, labour inspectors may ascertain cases of irregularities, may apply remedial measures, may apply sanctions for non-criminal offences, as well as measures for the restriction of the marketing or for the recall from the market of non-conforming products.

The products from this category included in the annual sectoral programme are established taking into account the information collected in the previous period, other member states' concerns in this field, the impact of the respective products on safety and on the health of users (high number of users, risk level), or other criteria.

Labour Inspection has signed, in this field, a cooperation protocol with the National Authority for Consumers' Protection, taking into consideration the interference between the specific duties covered by these two institutions (ANPC has consumer equipment intended competences, while Labour Inspection has competences over technical equipment machines)

Report on activities carried out under the previous planning period

During the course of 2015, 7479 products were controlled from the category of equipment operating at low voltage, 7206 of which were identified as compliant with the legal provisions in force, while non-conformities were identified in the case of 273 products.

As a result of the non-conformities ascertained, measures for bringing into conformity, as well as sanctions for non-criminal offences (fine or warnings) and restrictive measures (prohibition of the placement on the market, prohibition of marketing) were taken, as appropriate.

Sector 20 – National Authority for Consumers’ Protection

Responsible authority and contact details:

In the field of consumer intended electrical household appliances and equipment (EE) the national market surveillance authority is the National Authority for Consumers’ Protection (ANPC), whose contact details are:

National Authority for Consumers’ Protection (ANPC)
Bucharest, B-dul Aviatorilor, nr. 72, RO-011865, sector 1
URL: www.anpc.gov.ro; E-mail: office@anpc.ro
Tel: +4 021 3121275; Fax: +4 021 3143462

The budget allocated to market surveillance activities for the year 2016 is EUR 7 186 647.

In accordance with the provisions of Government Decision No 700/2012 on the structure and operation of ANPC, the central institution has under its authority 8 Regional Commissariats for Consumers’ Protection, which include 41 County Commissariats for Consumers’ Protection and the Commissariat for Consumers’ Protection in Bucharest, employing specialists in the area of non-food products.

Market surveillance procedures and strategy

By the market surveillance activity carried out, ANPC controls whether EE meet the requirements of the applicable technical regulations and whether economic operators act in accordance with their corresponding obligations in order for non-confirming EE to be brought into conformity with the provisions of the applicable technical regulations.

For the testing of electrical household appliances ANPC uses the services of laboratories accredited for the relevant test types.

Report from activities carried out under the previous planning period

Control actions were performed at manufacturers, importers and distributors, and irregularities were found at 310 economic operators, with the amount of the products with irregularities amounting to EUR 99 064.

Analysis of non-conformities identified during the control activity

The controls revealed deviations from the application of the special legislation on electrical equipment (Government Decision No 457/2003 on ensuring the safety of users of low tension electrical equipment), namely: the inscription of the name of the manufacturer, company or trademark and of the CE marking, the contents of the technical file, the contents of the declaration of conformity or the lack thereof.

Actions taken for the solution of non-conformities

- 203 fines were imposed in amount of EUR 146 564.
- The measure of temporary prohibition of marketing, was taken for the failure to observe labelling requirements on EE, amounting to EUR 75 208, and 48 measures were taken for the definitive cessation of marketing for the failure to observe safety requirements in case of EE, amounting to EUR 216.

- At request, economic operators were offered counselling services.

2.21. Sector: Electrical and electronic equipment under RoHS and WEEE and batteries

Authority responsible and contact details

National Environmental Guard (GNM)
Address: B-dul Unirii nr. 78, Bloc J2, Sect. 3, Bucharest
Tel: +4021 326 89 70
Fax: +4021 326 89 71
e-mail: gardamediu@gnm.ro

Staff responsible for control at GNM do not have responsibilities strictly delimited to product sector 21. Given the number of commissioners responsible for control, we estimate the participation in control activities which fall under the provisions of Regulation (EC) No 765/2008 for product sector 21 at 6 full-time units.

For control activities concerning market surveillance, GNM:

- does not have a separate budget;
- does not have its own laboratories;
- does not have a budget for paying the analyses carried out by third party accredited laboratories.

Market surveillance procedures and strategy

Market surveillance for product sector 21 is carried out:

- a) preventively – through scheduled or thematic controls
- b) reactively – as a result of referrals, complaints, etc.

