REPORT

ON THE REVIEW AND EVALUATION OF THE OPERATION OF MARKET SURVEILLANCE ACTIVITIES IN HUNGARY (2010 TO 2013)

CHAPTER I: OVERVIEW OF GENERAL MARKET SURVEILLANCE ACTIVITIES

1. <u>National Office of the Chief Medical Officer of the National Public Health</u> and Medical Officer Service (the 'ÁNTSZ')

A. Review of general market surveillance activities

Information on the general market surveillance organisation and infrastructures in place for the 2010–2013 period

In 2010, the ÁNTSZ was organised regionally, in a vertical sub-regional structure. Professional direction was the responsibility of the National Office of the Chief Medical Officer (the 'OTH') as its supreme body. The regional bodies operated in part as independent bodies managing their own affairs; the budgets required for the implementation of tasks were determined for the regional bodies by the Ministry of Health via the OTH. Feedback on implementation was given to the Ministry and the Treasury (Hungarian State Treasury) via the OTH. As part of the regional bodies, laboratory subcentres required for market surveillance activities performed the tests relating to the regulatory activities at cost price.

As of 1 January 2011, the regional bodies of the public health sector continued their operation integrated into government offices. The direction became dual and of a matrix nature. Professional direction and the assignment of responsibilities continued to remain with the OTH; however, the budget, financial, infrastructural and logistical possibilities to be provided for implementation were determined individually for the administration bodies via government offices. The authorities have their own institutional laboratories only at the old regional sub-centres, thus they have the tests carried out mostly on the basis of cooperation contracts. Feedback reporting on the implementation of the tasks continues to be provided to the professional management body, the OTH.

As of 1 January 2012, the sub-regional public health institutions were separated from the Public Health Administration Bodies, and since then have operated as the district public health institutions of the district offices. This divided up the organisational structure still further, and professional management, the setting of the terms of reference, the implementation of tasks as well as financial settlement also became more complex. The use of material resources (e.g. motor vehicle use) is coordinated by government offices, thus it is also necessary to adjust the implementation of the responsibilities of the market surveillance authority to the more limited possibilities within the government offices.

Information on total resources available for market surveillance activities

		2010	2011	2012	2013
1.1.	Budget available to market		5186801	5 361 560	3869582

	surveillance authorities in nominal terms (EUR)			
1.2.	Budget available to market surveillance authorities in relative terms (percentage of total national budget)	0.010494577%	0.009650523%	0.006787963%
2.	Staff available to market surveillance authorities (full-time equivalent units)	628.21	597.81	574.80
3.	Number of inspectors available to market surveillance authorities (full- time equivalent units)	319.59	324.41	332.72

B. Assessment of the functioning of market surveillance activities

Pursuant to Section 10(1)(a) of Government Decree No 6 of 18 January 2013 on the detailed rules of market surveillance activities, the Public Health Administration Bodies and the District Public Health Institutions are market surveillance authorities named as responsible for biocide active ingredients and products, products treated with biocides, cosmetic products, as well as chemicals, preparations, mixtures and certain products affected by restrictions.

The public health bodies engage in market surveillance activities pursuant to the legislation in force, as part of their responsibilities specified in the annual work plan issued by the OTH, as well as in connection with filings of public interest or of complaints, and in connection with alarms received from the rapid response information systems. The responsibilities and competence are assigned to the district public health institutions proceeding at first instance. At the county level, the setting of the terms of reference, the implementation of the tasks, financial and logistical implementation and feedback reporting on implementation are coordinated.

Information exchange and coordination with other market surveillance authorities at the regional level are contingent. This type of coordination and information exchange is performed at the level of the OTH and the national professional management bodies. Alarms affecting market surveillance are given to the area by the OTH, and feedback reporting and possible alarms are launched to the OTH. Voluntary corrective actions taken by service providers regularly precede the measures taken by the Authority in connection with the alarms.

2. Office of Health Authorisations and Administrative Procedures (the 'EEKH')

A. Review of general market surveillance activities

Information on the general market surveillance organisation and infrastructures in place for the period from 2010 to 2013

The safety of patients and health care staff requires the application of legislation allowing the free circulation of goods to be accompanied by appropriate market surveillance measures. Regulation (EC) No 765/2008 provides the definition of market surveillance as follows: 'activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Community harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection.' Based on this, the purpose of market surveillance activities is to examine whether the product meets the safety and performance requirements prescribed by legislation applicable to it.

These responsibilities were performed in the period reviewed and are still performed by the Office of Health Authorisations and Administrative Procedures (the 'EEKH').

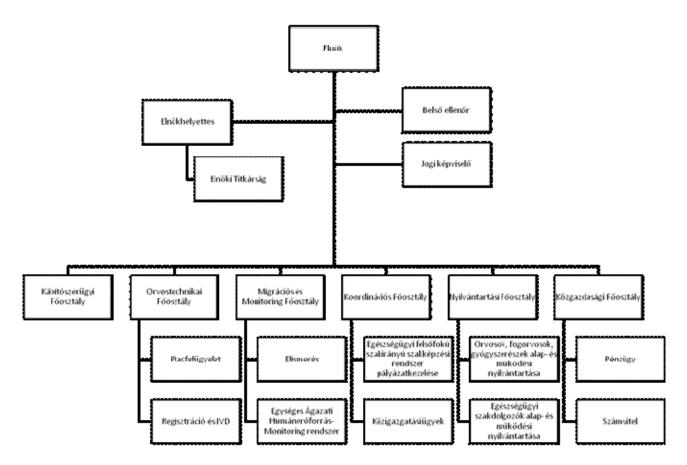
Organisation and infrastructure:

Legislation regulating market surveillance activities and setting forth conformity requirements in respect of market surveillance:

- Decree No 4 of 17 March 2009 of the Minister of Health on medical devices;
- Decree No 8 of 13 March 2003 of the Minister of Health, Welfare and Family Affairs on in vitro diagnostic medical devices;
- Act LXXXVIII of 2012 on the market surveillance of products;
- Government Decree No 6 of 18 January 2013 on the detailed rules of market surveillance activities.

The responsibilities of the market surveillance authority are referred to the responsibilities of the EEKH by legislation only in respect of medical devices (i.e. medical devices, active implantable medical devices, custom-made medical devices, medical devices intended for clinical trials and in vitro diagnostic medical devices). The EEKH performs these responsibilities with nationwide jurisdiction and competence through its organisational unit, the Medical Engineering Division; consequently, it does not have a local (county, etc.) organisation or horizontal infrastructure. In the period of 2010 to 2013, the Division operated with a staff of nine, of which one person (taken in the narrow sense, on the basis of his job description) has been performing market surveillance activities due to the other responsibilities incumbent on the Division.

The Division is integrated into the whole office organisation as shown in the following figure.



