

***NATIONAL MARKET SURVEILLANCE
PROGRAMME
2015
REPUBLIC OF BULGARIA***

1. GENERAL MARKET SURVEILLANCE ORGANISATION AND INFRASTRUCTURE

1.1 IDENTIFICATION AND RESPONSIBILITIES OF NATIONAL MARKET SURVEILLANCE AUTHORITIES

State Agency for Metrological and Technical Supervision (DAMTN)

The State Agency for Metrological and Technical Supervision (DAMTN) is the national authority responsible for the market surveillance of products covered by the New Approach Directives and Regulation (EU) No 305/2011, except for medical devices.

The DAMTN is also responsible for the quality control of liquid fuels. It conducts market surveillance in respect of products covered by Directive 2009/125/EC establishing a framework for the setting of ecodesign requirements for energy-related products; Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS); and Directive 2002/96/EC on waste electrical and electronic equipment (WEEE).

The DAMTN has a centralised structure, comprising the head offices of each of its Directorates-General and their respective local departments.

Market surveillance activities are conducted by a total of 188 agency employees.

The budget of the DAMTN earmarked for market surveillance is BGN 2 907 198 (EUR 1 486 427).

Consumer Protection Commission (KZP)

The Consumer Protection Commission (KZP) is Bulgaria's specialist government body responsible for consumer protection and one of the principal domestic market surveillance authorities. The KZP is a collegiate body with the Minister for Economy and Energy. It is a legal person, disbursing subsidies transferred from the budget of the central government, with a head office in Sofia, local departments throughout Bulgaria, and a total of 176 full-time employees. Its main competencies are stipulated in the Consumer Protection Act, the Tourism Act, the Consumer Loans Act, the Electronic Trade Act and the Distance Marketing of Financial Services Act. It has additional shared competencies under the Wine and Spirit Drinks Act, the Tobacco and Tobacco Products Act, the Genetically Modified Organisms Act, the Motoring Act, the Waste Management Act and the relevant implementing regulations thereto.

The KZP aims to:

- create conditions that enable the protection of basic consumer rights;
- conduct surveillance to ensure that the products and services available on the domestic market conform to general safety requirements;
- protect the economic interests of consumers;
- protect consumers against unlawful business practices;
- ensure consumer protection in respect of tourism products and services;

- develop an out-of-court system for the settlement of consumer disputes (conciliation and mediation);
- ensure compliance with the right to information and raise consumer awareness.

In 2013, the nominal budget available to the KZP for market surveillance was EUR 733 555.

The staff available for market surveillance activities (full-time equivalent units) was 129 employees.

The number of inspectors available to market surveillance authorities (full-time equivalent units) is 108.

The KZP does not have in-house (proprietary) product testing laboratories. Product testing is outsourced to independent laboratories.

Bulgarian Food Safety Agency (BABH)

The Bulgarian Food Safety Agency carries out controls on the production, import, packaging, repackaging, placing on the market, storage, and trade in and marketing of fertilisers, soil enhancers, biologically active substances and micro-nutrients in compliance with the requirements laid down in the relevant statutory acts and bylaws.

BABH website: <http://www.babh.government.bg>

Annual plans for the monitoring of fertilisers, soil enhancers, biologically active substances and micro-nutrients, subject to approval by a dedicated order issued by the Head of the BABH, are adopted and notified to the Heads of the Provincial Food Safety Directorates (ODBH).

Each ODBH implements a regional control plan, approved by an order of the Head of the respective ODBH.

In line with the approved regional control plans, inspectors from the Plant Protection Department conduct checks on production and repackaging sites, retail outlets and farm holdings and obtain samples from fertilisers, soil enhancers, biologically active substances and micro-nutrients in order to verify their compliance with the content declared by the respective producers.

The samples obtained for control purposes are submitted for testing to the Central Chemical Testing and Control Laboratory (TsLHIK) — the national reference laboratory.

In line with the 2015 National Control Plan for Fertilisers, approximately 50 samples will be obtained with a view to verifying the compliance of fertilisers with the requirements laid down in Regulation (EC) No 2003/2003 relating to fertilisers bearing the EC Fertiliser logo.

1.2 COORDINATION AND COOPERATION MECHANISMS BETWEEN MARKET SURVEILLANCE AUTHORITIES

State Agency for Metrological and Technical Supervision (DAMTN)

A Council on Coordination and Information Exchange between Market Surveillance Authorities was established pursuant to Decree No 180/2005 of the Council of Ministers. Performing the

functions of a coordination unit, it ensures a high standard of information exchange between market surveillance authorities in Bulgaria.

Agreements on cooperation have been concluded between the DAMTN and the Customs Agency, the Consumer Protection Commission, the National Construction Supervision Directorate, the Telecommunications Regulation Commission and the Technical Controls Inspection Service, respectively, for the purposes of market surveillance. The respective institutions cooperate by exchanging information, making inspections on the basis of complaints received by one of the parties, taking joint action, etc.

Bulgarian Food Safety Agency (BABH)

The BABH conducts market surveillance on fertilisers jointly with the Customs Agency. When fertilisers that do not comply with requirements are detected, the inspectors take the necessary actions within their remit as provided for in the Plant Protection Act and immediately inform the customs authorities by a notification specifying that a non-compliant product has been detected. In this case, the fertilisers concerned are not released for free circulation.

1.3 COOPERATION BETWEEN NATIONAL MARKET SURVEILLANCE AUTHORITIES AND CUSTOMS

State Agency for Metrological and Technical Supervision (DAMTN)

In accordance with Regulation (EC) No 765/2008, the DAMTN cooperates with the Customs Agency on the basis of guidelines on cooperation between the two institutions adopted in 2009. Regular working meetings take place between representatives of the two agencies to ensure a high standard of coordination.

Consumer Protection Commission (KZP)

The Consumer Protection Commission and the Customs Agency cooperate by conducting a nationwide, year-round joint campaign aiming to prevent the placing of dangerous products on the domestic market.

Bulgarian Food Safety Agency (BABH)

The Bulgarian Food Safety Agency and the Customs Agency cooperate on the basis of guidelines on cooperation between the two institutions with a view to stepping up controls on commercial consignments, and in particular on the import controls on fertilisers, soil enhancers, biologically active substances and micro-nutrients, taking other joint action, and exchanging information.

1.4. RAPID INFORMATION EXCHANGE SYSTEM — RAPEX

State Agency for Metrological and Technical Supervision (DAMTN)

The DAMTN receives notifications via the Rapid Alert System for Dangerous Products (RAPEX) through the designated national contact point — the Consumer Protection Commission. Checks conducted on the notified products and replies are prepared in respect of the notified products identified.

The measures envisaged in Article 20 of Regulation (EC) No 765/2008 are taken with regard to the identified products when their use carries a significant risk and the European Commission and other

Member States are notified via RAPEX in accordance with Article 22 of Regulation (EC) No 765/2008.

Consumer Protection Commission (KZP)

With regard to the measures and actions concerning non-food consumer products that present a risk to consumer health, the designated RAPEX (System for Rapid Exchange of Information between the Member States and the European Commission) contact point for Bulgaria is the Consumer Protection Commission. In that capacity, the KZP coordinates the work of the following bodies responsible for conducting controls under the Health Act on cosmetic products and the production, marketing and use of certain hazardous substances, compounds and products in compliance with the requirements laid down in Regulation (EC) No 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH): the State Agency for Metrological and Technical Supervision in respect of the safety of the products covered by the Technical Requirements for Products Act; the Ministry of the Environment and Water in respect of verifying compliance with the requirements laid down in Regulation (EC) No 1907/2006; the Labour Inspector General Executive Agency under the jurisdiction of the Minister for Labour and Social Policy in respect of verifying compliance with the requirements laid down in Regulation (EC) No 1907/2006; the Customs Agency in respect of the import of goods from third countries; and the National Police Service.

The KZP processes, analyses, and translates and forwards — electronically and on paper — information to the designated liaison officers of the respective competent authorities via the RAPEX system. It sends alerts about goods and products that the KZP has detected and ascertained to present a danger to consumers, having first conducted a comprehensive appraisal of the information to be sent to the European Commission.

Coordination is based on the Regulation laying down the rules and procedure for the provision of information about goods and services that present a risk to consumers and the procedure for cooperation between manufacturers, distributors, service providers and control authorities, and on the Rules governing the national system for information exchange between control bodies in respect of the presence of dangerous goods on the Bulgarian market.

1.5. ICSMS INFORMATION SYSTEM

State Agency for Metrological and Technical Supervision (DAMTN)

At national level the ICSMS is administered by the Ministry of Economy and Energy. The DAMTN is also involved in the process by publishing information in the ICSMS about products that present a risk; products that have been subjected to testing; and products in respect of which coercive administrative action has been taken. It also provides information about responses to RAPEX notifications and the results of extended checks taken over from the market surveillance authorities in other Member States, etc.

Since 2013, information about pyrotechnical products, construction products and electrical appliances has been published in the ICSMS in accordance with the Directive on electromagnetic compatibility, etc.

1.6. GENERAL DESCRIPTION OF MARKET SURVEILLANCE ACTIVITIES AND RELEVANT PROCEDURES

State Agency for Metrological and Technical Supervision (DAMTN)

Market surveillance is based on a uniform approach applied across all sectors, taking into account the specific nature of the different product groups.

Market surveillance is conducted on the basis of an approach that is both proactive and reactive.

The reactive approach entails taking action when notifications and alerts are received from the Customs Agency, via RAPEX and the ICSMS or from the market surveillance authorities of other Member States; or complaints are received from citizens, economic operators, public organisations, other national control bodies, the media, etc.

The active approach entails the following planned market surveillance activities:

- actions taken in line with the sectoral programme in compliance with Article 18(5) of Regulation (EC) No 765/2008;
- actions relating to the exchange of information within administrative cooperation groups (ADCO) and participation in joint projects implemented by PROSAFE.

The checks conducted as an element of the proactive approach are planned in advance. Product groups are determined on the basis of pre-selected criteria, such as an analysis of checks conducted; products for which non-compliance has been ascertained; analysis of the results of checks conducted on the basis of alerts and complaints received; product groups for which notifications via RAPEX and ICSMS have been received; products for which notifications from the Customs Agency have been received; products covered by directives/regulations that have recently entered into force or directives under which no checks have been conducted; products for seasonal use; product groups assessed by ADCO; and products included in the scope of EU-wide joint action projects, etc.

The reactive approach entails conducting checks on the basis of complaints and alerts received from citizens, economic operators, public organisations, other national control bodies and the media, via RAPEX and the ICSMS and from other Member States.

All actions taken from the planning stage up to that of reporting are based on procedures designed to ensure that market surveillance is conducted on the basis of a uniform approach.

The DAMTN follows a procedure for carrying out unannounced checks on the basis of complaints and alerts received from citizens, economic operators, public organisations, other national control bodies and the media, via RAPEX and the ICSMS and from other Member States.

Information about incidents involving lifting equipment, pressure appliances, elevators, etc. that present a higher danger is collected and analysed every six months. A record of incidents and accidents involving this type of equipment is kept.

The DAMTN publishes on its website information about products that present a proven danger to consumers and which are subject to RAPEX notifications or responses ('Dangerous products' section) as well as information about non-compliant products ('Non-compliant products' section).

After completing the checks conducted on a particular product group the results are published, identifying the most frequently encountered non-compliant features of the products concerned.

During the course of conducting market surveillance and when non-compliance is ascertained, administrative sanctions (fines) are imposed and coercive administrative action (suspension of distribution, market withdrawal and product seizure) is taken. The measures in question must conform to the principle of proportionality.

Fines ranging from BGN 250 up to 1 000, BGN 500 up to 15 000 and BGN 200 up to 5 000, respectively, are imposed on traders; manufacturers/importers and natural persons. The maximum fine of BGN 15 000 is imposed on operators marketing products that do not conform to the stipulated essential requirements for the products concerned and those marketing products for which no conformity assessment and verification are available.

The DAMTN imposes coercive administrative measures on non-compliant products and prohibits their distribution and/or orders their withdrawal from the market. Non-compliant products that present a serious risk and cannot be rectified by technical means are withdrawn from the market, seized and destroyed by the responsible economic operators.

As an element of its prevention activities the DAMTN contributes to raising the awareness of the business community and the general public by publishing the answers to questions received from businesses and other stakeholders, during meetings with representatives of the business community and via the media. The effort is focused on clarifying the requirements for products safety, compliance assessment procedures, etc. laid down in Community law.

Consumer Protection Commission (KZP)

The KZP conducts proactive and reactive market surveillance. Proactive surveillance is based on an analysis of the current state of the market, the outcomes of inspections conducted in previous periods, consumer complaints, information received from other control bodies, media publications, etc. It involves planning campaigns for specific product sectors and market shares. Reactive surveillance entails conducting immediate checks on the basis of notifications received via RAPEX, notifications received from the Customs Agency, information contained in media reports and consumer complaints.

Each complaint received by the KZP is registered in the single recordkeeping system (EDIS) and a corresponding case-file is opened, to be handled strictly within a stipulated period. The KZP pays special attention to ascertaining the level of consumer satisfaction and its development over time as it is considered a reliable indicator of the state of the market. For this purpose, it conducts a careful analysis of all complaints and alerts received in order to gain an understanding of the problems within individual sectors and plan corresponding surveillance campaigns.

The KZP has not set in place a procedure and system for the monitoring of incidents.

The efforts of the Commission to maintain an orderly and balanced market entail ongoing streamlining of the controls conducted to verify the safety of the goods and services available on the market by taking appropriate measures to achieve the goals set, and more specifically:

- ensuring maximum transparency about potential market risks with a view to ensuring that consumers have comprehensive information about the presence of dangerous goods by maintaining the following public registers on its webpage (www.kzp.bg):

- a record of the dangerous goods found on the Bulgarian market, which contains relevant information, including a description and photographs of the goods concerned, the nature of the risk they present, and details of the voluntary or coercive action taken;
- a record of the dangerous goods found on the Community market, which contains relevant information, including a description and photographs of the goods concerned, the nature of the risk they present and details of the voluntary or coercive action taken;
- providing consumers with more and diverse visual materials—educational brochures, intended as a learning aid aiming to raise the level of general and consumer awareness in Bulgaria;
- conducting information campaigns and media publications and appearances aiming to increase the number, thereby enhancing the effect, of the information and awareness campaigns targeting traders and consumers and promoting consumer rights and the obligations of traders and manufacturers.