In the event of identifying an offence, the following sanctions can be applied:

- main sanction: a fine ranging anywhere between EUR 2 238 – 111 192
- complementary sanction: temporary suspension of the activity.

The controls carried out on this product sector have a frequency determined by the environmental risk category established for each controlled economic operator. These controls are integrated into broader actions concerning environmental legislation and the legislation on chemicals.

2.22. Sector: A Chemical substances under REACH and Classification and Labelling Regulations; B Other chemicals (Detergents, Paints, Persistent Organic Pollutants, Fluorinated greenhouse gases, Ozone Depleting Substances, etc.)

Authority responsible and contact details

National Environmental Guard (GNM)

Address: B-dul Unirii nr. 78, Bloc J2, Sect. 3, Bucharest

Tel: +4021 326 89 70

Fax: +4021 326 89 71

e-mail: gardamediu@gnm.ro

Staff responsible for control at GNM do not have responsibilities strictly delimited to product sector 22. Given the number of commissioners responsible for control, we estimate the participation in control activities which fall under the provisions of Regulation (EC) No 765/2008 for product sector 22 at 4 full-time units.

For control activities concerning market surveillance, GNM:

- does not have a separate budget;
- does not have its own laboratories;
- does not have a budget for paying the analyses carried out by third party accredited laboratories.

Market surveillance procedures and strategy

Market surveillance for product sector 22 is carried out:

- a) preventively – through scheduled or thematic controls
- b) reactively – as a result of referrals, complaints, etc.

In the event of identifying an offence, the following sanctions can be applied:

- main sanction: a fine ranging anywhere between EUR 2 238 – 111 192
- complementary sanction: temporary suspension of the activity.

The controls carried out on this product sector have a frequency determined by the environmental risk category established for each controlled economic operator. These controls are integrated into broader actions concerning environmental legislation and the legislation on chemicals.

Report on activities carried out under the previous planning period

2.23. Sector: (a) Eco-design and Energy labelling

Authority responsible and contact details

- Authority responsible for market surveillance in this sector: Romanian Regulatory Authority for Energy (ANRE)

- Contact details of the authority:

Str. Constantin Nacu nr. 3, Bucharest, Sector 2, Cod poștal 020995, ROMANIA

Tel: 004021-327.81.74; 004021-327.81.00

Fax: 021-312.43.65.

E-mail: anre@anre.ro

- *Data concerning the resources at the disposal of the authority (estimate for the year 2016):*

2016 budget for market surveillance activities (EUR)	Number of staff (full-time equivalent)	Technical means
The budget cannot be revealed.	22	Vehicles used for field trips

Market surveillance procedures and strategy

The Department of Energy Efficiency under ANRE ensures the cooperation with the Ministry of Energy, with the National Authority for Consumers' Protection (ANPC), with the Romanian Accreditation Association (RENAR) and with the association of household appliance manufacturers.

At international level, ANRE participates in the workgroups within the 'Administrative Cooperation Group' (ADCO) on the issue of energy labelling, and eco-design, respectively.

Given the limited experience in the field of market surveillance, ANRE takes part in the INTAS project within the Horizon 2020 programme in order to ensure the transfer of the know-how required.

Report on activities carried out under the previous planning period

The details of the activity for 2015 are pending for completion and will be sent subsequently.

2.23. Sector: (b) Eco-design and Energy labelling – household washing machines and household dishwashers

Authority responsible and contact details

In the field of household washing machines and household dishwashers the national market surveillance authority is National Authority for Consumers' Protection (ANPC), whose contact details are:

National Authority for Consumers' Protection (ANPC)
Bucharest, B-dul Aviatorilor, nr. 72, RO-011865, sector 1
URL: www.anpc.gov.ro; E-mail: office@anpc.ro
Tel: +4 021 3121275; Fax: +4 021 3143462

The budget allocated to market surveillance activities for the year 2016 is EUR 7 186 647.

In accordance with the provisions of Government Decision No 700/2012 on the structure and operation of ANPC, the central institution has under its authority 8 Regional Commissariats for Consumers' Protection, which include 41 County Commissariats for Consumers' Protection and the Commissariat for Consumers' Protection in Bucharest, employing specialists in the area of non-food products.

Market surveillance procedures and strategy

By the market surveillance activity carried out, ANPC controls whether household washing machines meet the requirements of the requirements of the applicable technical regulations and whether economic operators act according to their corresponding obligations, in order for the non-conforming products to be brought into conformity with the requirements of the applicable technical regulations.