(Source: Appendix 1 to the Annex to Instruction No 3 of 26 February 2010 the Minister of Health)

Elnök	President
Elnökhelyettes	Vice-President
Belső ellenőr	Internal Controller
Elnöki titkárság	Secretariat of the President
Jogi képviselő	Legal Representative
Kábítószerügyi Főosztály	Narcotic Drugs Division
Orvostechnikai Főosztály	Medical Engineering Division
Migrációs és Monitoring Főosztály	Migration and Monitoring Division
Koordinációs Főosztály	Coordination Division
Nyilvántartási Főosztály	Registry Division
Közgazdasági Főosztály	Economics Division
Piacfelügyelet	Market Surveillance
Elismerés	Recognition
Egészségügyi felsőfokú szakirányú képzési	Management of applications for post-graduate
rendszer pályázatkezelése	health care specialist training
Orvosok, fogorvosok, gyógyszerészek alap- és	Basic and operational registry of physicians,
működési nyilvántartása	dentists and pharmacists
Pénzügy	Finances
Regisztráció és IVD	Registration and IVD
Egységes Ágazati Humánerőforrás-Monitoring	Uniform Sectoral Human Resources Monitoring
Rendszer	System
Közigazgatási ügyek	Administration matters
Egészségügyi szakdolgozók alap- és működési	Basic and operational registry of health care

nyilvántartása	specialists
Számvitel	Accounting

Cooperation and information exchange with partner authorities in Hungary and at the EU level:

The Hungarian Competition Authority (the 'GVH'), the Public Health Institutions, the regional Consumer Protection Authorities, the police and the courts contacted the Medical Engineering Division on several occasions as part of domestic legal assistance. The majority of our market surveillance inspection procedures are launched on the basis of such inquiries and signals received from the partner authorities (they are reactive).

On the initiative of the staff of the Division, the signing of a cooperation agreement is under way between the GVH and the EEKH. During the market surveillance of medical devices, it is often revealed that the device is not a medical device, but the manufacturer or the distributor attributes a medical effect to it; in these cases, the suspicion of misleading the consumers is raised. In this respect, the GVH is competent to proceed. The agreement, which allows official inquiries and continuous consultations, serves the protection of the consumers at a level as high as possible.

The EEKH works in close cooperation with the National Office of the Chief Medical Officer (the 'OTH') of the ÁNTSZ and its regional bodies.

In respect the verification of compliance with product safety rules by medical devices coming from third countries other than Member States of the Union, in order to facilitate the performance of the tasks of the EEKH, a cooperation agreement was made between the National Tax and Customs Authority (the 'NAV') and the EEKH on 16 June 2004, under which consultations are held between the two authorities on a continuous basis.

The legal bases for liaison with the medical engineering organisations of the EU were established by the Treaty of Accession. Technical issues are agreed with the partner authorities by using the institutional system of the EU at meetings held in Brussels, with the participation of one delegate of each of the national authorities.

Consultations between the competent authorities are held at the regularly convened work meetings of the Medical Engineering Sector, at the majority of which the EEKH was represented. Among these, the Authority regularly and, as far as possible, actively participated in the meetings of the Compliance and Enforcement Working Group (the 'COEN') and in the collaborative work.

In 2009, in order to help closer cooperation between EU countries, the circulation of notices regarding the market surveillance procedures of the competent authorities (COEN forms) between the authorities was started. Thus, it can be followed on a daily basis that the Authority of which country has instituted market surveillance procedures in respect of what medical device. The other partner authorities may send the issuing authority their opinions and remarks on them by a pre-set date, thereby helping develop a uniform position on the given device within the Union.

		2010	2011	2012	2013
1.1.	Budget available to market surveillance	n.a.	n.a.	n.a.	n.a.
	authorities in nominal terms (EUR)*				

Information on total resources available for market surveillance activities

1.2.	Budget available to market surveillance				
	authorities in relative terms (percentage				
	of total national budget)				
2.	Staff available to market surveillance	1	1	1	1
	authorities (full-time equivalent units)	1	1	1	1
3.	Number of inspectors available to				
	market surveillance authorities (full-time	1	1	1	1
	equivalent units)				

*The amount of the budget available for the specific market surveillance activity (EUR; see: Chapter I.A., points 1.1 and 1.2 of the table, as well as Chapter II.2., points 7.1 and 7.2) cannot be established responsibly, even by estimate, due to the work time spent on the task by the staff, which is different for each procedure, and the complexity of the market surveillance tasks.

B. Assessment of the functioning of market surveillance activities

The Medical Engineering Division of the EEKH and its legal predecessor organisation have been performing the surveillance of the market of medical devices since the accession of Hungary to the Union; however, the Authority itself made a proposal for the amendment of Decree No 8 of 2003 of the Minister of Health, Welfare and Family Affairs relating to IVD devices only in the first half of 2011, as a result of a specific case, in order to ensure that the provision referring to the market surveillance competence of the Authority is included in it in accordance with Decree No 4 of 17 March 2009 of the Minister of Health on medical devices. Together with this, on the initiative of the competent Ministry, reference to the market surveillance competence was also included in Government Decree No 295 of 28 October 2004 on the EEKH. The market surveillance activities of the EEKH performed in the period between 2010 and 2013 are well demonstrated by the figures shown in the tables of Chapter II. It is to be noted that of the staff of nine of the Division, a single staff member performs the market surveillance activities as his main activity in a specific job in addition to the other wide-ranging and increasing number of responsibilities to be performed as specified by legislation. This means conducting procedures instituted by it and overseeing and coordinating the activities of the other staff members that may affect market surveillance as project supervisor. With regard to the foregoing, the amount of the budget available for the specific market surveillance activity (EUR; see: Chapter I.A., points 1.1 and 1.2 of the table, as well as Chapter II.2., points 7.1 and 7.2) cannot be established responsibly, even by estimate, due to the work time spent on the task by the staff, which is different for each procedure, and the complexity of the market surveillance tasks.

In order to offset the shortage of resources and to increase the efficiency of market surveillance inspections, the market surveillance procedures are based on cooperation between the project supervisor of the market surveillance activities and the other staff of the Division. In market surveillance procedures, the what is called 'inside cover' as aimed at providing a trackable method for this, on which it can be followed which staff member performed what tasks corresponding to his or her field in the given procedure. Several new checklists have been introduced for the inspection of user manuals and labels with the intent not to miss the checking of any condition during the procedures.

3. <u>Lifts and Escalators Inspectorate of ÉMI Építésügyi Minőségellenőrző</u> <u>Innovációs Nonprofit Kft. (ÉMI Not-for-profit Company for Quality</u> <u>Control and Innovation in Construction) (the 'ÉMI FMF')</u>

A. Review of general market surveillance activities

Information on the general market surveillance organisation and infrastructures in place for the 2010–2013 period

The market surveillance activities of ÉMI FMF are primarily aimed at ensuring that products intended for distribution and those already in distribution meet the health, safety, consumer protection and other public interest requirements. It is regrettable, but the above requirements are not met in every case. The goal is that economic operators place on the market and resell only safe products meeting the legislative provisions in order to protect the life, health and safety of consumers and users.

		2010	2011	2012	2013
1.1.	Budget available to market surveillance authorities in nominal terms (EUR)				60 000
1.2.	Budget available to market surveillance authorities in relative terms (percentage of total national budget)				0.0001%
2.	Staff available to market surveillance authorities (full-time equivalent units)				10
3.	Number of inspectors available to market surveillance authorities (full-time equivalent units)				10

Information on total resources available for market surveillance activities

B. Assessment of the functioning of market surveillance activities

Acting within its responsibilities, the ÉMI FMF verifies whether lifts, escalators and passenger conveyors placed on the market, distributed or put into service in the territory of Hungary (the 'product') meet the relevant safety and statutory requirements. By conducting its inspections and taking its necessary measures, it contributes to ensuring that the products to be placed and already placed on the market do not pose a health and safety hazard to consumers and users.

As market surveillance authority, the ÉMI FMF is entitled to the check the safety, conformity and documentation of any product, and is entitled to enter the head offices and company sites of the economic operators concerned, to request submission of the necessary information and documentation from economic operators and to request economic operators to make decisions. In the case of products posing a serious hazard, it may order its withdrawal from distribution and/or recall.