Where a breach of statutory requirements is ascertained, fines ranging from BGN 300 up to 15 000 are imposed, depending on the type and severity of the breach. Procedures for imposing coercive administrative measures are also in place.

The KZP organises meetings, workshops and discussions with sectoral organisations and stakeholders on a regular basis in an effort to promote understanding and correct application of the relevant statutory requirements and identify problem areas.

Bulgarian Food Safety Agency (BABH)

As regards the monitoring of fertilisers, the Bulgarian Food Safety Agency conducts controls at production, packaging, repackaging and storage sites and on the marketing of fertilisers, soil enhancers, biologically active substances and micro-nutrients. Their goal is to ascertain the compliance of fertilisers with the requirements laid down in Regulation (EC) No 2003/2003 relating to fertilisers bearing the EC Fertiliser logo (composition, packaging and labelling).

The number of checks conducted in each area depends on the number and type of sites situated within it. Annual checks are conducted on all production, packaging, repackaging and storage sites for fertilisers, soil enhancers, biologically active substances and micro-nutrients within individual provinces. Depending on the specific nature of the retail sites, checks are also conducted on agricultural pharmacies and retail stores from which fertilisers are available.

The samples intended for laboratory testing are obtained by trained officials in accordance with an annual local plan for the control of fertilisers, soil enhancers, biologically active substances and micro-nutrients. The plan is drawn up by each Provincial Food Safety Directorate and includes a schedule of the inspections and a sampling schedule. The samples from fertilisers to be tested in order to ascertain their quality and composition are obtained in accordance with the methods described in Regulation (EC) No 2003/2003 relating to fertilisers, which have been tested in the laboratory notified in accordance with Article 30 of the same Regulation.

1.7 GENERAL FRAMEWORK OF COOPERATION WITH OTHER MEMBER STATES AND NON-MEMBER STATES

State Agency for Metrological and Technical Supervision (DAMTN)

DAMTN representatives participate in the working groups of the European Commission, the administrative cooperation (ADCO) groups, and market surveillance conferences and workshops, etc.

The Agency also participates in cross-border projects implemented by the European Commission and PROSAFE and in campaigns organised by the ADCO groups. It will participate in the Risk Assessment project to be implemented by PROSAFE.

Consumer Protection Commission

The Consumer Protection Commission participates in joint market surveillance projects concerning specific product groups and in the meetings of the Committee on application of the General Product Safety Directive and the Consumer Protection Network.

1.8 EVALUATION OF MARKET SURVEILLANCE ACTIONS AND REPORTING

Consumer Protection Commission (KZP)

The KZP reports on its monitoring activities on a monthly, quarterly, semi-annual and annual basis. The annual reports are publicly available on its website (www.kzp.bg). It also reports on a quarterly basis to the Ministry of Economy and Energy on the achievement of the targets set in the Consumer Protection Programme.

1.9 HORIZONTAL ACTIVITIES PLANNED FOR THE RELEVANT PERIOD

2. MARKET SURVEILLANCE IN SPECIFIC SECTORS

State Agency for Metrological and Technical Supervision (DAMTN)

The DAMTN conducts market surveillance in the abovementioned sectors, relying on a staff of 188 employees and a budget of BGN 2 907 198 (EUR 1 486 427).

The DAMTN operates an in-house laboratory for the testing of fuels, lubricants and additives.

2.1 Sector: Medical Devices — Directives 93/42/EEC, 98/79/EC and 90/385/EEC

2.1.1 Responsible authority and contact details

Drugs Executive Agency (IAL)

Address: Sofia 1303, 8 Damyan Gruev Street

Tel: (+359 2) 890 3555, Fax: (+359 2) 890 3434

E-mail: bda@bda.bg

2.1.2. Market surveillance procedures and strategy

The checks on medical devices placed on the market and/or put into operation are conducted on the basis of an annual market surveillance plan, approved in advance by the Head of the IAL, information received from other market surveillance authorities, and alerts and complaints received from citizens. Market surveillance is conducted by inspecting the devices placed on the market and/or put into operation by obtaining demonstration models and samples intended for testing.

When conducting market surveillance, the IAL may cooperate with departments of the Ministry of Health (Regional Health Inspection Service and the Medical Audit Executive Agency), the Ministry of the Interior, the Customs Agency and the competent authorities responsible for medical devices in other EU Member States and non-member states.

Market surveillance is conducted with a view to ensuring the compliance of medical devices launched on the market and/or put into operation with the requirements laid down in the Medical Devices Act and the relevant implementing regulations laying down the essential requirements for medical products.

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Medical devices	Directives 93/42/EEC, 98/79/EC and 90/385/EEC	Active implantable devices; Anaesthetic and respiratory devices; Dental devices; Electrical mechanical medical devices; Hospital equipment; In vitro diagnostic devices; Inactive implantable devices; Ophthalmic and optical devices; Multiple-use instruments; Disposable instruments; Aids for persons	2015	Todor Darakchiev — Inspector-General; todor.darakchiev@bda.bg ; Tel: (+359 2) 890 3483

		with disabilities; Diagnostic and therapeutic radiation devices; Supplementary therapeutic devices; Devices with a biological origin; Products and devices for hospitals and healthcare establishments; Laboratory equipment		
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2.1.3. Report on activities carried out under the previous planning period

In 2013, with a view to complying with the obligations stipulated in Article 86 of the Medical Devices Act (ZMI) and verifying the compliance of the medical devices placed on the market or put into operation with the requirements laid down by law, the relevant implementing regulations and the annual medical devices market surveillance plan, the experts and inspectors from the Directorate conducted 134 checks across Bulgaria as follows:

- on producers of medical devices: 5;
- on wholesalers trading in medical devices: 60;
- on retailers trading in medical devices: 13;
- on sites under the jurisdiction of the Agency for Disabled Persons: 10;
- on hospitals: 36;
- on the basis of complaints received: 10.

The most frequently encountered infringements of the ZMI include the lack of an authorisation for wholesale trade in medical devices, marketing of medical devices past their date of expiry and the retail sale of medical devices by wholesalers.

In 2013, monitoring of hospitals was stepped up and 36 inspections on healthcare establishments and their clinical laboratories and pharmacies were conducted.

2.2. Sector: Cosmetics — Regulation (EC) No 1223/2009

2.2.1. Responsible authority and contact details

Ministry of Health (MZ)

Public Health Directorate

Address: Sofia 1000, 5 Sveta Nedelya Square

Tel: (+ 359 2) 930 1268

E-mail: istefanova@mh.government.bg

The Ministry of Health (MZ) and the bodies responsible for public health control (28 Regional Health Inspection Services) are the designated competent authorities within the meaning of Article 34(1) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, hereinafter Regulation (EC) No 1223/2009.

The Ministry of Health is the national market surveillance authority for the cosmetics sector. Twenty-eight regional health inspection services operate at provincial level, each with an office in the administrative centre of the respective province.

The Regional Health Inspection Services (RZIs) conduct public health control within each province in order to ensure compliance with the statutory requirements for products with significance for human health (including cosmetic products).

The total staff of the RZIs is 2 904 employees.

The competent authorities at local level rely on the services of in-house laboratories, structured as directorates or departments, which conduct testing and analyses of cosmetic products for the purposes of public health control. The laboratories are accredited under Standards BDS EN ISO/IEC 17025 and/or BDS EN ISO/IEC 17020 and participate in national and international assessments of the suitability of cosmetic products for human health.

2.2.2 Market surveillance procedures and strategy

In order to ensure the efficient functioning of the single European market and in line with the obligation to ensure free movement of goods, since 2010 Bulgaria has been applying Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.

In order to ensure efficient compliance with the requirements for cosmetic products laid down in the relevant law, and in particular Regulation (EC) No 1223/2009 and Regulation (EU) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products, Bulgaria has designated bodies (MZ and RZIs) responsible for market surveillance.

Market surveillance activities include:

- 1. Targeted public health control** — based on alerts/complaints received, information about incidents that present a health risk for the population, cases of non-compliance, test results, notifications/responses to RAPEX notifications and other available information. The control activities include visual inspections, including of the outer appearance, packaging, labelling,

presentation and storage of cosmetic products, inspections of documents (including the product information file), checks conducted to verify good manufacturing practice, and laboratory testing.

When the MZ/RZI receives an alert/complaint from citizens, organisations and other parties, standard procedures are followed to handle complaints, adopt decisions on the proposals and complaints, and conduct follow-up controls.

When the MZ receives information that raises concerns about a serious undesirable effect (incident, malfunction, etc. that may result in temporary or permanent incapacity or cause permanent disability or an immediate threat to life), the RZI responsible for the area where the head office of the manufacturer, importer or distributor is situated conducts an inspection without delay and notifies the results to the MZ within the shortest practicable period to enable it to take further action in accordance with the relevant Community legislation.

2. Public health control conducted on a systematic basis: based on planned annual controls (inspections conducted on manufacturers, importers and distributors of cosmetic products, random and thematic checks) and planned laboratory tests;

3. Border control: in order to prevent the placing on the Community market of products and goods (including cosmetics) from third countries that present a serious and immediate risk to the life and health of consumers, guidelines on cooperation between the Customs Agency and the bodies responsible for public health control under the jurisdiction of the MZ have been developed, which set out the rules for conducting safety checks on products imported from third countries.

The guidelines set out the rules and procedure for cooperation between the Customs Agency and the bodies responsible for public health control when taking joint action and exchanging information relating to their market surveillance functions and the coordination of their activities in this area.

In planning and conducting market surveillance, there is a need to take into account numerous elements of risk assessment, such as the relevant threat level, typical target group, results from checks conducted in previous years, seasonal increase in consumer interest in certain categories of cosmetic products, etc.

Where violations of relevant national and Community law are ascertained, administrative sanctions and fines are imposed. These are stipulated in Articles 213a and 213b of Chapter Eight of the Administrative and Penal Provisions of the Health Act. The minimum fine is BGN 1 000 and the maximum BGN 12 000. The Health Act stipulates the necessary provisions that enable the application of Regulation (EC) No 1223/2009 in Bulgaria.

General market surveillance strategy for the cosmetics sector

1. Introduction of new methods for the laboratory testing of cosmetic products with a view to raising the efficiency of the controls conducted by the competent authorities;
2. Improved use of the Rapid Information Exchange System (RAPEX) to ensure compliance with Article 22 of Regulation (EC) No 765/2008;
3. Stepping up cooperation between the MZ and the RZIs and Customs Agency, respectively, in order to increase the efficiency of controls and prevent the placing on the market of cosmetic products from third countries that present a serious and immediate risk to the life and health of consumers.

Bulgaria conducts the activities listed above as a matter of high priority.

A specific market surveillance strategy for the Cosmetics sector to be implemented during the planning period, which entails conducting:

1. targeted thematic checks on cosmetic products intended for the skin (make-up and skin-lightening products), nail polish and teeth whitening products imported from third countries;
2. targeted thematic checks on certain categories of cosmetic products to verify compliance as regards their composition, labelling, packaging, storage, marketing, accompanying information files and other specific requirements laid down in relevant national and Community law;
3. laboratory tests on the microbiological and chemical parameters of certain groups of cosmetic products, such as those intended for children up to the age of 3 years and sunscreen products;
4. information campaign *Truth and fiction behind cosmetic products—is there such a thing as medical cosmetics?*

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Cosmetics	Regulation (EC) No 1223/2009; Regulation (EU) No 655/2013	Skin products; Hair and scalp products; Products for nails and cuticles; Dental hygiene products.	2015	Irena Stefanova, Tel: (+359 2) 930 1268, e-mail: istefanova@mh.government.bg

2.2.3 Report on activities conducted during the previous planning period (1 January–1 September 2014)

In the framework of the public health control conducted on a regular basis, the RZI inspectors carried out 13 374 checks (inspections) on sites for the production, storage and sale of cosmetic products.

A total of 1 577 and 3 498 tests on the chemical and microbiological properties of cosmetic products, respectively, were conducted and the presence of cadmium and lead — substances listed in points 68 and 289 of Annex II ‘List of prohibited substances in cosmetic products’ to Regulation (EC) No 1223/2009 — was ascertained in two samples. In line with the relevant law 2 notifications were prepared under the RAPEX alert system. One has already been sent (A12/1533/14) and a second one is currently pending for authorisation.

A targeted thematic check to ascertain whether cosmetic products containing heavy metals are present on the market was conducted.

During a check conducted on products notified on the European Commission’s Cosmetic Product Notification Portal (CPNP), a product containing *Phytonadione* — a substance listed in point 1371

of Annex II ‘List of prohibited substances in cosmetic products’ to Regulation (EC) No 1223/2009 — was detected. Notification A12/1088/14 was drawn up in respect of the cosmetic product and sent via RAPEX.

A total of 18 221 checks were conducted under the Rapid Information Exchange System to ascertain the presence of cosmetic products notified via the system. One of the notified products (A12/1226/14) was found on the Bulgarian market and a response to the corresponding RAPEX notification was prepared.

The MZ received 4 alerts in respect of suspected serious undesirable effects resulting from the use of cosmetic products. The Ministry of Health, acting in its capacity as competent authority, notified the serious undesirable effects to the competent authorities of other Member States and to the responsible authority in accordance with the applicable procedure.

Two training workshops aiming to facilitate the application of recently adopted national and Community statutory acts were conducted. They were attended by manufacturers, distributors and importers of cosmetic products operating across Bulgaria.

2.3 Sector: Toys — Directive 2009/48/EC

2.3.1 Responsible authority and contact details

State Agency for Metrological and Technical Supervision (DAMTN)

Address: 1797 Sofia, 52A G.M. Dimitrov Boulevard

<http://www.damtn.government.bg/>

E-mail: damtn@damtn.government.bg

Directorate-General for Market Surveillance (GDNP)

Director-General: Maria Kancheva

E-mail: Maria.Kancheva@damtn.government.bg

2.3.2 Market surveillance procedures and strategy

The proactive and reactive approaches mentioned in section 1.6 are applied in the sector. The sectoral experience gained to date shows a stable trend towards a decrease in the number of toys without a CE conformity marking found on the market. However, cases of formal non-compliance, including lack of information enabling the origin of toys to be traced, have been ascertained. Alternatively, other types of non-compliance have been visually ascertained (longer string/rope in toys intended for pulling and easy access to the battery compartment). Where non-compliance is suspected, samples of the products concerned are obtained for testing. Funds are earmarked for laboratory testing of the products included in the schedule of planned inspections and those identified following inspections conducted after receipt of alerts and complaints, and for participation in cross-border projects.