Report on activities carried out under the previous planning period

Control actions were performed at 5 economic operators, with irregularities identified at 3 economic operators.

The controls revealed irregularities with regard to the application of the specific legislation (Commission Regulations (EU) No 1015/2010 and No 1016/2010).

The following irregularities were found: for household washing machines – the power consumption is not specified in off-mode and left-on mode, no indicative information is provided regarding the duration of the programme, the remaining moisture content, energy and water consumption of the main programmes for full and/or partial load, as well as the lack of recommendations concerning the appropriate detergent types according to the different washing temperatures; and for household dishwashers it was found that in the user manual provided by the manufacturer no standard washing programmes were specified (a “standard programme”, meaning that this programme is suitable for washing normally soiled dishes and that it is the most efficient programme in terms of combined energy and water consumption for this type of dishes), the power consumption is not specified in off-mode and left-on mode, as well as no indicative information is provided regarding the duration of the programme, energy and water consumption of the main programmes.

2.23. Sector: (c) Efficiency requirements for hot-boilers fired with liquid or gaseous fuels

Authority responsible and contact details

National Authority for Control of Boilers, Pressure Vessels and Hoisting Equipment (ISCIR), Inspection, Market Surveillance and Regulatory Directorate, Market Surveillance Service

Address: Bucharest, Str. Sf. Elefterie nr. 47-49, Sector 5

Telephone/Fax: 004021.411.97.60; 004021.411.97.61 / 004021.410.00.19

E-mail: iscir@iscir.ro

Resources of the Market Surveillance Service under ISCIR:

- 8 full-time staff members;

- available budget: the funding of the activity of ISCIR is fully ensured from the state budget, by the Ministry of Economy, Commerce and Relations with the Business Environment as the Market Surveillance Service does not have a separate budget.

Market surveillance procedures and strategy

Inspections are conducted at economic operators for the verification of the products (visual check of the marking and labelling, as well as the verification of the documents attesting the assessment of the conformity of the products with the essential safety requirements set out in European directives).

In cases where non-conformities are found in the products, economic operators are offered a period of no less than 10 days to take the required corrective actions.

In the event that economic operators fail to bring the products into conformity, they are sanctioned with a fine and/or complementary measures (withdrawal from the market prohibition of marketing, etc.).

Report on activities carried out under the previous planning period

During the course of 2015, ISCIR did not perform any inspection in this sector.

2.24. Sector: Tyre labelling

Authority responsible and contact details

In the field of tyres intended for natural persons the national market surveillance authority is National Authority for Consumers' Protection (ANPC), whose contact details are:

National Authority for Consumers' Protection (ANPC)
Bucharest, B-dul Aviatorilor, nr. 72, RO-011865, sector 1
URL: www.anpc.gov.ro; E-mail: office@anpc.ro
Tel: +4 021 3121275; Fax: +4 021 3143462

The budget allocated for market surveillance activities for the year 2016 is EUR 7 186 647.

In accordance with the provisions of Government Decision No 700/2012 on the structure and operation of ANPC, the central institution has under its authority 8 Regional Commissariats for Consumers' Protection, which include 41 County Commissariats for Consumers' Protection and the Commissariat for Consumers' Protection in Bucharest, employing specialists in the area of non-food products.

Market surveillance procedures and strategy

By means of the market surveillance activity carried out, ANPC checks whether tyres meet the requirements of the applicable technical regulations and whether economic operators act according to their corresponding obligations in order for non-conforming tyres to be brought into conformity with the requirements of the applicable technical regulations.

2.24.3. Report on activities carried out under the previous planning period

Checks were performed at manufacturers and distributors, with irregularities found at 165 economic operators.

The checks revealed irregularities with regard to the application of the specific legislation on tyre labelling (Regulation (EC) No 1222/2009 on the labelling of tyres with respect to fuel efficiency and other essential parameters).

Thus the following were found: failure to affix on the tyre tread a sticker displaying the label indicating the fuel efficiency class, the external rolling noise class and the measured value of the tyre, as well as the wet grip class; failure of the distributor to supply the sticker; lack of information included at least in the technical promotional material on the fuel efficiency class, the external rolling noise class and the measured value of the tyre, as well as the wet grip class; lack of information concerning winter characteristics (from 1 November 2011, new "winter" tyres must display information concerning winter characteristics, namely the "M+S", "M.S" or "M&S" symbols, written with letters, on the sidewall (flank) of the tyre).