The ÉMI FMF carries out its responsibilities and activities falling within its competence independently, impartially and without prejudice, taking into consideration the principle of good faith and fair practices, and always cooperates with economic operators during its procedures. The ÉMI FMF performed its market surveillance activities in 2013 pursuant to Government Decree No 6 of 18 January 2013, in accordance with an action plan laid down in advance.

4. <u>National Institute for Quality and Organisational Development in</u> <u>Healthcare and Medicine (the 'GYEMSZI-OGYI')</u>

A. Review of general market surveillance activities

Information on the general market surveillance organisation and infrastructures in place for the 2010–2013 period

Pursuant to Section 10(1) of Government Decree No 6 of 18 January 2013 on the detailed rules of market surveillance activities, in the case of non-conforming or document-lacking imported medicines and therapeutic preparations that are not medicinal, the customs authority notifies the responsible and competent market surveillance authority, i.e. the GYEMSZI-OGYI, forthwith by fax or email, which passes a decision on the compliance of the imported product with the legislative provisions, which is immediately enforceable notwithstanding any appeal.

Considering the fact that the products subjected to inspection are products specified by legislation as subject to the obligation of distribution licensing and conformity assessment prior to their placement on the market, the inspection of the market surveillance authority includes to find out whether (a) a given product may be placed on the market on the basis of its efficiency, safety and quality, (b) the distributed product has an official license or a certificate, expert's report or registration certificate issued by an organisation examining, checking and certifying the conformity of the product or a registration organisation (such organisations designated by legislation), or a declaration of performance or declaration of conformity issued by the manufacturer and (c) it conforms to the contents of the official license, certificate, expert's report, declaration of performance or declaration of conformity.

During the inspection, the market surveillance authority may perform, or may ensure the performance of, product identification and other tests by a conformity assessment organisation, a body performing technical assessment or a notified body, or a laboratory; however, no conformity assessment organisation or other organisation designated on the basis of authorisation granted in legislation, which has evaluated the performance of the product, has participated in an evaluation procedure prior to its placement on the market or has tested the conformity of the product previously, may proceed.

If, during its procedure, the market surveillance authority establishes that the product does not meet the safety requirements, the finding of the authority applies, in the case of products with a lot identifier, to the quantity manufactured and placed on the market with the same lot identifier; and in the case of products not marked by lot identifier, to the total quantity manufactured and placed on the market with the same lot identifier. If, as a result of the nature of the defect, the manufacturer subsequently eliminates the source of hazard with regard to the already manufactured quantity, the product may be reintroduced to the market by using a modified lot identifier and product identifier.

The costs of tests relating to the market surveillance inspection of imported products as well as the costs of storage and destruction incurred are to be borne by the party requesting customs clearance.

If the customs authority suspects in the case of the consignment of a medicine or therapeutic preparation that is not medicinal that it is hazardous or non-conforming, it should notify GYEMSZI forthwith by email or fax. If there is suspicion, the customs authority suspends the customs procedure relating to the release of the product for free circulation in accordance with Section 20(3) of Act LXXXVIII of 2012 on the market surveillance of products ('Act LXXXVIII of 2012'). The notice received by GYEMSZI-OGYI should include, in every occasion, the email address and fax number to which GYEMSZI-OGYI is required to send the answer.

Considering that pursuant to Government Decree No 323 of 27 December 2010, GYEMSZI-OGYI has been also designated as a pharmaceutical administration body, it is exclusively competent for the regulatory verification and inspection of the manufacture, placement on the market, distribution, pharmacovigilance, brokering of medicinal products, the clinical trial of test preparations, the performance of laboratory activities examining the safe applicability of medicines, as well as the presentation of trading practices relating to medicines and therapeutic aids towards consumers and of medicines and therapeutic aides. Thus, the infrastructures required for the efficient performance of the market surveillance activities designated by the legislation referred to above to a high standard as well as the personnel and assets are available to it even if, in the case of products sent by the customs authority, it is necessary to use laboratory tests in addition to the organoleptic examination of the preparations.

		2010	2011	2012	2013
1.1.	Budget available to market surveillance				
	authorities in nominal terms (EUR)	41 41 4	32471	40794	97480
1.2.	Budget available to market surveillance				
	authorities in relative terms (percentage				
	of total national budget)				
2.	Staff available to market surveillance	2+1	2+1	2+1	4+2
	authorities (full-time equivalent units)				
3.	Number of inspectors available to	1	1	1	1
	market surveillance authorities (full-time				
	equivalent units)				

Information on total resources available for market surveillance activities

B. Assessment of the functioning of market surveillance activities

After the product is received by the GYEMSZI-OGYI, the officer of the GYEMSZI-OGYI responsible for the counterfeiting of medicines makes arrangements forthwith for testing the product, using a laboratory analysis, as required, in order to establish whether the product complies or perhaps does not comply with the legislation. The answer given by the GYEMSZI-OGYI to the customs authority has to clearly include reference to one of the following:

(a) the GYEMSZI is not competent for the product in question considering the fact that it is not a medicine or it is not one of the therapeutic preparations that are not medicinal;

(b) the GYEMSZI is competent for the product in question, and it does not pose a serious hazard to consumers;

(c) the GYEMSZI is competent for the product in question, and it is non-conforming or poses a serious hazard to consumers;

(d) the GYEMSZI is competent for the product in question, but further tests are required to decide whether the product in question is conforming and whether the product in question poses a hazard to consumers.

On the basis of the foregoing, it can be established that GYEMSZI, as market surveillance authority, proceeds on the initiative or on the basis of a notice received from the customs authority during its market surveillance procedures, may not institute market surveillance procedures on its own, but the GYEMSZI-OGYI may request the customs authority and the National Police Headquarters to conduct intensive inspections of certain product groups and countries of origin and, if warranted, importers. The detailed rules for the relevant inquiries are regulated in an agreement made between the GYEMSZI-OGYI, the customs authority and the National Police Headquarters.

5. Hungarian Office for Mining and Geology (the 'MBFH')

A. Review of general market surveillance activities

Information on the general market surveillance organisation and infrastructures in place for the 2010–2013 period

The MBFH and its regional bodies of first instance, the Regional Mining Authorities (collectively: the 'Mining Supervisory Authority'), exercised their market surveillance responsibilities and competence pursuant to:

- Section 43(11) of Act XLVIII of 1993 on mining ('Act XLVIII of 1993');
- the Product Market Surveillance Act (Act LXXXVIII of 2012) and separate legislation;
- Decree No 94 of 18 December 2003 of the Minister for the Economy and Transport on the rules and regulatory supervision of the distribution of liquefied propane and butane gases and their mixtures (LPG) in tanks or cylinders;
- Government Decree No 23 of 3 February 2006 on regulatory supervision of certain pressure equipment falling within the competence of the Mining Supervisory Authority;
- Decree No 29 of 3 August 2011 of the Minister for the National Economy on the certification of the safety requirements and conformity of transportable pressure equipment;
- Government Decree No 191 of 4 November 2002 on the distribution and supervision of explosives for civil uses;
- Decree No 16 of 30 August 2008 of the Minister for National Development and the Economy on the certification of the safety and conformity of machinery;
- Decree No 9 of 5 April 2001 of the Minister for the Economy on the certification of the safety requirements and conformity of pressure equipment and systems;
- Decree No 8 of 16 February 2002 of the Minister for the Economy on the requirements for equipment and protection systems to be applied in potentially explosive environments;
- Decree No 18 of 3 December 2008 of the Minister of Welfare and Labour on the requirements for, and certification of the conformity of, individual protective equipment.