The DAMTN participates in the cross-border project ‘Joint Market Surveillance Action – Scooters’, which is implemented by PROSAFE and funded by the European Commission.

A market surveillance strategy is applied in the sector. It is based on the conduct of checks on previously detected non-compliant products and products covered by projects implemented by the European Commission, as demonstrated by the planned activities for 2015 set out below.

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Toys	Directive 2009/48/EC	Tricycles (Scooters)	1 March 2015	Temenuzhka Grancharova Temenujka.Grancharova@damtn.government.bg , Tel: (+359 2) 892 9768
		Toys designed to produce a sound	1 November 2015	Temenuzhka Grancharova Temenujka.Grancharova@damtn.government.bg , Tel: (+359 2) 892 9768

2.3.3 Report on activities conducted during the previous planning period

Summary of the outcome of market surveillance conducted in the sector during the first half of 2014

The main product groups on which inspections were conducted during the period are electrically powered toys intended for moving, tricycles, scooters and bicycles.

In line with the annual plan, checks were conducted on 283 toys (electrically powered toys intended for moving and tricycles).

Checks were also conducted on 69 toy models following the receipt of notifications from customs authorities.

Six inspections on toys were conducted following the receipt of alerts and complaints.

In the framework of planned inspections conducted at the end of 2013, a total of 154 toy masks with sharp and unpolished edges were confiscated from an economic operator and destroyed.

Sanctions/fines were imposed on economic operators for infringements relating to four toys.

2.4. Sector: Personal Protective Equipment — Directive 89/686/EEC

2.4.1. Responsible authority and contact details

State Agency for Metrological and Technical Supervision (DAMTN)

Address: 1797 Sofia, 52A G.M. Dimitrov Boulevard

<http://www.damtn.government.bg/>

E-mail: damtn@damtn.government.bg

Directorate-General for Market Surveillance (GDNP)

Director-General: Maria Kancheva

E-mail: Maria.Kancheva@damtn.government.bg

2.4.2 Market surveillance procedure and strategy

The proactive and reactive approaches mentioned in section 1.6 are applied in the sector. In most cases, non-compliant products lack the requisite markings; are not accompanied by a full translation of the instructions for use; or the responsible economic operator cannot be easily identified. In many cases corrective action is taken to rectify non-compliant products.

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Personal protective equipment	Directive 89/686/EEC	Safety helmets in Alpine skiing and snowboarding	1 February 2015	Vasya Milanova Vasia.Gerova@damtn.government.bg , Tel: (+359 2) 892 9768
Personal protective equipment	Directive 89/686/EEC	Hard hats for industry	10 August 2015	Vasya Milanova Vasia.Gerova@damtn.government.bg , Tel: (+359 2) 892 9768

2.4.3 Report on activities conducted during the previous planning period

Summary of the outcome of market surveillance conducted in the sector during the first half of 2014

A. High-visibility (HV) protective clothing

Checks were conducted on 188 different models and makes of HV protective clothing. The outcome of the inspections showed that 139 items of personal protective equipment conform to the requirements laid down in Directive 89/686/EEC.

Forty-five models of HV protective clothing did not conform to requirements, including 16 that lacked the requisite conformity markings or displayed other visually ascertainable defects and 29 that were marketed along with instructions for use in Bulgarian that did not fully correspond to those of the manufacturer. The responsible economic operator will be asked to take corrective action and ensure that the gloves are marketed along with appropriate instructions for use.

B. Protective gloves guarding against mechanical hazards

Inspections were conducted on 445 different makes and models of gloves and 323 were found to be compliant with the requirements laid down in Directive 89/686/EEC.

One hundred and twenty-two different glove models did not conform to requirements, including 21 that lacked the requisite conformity markings or did not conform to the essential requirements laid down in the Directive; 88 models were marketed along with instructions for use in Bulgarian that did not fully correspond to those of the manufacturer. The responsible economic operator will be asked to take corrective action and ensure that the gloves are marketed along with appropriate instructions for use; 13 models lacked the requisite conformity marking. The corresponding declarations of conformity and, where necessary, the relevant technical files will therefore be requested. The documents will be examined prior to any decision on further action to be taken in the case.

C. Inspections undertaken on the initiative of the customs authorities

As a result of the inspections concerned, checks were conducted on 13 models and makes of personal protective equipment. During the reporting period, approvals for release for free circulation were refused to 110 products that did not conform to the requirements laid down in Directive 89/686/EEC.

2.5. Sector: Construction Products — Regulation (EU) No 305/2011

2.5.1. Responsible authority and contact details

State Agency for Metrological and Technical Supervision (DAMTN)

Address: 1797 Sofia, 52A G.M. Dimitrov Boulevard

<http://www.damtn.government.bg/>

E-mail: damtn@damtn.government.bg

Directorate-General for Market Surveillance (GDNP)

Director-General: Maria Kancheva

E-mail: Maria.Kancheva@damtn.government.bg

In 2015, a budget of BGN 7 000 is available for product testing in the sector.

2.5.2 Market surveillance procedures and strategy

The proactive and reactive approaches mentioned in section 1.6 are applied in the sector.

The sectoral experience gained to date shows a stable trend towards a decrease in the number of products without a CE conformity marking on the market. Most cases involve formal non-compliance or suspicions regarding the authenticity of the technical documentation. The results of product testing conducted on models purchased by the surveillance authority show that although a conformity assessment had been conducted, in some cases product parameters did not conform to those declared. Product testing is conducted where doubts arise as regards product conformity.

The forms of cooperation used in the sector are described in sections 1.2, 1.3 and 1.7.

The general market surveillance strategy described in section 1 is applied in the sector, with an emphasis on harmonised products.

The product categories that will be included in the 2015 annual plan of the GDNP are set out in the table below.

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Construction products	Regulation (EU) No 305/2011	1. Bitumen wave slates 2. Bitumen shingles with mineral wool insulation and/or synthetic reinforcement 3. Flexible hydro insulation oil cloth. Reinforced bitumen oil cloth used as roof insulation coverings	1 July 2015	Miroslav Yotov Miro.Yotov@damtn.government.bg , Tel: (+359 2) 892 9769

2.5.3. Report on activities conducted during the previous planning period

Summary of the outcome of market surveillance conducted in the sector during the first half of 2014

The main product groups on which inspections were conducted during the period were toilet bowls, heating radiators, and copper water and gas pipes.

In line with the annual plan, inspections were conducted on 354 types of toilet bowls.

Inspections on 50 products were carried out on the initiative of customs authorities.

Inspections were conducted on 142 products following the receipt of alerts and complaints.

Economic operators took (voluntary) corrective action in respect of 224 products.

Tests were conducted on 22 cement samples and three types of ceramic tile adhesives. One of the adhesives and three cement samples were found to be non-compliant with the declared product parameters.

Two orders suspending the distribution of non-compliant products were issued.

A fine was imposed on an economic operator in respect of three non-compliant products.

2.6 Aerosol dispensers — Directive 75/324/EEC

2.6.1 Responsible authority and contact details

Consumer Protection Commission

Address: 1000 Sofia, 4a Slaveykov Square

www.kzp.bg

Directorate-General for Market Surveillance

Director-General: Emilia Elchinova

Rumyana Pekanova, Head of Product Control and Safety Department

E-mail: gl.direkcia@kzp.bg; r.pekanova@kzp.bg

In 2013, the budget available to the market surveillance authority, expressed in nominal terms, was EUR 12 290. The staff engaged in market surveillance during the same year (expressed as full-time equivalent units) was 108 employees.

2.6.2. Market surveillance procedures and strategy

The controls carried out were based on an annual thematic plan and inspections are initiated by the market surveillance authority (planned), including physical and documentary checks.

2.6.3. Report on activities conducted in previous planning periods

During the previous planning period (2013), a total of 367 inspections were carried out in the sector.

2.7. Sector: Simple Pressure Vessels and Pressure Equipment — Directives 2009/105/EC and 97/23/EC

2.7.1. Responsible authority and contact details

State Agency for Metrological and Technical Supervision (DAMTN)

Address: 1797 Sofia, 52A G.M. Dimitrov Boulevard

<http://www.damtn.government.bg/>

E-mail: damtn@damtn.government.bg

Directorate-General for Market Surveillance (GDNP)

Director-General: Maria Kancheva

E-mail: Maria.Kancheva@damtn.government.bg

State Technical Supervision Inspection Service Directorate General

Director-General: Antoaneta Genova

E-mail: antoaneta.genova@damtn.government.bg

2.7.2 Market surveillance procedures and strategy

The principles and procedures described in section 1.6 are applied in the sector.

A reactive approach, which is also described in section 1.6, is applied.

The forms of cooperation used in the sector are described in sections 1.2, 1.3 and 1.7.

The general market surveillance strategy described in section 1 is applied in the sector.

2.7.3. Report on activities conducted during the previous planning period

Summary of the outcome of market surveillance conducted in the sector during the first half of 2014

The main product groups on which inspections were conducted during the period were portable (dry powder, water and CO₂) fire extinguishers covered by the Directive on pressure vessels.

A total of 190 products were inspected. According to their declared origin, most were from China, with approximately 31.5 % of the fire extinguishers sold in retail stores originating from the EU.

The inspections conducted on 140 products have been finalised.

Economic operators have taken (voluntary) corrective action in respect of 43 products.

Ten fines were imposed on economic operators for infringements found in 11 products.

Due to the lack of any alerts and complaints, no inspections have been conducted on products covered by the Directive on simple pressure vessels.

2.8 Sector: Transportable Pressure Equipment — Directive 2010/35/EU

2.8.1 Responsible authority and contact details

State Agency for Metrological and Technical Supervision (DAMTN)

Address: 1797 Sofia, 52A G.M. Dimitrov Boulevard

<http://www.damtn.government.bg/>

E-mail: damtn@damtn.government.bg

Directorate-General for Market Surveillance (GDNP)

Director-General: Maria Kancheva

E-mail: Maria.Kancheva@damtn.government.bg

State Technical Supervision Inspection Service Directorate-General

Director-General: Antoaneta Genova

E-mail: Antoaneta.Genova@damtn.government.bg

2.8.2. Market surveillance procedures and strategy

The principles and procedures described in section 1.6 are applied in the sector.

A reactive approach, which is also described in section 1.6, is applied.

The forms of cooperation used in the sector are described in sections 1.2, 1.3 and 1.7.

The general market surveillance strategy described in section 1 is applied in the sector.

2.8.3. Report on activities conducted during the previous planning period

Due to the lack of any alerts and complaints, no inspections were conducted in the sector in 2014.

2.9 Sector: Machinery — Directive 2006/42/EC

2.9.1 Responsible authority and contact details

State Agency for Metrological and Technical Supervision (DAMTN)

Address: 1797 Sofia, 52A G.M. Dimitrov Boulevard

<http://www.damtn.government.bg/>

E-mail: damtn@damtn.government.bg

Directorate-General for Market Surveillance (GDNP)

Director-General: Maria Kancheva

E-mail: Maria.Kancheva@damtn.government.bg

State Technical Supervision Inspection Service Directorate-General

Director-General: Antoaneta Genova

E-mail: Antoaneta.Genova@damtn.government.bg

2.9.2 Market surveillance procedure and strategy

In the machinery sector, the DAMTN applies both a proactive and a reactive approach.

The main focus of market surveillance in the sector is on active cooperation with economic operators to rectify detected non-conformities that present residual risks, taking corrective measures and conducting follow-up checks to verify the outcome of corrective action declared by operators.

The procedures described in section 1.6 are applied in the sector.

The forms of cooperation used in the sector are described in sections 1.2, 1.3 and 1.7.

The general market surveillance strategy described in section 1 is applied in the sector.

The DAMTN has plans to join the cross-border project ‘Joint market surveillance action — portable drilling machines’, which is implemented by PROSAFE and financed by the European Commission.

The annual plan of the GDNP will cover the following product categories in the sector:

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Machinery	Directive 2006/42/EC	Portable hedge trimmers	April 2015	Maria Barzeva—Yankova Maria.Yankova@damtn.government.bg
Machinery	Directive 2006/42/EC	Portable drilling machines	September 2015	Maria Barzeva—Yankova Maria.Yankova@damtn.government.bg
Machinery	Directive 2006/42/EC	Elevators and moving walkways	Q1 2015	Zdravka Toteva zdravka.toteva@damtn.government.bg ,

				Tel: (+359 2) 892 9774
Machinery	Directive 2006/42/EC	Stair wheelchair lifts	Q2 2015	Zdravka Toteva zdravka.toteva@damtn.government.bg Tel: (+359 2) 892 9774

2.9.3 Report on activities conducted during the previous planning period

In 2014, inspections on the following product groups in the machinery sector were conducted on the basis of an approved annual plan: manual electrical instruments, battery-powered garden equipment and manual crushers. Several machinery inspection campaigns were also conducted. The checks on manual electrical instruments and battery-powered garden equipment covered 432 items and 78 non-compliant products were detected. A total of 158 manual crushers and hammers of different models and makes were inspected and 27 non-compliant products were found. During the general inspection campaign in March 2014, a total of 66 items of machinery were inspected and 6 non-compliant products were found.

In 2014, three complaints were received in respect of a sabre saw, 10 glandless standalone circulators and a gasoline-powered trimmer.

Administrative sanctions were imposed in respect of 11 items of machinery.

2.10. Sector: Elevators — Directive 1995/16/EC

2.10.1. Responsible authority and contact details

State Agency for Metrological and Technical Supervision (DAMTN)

Address: 1797 Sofia, 52A G.M. Dimitrov Boulevard

<http://www.damtn.government.bg/>

E-mail: damtn@damtn.government.bg

State Technical Supervision Inspection Service Directorate-General

Director-General: Antoaneta Genova

E-mail: Antoaneta.Genova@damtn.government.bg

2.10.2 Market surveillance procedures and strategy

The procedures described in section 1.6 are applied in the sector.