Actions taken to rectify non-conformities

- 76 fines were imposed in the amount of EUR 111 812.
- Marketing was temporarily prohibited for 825 new tyres.
- Upon request, economic operators were offered counselling services.

2.25. Sector: Recreational craft

Authority responsible and contact details

- Authority responsible for market surveillance in this sector: Romanian Naval Authority, under the authority of the Ministry of Transport
- Contact details of the authority:

Incinta Port Constanța Nr. 1, Clădirea ANR, Constanța 900 900
Tel: +40 241 61.61.24, +40 241 61.61.04
Fax: +40 241 61.62.29
www.rna.ro
e-mail: rna@rna.ro

Data concerning the resources at the disposal of the authority: the budget intended for the market surveillance activity is not highlighted separately; allocated staff: 3 employees.

Market surveillance procedures and strategy

- Relevant procedures: the market surveillance activity is performed according to operational procedure ANR PO-ICSN21 – Market surveillance in the regulated fields. The procedure establishes the course of procedures and the monitoring of the handling of complaints. The applicable penalties are specified in the implementation act, namely in Government Decision No 2195/2004 establishing the conditions for placing on the market and/or putting into service recreational craft.
- Any form of specific cooperation concerning the sector: cooperation with the customs authority takes place pursuant to Regulation (EC) No 765/2008. Cooperation with the authorities of other Member States takes place within the Administrative Cooperation Group on recreational crafts (ADCO RCD).

The general market surveillance strategy in the sector: the priorities for enforcement measures are established based on the analysis of the results of the market surveillance inspections of the previous year; the priorities and market surveillance campaigns established at the ADCO RCD meetings are also taken into consideration. Report from activities carried out under the previous planning period

2.25.3. Report on activities carried out under the previous planning period

During the course of 2015, five scheduled inspections were conducted at three Romanian manufacturers of recreational craft. At one of the manufacturers a non-conformity was identified, which was remedied within the requested deadline.

The exhibitors of the Bucharest International Boat Show that took place on 4–8 March 2015 were also subject to a check. The results of the check were satisfactory, as the exhibitors met the requirements of the legislation on the placement of products on the market.

2.26. Sector: Marine equipment

Authority responsible and contact details

- Authority responsible for market surveillance in this sector: Romanian Naval Authority, under the authority of the Ministry of Transport
- Contact details of the authority:

Incinta Port Constanța Nr.1, Clădirea ANR, Constanța 900 900
Tel: +40 241 61.61.24, +40 241 61.61.04

Fax: +40 241 61.62.29

www.rna.ro

e-mail: rna@rna.ro

Data concerning the resources at the disposal of the authority: the budget intended for the market surveillance activity is not highlighted separately; allocated staff: 3 employees.

Market surveillance procedures and strategy

- Relevant procedures: the market surveillance activity is performed according to operational procedure ANR PO-ICSN21 – Market surveillance in the regulated fields. The procedure establishes the course of procedures, the monitoring of the handling of complaints. The applicable penalties are specified in the implementation act, namely in Government Decision No 494/2006 on marine equipment.
- Any form of specific cooperation concerning the respective sector: cooperation with the customs authority takes place pursuant to Regulation (EC) No 765/2008. Cooperation with the authorities of other Member States takes place within the Administrative Cooperation Group in the field of marine equipment (ADCO MED).
- The general market surveillance strategy in the respective sector: the priorities for the application of the measures of ensuring compliance with the legislation are established based on the analysis of the results of the market surveillance inspections of the previous year; the priorities and market surveillance campaigns established at the ADCO MED reunions are also taken into consideration.

Report on activities carried out under the previous planning period

During the course of 2015, 13 scheduled inspections were conducted at 3 Romanian marine equipment distributors. No non-conformities were found.

2.27. Sector: Motor vehicles and tractors

Authority responsible and contact details

Market surveillance and control activities in the field of road vehicles is carried out by the staff of the Market Surveillance Department under “Romanian Automotive Registry” Autonomous Regie.