The Mining Supervisory Authority, as market surveillance authority, verifies that the following items used during the performance of mining activities and gas operations or installed in facilities overseen by the authority meet the safety and conformity certification requirements set forth in the governing legislation:

- (a) products, machinery, equipment,
- (b) pressure equipment and systems, transportable pressure equipment,
- (c) personal protective equipment,
- (d) electrical products,
- (e) equipment and protection systems to be applied in potentially explosive environments.

No inspections prompted by specific complaints from consumers/users, notified bodies, competing businesses, trade unions, etc., accidents or unexpected incidents, information provided by other Member State authorities (e.g. via RAPEX notifications), etc. took place in the period reviewed. During on-site inspections, the representatives of the Regional Mining Authorities regularly inspected mining workplaces and other construction sites where products were installed in the plant and put into service. The purpose of such inspections is to verify product safety and conformity, which means, in most cases, the visual examination of the products and the checking of the existence of markings, warnings and information in order to determine obvious technical shortcomings relating to compliance with the requirements of the applicable Union legislation.

The <u>subject-matter of the inspections</u> was usually the verification of the conformity of the products installed in the facility, the placement of the CE marking, and the existence of the accompanying documentation, the declaration of conformity and, if necessary, the technical documentation compiled in accordance with the legislation.

The Mining Supervisory Authority exercised competence over the market surveillance segment together with its technical and safety, industrial safety and construction supervision competences associated with its basic responsibilities as part of ad hoc and targeted inspections. Thus, the product safety inspections were quasi 'integrated with' the procedures. If non-conformity is detected, it can be decided during an investigation conducted in the listed competences whether, in a given case, the non-conforming use of a safe product or the placement on the market (use) of a product failing to meet the safety requirements is involved.

In the period reviewed, the Mining Supervisory Authority <u>did not take product samples and did</u> not initiate its own tests or testing by a third party.

<u>It is important to point out</u> that the activities of the Mining Supervisory Authority in relation to market surveillance are related to the inspection activities of the overseen area from a technical and safety point of view, and neither separate staff (inspector or controller) nor separate resources are available to the Mining Supervisory Authority for performing independent market surveillance activities.

Information on total resources available for market surveillance activities

		2010	2011	2012	2013
1.1.	Budget available to market surveillance authorities in nominal terms (EUR)	173 544	440 635	532680	299 517
1.2.	Budget available to market surveillance authorities in relative terms (percentage of total national budget)	0.0003%	0.0009%	0.0010%	0.0005%
2.	Staff available to market surveillance	24	24	22	21

	authorities (full-time equivalent units)				
3.	Number of inspectors available to market surveillance authorities (full- time equivalent units)	18	18	18	17

B. Assessment of the functioning of market surveillance activities

Analysing the cases found and conducted by the individual Regional Mining Authorities in the period reviewed, the following can be established.

(a) According to its work plan, the <u>Budapest Regional Mining Authority</u> inspected aboveground warehouse of explosives located on the parcel of land under topographical lot No 0121/2 of Nagylóc-Zsunypuszta as part of its targeted inspection on 26 January 2012. According to the inspection record filed under No BBK/269-1/2012, explosives called ANDO-PRILL-M and RIOGEL TRONER as well as mining electric detonators called DEM-S were stored at the warehouse by the license holder MAPIFKŐ Kft. "f.a." (MAPIFKŐ LLC in liquidation) at the time of the inspection. According to the archive data downloaded from the website of the National Meteorological Service, the minimum temperature was -17°C in the area of Nagylóc and Hollókő on 6 February 2012.

According to the safety data sheets and operating instructions obtained from the distributor of the electric detonators, AUSTIN POWDER Hungary Kft. (AUSTIN POWDER Hungary LLC) and the manufacturer of ANDO-PRILL-M, MIKEROBB Kft. (MIKEROBB LLC) and the Hungarian distributor of RIOGEL TRONER, MAXAM-Magyarország Kft. (MAXAM-Hungary LLC), RIOGEL TRONER can be used between the temperature limits of -10° C and $+60^{\circ}$ C and the recommended storage temperature of 0°C to $+30^{\circ}$ C is stated in Section 7.2 of the safety data sheet of the explosives. The occurrence of a temperature lower than the minimum storage temperature for the explosive ANDO-PRILL-M and the detonator DEM-S cannot be proven.

In its Order No BBK/269-2/2012, the Regional Mining Authority ordered the termination of the storage of the explosive called RIOGEL TRONER and to be regarded frozen and ordered its destruction.

(b) Of the inspections carried out in the territory of the Mining District Authority of Miskolc, the following are to be pointed out:

- Of the machinery, oil and water well drilling equipment was inspected in high numbers. The incomplete documentation (operating and maintenance instructions in Hungarian) and the declarations of conformity of used drilling equipment imported from abroad or their Hungarian translation appeared as a frequent issue. As a result of inspections, the operators usually made up for the missing documents prescribed by legislation and met the requirements of the safety regulations.

- During the inspections of LPG cylinders, 11.5 kg LPG cylinders were found with <u>expired</u> <u>inspection dates</u> at the LPG cylinder exchange sites on several occasions. The defective cylinders were presumably filled not at the licensed filling plant, the fact of which the Mining District Authority could not prove considering the fact that gas distributors use not only their own cylinders, but they may use also each other's cylinders as per agreement. <u>At the instruction</u> of the Mining District Authority, the gas

distributor had the defective products removed from site and withdrew them from commercial distribution.

- Of pressure equipment, the Mining District Authority most often verified the conformity of the various equipment installed in gas and oil facilities (globe valves, flap valves, gate valves and pressure regulators). In several cases, prohibition had to be imposed on the applicability of products without CE markings, but it also occurred in a few cases that the operator or the contractor demonstrated that the product had been placed into the warehouse prior to the entry into force of the legislation. It occurred once at a manufacturer of LPG storage tanks that the shape of the conformity marking did not comply with the legislative provisions, and in the case of one pressure vessel manufactured on the site, the Mining District Authority had to arrange for the correction of the documents approving design (Test Report on Design Examination) and a design parameter with the certification organisation.

- Of the equipment and protection systems to be applied in <u>potentially explosive</u> environments, the Mining District Authority examined products belonging to Application Group II (for purposes other than mining) as part of construction surveillance inspection. These products included various intrinsically safe remote pressure and temperature transmitters, electromotors, electrical boxes, switches, lighting fittings and radiators. In addition to electrical equipment and appliances, the Regional Mining Authority laid special emphasis on the use, marking and certification of non-electrical equipment also included in the ATEX Directive. Among non-electrical devices, various pumps and compressors and drive mechanisms were inspected. No remarks were made during their visual examination and the review of their documentation.

- In the past years, the Mining District Authority laid emphasis on protective clothing among individual protective equipment; it has inspected almost all mining undertakings active in the gas and oil industry as well as businesses participating in the distribution and transport of hydrocarbons and the distribution of LPG gas. After Hungary's accession to the Union, the <u>manufacturers of protective clothing did not prepare</u> thoroughly for the changed statutory environment, and they were still using the certificates issued by the National Inspectorate General for Industrial Safety and Labour (the 'OMMF') even after 2007, although their validity was maximum three years.