The forms of cooperation applied in the sector are described in sections 1.2, 1.3 and 1.7.

The general market surveillance strategy described in section 1 is applied.

The sector has certain specificities in that the DAMTN conducts checks to verify the compliance of elevators installed in public buildings with the essential requirements for their registration. This is necessary because in accordance with national law they are considered to present a higher danger and are subject to regular inspections. The elevators installed in residential buildings are subject to inspections by licensed technicians. The DAMTN conducts reactive controls on elevators installed in residential buildings on the basis of alerts and complaints received.

In 2015, planned inspections will be conducted on elevators installed in buildings accessible to a large number of visitors.

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Elevators	Directive 95/16/EC	Hotel elevators	Q3 2015	Zdravka Toteva zdravka.toteva@damtn.government.bg , Tel: (+359 2) 892 9774

2.10.3 Report on activities conducted during the previous planning period

Following an accident caused by a malfunctioning elevator installed in a residential building, which resulted in the death of one and injuries to another passenger, a large scale monitoring and inspection campaign was conducted in 2014, including on the basis of alerts and complaints. The initiative was separate from the inspections carried out at the time of elevator registration.

The incident has been investigated and a report containing the findings and conclusions of the technical experts has been submitted to the competent authorities.

2.11 Sector: Cableways — Directive 2000/9/EC

2.11.1 Responsible authority and contact details

State Agency for Metrological and Technical Supervision (DAMTN)

Address: 1797 Sofia, 52A G.M. Dimitrov Boulevard

<http://www.damtn.government.bg/>

E-mail: damtn@damtn.government.bg

State Technical Supervision Inspection Service Directorate-General

Director-General: Antoaneta Genova

E-mail: Antoaneta.Genova@damtn.government.bg

2.11.2 Market surveillance procedures and strategy

The principles and procedures described in section 1.6 are applied in the sector.

The forms of cooperation used in the sector are described in sections 1.2, 1.3 and 1.7.

The general market surveillance strategy described in section 1 is applied.

The DAMTN conducts market surveillance on cableways prior to their commissioning. In view of the limited number of cableways operating in Bulgaria at present, no planned inspections will take place in 2015. Reactive controls on cableways used for passenger transportation are carried out on the basis of complaints received and registered incidents.

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Cableways	Directive 2000/9/EC	Cableways	Upon the receipt of an alert	Zdravka Toteva zdravka.toteva@damtn.government.bg Tel: (+359 2) 892 9774

2.11.3. Report on activities conducted during the previous planning period

In 2014 no new cableways were put into operation and no incidents were reported.

2.12 Sector: Noise Emissions from Outdoor Equipment — Directive 2000/14/EC

2.12.1 Responsible authority and contact details

State Agency for Metrological and Technical Supervision (DAMTN)

Address: 1797 Sofia, 52A G.M. Dimitrov Boulevard

<http://www.damtn.government.bg/>

E-mail: damtn@damtn.government.bg

Directorate-General for Market Surveillance (GDNP)

Director-General: Maria Kancheva

E-mail: Maria.Kancheva@damtn.government.bg

2.12.2 Market surveillance procedures and strategy

A proactive and a reactive approach are applied in parallel.

The main focus of market surveillance in the sector is on active cooperation with economic operators to rectify detected non-conformities that present residual risks, taking corrective measures and conducting follow-up checks to verify the outcome of corrective action declared by operators.

The general procedures of the GDNP described in section 1.6 are applied in the sector.

The forms of cooperation used in the sector are described in sections 1.2, 1.3 and 1.7.

The general market surveillance strategy described in section 1 is applied.

In 2015, the following product categories in the sector will be included in the annual plan of the GDNP:

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Noise emissions from outdoor equipment	Directive 2000/14/EC	Portable hedge trimmers	April 2015	Maria Barzeva—Yankova Maria.Yankova@damtn.government.bg

2.12.3. Report on activities conducted during the previous planning period

In 2014, checks were conducted on manual crushers and hammers on the basis of an approved annual plan. A total of 158 machinery items of different models and makes were inspected and 27 non-compliant products were detected.

2.13. Sector: Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres — Directive 1994/9/EC

2.13.1. Responsible authority and contact details

State Agency for Metrological and Technical Supervision (DAMTN)

Address: 1797 Sofia, 52A G.M. Dimitrov Boulevard

<http://www.damtn.government.bg/>

E-mail: damtn@damtn.government.bg

Directorate-General for Market Surveillance (GDNP)

Director-General: Maria Kancheva

E-mail: Maria.Kancheva@damtn.government.bg

2.13.2. Market surveillance procedures and strategy

The principles and procedures described in section 1.6 are applied in the sector.

A reactive approach, which is also described in section 1.6, is applied.

The forms of cooperation used in the sector are described in sections 1.2, 1.3 and 1.7.

The general market surveillance strategy described in section 1 is applied.

No specific product categories in the sector have been included in the 2015 annual inspection plan.

2.13.3. Report on activities conducted during the previous planning period

Due to the lack of any alerts and complaints, no inspections were conducted in the sector.

2.14 Sector: Pyrotechnic Articles — Directive 2007/23/EC

2.14.1 Responsible authority and contact details

State Agency for Metrological and Technical Supervision (DAMTN)

Address: 1797 Sofia, 52A G.M. Dimitrov Boulevard

<http://www.damtn.government.bg/>

E-mail: damtn@damtn.government.bg

Directorate-General for Market Surveillance (GDNP)

Director-General: Maria Kancheva

E-mail: Maria.Kancheva@damtn.government.bg

2.14.2. Market surveillance procedures and strategy

The principles and procedures described in section 1.6 are applied in the sector.

The proactive and reactive approaches mentioned in section 1.6 are applied.

The outcome of the inspections conducted in the sector show a stable decrease in the number of products not bearing a CE conformity marking and that most cases involve formal non-compliance.

The forms of cooperation used in the sector are described in sections 1.2, 1.3 and 1.7.

The general market surveillance strategy described in section 1 is applied.

The DAMTN intends to take part in the cross-border project ‘Joint Market Surveillance Action — Pyrotechnics’, implemented by PROSAFE and funded by the European Commission.

The product categories to be included in the 2015 annual plan of inspections to be conducted in the sector are set out in the following table:

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Pyrotechnics	Directive 2013/29/EU	Pyrotechnic articles from categories 1, 2, 3 and 4 and stage pyrotechnics from categories T1 and T2	1 December 2015	Miroslav Yotov Miro.Yotov@damtn.government.bg Tel: (+359 2) 892 9769

2.14.3. Report on activities conducted during the previous planning period

Summary of the outcomes of the market surveillance conducted in the sector during the first half of 2014

The main product groups inspected during the reporting period comprised category 1, 2 and 3 fireworks, etc.

Inspections on 68 types of fireworks were conducted on the initiative of the customs authorities.

A total of 58 inspections on pyrotechnic articles that had commenced in 2013 were finalised.

Economic operators took corrective action (voluntary measures) in respect of 26 products.

Coercive measures and corresponding administrative action was taken in respect of 6 non-compliant products.

Six fines were levied on economic operators in respect of infringements with implications for 15 products.

2.15 Sector: Explosives for Civil Uses — Directive 93/15/EEC

2.15.1 Responsible authority and contact details

State Agency for Metrological and Technical Supervision (DAMTN)

Address: 1797 Sofia, 52A G.M. Dimitrov Boulevard

<http://www.damtn.government.bg/>

E-mail: damtn@damtn.government.bg

Directorate-General for Market Surveillance (GDNP)

Director-General: Maria Kancheva

E-mail: Maria.Kancheva@damtn.government.bg

2.15.2 Market surveillance procedures and strategy

The principles and procedures described in section 1.6 are applied in the sector.

A reactive approach, which is also described in section 1.6, is applied.

During the inspections, no products without the requisite CE marking and no cases of formal non-compliance were detected.

The forms of cooperation used in the sector are described in sections 1.2, 1.3 and 1.7.

The general market surveillance strategy described in section 1 is applied.

No special product categories are to be included in the 2015 annual control plan.

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Explosives for civil uses	Directive 93/15/EEC	Products covered by the Directive	Throughout the year	Miroslav Yotov Miro.Yotov@damtn.government.bg Tel: (+359 2) 892 9769

2.15.3 Report on activities carried out during the previous planning period

Due to the lack of any alerts and complaints, no checks were conducted in the sector.

2.16 Sector: Appliances burning gaseous fuels — Directive 2009/142/EC

2.16.1 Responsible authority and contact details

State Agency for Metrological and Technical Supervision (DAMTN)

Address: 1797 Sofia, 52A G.M. Dimitrov Boulevard

<http://www.damtn.government.bg/>

E-mail: damtn@damtn.government.bg

Directorate-General for Market Surveillance (GDNP)

Director-General: Maria Kancheva

E-mail: Maria.Kancheva@damtn.government.bg

State Technical Supervision Inspection Service Directorate-General

Director-General: Antoaneta Genova

E-mail: antoaneta.genova@damtn.government.bg

2.16.2 Market surveillance procedures and strategy

The principles and procedures described in section 1.6 are applied in the sector.

The proactive and reactive approaches mentioned in section 1.6 are applied.

The forms of cooperation used in the sector are described in sections 1.2, 1.3 and 1.7.

The general market surveillance strategy described in section 1 is applied.

The outcome of the inspections conducted in the sector show a trend of most cases of non-compliance being formal.

In 2015, there are no plans to use the proactive approach or include any sector-specific groups in the annual control plan. The reactive approach and procedures described in section 1.6 will be used exclusively.

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Appliances burning gaseous fuels	Directive 2009/142/EC	Products covered by the Directive	Throughout the year	Mitko Todorov Mitev mitko.mitev@damtn.government.bg , Tel:(+359 2) 825 888

2.16.3 Report on activities conducted during the previous planning period

During the first half of 2014, no alerts or complaints in respect of products from the sector were received.

In accordance with the approved 2014 annual plan, the checks on appliances burning gaseous fuels are currently being conducted and we are unable to report their outcomes at present.

2.17 Sector: Measuring instruments, Non-automatic weighing instruments and Pre-packaged products —Directives 2004/22/EC, 2009/23/EC and 2007/45/EC

2.17.1 Responsible authority and contact details

State Agency for Metrological and Technical Supervision (DAMTN)

Address: 1797 Sofia, 52A G.M. Dimitrov Boulevard

<http://www.damtn.government.bg/>

E-mail: damtn@damtn.government.bg

Directorate-General for Metrological Supervision

Director-General: Pavlina Danailova

Pavlina.Danailova@damtn.government.bg

2.17.2 Market surveillance procedures and strategy

The sector is specific in that weighing instruments entail a risk of potential abuse when used for direct sales to customers and/or in commercial payments and public debt collection, which means that they may affect significant economic interests of both private individuals and society. Market surveillance checks and inspections are typically conducted on weighing instruments in use. The DAMTN conducts metrological supervision on weighing instruments in use (often in parallel with market surveillance) and the outcome of inspections is used to determine the market surveillance priorities for future periods.

In 2015, the main focus of controls will be on weighing scales used at airports to weigh passenger baggage and motor vehicle scales used in the grain crop trade and to calculate excise duty. The inspections will also include electricity, heating, water and gas meters, which are in widespread use and are always the focus of public attention. Controls will be carried out on other types of measuring instruments in accordance with the reactive approach.

The risk assessment in the sector is based primarily on the manuals developed by Working Group 5 of WELMEC.

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Non-automatic weighing instruments	Directive 2009/23/EC	Airport passenger baggage weighing scales	12 January 2015	Pavlina Danailova Pavlina.Danailova@damtn.government.bg
		Motor vehicle scales	13 July 2015	
Measuring instruments	Directive 2004/22/EC	Fuel dispensers	12 January 2015	Tel: (+359 2) 986 2266 (+359 888) 798 664
		Water meters		
		Active power electricity meters		
		Heat meters		
		Gas meters and volume correction devices		

2.17.3 Report on activities conducted during the previous planning period

The market surveillance conducted during the first half of 2014 entailed thematic checks and observations on 4 811 measuring instruments placed on the market and/or put into operation at a total of 1 341 sites: scales, electricity meters, gas meters and volume correction devices, heat meters, water meters and material measures of length. In three cases formal non-compliance with implications for industrial scales was detected and voluntary corrective action was taken by the economic operators concerned. An automatic belt scale was not allowed to be put into operation due to failure to undergo the requisite conformity assessment.

2.18 Sector: Electrical equipment under EMC — Directive 2004/108/EC

2.18.1 Responsible authority and contact details

State Agency for Metrological and Technical Supervision (DAMTN)

Address: 1797 Sofia, 52A G.M. Dimitrov Boulevard

<http://www.damtn.government.bg/>

E-mail: damtn@damtn.government.bg

Directorate-General for Market Surveillance (GDNP)

Director-General: Maria Kancheva

E-mail: Maria.Kancheva@damtn.government.bg

The budget available for product testing in 2015 is BGN 4 000.

2.18.2 Market surveillance procedures and strategy

The principles and procedures described in section 1.6 are applied in the sector.

The proactive and reactive approaches mentioned in section 1.6 are applied.

The outcome of the inspections conducted in the sector shows a stable decrease in the number of products not bearing a CE conformity marking and that most cases of non-compliance are formal. The unavailability of information enabling product tracing has been repeatedly detected. In some cases, the requisite technical documentation is available but conducted tests reveal that the samples do not consistently conform to test parameters. This is the reason why, where doubts arise as to product conformity, tests are conducted despite their high cost. Funds have been earmarked for product testing within the framework of national campaigns and cross-border projects under EMC.

The forms of cooperation used in the sector are described in sections 1.2, 1.3 and 1.7.

The general market surveillance strategy described in section 1 is applied.

The product categories from the sector to be included in the 2015 annual plan of the GDNP are set out in the table below:

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Electrical equipment under the EMC Directive	Directive 2004/108/EC	LED lights	Second half of 2015	Radka Ivanova Radka.Ivanova@damtn.government.bg
Electrical equipment under the EMC Directive	Directive 2004/108/EC	Microwaves	February 2015	Radka Ivanova Radka.Ivanova@damtn.government.bg

2.18.3 Report on activities conducted during the previous planning period

Summary of the outcomes of the market surveillance conducted in the sector during the first half of 2014

During the period, checks were conducted on the following main groups of products: simple set-top-boxes; LED and CFL lights (inspections are to continue from previous periods); other products.