Contact details of the authority:

Address: Calea Griviței 391A, Sector 1, Cod Poștal 010719, Bucharest, Romania

Tel: +4021.2027051, +40722775290

E-mail: dsp@rarom.ro

Data concerning the resources at the disposal of the authority:

- Staff available to the market surveillance authority: 14 employees

- The budget intended for market surveillance activities is included in the “Romanian Automotive Registry” Autonomous Regie’s own budget. No budgetary funding is available for this activity. As the performed market surveillance activities also refer to other aspects besides the activities referred to in this report, the budget specifically allocated for market surveillance under Directives 2002/24 and 2007/46 and Regulations (EU) No 167/2013 and (EU) No 168/2013 cannot be clearly identified.

Market surveillance procedures and strategy

The control, verification and surveillance of economic operators with regard to compliance with the regulations on the manufacturing/import/distribution of road vehicles, as well as of the products and materials related to their use is carried out according to the law.

Report on activities carried out under the previous planning period

During the course of 2015, 948 physical controls were carried out on the products, as a result of which 228 sanctions/penalties were imposed.

2.28. Sector: Non-road mobile machinery

Authority responsible and contact details

Responsible authority: Labour Inspection

Contact details: Labour Inspection
Strada Matei Voievod nr. 14, sector 2, Bucharest
E-mail: daniel.stoicescu@inspectiamuncii.ro;
cristian.nedu@inspectiamuncii.ro
Tel. 0040213027031 / Fax. 0040212520097

Resources: The activity of market surveillance is coordinated at central level by a specific structure, and within each territorial labour inspections there are two labour inspectors having also market surveillance-related responsibilities. Overall, there are 42 territorial labour inspections, organised in each county and in the capital city of Bucharest. The institution does not have its own laboratories for product testing.

Market surveillance procedures and strategy

Labour Inspection carries out controls, both proactive controls generally focusing on the products included in the sectoral programme of the institution, and reactive controls as a result of the referrals received, or at the request of other institutions with competences in the field, such as custom institutions, as well as a result of the decisions of the European Commission referring to the application of safeguard clauses.

Following these controls, labour inspectors may ascertain cases of irregularities, may apply remedial measures, may apply sanctions for non-criminal offences, as well as measures for the restriction of the marketing or for the recall from the market of non-conforming products.

The products from this category included in the annual sectoral programme are established taking into account the information collected in the previous period, other member states' concerns in this field, the impact of the respective products on safety and on the health of users (high number of users, risk level), or other criteria.

Report on activities carried out under the previous planning period

During the course of 2015, 1212 products were controlled from the non-road mobile machinery category, 1162 of which were identified as compliant with the legal provisions in force, while non-conformities were identified in the case of 50 products.

As a result of the non-conformities ascertained, measures for bringing into conformity, as well as sanctions for non-criminal offences (fine or warnings) and restrictive measures (prohibition of the placement on the market, prohibition of marketing) were taken, as appropriate.

2.29. Sector: Fertilisers

Authority responsible and contact details

Ministry of Agriculture and Rural Development (MADR) – Inspection, Verification and Control Monitoring Directorate (DMIVC)

Bucharest- B-dul Carol I, nr.2-4, sector 3

Tel: +4021.3072340

E-mail: fertilizanti@madr.ro

Data concerning the resources at the disposal of the authority:

2016 budget for market surveillance activities (EUR)	Number of staff (full-time equivalent)
327273	42*

*an inspector each under DMIVC in each county

Accredited laboratories are used for performing chemical analyses for fertilisers. The laboratories accredited and notified to the European Union for carrying out chemical analyses for determining the conformity of fertilisers, in accordance with Regulation (EC) No 2003/2003 are:

1. National Research and Development Institute for Soil Science, Agricultural Chemistry and Environmental Protection – ICPA Bucharest;
2. National Research and Development Institute for Chemistry and Petrochemistry (ICECHIM), through the Fertilisers and Biocide Testing Laboratory;

3. National Research and Development Institute for Mining Security and Anti-explosion Protection – INSEMEX Petroșani through the Explosive Materials and Pyrotechnic products Laboratory – L.M.E.A.P.

Market surveillance procedures and strategy

For the non-conformities identified, inspectors with inspection competences in the field of fertilisers at county level apply warnings for which they establish a time frame for correction. The correction of the irregularities ascertained represents an important and compulsory element in repeating the conformity controls of fertilisers.

If the irregularities found are deemed serious infringements in accordance with the legal provisions in force, sanctions are applied (fines).

MADR –DMIVC – no other form of cooperation with other Member States was involved in the field of fertilisers.