- The Mining District Authority had to perform a significant <u>activity to provide information</u> to the undertakings concerned in order for the undertakings to acknowledge that according to legislation, 1 May 2007 was the last day after accession to place individual protective equipment on the market without a rating certificate (OMMF certificate). In the case of protective clothing procured prior to 1 May 2007, the Mining District Authority accepted the previous certificates and test certificates, but after 1 May 2007, it accepted only the use of protective equipment provided with an EC type certificate prescribed by legislation. During this transitional period, it occurred several times that the manufacturer did not rate the protective clothing or every member of the protective clothing line made by it, attributed properties that were not covered by the test and certification to the product (antistatic) in its information brochure, the product did not meet the statutory requirements, and that protection was not shown by a symbol on the clothing. At the request of the Mining District Authority, the economic operators took voluntary measures to meet the statutory requirements.

(c) In connection with the inspections conducted (also) in market surveillance competence in the territory of the **Mining District Authority of Pécs**, the following are to be pointed out:

- During the inspection of <u>machinery and equipment</u> operated in the mines, it was necessary to take a record on the spot on three occasions, in part in exercise of market surveillance powers. Typically, they could not present the <u>type certificates</u> and commissioning documents <u>of the machinery</u> used at the sites of inspection.

- During the inspection of <u>individual breathing apparatuses for escape</u>, the Mining Supervisory Authority prohibited the use of the MSI-94 individual breathing apparatuses for escape, equipped with a CO filter, put to use by Mecsekérc Zrt. (Mecsekérc Pte. Ltd.) at the underground construction of the Bátaapáti National Radioactive Waste Repository until a risk assessment is carried out and the possible necessary measures are taken. During the inspection, <u>it could not be fully demonstrated</u> that the MSI-

94 breathing apparatuses for escape put to use by Mecsekérc Zrt. might be used for the underground construction of the Bátaapáti National Radioactive Waste Repository and, if they might be, whether they provide appropriate protection.

- Inspections were held 15 times in the areas of hydrocarbon mining and natural gas transmission and distribution regarding the product safety and the certification of the conformity of the equipment and materials installed and used and the existence of markings in accordance with the regulations. During the inspections conducted, it did not find any deficiency, the installed equipment and the products and materials used met the relevant regulations.

- In the area of LPG distribution, inspections were held four times at filling plants and 32 times at LPG cylinder exchange sites to verify the conformity of the distribution of LPG gas in cylinders with the product safety requirements and the existence of markings and warnings in accordance with the regulations. The Mining District Authority did not establish any deficiency or non-conformity during the inspections held at the LPG filling plant regarding the distribution of LPG gas in cylinders. During the inspection of the distribution of LPG gas in cylinders performed at LPG cylinder exchange sites, LPG gas was placed on the market in cylinders without a distribution license on five occasions, in the case of which the identity of the persons distributing LPG gas in cylinders without a license were established on four occasions. The Mining District Authority imposed a fine for distribution without a license and prohibited any further distribution.

(d) In the territory of the **Mining** District **Authority of Szolnok**, the following are to be pointed out:

- With respect to the procurement of <u>individual protective equipment</u>, the employers obtain the certificates prescribed by legislation in force from the distributor during the procurement of protective equipment. These documents were presented during the inspection. The use before dates of the protective equipment are continuously monitored and the protective equipment is replaced before their expiry. During the use of protective equipment, no accident took place as a result of a possible defect of the protective equipment. In respect of an accident that occurred during the <u>proper application</u> and use of individual protective equipment, it can be mentioned as an example that in the case of an external impact on the head, a serious head injury was prevented from occurring by a protective helmet, complying with the above regulations, and its use.

- During inspections involving <u>explosives for civil uses</u>, the Mining District Authority did not find any minor offence falling within market surveillance competence. The storage of explosives is satisfactory, and the Mining District Authority did not find any explosives with expired use before dates or damaged packaging during the inspections. The licence holders use the explosives before their use before dates. No arrangements had to be made for the destruction of explosives due to any deficiency found during the inspection of the market surveillance activities.

(e) In the territory of the **Mining** District **Authority of Veszprém**, the following are to be pointed out:

- The <u>construction surveillance inspection</u> of facilities subject to a licence, the use of which may be commenced on the basis of notification, includes the <u>examination of built-in materials</u> and parts and, if necessary, <u>their certificates</u>. They include ones classified in the specified product sectors and coming under the effect of harmonised legislation (e.g. the ATEX, PED, MPED and Machinery EC Directives). In this area, no market surveillance procedure was instituted in the area of jurisdiction of the Mining District Authority of Veszprém.

- <u>Individual protective equipment</u> was examined during industrial safety inspections. The Mining District Authority of Veszprém instituted a market surveillance procedure regarding protective devices for self-rescue considered to be non-conforming. Previously (2008), the Mining District Authority restricted then prohibited the distribution and use of the POG-8M protective device for self-rescue

used in underground mining. In 2011 and 2012, the Mining District Authority examined the use and conformity of the MSI 94 protective device for self-rescue procured to replace it. Since the condition of the opened devices did not meet the requirements due to the significant dust emissions, it prohibited their use and instituted a procedure for the examination of conformity (and the conditions of use).

- During the market surveillance procedure, it established that the device manufactured by S.C. Romkarbon S.A. and distributed by Metal-Carbon Kereskedelmi Kft. (Metal-Carbon Trading LLC) met the conditions of normal use, <u>but is not for heavy duty use</u>. Since Metal-Carbon Kereskedelmi Kft. <u>discontinued distribution</u> after the first complaints, <u>the Mining</u> District <u>Authority closed its procedure</u>.

- The Regional Supervisory Authority also checked the distribution of <u>liquefied LPG gases</u> in tanks or cylinders in ad hoc and targeted inspections at the cylinder exchange sites, during the investigation of complaints as well as on the basis of inquiries by the National Tax and Customs Authority (the 'NAV') and the County Disaster Management Directorates.

- On the basis of the inspections, it established in 2011 that the LPG gas distributed by Prvá Slovenská Propánbutánová Spolocnost a.s. (1.SPS) as part of cross-border services did not meet the technical and safety regulations (it was placed on the market in overfilled cylinders in a considerable proportion), therefore, it <u>instituted a</u> market surveillance <u>procedure</u>. It obliged the distributor, 1.SPS, to make the cylinders risk free. In the opinion of the Mining District Authority, the severity of the infringement did not reach the level on the basis of which it would have been justified to use the alarm mechanism, but in the interest of the safe distribution of gas, <u>it contacted the Slovakian authority</u> to conduct intensive inspections and to take the necessary measures.

- On the basis of an inquiry of the NAV, in 2012 the Mining District Authority inspected the <u>cylinders</u> reclassified by ÁEF Materials Testing Laboratory for filling pure propane gas as commissioned by NOVAGÁZ Kereskedelmi és Szolgáltató Kft. (NOVAGÁZ Trading and Service LLC). On the basis of the inspection, it established that the rating test did not comply with the legislation, the date indicated for the next test was incorrect, and the age of a few cylinders exceeded the permitted one. The Mining District Authority <u>ordered the correction of the marking and the withdrawal of the overaged cylinders from distribution.</u>

- During an inspection conducted in 2013, the Mining District Authority established that the pressure of propane gas UN 1978 distributed in aluminium <u>household LPG cylinders</u> made in Hungary by LAMPOGAS sk. s.r.o. <u>as part of cross-border services</u> might exceed the test pressure of the cylinder, therefore, it <u>prohibited distribution and ordered</u> that the cylinders in distribution should be made risk free. The distributor declared during the procedure that it had terminated filling propane gas into aluminium cylinders.