In line with the annual plan, inspections were conducted on a total of 207 products (under LVD and EMC), which had commenced during the previous period.

Economic operators have taken corrective action (voluntary measures) in respect of 15 products.

Tests under EMC were conducted on 3 LED and CFL lamps. Two LED lamps did not conform to requirements. Restrictive measures were imposed.

Fines/administrative sanctions were imposed on 19 economic operators.

2.19 Sector: Radio and telecom equipment under RTTE — Directive 1999/5/EC

2.19.1 Responsible authority and contact details

State Agency for Metrological and Technical Supervision (DAMTN)

Address: 1797 Sofia, 52A G.M. Dimitrov Boulevard

<http://www.damtn.government.bg/>

E-mail: damtn@damtn.government.bg

Directorate-General for Market Surveillance (GDNP)

Director-General: Maria Kancheva

E-mail: Maria.Kancheva@damtn.government.bg

2.19.2 Market surveillance procedures and strategy

The principles and procedures described in section 1.6 are applied in the sector.

The proactive and reactive approaches mentioned in section 1.6 are applied.

The outcome of the inspections conducted in the sector shows a stable decrease in the number of products not bearing a CE conformity marking and that most cases of non-compliance are formal. The instructions for use intended for customers are partially translated. Economic operators translate only the sections concerning the ‘quick installation’ of the devices. The items of radio equipment available from retail stores have been steadily decreasing in number, with most products being sold online, which creates difficulties in tracing their origin and conducting physical checks. There are no accredited laboratories for radio equipment testing in Bulgaria. This, along with the high cost of testing, is an obstacle to participation in cross-border sample testing campaigns. Where doubts arise as to the conformity of a product, the approach typically taken is to inspect the accompanying technical documentation.

The forms of cooperation used in the sector are described in sections 1.2, 1.3 and 1.7.

The general market surveillance strategy described in section 1 is applied.

The product categories from the sector to be included in the 2015 annual plan of the GDNP are set out in the table below:

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Radio and telecom equipment under RTTE	Directive 1999/5/EC	Short-range radio equipment, wireless alarm systems	May 2015	Radka Ivanova Radka.Ivanova@damtn.government.bg
Radio and telecom equipment under RTTE	Directive 1999/5/EC	Wireless audio appliances, FM transmitters	May 2015	Radka Ivanova Radka.Ivanova@damtn.government.bg

2.19.3. Report on activities conducted during the previous planning period

Summary of the outcomes of market surveillance conducted in the sector during the first half of 2014

The main product groups on which checks were conducted during the period included wireless DECT telephones, etc. In line with the annual plan, these covered 136 products, with some inspections that commenced during the previous period still being under way. Non-compliant products typically do not satisfy the requirements for the requisite CE markings, conformity declarations and instructions for use.

During the reporting period, economic operators took corrective action (voluntary measures) in respect of 20 products.

2.20 Sector: Electrical Appliances and Equipment under LVD—Directive 2006/95/EC

2.20.1. Responsible authority and contact details

State Agency for Metrological and Technical Supervision (DAMTN)

Address: 1797 Sofia, 52A G.M. Dimitrov Boulevard

<http://www.damtn.government.bg/>

E-mail: damtn@damtn.government.bg

Directorate-General for Market Surveillance (GDNP)

Director-General: Maria Kancheva

E-mail: Maria.Kancheva@damtn.government.bg

2.20.2 Market surveillance procedures and strategy

The principles and procedures described in section 1.6 are applied in the sector.

The proactive and reactive approaches mentioned in section 1.6 are applied.

The following cases of non-compliance were detected: incorrectly affixed conformity markings, partial instructions for use, unidentified device parameters, lack of information enabling product tracing, etc. Since 2012, the number of products that do not conform to the requirements relating to instructions for use has decreased.

The general market surveillance strategy described in section 1 is applied in the sector.

The DAMTN is planning to take part in the EU-financed cross-border project ‘Joint market surveillance action — LED floodlights’.

The product categories from the sector to be included in the 2015 annual plan of the GDNP are set out in the table below:

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Electrical appliances	Directive 2006/95/EC	Microwave ovens	February 2015	Tinka Pencheva Tinka.Pencheva@damtn.government.bg, Tel: (+359 62) 600 526
		Heat accumulating devices (boilers)	March 2015	Dilyana Todorova Dilyana.Todorova@damtn.government.bg, Tel: (+359 2) 892 9767
		Electrical devices used in fish tanks: air pumps, water heaters	April 2015	Venetsia Gradinarova Venetsia.Gradinarova@damtn.government.bg, Tel: (+359 2) 892 9767
		Kitchen equipment	July 2015	
		LED lights	Second half of 2015	
		Kitchen aspirators	July 2015	Dilyana Todorova Dilyana.Todorova@damtn.government.bg, Tel: (+359 2) 892 9767

2.20.3. Report on activities conducted during the previous planning period

Summary of the outcomes of market surveillance conducted in the sector during the first half of 2014

During the period, planned inspections were carried out on electrical blankets and pillows, decoders, bedside lamps, immersion heaters and soldering irons, etc.

In line with the annual plan, checks were conducted on 624 products.

A total of 603 checks on electrical appliances were conducted on the initiative of customs authorities.

Nine checks were conducted following the receipt of alerts/complaints.

Tests were conducted on 6 electrical appliances.

Coercive administrative measures were taken in respect of 59 products.

A total of 51 non-compliant electrical appliances were destroyed on the initiative of the responsible economic operators.

Administrative sanctions/fines were imposed on economic operators in respect of 101 products.

**2.21 Sector: Electrical and electronic equipment under RoHS and WEEE and batteries
— Directive 2011/65/EU, Directive 2002/96/EC and Directive 2006/66/EC**

2.21. Responsible authority and contact details

State Agency for Metrological and Technical Supervision (DAMTN)

Address: 1797 Sofia, 52A G.M. Dimitrov Boulevard

<http://www.damtn.government.bg/>

E-mail: damtn@damtn.government.bg

Directorate-General for Market Surveillance (GDNP)

Director-General: Maria Kancheva

E-mail: Maria.Kancheva@damtn.government.bg

2.21.2 Market surveillance procedures and strategy

The principles and procedures described in section 1.6 are applied in the sector.

The forms of cooperation used in the sector are described in sections 1.2, 1.3 and 1.7.

The general market surveillance strategy described in section 1 is applied.

The product categories from the sector to be included in the 2015 annual plan of the GDNP are set out in the table below:

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Electrical and electronic equipment under RoHS	Directive 2011/65/EU	Microwaves	February 2015	Radka Ivanova Radka.Ivanova@damtn.government.bg , Tel: (+359 32) 625 567 Mob: (+359 885) 398 459
Electrical and electronic equipment under WEEE	Directive 2002/96/EC	Heat accumulating devices (boilers)	March 2015	Dilyana Todorova Dilyana.Todorova@damtn.government.bg , Tel: (+359 2) 892 9767 Mob.: (+359 879) 504 386
Electrical and electronic equipment under WEEE	Directive 2002/96/EC	Kitchen equipment	July 2015	Venetsia Gradinarova Venetsia.Gradinarova@damtn.government.bg , Tel: (+359 2) 892 9767 Mob: (+359 879) 519 214

2.21.3 Report on activities conducted during the previous planning period

Summary of the outcomes of market surveillance conducted in the sector during the first half of 2014

During the period, checks were conducted on wireless DECT telephones to verify compliance with the requirements laid down in Directive 2011/65/EU (RoHS).

Checks were conducted on 127 products.

Economic operators took corrective action (voluntary measures) in respect of 12 products.

2.22(A) Sector: Chemical substances under REACH and Classification and Labelling Regulations — Regulation (EC) No 1907/2006 and Regulation (EC) No 1272/2008

2.22A.1 Responsible authority and contact details

Ministry of Health (MZ)

Public Health Directorate

Address: 5 Sveta Nedelya Square, Sofia

Tel: (+359 2) 931 214

E-mail: nddimitrova@mh.government.bg

The Ministry of Health (MZ) is the national authority responsible for market surveillance in the chemical substances and compounds sector under Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP).

Twenty-eight Regional Health Inspection Services — funded through subsidies from the central government budget, disbursed by the MZ — each with a head office in the administrative centre of their respective province, operate at local level.

The Regional Inspection Services (RZIs) exercise control over the chemical substances, compounds and products marketed within the province to ensure compliance with the requirements laid down in Regulation (EC) No 1907/2006 (REACH), Regulation (EC) No 1272/2008 (CLP) and the Protection from the Hazardous Impact of Chemical Substances and Compounds Act (ZZVVHVS). They are responsible, in particular, for the classification, labelling and packaging of the chemical substances and compounds placed on the market in accordance with Regulation (EC) No 1272/2008 (CLP), the compliance of the safety datasheets with the requirements laid down in Regulation (EC) No 1907/2006 (REACH), making information available along the supply chain in accordance with Regulation (EC) No 1907/2006 (REACH) and for the control of the composition of chemical compounds and products in view of the prohibitions and limitations laid down in Annex XVII to Regulation (EC) No 1907/2006 REACH).

The total staff of the RZIs is 2 904 employees.

The authorities operating at local level rely on the services of laboratories, structured as directorates or departments, which carry out laboratory tests for control purposes. They have been accredited under standards BDS EN ISO/IEC 17025 and/or BDS EN ISO/IEC 17020 and participate in national and international suitability tests.

2.22A.2 Market surveillance procedures and strategy

In order to ensure strict compliance with the statutory requirements for chemical substances and compounds laid down in Regulation (EC) No 1272/2008 (CLP) and Regulation (EC) No 1907/2006 (REACH), Bulgaria has set up a system of bodies (Ministry of the Environment and Water, Regional Environment and Water Inspection Services, MZ, RZI and the Customs Agency), which are responsible for surveillance.

The Regional Health Inspection Services carry out the following market surveillance activities in the chemical substances and compounds sector:

- controls on the classification, labelling and packaging of chemical substances and compounds placed on the market;

- controls to verify the compliance of data safety sheets with the requirements laid down in Regulation (EC) No 1907/2006 (REACH);
- controls on the provision of information along the supply chain for chemical substances and compounds in accordance with Regulation (EC) No 1907/2006 (REACH);
- laboratory tests on the composition of chemical substances and compounds in view of the restrictions on the marketing and use of certain hazardous substances listed in Annex XVII to Regulation (EC) No 1907/2006 (REACH);
- targeted controls under the rapid exchange of information system (RAPEX);
- targeted controls conducted on the market following the receipt of complaints/alerts from natural and legal persons, information about incidents involving the use of chemical substances and compounds, etc.

Where the MZ/RZI receives an alert/complaint from citizens, organisations, etc. a standard operating procedure has been developed, which determines the actions to be taken in order to examine the case, adopt a decision on the alert/complaint and carry out follow-up monitoring.

Planned thematic checks — control activities in the chemical substances and compounds sector are planned by taking into account the risk to the typical professional users of hazardous substances and compounds, the outcomes of checks/inspections conducted in previous years and new available information about the hazards associated with their use.

Where a breach of the requirements laid down in (Community and national) law is ascertained, the action envisaged in Articles 28(6) and (7) and Chapter Eight ‘Administrative and Penal Measures’ of the ZZVVHVS is taken. The minimum and maximum fines are BGN 5 000 and 100 000, respectively.

In order to preclude the placing on the Community market of products and goods from third countries that present a risk to the life and health of users, Guidelines on cooperation between the Customs Agency and the bodies responsible for control under the jurisdiction of the MZ have been drawn up for the checks to be carried out on the composition of certain chemical compounds and products, in order to ascertain their compliance with the requirements laid down in Annex No XVII of Regulation (EC) No 1907/2006 (REACH). The Guidelines set out the rules and procedure for cooperation between the Customs Agency and the competent control bodies when taking joint action and exchanging information, i.e. notification on an *ad hoc* basis.

Working meetings on coordination are organised to discuss joint action taken by the Customs Agency and other national market surveillance authorities.

General market surveillance strategy for the chemical substances and compounds sector

1. Control of the classification, labelling and packaging of chemical substances and compounds placed on the market;
2. Streamlining the functioning of the system for rapid exchange of information (RAPEX) to ensure compliance with Article 22 of Regulation (EC) No 765/2008;
3. Introduction of new methods for laboratory testing of SVHC substances, including those listed in Annex XVII to Regulation (EC) No 1907/2006 (REACH) with a view to increasing the efficiency of the controls carried out by the RZI, in connection with the restrictions stipulated therein, the

system for rapid exchange of information (RAPEX) and forthcoming controls to be carried out under Annex XIV to Regulation (EC) No 1907/2006 (REACH) — substances subject to authorisation.

Specific market surveillance strategy for the chemical substances and compounds sector, to be followed during the planning period:

1. Analysis of incident reports on the use of hazardous substances and compounds as a basis for conducting targeted inspections on the market;
2. Thematic checks on hazardous chemical substances and compounds following an analysis of the outcomes of inspections conducted in previous years and new information about the dangers associated with their use;
3. Developing up-to-date instructions laying down the rules and procedure for cooperation between the Ministry of Health and the Ministry of the Environment and Water in connection with the joint inspections conducted under Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP).

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Chemical substances, compounds and products	Regulation (EC) No 1272/2008 and Regulation (EC) No 1907/2006	Chemical substances, compounds and products (Regulation (EC) No 1272/2008— classification, packaging, labelling and Regulation (EC) No 1907/2006— prohibitions and restrictions under Annex XVII; safety datasheets; Provision of information along the supply chain	2015	Neliya Dimitrova nddimitrova@mh.government.bg ; Tel: (+359 2) 930 12 14

2.22A.3 Report on activities conducted during the previous planning period

In terms of control, RZI inspectors carry out checks to verify the compliance of chemical substances and compounds placed on the market with the requirements for their classification, labelling, the accompanying safety datasheets, the provision of information along the supply chain and the control of the composition of chemical substances and compounds in view of the restrictions stipulated in Annex XVII to Regulation (EC) No 1907/2006 (REACH).