Report on activities carried out under the previous planning period

During the period January–October 2015 464 controls were performed at 424 economic operators dealing with fertilisers, which manufacture, import and market fertilisers in Romania.

Following the verifications performed, 7 warnings were applied with a time frame for correction of the identified non-conformities of anywhere between 3 and 14 days.

The warnings with a time frame for correction, were applied to economic operators for:

- the failure to ensure the traceability of fertilisers circulating on the Romanian market, by the absence of the documents accompanying the fertilisers;
- the economic agents failed to present proof for carrying out the test of resistance to detonation for each batch before placing them on the market/or for presenting the test of resistance to detonation in English;
- the lack of the RO-fertiliser marking on the labels.

Furthermore, 32 chemical fertiliser samples were taken and sent to the accredited laboratories ICPA Bucharest and ICECHIM Bucharest, in order to analyse them and to determine their conformity. The results of the analyses of the samples obtained by the inspectors appointed for the control of the fertilisers were compliant.

2.30. Sector: (a) Other consumer products under GPSD – used tyres

Authority responsible and contact details

The national market surveillance authority in the field of used tyres intended for natural persons is the National Authority for Consumers' Protection (ANPC), whose contact details are:

National Authority for Consumers' Protection (ANPC)
Bucharest, B-dul Aviatorilor, nr. 72, RO-011865, sector 1
URL: www.anpc.gov.ro; E-mail: office@anpc.ro
Tel: +4 021 3121275; Fax: +4 021 3143462

The budget allocated to market surveillance activities for the year 2016 is EUR 7 186 647.

In accordance with the provisions of Government Decision No 700/2012 on the structure and operation of ANPC, the central institution has under its authority 8 Regional Commissariats for Consumers' Protection, which include 41 County Commissariats for Consumers' Protection and the Commissariat for Consumers' Protection in Bucharest, employing specialists in the area of non-food products.

Market surveillance procedures and strategy

By the market surveillance activity carried out, ANPC controls whether used tyres intended for natural persons fulfil the requirements of Act No 245/2004 on general product safety.

Report on activities carried out under the previous planning period

Control actions were performed at the concerned economic operators, with irregularities found at 192 economic operators.

The controls revealed inconsistencies with Act No 245 on general product safety, and infringements were ascertained regarding the visibility of basic information, contained on the sidewall (flank) of the tyre, namely: tyre section width in mm; tyre construction (R=radial); rim diameter; date of manufacture (week, year), as well as irregularities consisting of physical defects, such as: tyres with deep cuts and cracks; damaged tyres and pronounced uneven wear.

2.30. Sector: (b) Other consumer products under GPSD – decoration candles

Authority responsible and contact details

The national market surveillance authority is the National Authority for Consumers' Protection (ANPC), whose contact details are:

National Authority for Consumers' Protection (ANPC)
Bucharest, B-dul Aviatorilor, nr. 72, RO-011865, sector 1
URL: www.anpc.gov.ro; E-mail: office@anpc.ro
Tel: +4 021 3121275; Fax: +4 021 3143462

The budget allocated to market surveillance activities for the year 2016 is EUR 7 186 647.

In accordance with the provisions of Government Decision No 700/2012 on the structure and operation of ANPC, the central institution has under its authority 8 Regional Commissariats for Consumers' Protection, which include 41 County Commissariats for Consumers' Protection and the Commissariat for Consumers' Protection in Bucharest, employing specialists in the area of non-food products.

Market surveillance procedures and strategy

By the market surveillance activity carried out, ANPC controls whether decoration candles fulfil the requirements of Act No 245/2004 on general product safety.

Report on activities carried out under the previous planning period

The control actions were carried out at the distributors, with irregularities identified at 276 economic operators.

The controls revealed inconsistencies with Act No 245 on general product safety, and infringements were ascertained regarding the information of consumers and the translation into Romanian of the information intended for consumers, as well as irregularities were found regarding the safety labels.

Actions taken for the solution of non-conformities

- 166 fines were imposed, in amount of EUR 126 407.
- 201 measures were taken for the temporary interruption of marketing due to the failure to comply with labelling requirements, in amount of EUR 19 352 at the direct sales and 5 remedial measures were taken (correction or supplementation of the information contained on the advertising websites where irregularities were found) at the online sales.
- At request, economic operators were offered counselling services.