- The inspections of the Mining District Authority relating to the manufacture and use of <u>explosives for civil uses</u> did not warrant any market surveillance procedure. The inspections stated above include all inspections conducted in the sector, and were aimed at the verification of the origin and markings of products within market surveillance competence as part of general inspection, and <u>no</u> separate document was produced about them.

6. Hungarian Trade Licensing Office (the 'MKEH')

A. Review of general market surveillance activities

Information on the general market surveillance organisation and infrastructures in place for the 2010–2013 period

(a) Market surveillance organisation

The market surveillance of certain equipment intended for targeted economic use and measuring devices subject to mandatory calibration was carried out by

- the Trade and Market Surveillance Authority of the MKEH as of 1 January 2007;
- the Trade, Market Surveillance and Noble Metals Testing and Authentication Authority of the MKEH as of May 2010;
- the Trade and Market Surveillance Authority of the MKEH, Budapest as of 1 January 2011 on the basis of the authorisation granted in Government Decree No 320 of 27 December 2010; and
- as of 2 February 2013, has been carried out by the Market Surveillance and Technical Supervisory Authority within the MKEH, still on the basis of the authorisation granted in Government Decree No [3]20 of 27 December 2010.

(b) Jurisdiction, responsibilities and competence

In respect of the following product sectors, the MKEH authority in charge of market surveillance acts at first instance in market surveillance procedures with nationwide jurisdiction, and the central body of the MKEH acts at second instance.

The market surveillance activities of the MKEH are regulated by Act LXXXVIII of 2012 on the market surveillance of products, Government Decree No 321 of 27 December 2010, Government Decree No 6 of 18 January 2013 on the detailed rules governing market surveillance activities and Regulation (EC) No 765/2008 of the European Parliament and of the Council.

The MKEH carries out the market surveillance of certain equipment intended for targeted economic use in respect of 13 directives (product sectors). In the case of measuring instruments (MID) and non-automatic weighing instruments (NAWID), the competence of the MKEH also extends to products intended for targeted non-economic use.

The responsibilities and competence of the MKEH are limited to Application Group II in respect of ATEX and to Product Groups 9 and 10 in Annex 7 in the case of RoHS.

The responsibilities and competence of the MKEH were extended as of 22 October 2011 in respect of the inspection of marking with labels and standard product brochures, and as of 3 January 2013 under the RoHS Directive, and are also continuously expanded with the product-specific EU regulations associated with the Ecodesign Directive.

(c) Coordination

The market surveillance activities of the MKEH are coordinated by the Head of the Market Surveillance Department under the direction of the Head of the Market Surveillance and Technical Supervisory Authority. During the compilation of the annual inspection plan, it takes into account the experience from previous inspections, the information received from other market surveillance authorities and partner agencies, user complaints and filings, new products that have appeared on the market and changes in legislation.

The MKEH cooperates with the National Tax and Customs Administration (the 'NAV') in order to filter out non-conforming products from third countries, thus, in addition to its obligation prescribed by legislation, the MKEH entered into a separate cooperation agreement with the NAV. In the area of information exchange, the MKEH also cooperates with the measurement and technical safety authorities of government offices and the Hungarian Authority for Consumer Protection. Joint inspections were also carried out.

In order to perform the market surveillance activities more efficiently, the MKEH took part in several joint market surveillance actions. Between 2010 and 2012, they collaborated with 11 Member States in the joint market surveillance action Sunbeds 2. Under the project, they carried out coordinated market surveillance activities by applying best practices in the most efficient way. The MKEH also took part in a joint ATEX inspection action.

As member of a consortium, the MKEH is currently participating in the ECOPLIANT ecodesign inspection project together with nine other Member States. As a result of the joint action, the participating Member States are devising a framework for coordinated European market surveillance inspections under the Ecodesign Directive. The work performed under the project is coordinated by the British partner authority. The consortium also cooperates with the representatives of industry, consumer organisations and other Member States.

(d) Available resources, infrastructure

The number of staff in charge of market surveillance action tasks and the available budget were as follows in the reporting period:

Year:	2010	2011	2012	2013
Number of inspectors (persons/year):	4,13	5,82	10,65	7,51
Available budget (EUR):	128 993	325 098	310 963	296 116

The market surveillance inspections are carried out by specialists holding higher education qualifications in engineering.

In order to carry out the increased tasks, the headcount and the budget were increased in 2011 and subsequently primarily in the area of inspections under the Ecodesign and Machinery Directives.

As a result of application for resources started in 2011, measuring devices were procured to the value of HUF 24 million (EUR 77000), because the laboratory required for the verification of compliance with the Low-voltage Directive and the ecodesign requirements was not available previously. The laboratory implemented as a result of the project became suitable for measuring and testing the efficiency of circulating pumps and a number of technical parameters of electrical equipment.

The MKEH also has a measuring device suitable for testing the ultraviolet radiation of sunbeds and is prepared for their calibration.

(e) Information exchange, communication

The MKEH published market surveillance newsletters and studies on its official website in order to provide information to economic operators and users, and drew attention to dangerous products in public notices. The authority publishes its annual market surveillance inspection programme and information on its market surveillance activities on its website.

The staff of the Market Surveillance Department gave presentations on a number of occasions at conferences organised for professional organisations and small and medium-sized enterprises, and published publications in specialist journals. Its representatives gave radio and TV interviews on issues

affecting a wide range of users on several occasions. We provided information on the market surveillance activities to delegations of non-Member States on several occasions.

		2010	2011	2012	2013
1.1.	Budget available to market surveillance authorities in nominal terms (EUR)	128993	325 098	310963	296116
1.2.	Budget available to market surveillance authorities in relative terms (percentage of total national budget)	0,000259%	0,000658%	0,000560%	0,000519%
2.	Staff available to market surveillance authorities (full-time equivalent units)	5.12	6.81	11.52	8.46
3.	Number of inspectors available to market surveillance authorities (full-time equivalent units)	4.13	5.82	10.65	7.51

Information on total resources available for market surveillance activities

B. Assessment of the functioning of market surveillance activities

(a) Introduction

During the reporting period, the Market Surveillance Department of the Hungarian Trade Licensing Office carried out the market surveillance of certain equipment intended for targeted economic use and measuring devices subject to mandatory calibration at first instance with nationwide jurisdiction in respect of a total of 15 directives (product sectors).

The responsibilities and competence of the MKEH with respect to measuring devices and nonautomatic weighing instruments also extend to products intended for targeted non-economic use, while they are limited only to a specific part of products in respect of the ATEX and RoHS Directives. The market surveillance competence of the MKEH was extended as of 2 February 2013 in respect of the inspection of marking with labels and standard product brochures, while as of 3 January 2013 under the RoHS Directive, and are also continuously expanded with the product-specific EU regulations associated with the Ecodesign Directive.

The Market Surveillance Department operated within the various regulatory frameworks of the MKEH between 2010 and 2013. As of 2 February 2013, the market surveillance tasks have been performed by the Market Surveillance and Technical Supervisory Authority on the basis of the authorisation laid down in Government Decree No 320 of 27 December 2010.

(b) Market surveillance procedure, evaluation of the experience of inspections by sector

The MKEH performs its market surveillance activities pursuant to the directly applicable European Union legislation and the national regulations. The market surveillance procedure of the Market Surveillance and Technical Supervisory Authority is regulated within the framework of the ISO 9001 quality assurance system. The purpose of the procedure is to operate customer-friendly regulatory market surveillance activities, which meet the EU or Hungarian public administration requirements.

The vast majority of the completed market surveillance inspections are carried out by the review of compliance with the statutory requirements, the physical testing of the products/equipment and the inspection of the manufacturing and certification documentation.