Following the receipt of RAPEX notifications in respect of the presence of chemical compounds and substances on the Community market that present a danger to human life and health during the calendar year 2014, local health inspection services conducted more than 11 704 inspections across Bulgaria. One notified product (a paint remover) was detected and a corresponding response notification has been drawn up. Laboratory tests are conducted to determine the content of nicotine in electronic cigarettes that do not conform to the requirements for classification, packaging and labelling, which will be notified via RAPEX.

**2.22(B) Sector: Other Chemicals — Directive 2004/42/EC, Regulation (EC) No 842/2006,
Regulation (EU) No 517/2014, Regulation (EC) No 1005/2009 and Regulation (EC)
No 648/2004**

Subsector Fluorinated Greenhouse Gases, Ozone Depleting Substances

2.22.B.1 Responsible authority and contact details

The bodies responsible for market surveillance in the subsector are the Regional Environment and Water Inspection Services (RIOSVs) under the jurisdiction of the Ministry of the Environment and Water (MOSV). There are 16 RIOSVs in Bulgaria and their work is coordinated by the MOSV.

Ministry of the Environment and Water

Address: Sofia 1000, 67 William Gladstone Street

Air Quality Protection Directorate

Head: Ivan Angelov

Fax: (+359 2) 981 09 54

Tel: (+359 2) 940 63 05

E-mail: angelov@moew.government.bg

The Heads of the RIOSVs carry out the functions of bodies of the central government. They disburse central government subsidies transferred to each RIOSV via the budget of the Ministry of the Environment and Water, which is an element of the Bulgarian state budget for the respective year. At each Regional Inspection Service, at least one expert is responsible for the application of the Regulations governing fluorinated greenhouse gases (Regulation (EC) No 842/2006 and Regulation (EU) No 517/2014) and the Regulation on ozone depleting substances (Regulation (EC) No 1005/2009). These experts are responsible for market surveillance in connection with the requirements laid down in the regulations. Portable gas analysers are available to the RIOSVs and are used to conduct checks on the installations and products covered by the abovementioned regulations.

2.22.B.2 Market surveillance procedures and strategy

The equipment and products containing refrigerating agents that are placed on the market are subject to proactive control (checks conducted on the basis of risk assessment — at the end of each year a plan setting out the number of control checks to be conducted during the next year is elaborated, reactive controls—checks conducted on the basis of received complaints, and border control, which is conducted jointly by the RIOSV and the local departments of the Customs Agency.

With a view to ensuring better application of the requirements laid down in Regulation (EC) No 842/2006 and Regulation (EC) No 1005/2009, the MOSV has developed and applies the following statutory instruments:

- *Articles 17 and 34i of the Purity of Air Act;*
- *Regulation laying down measures implementing Regulation (EC) No 1005/2009 on ozone depleting substances;*

- *Regulation laying down measures on the implementation of Regulation (EC) No 842/2006 on certain fluorinated greenhouse gases that provide methodological guidance on the control of the placing on the market of products and equipment containing refrigerant agents, including sanctions for ascertained infringements of the requirements laid down by law.*

The general procedure for handling the complaints received by the RIOSV comprises the following steps:

- Step 1** The complaint must be received by letter and/or e-mail by the RIOSV responsible for the area in which the suspected infringement has been detected. A special hotline has been published on the webpage of each RIOSV, which may also be used to report infringements.
- Step 2** The complaints are examined and, depending on the outcome of the review, the RIOSV may conduct an on-the-spot check;
- Step 3** The RIOSV conducts a documentary check, visual inspection or a check using technical means (portable gas analysers);
- Step 4** A statement of findings is drafted on the basis of the conducted check. Where the competent authority has ascertained an infringement, an order is issued to prohibit the placing on the market, distribution or use, or to recall of the products and equipment concerned from the market;
- Step 5** Depending on the outcome of the inspection as set out in the statement of findings drawn up by the RIOSV, action is taken to impose a sanction for the ascertained infringement;
- Step 6** The complainant is notified of the result of the inspection.

The RIOSV responsible for the area in which irregularities were detected keeps a record of the complaints received.

Following the issuance of guidelines after the RIOSV has ascertained an infringement, a follow-up inspection is conducted to verify the corrective action taken by the responsible party.

At national level, the print media, radio and television and online announcements are used to alert customers to products and equipment that present a danger (do not conform to the requirements laid down in Regulation (EC) No 842/2006, Regulation (EU) No 517/2014 and Regulation (EC) No 1005/2009).

At international level, the system for rapid exchange of information (RAPEX) and the ICSMS are used.

Depending on the severity of the infringement, the party responsible for placing on the market products and equipment that contains fluorinated greenhouse gases or ozone depleting substances in violation of applicable regulations is sanctioned by a fine ranging from BGN 3 000 up to 6 000 (approximately EUR 1 500 up to 3 000) or a fine from BGN 8 000 up to 15 000 (approximately EUR 4 000 up to 7 500).

Information campaigns are conducted on a regular (annual) basis, involving workshops and published announcements and guidelines. In addition, interested parties are notified in writing of forthcoming amendments to applicable regulations or prohibitions prior to their effective date.

In order to ensure efficient market surveillance in accordance with the requirements laid down in Regulation (EC) No 842/2006 and Regulation (EC) No 1005/2009, the experts at the MOSV, or the RIOSV, as applicable, work in close cooperation with the Customs Agency and its local departments to ensure sound border control over the import/export of products and/or equipment containing refrigerant agents. The exchange of information between the two institutions is ensured through workshops and training events, the exchange of annual reports on imports/exports, joint inspections, and participation in working groups tasked with drafting legislation.

The general approach to setting the priorities for market surveillance to ensure compliance with the requirements laid down in Regulation (EC) No 842/2006 and Regulation (EC) No 1005/2009 reflects the priorities for market surveillance of the sector at Community level. Bulgaria does not define a separate set of (national) priorities that differ from those at Community level.

The RIOSVs draft plans and working schedules for the inspections to be conducted in connection with the priorities on an annual and monthly basis. In addition, joint inspections are conducted with customs officials upon request.

2.22.B.3 Report on activities carried out during the previous planning period

In 2013, a total of 680 inspections were conducted. These resulted in the drafting of 211 guidelines and 8 decisions in respect of ascertained infringements of Regulation (EC) No 842/2006 and Regulation (EC) No 1005/2009 (unavailability of technical files, and failure to provide information in accordance with statutory requirements and comply with instructions issued as a result of conducted checks).

Subsector: Paints, varnishes and self-repairing products — Directive 2004/42/EC

2.22.B.1 Responsible authority and contact details

The competent authority for the application of Directive 2004/42/EC is the Ministry of the Environment and Water (MOSV). As one of its functions, it coordinates the work of the competent authorities, the Environment Executive Agency, the Regional Environment Inspection Services (RIOSVs) and other stakeholders in connection with the requirements stipulated in the abovementioned Directive.

Ministry of the Environment and Water

Address: Sofia 1000, 67 William Gladstone Street

Air Quality Protection Directorate

Head: Ivan Angelov

Fax: (+359 2) 981 09 54

Tel: (+359 2) 940 63 05

E-mail: angelov@moew.government.bg

There are sixteen (16) regional Environment Inspection Services responsible for market surveillance in the sector. One expert who is responsible for the implementation of Directive 2004/42/EC, including market surveillance, has been appointed to each RIOSV.

2.22.B.2 Market surveillance strategies and procedure

The competent authorities (RIOSV) conduct controls in the sector by means of the following checks:

- **On-the-spot checks** (proactive controls):
 - checks on product labels and the information and documents relating to the classification, packaging, labelling and drawing up of safety datasheets for the compounds and substances. The products and documents checked must fully conform to the relevant legislation;
- **Documentary checks** (reactive control when alerts or complaints are received):
 - requirement to present documents for the inspected products—financial and commercial, and conformity and test certificates for the products placed on the market, etc.;
 - requirement to present information, statements and other third-party documents necessary for the purposes of control;
 - requirement to present a test protocol for the maximum permissible levels of volatile organic compounds or to obtain a sample, if necessary (in the case of missing or non-compliant labels, etc.);
- **Planned checks:**

In line with the plan of each RIOSV, checks are conducted at least one a year on manufacturers and importers and, where possible, wholesalers operating in the area under the jurisdiction of the respective RIOSV. Inspections on other parties, such as retailers, automotive paint operators carrying out work outside of the premises of the manufacturer, i.e. during repairs, conservation or decoration of motor vehicles etc., are conducted at the discretion of the competent RIOSV;

- **Unannounced checks** conducted to verify compliance with instructions for follow-up action; checks conducted on new enterprises and on enterprises not included in the annual plans of the RIOSV;
- **Checks conducted following the receipt of complaints.**

As a matter of priority, the RIOSV conducts checks on manufacturers, importers and wholesalers.

Statements of findings are drawn up in respect of conducted checks, which detail the facts and circumstances ascertained and set out instructions, as necessary.

Where products are found that do not conform to the requirements stipulated in the Regulation on limiting the emissions of volatile organic compounds (VOC) in the use of organic solvents in certain paints, varnishes and self-repairing products, hereinafter the Regulation, which transposes Directive 2004/42/EC into national law, the control authority issues mandatory instructions to restrict, prohibit the placing on the market, distribution or use, or recall the products covered by the Regulation.

Sanctions and fines imposed

Where the detected infringement has implications for the requirements laid down in the Regulation (Articles 34e, 34h and 34k of the Purity of Ambient Air Act (ZChAV)), the control authority (RIOSV) draws up a statement in respect of the infringement on the basis of which a decision on the sanction to be imposed is issued.

The sanctions and fines imposed for infringement of the cited provisions of the ZChAV vary from BGN 500 (EUR 250) up to BGN 15 000 (EUR 7 500). In the case of repeated violated, their amounts are doubled. Fines and sanctions depend on the severity of the ascertained infringement: the number/quantity of non-compliant products placed on the market in terms of labelling, VOC content, etc.

2.22.B.3 Report on activities conducted during the previous planning period

During the previous year, a total of 180 planned inspections were conducted on manufacturers, importers and wholesalers and 292 inspections were carried out on retailers, automotive paint operators carrying out works outside of the premises of the manufacturer, i.e. during repairs, conservation or decoration of motor vehicles, etc. A total of 5 unannounced checks were conducted on manufacturers, importers and retailers and a total of 20 on all other operators.

Subsector: Detergents — Regulation (EC) No 648/2004

2.22B.1. Responsible authority and contact details

Ministry of Health (MZ)

Public Health Directorate

Address: Sofia, 5 Sveta Nedelya Square

Tel: (+359 2) 931 214

E-mail: nddimitrova@mh.government.bg

The Ministry of Health (MZ) is the national market surveillance authority for the detergents sector under Regulation (EC) No 648/2004.

Twenty-eight Regional Health Inspection Services operate at provincial level, each with its head office in the administrative centre of the respective province.

The Regional Health Inspection Services (RZIs) conduct public health control within each province in order to ensure that the detergents and the surface-active substances intended for detergents that have been placed on the market conform to the requirements laid down in the Regulation, and in particular those for labelling and packaging in accordance with Regulation (EC) No 648/2004, and for the data safety sheets and the provision of information along the supply chain about detergents and VOC in accordance with Regulation (EC) No 1907/2006 (REACH) in view of the requirements for the substances present in detergents and the restrictions under Annex XVII to Regulation (EC) No 1907/2006 (REACH).

The total staff of the RZIs is 2 904 employees.

The competent authorities at local level rely on the services of in-house laboratories, structured as directorates or departments, which conduct tests and analyses for the purposes of public health control. They are accredited under Standards BDS EN ISO/IEC 17025 and/or BDS EN ISO/IEC 17020 and participate in national and international product suitability tests.

2.22B.2. Market surveillance procedures and strategy

In order to ensure strict compliance with the statutory requirements for the detergents sector laid down in Regulation (EC) No 648/2004, Bulgaria has set up a system of bodies (Ministry of the Environment and Water, Regional Environment and Water Inspection Services, MZ, RZI and the Customs Agency), which are responsible for surveillance.

The Regional Health Inspection Services carry out the following market surveillance activities in respect of detergents and surface-active substances intended for detergents:

- controls on the classification, labelling (including making information available online) and packaging of detergents and surface-active substances intended for detergents that have been placed on the market;
- laboratory tests to verify that the content of detergents conforms to the information indicated on the label and published online;
- controls to verify that safety data sheets conform to the statutory requirements laid down in Regulation (EC) No 1907/2006 (REACH);
- controls on the provision of information along the supply chain about detergents and surface-active substances intended for detergents in accordance with Regulation (EC) No 1907/2006 (REACH);
- controls to verify the content of detergents in view of the restrictions on the placing of the market and use of certain hazardous substances listed in Annex XVII to Regulation (EC) No 1907/2006 (REACH);
- targeted controls under the rapid exchange of information system (RAPEX);
- targeted controls conducted after the receipt of complaints/alerts from natural and legal persons, and information about incidents involving the use of detergents.

Where the MZ/RZI receives an alert/complaint from citizens, organisations, etc., a standard operating procedure has been developed, which determines the actions to be taken in order to examine the case, adopt a decision on the alert/complaint and carry out follow-up monitoring.

Planned thematic checks — control activities in the detergents sector are planned by taking into account the risk for the typical professional users of hazardous substances and compounds, the outcomes of checks/inspections conducted in previous years and new available information about the hazards associated with their use.

Where a breach of statutory requirements is ascertained, the action envisaged in Article 28(6) and (7) and Chapter Eight ‘Administrative and Penal Measures’ of the ZZVHVS is taken. The minimum and maximum fines are BGN 1 000 and BGN 40 000.

General market surveillance strategies for the detergents sector:

1. Control of the classification, labelling (including online information) and packaging of detergents and surface-active compounds intended for detergents placed on the market;
2. Development of new methods for laboratory testing of detergents and surface-active substances intended for detergents with a view to increasing the efficiency of the controls carried out by the competent control bodies. The controls are conducted in order to verify that the content of detergents corresponds to the information indicated on their labels and that published online in connection with the restrictions stipulated in Annex XVII to Regulation (EC) No 1907/2006 (REACH), and to improve the activities relating to the system for rapid exchange of information (RAPEX).