2.30. Sector: (c) Other consumer products under GPSD – lighters

Authority responsible and contact details

The national market surveillance authority is the National Authority for Consumers' Protection (ANPC), whose contact details are:

National Authority for Consumers' Protection (ANPC)
Bucharest, B-dul Aviatorilor, nr. 72, RO-011865, sector 1
URL: www.anpc.gov.ro; E-mail: office@anpc.ro
Tel: +4 021 3121275; Fax: +4 021 3143462

The budget allocated to market surveillance activities for the year 2016 is EUR 7 186 647.

In accordance with the provisions of Government Decision No 700/2012 on the structure and operation of ANPC, the central institution has under its authority 8 Regional Commissariats for Consumers' Protection, which include 41 County Commissariats for Consumers' Protection and the Commissariat for Consumers' Protection in Bucharest, employing specialists in the area of non-food products.

Market surveillance procedures and strategy

By the market surveillance activity carried out, ANPC whether lighters fulfil the requirements of Act No 245/2004 on general product safety.

Report on activities carried out under the previous planning period

The controls revealed inconsistencies with Act No 245 on general product safety, and infringements were ascertained regarding: the marketing of banned lighters (lighters without safety features for children and fantasy lighters), marking of lighters, the existence and content of the declaration of conformity, the obligations of the manufacturers/importers (to test the lighters prior to their placement on the market and to

continuously monitor their conformity, but also concerning the contents of the reports on the tests), obligations of the distributors (to keep and supply the documentation and to identify the traceability in the supply chain).

Actions taken for the solution of non-conformities

- 152 fines were applied in amount of EUR 111 118.
- Measures were taken for the temporary interruption of marketing due to the failure to comply with labelling requirements, in amount of EUR 7 595 measures were taken for the definitive cessation of marketing for banned lighters (lighters without safety features for children and fantasy lighters), in amount of EUR 958.

2.31. Sector: Biocides

Authority responsible and contact details

Contact details of the competent authority:

Ministry of Health, str. Cristian Popișteanu nr. 1-3, 010024, sector 1, Bucharest

Person responsible for the sectoral plan: Conf. univ. Dr. Lucian L. INDREI – Head of Service, State Health Inspection

e-mail: lucian.indrei@ms.ro, tel. 004021.307.25.56

Data concerning the resources at the disposal of the competent authority

- health inspectors of county level public health directorates
- laboratories of the National Institute of Public Health and of county level public health directorates

Contact details of the authority with responsibilities:

1. National Sanitary Veterinary and Food Safety Authority, Piața Presei Libere nr. 1, Corp D1, Sector 1, 013701, sector 1, Bucharest

Person responsible: Dr. Sorin Ion Mitrea, general director, Directorate General for Official Control, Inspections and Official Control Directorate, Control Service of Medicinal Products, Nutrition and Laboratories

E-mail: office@ansvsa.ro, Web: www.ansvsa.ro

2. National Environmental Guard, B-dul. Unirii, nr.78, bl.J2, sector 3, Bucuresti

Person responsible: Octavian Popescu, General director, Control Service of Waste Management and Dangerous Chemical Preparations

E-mail: gardamediu@gnm.ro, Web: www.gnm.ro

Data concerning the resources at the disposal of the authority with responsibilities

- appointed person at the National Sanitary Veterinary and Food Safety Authority
- appointed staff of the National Environmental Guard

Market surveillance procedures and strategy

Market surveillance activity in the field of biocidal products is carried out according to the provisions of:

- Government Decision No 617/2014 establishing the institutional framework and measures for the implementation of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products
- Joint Order No 726/1178/96/2015 of the Ministry of Health/ Ministry of Environment, Waters and Forests/ANSVSA establishing the necessary measures for carrying out official controls by the appointed staff of the responsible public authorities set out in Article 4(1) of Government Decision No 617/2014 establishing the institutional framework and measures for the implementation of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, in order to ensure compliance with Regulation (EU) No 528/2012

Government Decision No 617/2014 establishes the responsibilities of the Ministry of Health acting as competent authority and are appointed the institutions with duties for carrying out official controls, namely: the Ministry of Health through public health directorates; Ministry of Environment, Waters and Forests through the National Environmental Guard; the National Sanitary Veterinary and Food Safety Authority through county level sanitary-veterinary directorates and food safety directorates, and Bucharest. Moreover, the act specifies the actions considered non-criminal offences, the amount of fines and the appointed persons within the above mentioned institutions to ascertain irregularities and apply sanctions.