In addition, the MKEH also carried out a significant number of laboratory or on-site measurement tests, for conformity to certain regulations can be determined primarily by measurements, such as the

ultraviolet radiation of sunbeds, calculation data on the energy efficiency index of circulating pumps and safety distances specified for machinery.

In cases where the MKEH did not have the necessary measuring device or the relevant legislation prescribed the involvement of a notified body, it commissioned an external laboratory to perform the tests, such as during the testing of pressure equipment on several occasions.

The market surveillance activities of the MKEH were characterized by continuous development in the period reviewed both in respect of the material and human resources used and the number of sectors subjected to inspection and non-conformities found.

Inspections PED, SPV Lifts — _ — — GAD LVD Efficiency of boilers TPED Noise MID, NAWID RoHS _ _ MD ATEX EMC ECO + Label Total inspections

The following table contains the number of inspections completed by sector.

Comparing the number of inspections carried out by the Market Surveillance Department to the number of inspection personnel available, a significant development took place in the specific indices as well. According to the following statement, the number of inspections performed per staff member almost tripled in 2013 compared to 2010, while the number of infringements detected also increased.

	2010	2011	2012	2013
number of inspections	161	288	936	666
number of inspectors				
_persons/year	4.13	5.82	10.65	7.51
inspections/inspector	39	49.5	87.9	88.7

The annual budget resources used in connection with the market surveillance activities of the authority more than doubled in respect of the period reviewed:

	2010	2011	2012	2013
annual budget, EUR	128993	325 098	310963	296116

In 2011, market surveillance work relating to ecodesign emerged as a new task. Preparing for the task, the MKEH obtained the necessary laboratory test equipment.

Calculating the average cost per inspection from the budget reduced by the amount of investment, it can be established that the average cost of inspections decreased almost to half of the specific cost in 2010 and 2011 as a result of the increased number of inspections as follows:

	2010	2011	2012	2013
number of inspections	161	288	936	666
annual budget, EUR	128993	248098	310963	296116
cost per inspection, EUR	801	862	332	445

With regard to all market surveillance activities, annual trends in the non-conformities detected:

	2010	2011	2012	2013	total
number of inspections	161	288	936	666	2051
non-conforming product					
types	105	148	309	252	814
non-conformity, %	65.2	51.4	33	37.8	39.7

In the majority of the non-conformities detected, economic operators complied with the request made for bringing the products into compliance. In 4.8% of the inspections, restrictive measures had to be ordered in the case of 98 product types; in these cases, the MKEH prohibited the distribution of the products, ordered their withdrawal from distribution, and in the case of one product, also ordered its recall. In the case of dangerous swimming pool hair dryers, the market surveillance authority of the MKEH prohibited the continued use of the products on the spot during its market surveillance inspection.

In the period reviewed, investigations were launched in 1.2% of all inspections, on the basis of about 25 consumer complaints or accidents. Half of the complaints were received in connection with the radiation intensity of sunbeds, in addition, reports were received about pressure equipment, machinery and appliances burning gaseous fuels.

The MKEH had to proceed in 12 cases, 0.6% of the cases, on the basis of complaints about unfair market competition. The complaints were received from sunbed operators, and it also had to proceed once in connection with industrial gas cylinders and a product intended for use in explosive atmospheres.

The MKEH has been designated for the market surveillance verification of conformity with Directive No 95/16/EC on lifts since 5 June 2014. Therefore, in the absence of designation, the MKEH did not conduct any lift inspections during the reference period of this Report. A separate report has been prepared on the market surveillance activities of ÉMI Nonprofit Kft. performed in the reporting period.

During its market surveillance activities, the MKEH liaised with the market surveillance and other partner authorities that have information for the performance of its work. It cooperated with the National Tax and Customs Authority (the 'NAV') in order to exclude non-conforming products coming from third countries from free circulation. In the area of information exchange, it cooperated with the measurement and technical safety authorities of government offices as well as with the Hungarian Authority for Consumer Protection. Joint inspections were also held with certain partner authorities, and the cooperation of a foreign partner authority was requested in the case of one product type.

As part of coordinated cooperation, we participated in several joint actions launched by the European Union and involving several countries. The MKEH achieved a significant result in bringing the ultraviolet radiation of sunbeds into compliance as part of the joint 'Sunbeds 2' action. At the beginning of the action, practically all sunbeds subjected to inspection emitted higher radiation than allowed in violation of legislation; however, when the action was closed, the national conformity rate exceeded 50%.

The MKEH also took part in a joint targeted market surveillance inspection with 11 Member States in 2010. The purpose of the action was to inspect 10 electrical and non-electrical products, if possible, made in Hungary and coming under the ATEX Directive.

As a member of a consortium, the MKEH has been participating in the joint European ECOPLIANT ecodesign inspection project together with nine other Member States as of 2012. The participating Member States conduct coordinated inspections and devise a framework for the coordinated European market surveillance inspections coordinated by the Ecodesign Directive. The work performed under the project is coordinated by the British partner authority.

The MKEH informs economic operators and users through its official website as well as maintains personal contact and communicates with manufacturers and operating organisations, participates in their events, gives presentations and issues press releases.

(c) Summary

The Market Surveillance Department of the MKEH underwent significant development between 2010 and 2013: the material and human resources available to it gradually increased, and the number of inspections and infringements detected increased in a proportion exceeding it several times. On the basis of experience, the market surveillance activities can be made even more efficient through communication with economic operators and users, which appears in the activities as a planned priority for the future.

7. Hungarian Authority for Consumer Protection (the 'NFH')

A. Review of general market surveillance activities

Information on the general market surveillance organisation and infrastructures in place for the 2010–2013 period

The most important goal of market surveillance is to ensure that products intended for distribution and those already in distribution meet the health, safety, consumer protection and other public interest requirements. In Hungary, primarily the Authority for Consumer Protection (the 'NFH') and its regional bodies are responsible for performing the tasks of the consumer protection authority. This includes the protection of the life, health and safety of consumers through the performance of market surveillance activities.

The NFH and the consumer protection inspectorates operating within the metropolitan and county government offices (19 in the counties and one in the capital) continuously inspect and examine the safety and conformity of the products falling within their responsibilities and competence. Professional direction and coordination of the work of the inspectorates are performed by the NFH. Competent at the county level as authorities of first instance, the regional inspectorates conduct inspections and sampling. The NFH is entitled to review the decisions of the inspectorates at second instance on the basis of an appeal or review procedure.

The market surveillance activities of the authority include the following product groups:

- electrical products,
- machinery,
- personal protective equipment,
- clothing products,
- footwear,
- playground equipment,
- showman's equipment,
- cigarette lighters,
- children's toys,
- furniture, detergents and cleaning agents,
- construction products,
- paints and lacquers,
- cosmetics,
- and all other products intended for distribution to consumers.

If the authority establishes a violation of the relevant legislative provisions, it may:

- prescribe that the economic operator cease the infringement;
- prohibit the continuation of the unlawful practices;
- oblige the economic operator to eliminate the deficiencies;
- prohibit the distribution of the product or make it subject to conditions;
- order the withdrawal of a product that poses a hazard to the life, health and safety of consumers from
- commercial distribution and, where necessary, its destruction; and

– impose a fine.

The rapid information system of the EU (RAPEX) and the central Market Surveillance Information System (the 'KPIR') operated by the NFH provide an appropriate baseline for the planning of inspections relating to the safety of goods. These two systems serve information sharing among the authorities. In addition, the authority has also begun to use the ICSMS system as of 1 January 2014, and tries to exploit the advantages inherent in the system. In Hungary, the NFH performs the tasks of the national RAPEX Contact Point and operates the KPIR system.