Specific market surveillance strategy for the chemical substances and compounds sector to be followed during the planning period:

1. Analysis of incident reports on the use of detergents, as a basis for planning and conducting targeted and thematic checks;
2. Development of up-to-date instructions laying down the rules and procedure for cooperation between the Ministry of Health and the Ministry of the Environment and Water in connection with the joint inspections conducted under Regulation (EC) No 648/2004.

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Detergents	Regulation (EC) No 648/2004	Detergents and surface-active compounds (SAC) intended for detergents (classification, labelling, packaging, and providing information about the constituent substances; prohibitions and restrictions under Annex XVII to Regulation (EC) No 1907/2006; Safety datasheets; provision of information along the supply chain)	2015	Neliya Dimitrova nddimitrova@mh.government.bg ; Tel: (+359 2) 930 1214

2.22B.3. Report on activities conducted during the previous planning period

The controls carried out by the inspectors from the Regional Health Inspection Services involve checks to verify compliance with the requirements for the classification, labelling and packaging of detergents that have been placed on the market and for safety datasheets and the provision of information along the supply chain about detergents and surface-active compounds intended for detergents, in light of the requirements for the content of detergents stipulated in Annex XVII to Regulation (EC) No 1907/2006 (REACH).

No information is available yet about the inspections and laboratory tests conducted by the RZIs in 2014. According to the available information about the systematic and targeted controls on detergents conducted by RZIs in 2013, laboratory tests to verify the content of 137 detergents were performed and 28 products were found to be non-compliant.

2.23. Sector: Eco Design — Directive 2009/125/EC

2.23.1. Responsible authority and contact details

State Agency for Metrological and Technical Supervision (DAMTN)

Address: 1797 Sofia, 52A G.M. Dimitrov Boulevard

<http://www.damtn.government.bg/>

E-mail: damtn@damtn.government.bg

Directorate-General for Market Surveillance (GDNP)

Director-General: Maria Kancheva

E-mail: Maria.Kancheva@damtn.government.bg

2.23.2. Market surveillance procedure and strategy

The principles and procedures described in section 1.6 are applied in the sector.

The forms of cooperation in the sector are described in sections 1.2, 1.3 and 1.7.

Planned checks are conducted on products selected on the basis of the complaints received during the previous years and the entry into force of the new regulations.

The specific products from the sector that will be included in the 2015 annual inspection plan of the GDNP are set out in the table below.

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Eco design	Directive 2009/125/EC Regulation (EU) No 66/2014	Kitchen aspirators		Mariana Mineva mariana.mineva@damtn.government.bg Tel: (+359 2) 892 9765

2.23.3 Report on activities conducted during the previous planning period

During the previous planning period, inspections were conducted on TV set-top boxes and household refrigerating devices.

A total of 207 simple TV set-top boxes were checked, of which 11 did not conform to eco design requirements; a total of 213 household refrigerating devices were checked, of which 31 did not conform to eco design requirements in connection with the information provided by manufacturers in the instructions for use.

Eleven (11) inspections were conducted following the receipt of notifications from the customs authorities.

Inspections were also conducted following the receipt of alerts on circulator pumps, air conditioning devices and television sets.

Administrative, penal and coercive administrative action was taken in respect of the detected non-compliant products.

2.24 Sector: Type labelling — Regulation (EC) No 1222/2009

2.24.1. Responsible authority and contact details

Consumer Protection Commission

Address: 1000 Sofia, 4a Slaveykov Square

www.kzp.bg

Directorate-General for Market Surveillance

Director-General: Emilia Elchinova

Rumyana Pekanova — Head of product Control and Safety Department

E-mail: gl.direkcia@kzp.bg; r.pekanova@kzp.bg

In 2013, the nominal budget available to the market surveillance authority was EUR 20 661 and the staff available to the KZP, expressed as full-time equivalent units, was 108 employees.

2.24.2 Market surveillance procedures and strategy

Controls were conducted on the basis of annual thematic planning and complaints received from consumers in the respective product groups in the sector. The inspections conducted on the initiative of the KZP (planned) and following the receipt of complaints or at the request of the customs authorities included documentary checks and physical checks on products.

2.24.3 Report on activities conducted during the previous planning period

During the previous planning period (2013), a total of 617 inspections were conducted in the sector.

2.25. Sector: Recreational Craft — Directive 1994/25/EC

2.25.1 Responsible authority and contact details

State Agency for Metrological and Technical Supervision (DAMTN)

Address: 1797 Sofia, 52A G.M. Dimitrov Boulevard

<http://www.damtn.government.bg/>

E-mail: damtn@damtn.government.bg

Directorate-General for Market Surveillance (GDNP)

Director-General: Maria Kancheva

E-mail: Maria.Kancheva@damtn.government.bg

2.25.2. Market surveillance procedure and strategy

The principles and procedures described in section 1.6 are applied in the sector. The forms of cooperation in the sector are described in sections 1.2, 1.3 and 1.7.

General market surveillance strategy for the sector: the legal principles of proportionality and consistency are applied and minimum and maximum fines and sanctions for non-compliance with stipulated requirements are imposed.

The specific strategy that will be applied during the planning period is based on the principles of proportionality and consistency; corrective action is to be taken within reasonable timeframes as necessary.

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Recreational craft	Directive 94/25/EC	Inflatable boats		Marieta Muhtarova @damtn.government.bg

2.25.3 Report on activities conducted during the planning period

In the second half of June 2014, inspections on recreational craft (Category C and D inflatable boats) commenced to verify their compliance with the requirements laid down in Directive 94/25/EC. No reports are available at present as checks are still ongoing.

Market surveillance in the sector mainly involves reactive controls.

2.27. Sector: Motor Vehicles — Directive 2007/46/EC

2.27.1 Responsible authority and contact details

Consumer Protection Commission

Address: 1000 Sofia, 4a Slaveykov Square

www.kzp.bg

Directorate-General for Market Surveillance

Director-General: Emilia Elchinova

Rumyana Pekanova — Head of Product Control and Safety Department

E-mail: gl.direkcia@kzp.bg; r.pekanova@kzp.bg

In 2013, the nominal budget available to the market surveillance authority was EUR 20 661 and the staff available to the KZP, expressed as full-time equivalent units, was 108 employees.

2.27.2 Market surveillance produces and strategy

Controls were conducted on the basis of annual thematic planning and complaints received from consumers in the respective product groups in the sector. The inspections conducted on the initiative of the KZP (planned) and following the receipt of complaints or at the request of the customs authorities included documentary checks and physical checks on products.

2.27.3 Report on activities conducted during the previous planning period

During the previous planning period (2013), a total of 617 inspections were conducted in the sector.

2.28 Sector: Non-road Mobile Machinery — Directive 97/68/EC

2.28.1 Responsible authority and contact details

Control and Technical Inspection Service (KTI)

Milena Atanasova, Senior Expert on European Coordination

E-mail: matanasova@kti.government.bg

Inspections are funded from the general budget of the KTI. Monthly market surveillance checks are conducted by 28 inspectors in connection with the application of Article 15 of the Registration and Monitoring of Machinery Used in the Farming and Forestry Sectors Act.

2.28.2 Market surveillance procedures and strategy

The following procedures are applied in the sector: proactive countrywide controls, checks on the supply chain, retail stores and trade fairs.

Forms of cooperation: joint activities with the Customs Agency.

At this level, an assessment is made of the activities of importers, to appraise their compliance with the requirements for approval of types of engines imported from third countries. Guidelines on cooperation with the Customs Agency were approved and have been applied since July 2010 with regard to the import of new goods from third countries that have been released for free circulation and are subject to EC-type approval in accordance with the Registration and Monitoring of Machinery Used in the Farming and Forestry Sectors Act (ZRKZGT). The aim of border controls is to prevent the placing on the Community market of goods originating from third countries that do not conform to the requirements stipulated in the ZRKZGT.

The market surveillance checks conducted by the inspectors from the KTI in accordance with Article 15 of the ZRKZGT entail:

1. checks on the premises of manufacturers, at trade fairs and exhibitions, business buildings, farm holdings and during works carried out in the farming and forestry sectors;
2. obtaining requisite documents for inspection;
3. checking the presence of the requisite markings and identifications on components, systems or individual technical elements of the equipment;
4. issuing mandatory instructions on the basis of statements of findings;
5. issuing statements in respect of ascertained infringements when applicable.

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Non-road mobile machinery	Directive 97/68/EC	Engines for non-road mobile machinery	January 2015	Milena Atanasova matanasova@kti.government.bg Tel: (+359 2) 895 2331

2.28.3 Report on activities conducted during the previous planning period

In line with Article 15 of the Registration and Monitoring of Machinery Used in the Farming and Forestry Sectors Act, the Control and Technical Inspection Service monitors the registration of engines for non-road mobile machinery on an ongoing basis through its local departments (RS-KTI).

The RS-KTI draw up monthly reports containing a detailed description of the engines checked to the head office where the information is analysed and a summary is compiled.

Market surveillance functions adequately. When conducting the controls envisaged in Article 15 of the ZRKZGT, the KTI employees may:

1. conduct checks on production sites, warehouses, retail and exhibition premises, business buildings, farm holdings and during work conducted in the farming and forestry sectors;
2. request EC-type approval certificates from their holders as an element of the technical file for inspection.

The employees of the Control and Technical Inspection Service must ascertain facts accurately while conducting controls, maintain the confidentiality of the information obtained during inspections until they are finalised, and refrain from using such information for purposes other than those intended. During 2013, checks were conducted on 68 engines.

2.29 Sector: Fertilisers — Regulation (EC) No 2003/2003

2.29.1 Responsible authority and contact details

Bulgarian Food Safety Agency

Address: Sofia 1000, 4a Slaveykov Square

<http://www.babh.government.bg>

Plant Protection Department

Marieta Hristova

E-mail: orz@bfsa.bg

2.29.2 Market surveillance procedures and strategy

The specific product categories from the sector that will be included in the 2015 annual inspection plan are set out in the table below.

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Fertilisers	Regulation (EC) No 2003/2003	Fertilisers, soil enhancers, biologically active substances and micro-nutrients		Marieta Hristova orz@bfsa.bg ; Tel: (+359 2) 917 3723

2.30 Sector: Other consumer products: products intended for children (including clothing for children); camping and recreational equipment; laser products; portable ladders; bicycles; electrical equipment up to 50V — Directive 2001/95/EC

2.30.1 Responsible authority and contact details

Consumer Protection Commission

Address: 1000 Sofia, 4a Slaveykov Square

www.kzp.bg

Directorate-General for Market Surveillance

Director-General: Emilia Elchinova

Rumyana Pekanova — Head of Product Control and Safety Department

E-mail: gl.direkcia@kzp.bg; r.pekanova@kzp.bg;

In 2013, the nominal budget available to the market surveillance authority was EUR 195 394 and the staff available to the KZP, expressed as full-time equivalent units, was 108 employees.

2.30.2 Market surveillance procedures and strategy

Ongoing controls are conducted in this product sector on the basis of RAPEX notifications, notifications received from the customs authorities, consumer complaints and feedback from priority groups in the framework of monthly planning. The procedure includes physical and documentary checks, sampling and testing, risk assessment, sanctions, and coercive administrative measures.

2.30.3 Report on activities conducted during the previous planning period

During the previous planning period (2013), a total of 5 835 inspections were conducted in the sector.

2.31 Sector: Biocides — Regulation (EU) No 528/2012

2.31.1. Responsible authority and contact details

Ministry of Health (MZ)

Public Health Directorate

Address: Sofia 1000, 5 Sveta Nedelya Square

Tel: (+ 359 2) 931 214

E-mail: nddimitrova@mh.government.bg

The Ministry of Health (MZ) is the designated competent authority within the meaning of Article 81(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocides, hereinafter ‘Regulation (EU) No 528/2012’.

Organisation of national market surveillance authorities

The Ministry of Health is the competent national market surveillance authority for the biocides sector. Twenty-eight regional health inspection services operate at provincial level, each with a head office in the administrative centre of the respective province.

The Regional Health Inspection Services conduct controls on the biocides placed on the market within the respective area to ensure compliance with the statutory requirements laid down in Regulation (EU) No 528/2012, the Protection from the Hazardous Impact of Chemical Substances and Compounds Act (ZZVVHVS) and the Regulation laying down the requirements and procedure for making available on the market of biocides, and in particular to verify the presence of authorisations for making biocides available on the market issued in accordance with the procedure stipulated in Article 14(1) of the ZZVVHVS, compliance with the requirements for classification, labelling and packaging of authorised biocides placed on the market and for their laboratory testing.

The total staff of the RZIs is 2 904 employees.

The competent authorities at local level rely on the services of in-house laboratories, structured as directorates or departments, which conduct testing and analyses of cosmetic products for the purposes of public health control. The laboratories are accredited under Standards BDS EN ISO/IEC 17025 and/or BDS EN ISO/IEC 17020 and participate in national and international suitability tests.

2.31.2. Market surveillance procedures and strategy

In 2005, Bulgaria introduced an extended procedure for authorising the placing of biocides on the market in order to ensure compliance with the statutory requirements for biocides (Regulation (EU) No 528/2012 and the ZZVVHVS). According to Article 14(1) of the ZZVVHVS, biocides are made available on the market and used following the issuance of an authorisation by the Minister of Health. When biocides contain an active substance/active substances included in the list of approved active substances for a specific product type (Article 9(2) of Regulation (EU) No 528/2012) the authorisation procedures provided for in that Regulation are followed. If the active substance contained in biocides is an existing substance included in the list set out in Annex No 2 to Regulation (EC) No 1451/2007, the European Commission has not adopted a decision on its non-inclusion in the respective product type and it has not yet been included in the list of approved active substances for the respective product type, the MZ issues an authorisation in accordance with the relevant national procedure for making it available on the market.

The Regional Health Inspection Services conduct the following market surveillance activities:

- controls to verify the presence of authorisations for the marketing of biocides issued in accordance with Article 14(1) of the ZZVHVHS for the biocides made available on the market;
- controls to verify compliance with the requirements for the classification, labelling and packaging of biocides placed on the market and with the respective issued authorisations, as well as the correspondence between safety data sheets and the conditions stipulated in the authorisation;
- laboratory analysis of the active substances in biocides and the content of biocides to verify their correspondence to issued authorisations;
- targeted market controls on the basis of complaints/alerts received from natural and legal persons and information about incidents involving the use of biocides.