Joint Order No 726/1178/96/2015 establishes the responsibilities regarding the performance of official controls at manufacturers, importers, distributors and professional/industrial users for biocidal product types, shared between the three institutions, according to their respective competences. The Order specifies that the appointed staff carries out official controls on the basis of: annual official control schedule with established thematic areas; complaints and referrals when the presented situation requires so; at the request of other authorities. Furthermore, the act mentions the fact that the appointed persons have the responsibility to ensure the confidentiality of information and data, signing a declaration concerning confidentiality to this end.

Moreover, the Order establishes that during the official control, the biocidal product may be investigated, including samples may be obtained during thematic controls and in the event of a suspicion, the respective product may be analysed in an accredited laboratory in order to certify that the biocidal product complies with the legal provisions and conditions contained in the administrative act for the placement on the market of biocidal products or in the assessment report, as appropriate.

Report on activities carried out under the previous planning period

The market surveillance programme established by the Ministry of Health during the course of 2015 and published on the website of the Ministry of Health, established the performance of controls by health inspectors within the Ministry of Health. The objectives of the thematic action were the following:

- Inspections at manufacturers, importers, distributors in storage, sales and service units, at users for the verification of biocidal products placed on the market, pursuant to the provisions of Order No 726/1178/96/2015;
- Information of all holders of biocidal product endorsements for fulfilling the provisions of Article 95 of Regulation (EU) No 528/2012.

During these actions a number of 2416 units were controlled:

- 41 biocidal product manufacturers
- 21 biocidal product importers
- 73 biocidal product distributors

- 1953 biocidal product users (e.g. hospitals, schools, beauty salons)
- 82 biocidal product professional users
- 246 biocidal product retailers.

During 2015 health inspectors carried out permanent control actions in order to verify the conformity of biocidal products, as well as on the basis of complaints, notifications and incidents. Altogether 39448 controls were conducted at national level at:

- 53 manufacturers
- 19 importers
- 195 distributors
- 35856 users (health units, schools, tourism facilities, beauty salons, etc.)
- 257 professional users.

As a result of the verifications, a number of 427 warnings and 84 fines were applied with a total amount of EUR 26 727.

During the course of the control mission 267 litres of biocidal products and 109 379 items of biocidal products (e.g. bottles, pills, tablets, insect-repellent bracelets) were withdrawn from the market. Furthermore, the placement on the market of 4 litres of biocidal products and 549 items of biocidal products (e.g. bottles, pills, tablets) was prohibited.

The outcomes of the control actions performed at national level in the field of biocidal products, grouped into specific information categories, may be accessed on the following website: <http://www.ms.ro/?pag=195>

2.32. Sector: Textile labelling

Authority responsible and contact details

The national market surveillance authority in the field of textile products is the National Authority for Consumers' Protection (ANPC), whose contact details are:

National Authority for Consumers' Protection (ANPC)
 Bucharest, B-dul Aviatorilor, nr. 72, RO-011865, sector 1
 URL: www.anpc.gov.ro; E-mail: office@anpc.ro
 Tel: +4 021 3121275; Fax: +4 021 3143462

The budget allocated to market surveillance activities for the year 2016 is EUR 7 186 647.

In accordance with the provisions of Government Decision No 700/2012 on the structure and operation of ANPC, the central institution has under its authority 8 Regional Commissariats for Consumers' Protection, which include 41 County Commissariats for Consumers' Protection and the Commissariat for Consumers' Protection in Bucharest, employing specialists in the area of non-food products.

Furthermore, for textile products, ANPC has its own accredited laboratory – CNIEP LAREX.

Market surveillance procedures and strategy

By the market surveillance activity carried out, ANPC controls whether textile products fulfil the requirements of the applicable technical regulations and whether economic operators act according to their corresponding obligations, in order for these to be brought into conformity with the requirements of the applicable technical regulations.

Report on activities carried out under the previous planning period

Control actions were performed at several economic operators, with irregularities found regarding the requirements on the marking/labelling of textile products at 647 economic operators.

Actions taken for the solution of non-conformities

- 457 fines were applied, in amount of EUR 409 278.
- 471 measures were taken for the temporary interruption of marketing due to the failure to comply with labelling requirements.
- At request, economic operators were offered counselling services.