Where the MZ/RZI receives an alert/complaint from citizens, organisations, etc., a standard operating procedure has been developed, which determines the actions to be taken in order to examine the case, adopt a decision on the alert/complaint and carry out follow-up monitoring.

Planned thematic checks — control activities in the biocides sector are planned by taking into account the risk for the typical and professional users of biocides, the outcomes of checks/inspections conducted in previous years and new available information about the hazards associated with their use.

Where violations of relevant national and Community legislation are ascertained, administrative sanctions and fines are imposed in accordance with Articles 28(6) and (7) and Chapter Eight ‘Administrative and Penal Measures’ of the ZZVHVHS. The minimum fine is BGN 5 000 and the maximum BGN 100 000.

General market surveillance strategy for the chemical substances and compounds sector

1. Control of the classification, labelling and packaging of biocides placed on the market on the basis of authorisations issued in accordance with the procedure provided for in Article 14(1) of the ZZVHVHS and of the correspondence of their classification, labelling and packaging with the terms and conditions stipulated in the issued authorisations;
2. Introduction of new methods for laboratory testing of the active substances contained in biocides with a view to increasing the efficiency of the controls carried out by the competent authorities.

Specific market surveillance strategies to be followed in the biocides sector during the planning period:

1. Thematic checks on product type 14 biocides (rodenticides) in connection with the risk of acute poisoning in children and non-target animals in the case of incorrect packaging, labelling and application and in connection with the re-classification of the products concerned;
2. Analysis of information about incidents involving the use of biocides with a view to taking adequate measures to manage the risk associated with their use;

3. Strengthening the cooperation between the MZ and the RZI/Customs Agency, as relevant, with a view to preventing the placing on the market of biocides originating from third countries which are not accompanied by a marketing authorisation issued in accordance with Article 14(1) of the ZZVVHVS.

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Biocides	Regulation (EU) No 528/2012	Biocides (authorisation of the marketing of biocides, conducting checks on biocides placed on the market)	2015	Neliya Dimitrova nddimitrova@mh.government.bg ; Tel: (+ 359 2) 930 1214

2.31.3. Report on activities conducted during the previous planning period

In the framework of market surveillance activities in 2013, the RZI inspectors conducted a total of 1 068 inspections on biocides placed on the market on the basis of marketing authorisations issued in accordance with Article 14(1) of the ZZVVHVS to verify their compliance with the requirements for their classification, labelling and packaging with the terms and conditions stipulated in the respective authorisations. A total of 106 infringements were ascertained.

Eighty-four laboratory tests to determine the content of biocides and the active substances contained in them were conducted. Discrepancies were ascertained in 20 cases.

No information is currently available about the controls conducted in 2014.

2.32 Sector: Labelling of textile products — Regulation (EU) No 1007/2011

2.32.1 Responsible authority and contact details

Consumer Protection Commission

Address: 1000 Sofia, 4a Slaveykov Square

www.kzp.bg

Directorate-General for Market Surveillance

Director-General: Emilia Elchinova

Rumyana Pekanova — Head of product Control and Safety Department

E-mail: gl.direkcia@kzp.bg; r.pekanova@kzp.bg; r.pekanova@kzp.bg

In 2013, the nominal budget available to the market surveillance authority was EUR 64 160 and the staff available to the KZP, expressed as full-time equivalent units, was 108 employees.

2.32.2 Market surveillance procedures and strategy

The controls carried out were based on an annual thematic plan and comprised inspections initiated by the market surveillance authority (planned) and the customs authorities, including physical and documentary checks.

2.32.3 Report on activities conducted during the previous planning period

During the previous planning period (2013), a total of 1 916 inspections were conducted in the sector.

2.33 Sector: Liquid fuels — Directive 2009/30/EC, Directive 2009/28/EC, Directive 2012/33/EU, Directive 2011/63/EU and Directive 98/70/EC

2.33.1 Responsible authority and contact details

State Agency for Metrological and Technical Supervision (DAMTN)

Sofia 1784, Mladost, Poligona, 2 Professor Petar Mutafchiev Street

<http://www.damtn.government.bg/>

E-mail: damtn@damtn.government.bg

Directorate-General for Liquid Fuel Quality Control

Director-General: Vasil Nenchev

E-mail: Vasil.Nenchev@damtn.government.bg

The DAMTN has an accredited laboratory for the testing of liquid fuels, lubricants and additives comprising a stationary and two mobile units.

2.33.2. Market surveillance procedures and strategy

The principles and procedures applied in the sector are described in section 1.6.

The forms of cooperation used in the sector are described in sections 1.2, 1.3 and 1.7.

Market surveillance activities conducted in the sector are focused on ensuring compliance with the quality requirements for liquid fuels at the time of their placing on the market, distribution, transportation and use and with the requirements for the quality of biofuels, their mixtures with liquid fuels of petroleum origin and of liquid fuels from biomass in accordance with the relevant statutory requirements.

The general market surveillance strategy described in section 1 is applied in the sector.

The planned inspections to be conducted in the sector in 2015 are set out in the table below.

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Liquid fuels	Directives 2009/30/EC, 2012/33/EU, 2009/28/EC, 2011/63/EU, 98/70/EC	Gasoline Diesel Gas oil Biodiesel	January 2015	Vasil Nenchev Vasil.Nenchev@damtn.government.bg Tel: (+359 2) 975 3812

2.33.3 Report on activities conducted during the previous planning period

During the first half of 2014 checks were conducted on 463 liquid fuels as follows:

- Gasoline fuels: 230;
- Diesel engine fuels: 233;

- Statements of findings ascertaining the compliance of liquid fuels with quality requirements: 463;
- Statements of findings ascertaining the compliance with the requirements for the content of biofuel in liquid fuels: 275;
- Detected cases of non-compliance with quality requirements: 27;
- Number of detected cases of non-compliance with the requirement for the content of biofuel in liquid fuels: 7;
- Coercive and administrative measures applied: 47;
- Penal injunctions issued: 26.

2.34 Sector: Lighters — Directive 2001/95/EC; Decision 2006/502/EC

2.34.1 Responsible authority and contact details

Consumer Protection Commission

Address: 1000 Sofia, 4a Slaveykov Square

www.kzp.bg

Directorate-General for Market Surveillance

Director-General: Emilia Elchinova

Rumyana Pekanova — Head of Product Control and Safety Department

E-mail: gl.direkcia@kzp.bg; r.pekanova@kzp.bg; r.pekanova@kzp.bg

In 2013, the nominal budget available to the market surveillance authority was EUR 9 979 and the staff available to the KZP (expressed as full-time equivalent units) was 108 employees.

2.34.2 Market surveillance procedures and strategy

The controls carried out in the product sector were based on RAPEX notifications, notifications received from the customs authorities, customer complaints and monthly planning. The procedure includes physical and documentary checks, product testing, risk assessment, sanctions, and coercive administrative measures.

2.34.3 Report on activities conducted during the previous planning period

During the previous planning period (2013), a total of 298 inspections were conducted in the sector.

2.35 Sector: Crystal Glass — Directive 69/493/EEC

2.35.1 Responsible authority and contact details

Consumer Protection Commission

Address: 1000 Sofia, 4a Slaveykov Square

www.kzp.bg

Directorate-General for Market Surveillance

Director-General: Emilia Elchinova

Rumyana Pekanova — Head of Product Control and Safety Department

E-mail: gl.direkcia@kzp.bg; r.pekanova@kzp.bg; r.pekanova@kzp.bg

In 2013, the nominal budget available to the market surveillance authority was EUR 25 081 and the staff available to the KZP (expressed as full-time equivalent units) was 108 employees.

2.35.2. Market surveillance procedures and strategy

The controls carried out were based on an annual thematic plan for inspections initiated by the market surveillance authority (planned) and inspections further to alerts (complaints), as well as through the customs authorities, including physical and documentary checks.

2.35.3 Report on activities conducted during the previous planning period

During the previous planning period (2013), a total of 749 inspections were conducted in the sector.

2.36 Sector: Products resembling foodstuffs— Directive 87/357/EEC

2.36.1 Responsible authority and contact details

Consumer Protection Commission

Address: 1000 Sofia, 4a Slaveykov Square

www.kzp.bg

Directorate-General for Market Surveillance

Director-General: Emilia Elchinova

Rumyana Pekanova — Head of Product Control and Safety Department

E-mail: gl.direkcia@kzp.bg; r.pekanova@kzp.bg; r.pekanova@kzp.bg

In 2013, the nominal budget available to the market surveillance authority was EUR 5 961 and the staff available to the KZP (expressed as full-time equivalent units) was 108 employees.

2.36.2. Market surveillance procedures and strategy

The controls carried out in the product sector were based on RAPEX notifications, notifications received from the customs authorities, customer complaints and monthly planning. The procedure includes physical and documentary checks, product testing, risk assessment, sanctions, and coercive administrative measures.

2.36.3. Report on activities conducted during the previous planning period

During the previous planning period (2013), a total of 178 inspections were conducted in the sector.

2.37. Sector: Packaging — Directive 94/62/EC

2.37.1 Responsible authority and contact details

Consumer Protection Commission

Address: 1000 Sofia, 4a Slaveykov Square

www.kzp.bg

Directorate-General for Market Surveillance

Director-General: Emilia Elchinova

Rumyana Pekanova — Head of Product Control and Safety Department

E-mail: gl.direkcia@kzp.bg; r.pekanova@kzp.bg; r.pekanova@kzp.bg

In 2013, the nominal budget available to the market surveillance authority was EUR 308 612 and the staff available to the KZP (expressed as full-time equivalent units) was 108 employees.

2.37.2 Market surveillance procedures and strategy

Control on the packaging of all products within the remit of the Consumer Protection Commission and those included in the National Sectoral Programme for Market Surveillance is conducted on an ongoing basis. Although no thematic controls on packaging have been planned, when conducting checks on each product group, packaging is inspected to verify that it conforms to relevant requirements as regards labelling, composition, processing after use and separate collection — a form of control that has proven its efficiency.

2.37.3 Report on activities conducted during the previous planning period

During the previous planning period (2013), a total of 9 126 inspections were conducted in the sector.

2.38 Sector: Electrical appliances — Delegated Regulation (EU) No 665/2013; Delegated Regulation (EU) No 874/2012; Delegated Regulation (EU) No 392/2012; Delegated Regulation (EU) No 626/2011; Delegated Regulation (EU) No 1062/2010; Delegated Regulation (EU) No 1059/2010; Delegated Regulation (EU) No 1060/2010; and Delegated Regulation (EU) No 1061/2010

2.38.1 Responsible authority and contact details

Consumer Protection Commission

Address: 1000 Sofia, 4a Slaveykov Square

www.kzp.bg

Directorate-General for Market Surveillance

Director-General: Emilia Elchinova

Rumyana Pekanova — Head of Product Control and Safety Department

E-mail: gl.direkcia@kzp.bg; r.pekanova@kzp.bg; r.pekanova@kzp.bg

In 2013, the nominal budget available to the market surveillance authority was EUR 39 949 and the staff available to the KZP (expressed as full-time equivalent units) was 108 employees.

2.38.2 Market surveillance procedures and strategy

The controls carried out were based on annual thematic plans and complaints received from consumers in respect of the respective product groups in the sector. They comprised inspections initiated by the market surveillance authority (planned) and the customs authorities, including physical and documentary checks.

2.38.3 Report on activities conducted during the previous planning period

During the previous planning period (2013), a total of 1 193 inspections were conducted in the sector.

2.39 Sector: Tractors — Directive 2003/37/EC

2.39.1. Responsible authority and contact details

Control and Technical Inspection Service (KTI)

Milena Atanasova, Senior Expert on European Coordination

E-mail: matanasova@kti.government.bg

2.39.2 Market surveillance procedures and strategy

The following procedures are applied in the sector: proactive countrywide controls and checks on the supply chain, retail stores and trade fairs and border control.

Forms of cooperation: joint activities with the Customs Agency.

At this level an assessment is made of the activities of importers to appraise their compliance with the requirements for approval of the types of engines imported from third countries. Guidelines on cooperation with the Customs Agency were approved and have been applied since July 2010 with regard to the import of new goods from third countries that have been released for free circulation and are subject to EC-type approval in accordance with the Registration and Monitoring of Machinery Used in the Farming and Forestry Sectors Act (ZRKZGT). The aim of border controls is to prevent the placing on the Community market of goods originating from third countries that do not conform to the requirements stipulated in the ZRKZGT.

2.39.3 Report on activities conducted during the previous planning period

In accordance with Article 15 of the ZRKZGT the Control and Technical Inspection Service monitors the registration of new tractors on an ongoing basis through its local departments (RS-KTI).

The RS-KTI sends monthly reports containing a detailed description of the inspected tractors to the head office where they are analysed and summaries are compiled.

With regard to import from third countries, the KTI relies on a long tradition of sound cooperation with the Customs Agency. The two agencies take joint action on the basis of guidelines on cooperation adopted in accordance with Regulation (EC) No 765/2008. The guidelines apply to new goods originating from third countries which have been released for free circulation and are subject to EC-type approval requirements. Where information is received from a local department of the Customs Agency, inspections of new tractors are conducted by RS-KTI inspectors in order to ascertain the availability of all requisite documents.

In line with Article 12 of the guidelines on cooperation, since October 2010 the local departments of the Customs Agency and the head office of the KTI have been exchanging reports detailing the activities carried out during the previous month. Available information shows that to date, the local departments of the KRI have responded to all notifications received from the local departments of the Customs Agency within the time periods stipulated by law and have conducted the necessary inspections and provided feedback. In 2013, inspections were conducted on 303 new tractors.

Sector	Relevant Community legislation	Product categories	Commencement period	Contact person at the market surveillance authority (names, e-mail and telephone)
Non-road equipment	Directive 97/68/EC	Engines for non-road equipment	January 2015	Milena Atanasova matanasova@kti.government.bg Tel: (+359 2) 895 2331
New tractors	Directive 2003/37/EC	New tractors and components for them	January 2015	Milena Atanasova matanasova@kti.government.bg Tel: (+359 2) 895 2331