In addition, the authority closely cooperates with the various partner authorities, the customs authority and non-governmental organisations. The authority regularly checks the conformity and safety of imported products on the basis of alarms given by the customs authority. In the past period, a number of customs alarms have been received from the customs authority, as a result of which the distribution of a number of products was prohibited.

In addition, the authority has also tried to widen its international relations in the past period, thus it also cooperates with a number of non-EU countries (e.g. China, Serbia, Bosnia and Herzegovina, Kosovo, Turkey and Egypt).

		2010	2011	2012	2013
1.1.	Budget available to market surveillance	1 330 062	2131214	1975866	1855328
	authorities in nominal terms (EUR)				
1.2.	Budget available to market surveillance	0.00267	0.00431	0.00355	0.00325
	authorities in relative terms (percentage				
	of total national budget)				
2.	Staff available to market surveillance	131	143	120	137
	authorities (full-time equivalent units)				
3.	Number of inspectors available to	85	93	79	89
	market surveillance authorities (full-time				
	equivalent units)				

Information on total resources available for market surveillance activities

B. Assessment of the functioning of market surveillance activities

Between 2010 and 2013, during the inspections and targeted sampling, the authority subjected a number of product groups to inspection on the basis of its annual inspection programme and consumer filings. The purpose of the inspections of the authority was to ensure that products that did not meet the statutory requirements and, in a given case, posed a hazard to the life, health and safety of consumers are filtered out.

In the past period, the authority has treated the following product groups, among others, as priority:

- tracing products prohibited in the RAPEX or KPIR system;
- filtering out unsafe products intended for children and those under the age of three;
- finding electrical products posing an electric shock hazard and withdrawing them from distribution;
- making the operation of playground equipment and showman's equipment lawful;

- product groups coming under the General Product Safety Directive but not yet inspected;
- filtering out non-conforming cosmetic and chemical products;
- verification of the conformity of construction products in various product categories.

In addition to the above, the authority continuously inspected the safety and conformity of, among other things, machinery, individual protective equipment, clothing products, footwear, furniture, detergents and cleaning agents, construction products, paints and lacquers, and a wide range of consumer goods as part of thematic reviews between 2010 and 2013.

The number of non-conforming and dangerous products found indicates that the staff of the authority performed their activities aimed at finding products that do not meet the safety requirements very efficiently. With regard to the number of dangerous products representing a serious risk found and reported to the RAPEX, Hungary always had a distinguished place among Member States in the past years. This also means that the consumer protection authority efficiently and successfully filters out unsafe products from the market in Hungary.

Between 2010 and 2013, the NFH established a number of good working relationships with the various partner authorities and the customs authority. In addition, the NFH was also very active in international cooperation, and established close relations with, among other things, the following countries and authorities:

- Market Surveillance Agency of Bosnia and Herzegovina;
- Trade Surveillance Authority of the Czech Republic;
- State Inspectorate of Croatia;
- State Industrial and Trade Directorate of the People's Republic of China;
- Competition and Consumer Protection Authority of the Republic of Poland;
- Ministry of Trade and Services of Serbia;
- Market Surveillance Authority of Slovenia;
- State Consumer Protection Surveillance Authority of Ukraine.

On the whole, it can be stated that the consumer protection authority considers its market surveillance activities its high priority task, and aims at acting efficiently and successfully also in the future in order to avoid dangerous and non-conforming products being placed on the market in Hungary and thereby in the Union.

8. National Transport Authority (the 'NKH')

A. Review of general market surveillance activities

Information on the general market surveillance organisation and infrastructures in place for the 2010–2013 period

I. Market surveillance organisation:

In the case of **the market surveillance of products,** no independent organisation or organisational unit has been set up at the NKH until the current provision of data. According to the report, other activities of the NKH not related to the enforcement of product legislation should be excluded from this Report in the future. In the case of products, rules implying the jurisdiction of the market surveillance authority are only regulated in the designating legislation. However, in the absence of related task and competence rules and detailed implementation legislation, the NKH did not perform any general product market surveillance activity within the transport sector in the case of the transport authorities in the period concerned.

In accordance with Act LXXXVIII of 2012 on the market surveillance of products, Government Decree No 6 of 18 January 2013 on the detailed rules of market surveillance activities designates the National Transport Authority and the transport inspectorates of government offices as market surveillance authorities in respect of product surveillance relating to road vehicles. Pursuant to Section 2(3) of [Government Decree] No 263 of 20 December 2006 on the National Transport Authority, '[t]he authority performs its responsibilities through its unincorporated central body and bodies of first instance with nationwide jurisdiction and special competence (the "body of first instance of the authority")'. With regard to this, the authority involved the offices concerned and the bodies of first instance in order to provide the data for this Report, and establish the following.

Prior to designation, neither the NKH nor its bodies of first instance had regulated responsibilities and competence for product surveillance. Pursuant to the EU regulations in force, the **product surveillance activities apply to road vehicles,** and products surveillance extends to road vehicles, two- or three-wheel vehicles and quadricycles, agricultural and forestry vehicles, and their accessories and parts.

In connection with the general market surveillance organisation, it is necessary to indicate that the following tasks were defined in Government Decree No 263 of 20 December 2006 on the National Transport Authority:

Section 4(3) The Road Vehicle Transport Office shall proceed at first instance as transport authority: 6. Exercise of competences relating to the approval of road vehicle parts, vehicle accessories and vehicle properties, the rating tests of certain spare parts and accessories, and approval markings,

(5) the county (metropolitan) transport authority with jurisdiction over the area shall proceed at first instance as transport authority:

21. performance of the tasks not regulated in paragraphs (2) to (4), falling within the competence of the transport authority,'

The previous piece of legislation, Government Decree No 79 of 29 April 1998 on the safety of goods and services and related market surveillance procedures also contained market surveillance tasks associated with the transport authority, which the counties carried out by inspecting parts.

The Community Rapid Information Exchange System (the 'RAPEX') operated and still operates at present pursuant to the Government Decree, a part of which is the NKH, too. The Decree lays down the market surveillance of customs goods (where the NHK is also named):

'Section 11/B(1) In the case of the deficiencies set forth in Article 2 of Council Regulation (EEC) 339/93 on checks for conformity with the rules on product safety in the case of products imported from third countries, the National Command Headquarters of the Customs and Excise Office (the "customs authority") notifies the Hungarian Authority for Consumer Protection responsible for market surveillance forthwith and, via the KPIR, the competent consumer protection inspectorate or, in the case of road vehicles, the Central Office of the National Transport Authority.'

On the basis of this provision, in May 2012, the NKH issued, as expert authority, a position statement on products imported from third countries. The RAPEX tasks have been performed by the Road Vehicle Transport Office of the NKH since 2006, which includes 150 to 250 inquiries per year and the related documents generated.

This inspection tasks specified in the Act and Government Decree on market surveillance, currently in force, are performed by the transport authorities, because product inspections are typical inspection activities belonging to market surveillance (see Section 15(2) of the Act). The inspections were reported every year under the heading of inspection of parts. The campaigns introduced in recent years (baby seats, tyres) are also about market surveillance. In the case of some of the inspectorates, there is a 'repair inspector status', or where there is not, the inspection of parts is also included among the inspector's tasks.

The sphere of tasks applicable to the NKH, indicated above, was included in the text, in force between 16 April 2011 and 14 August 2012, of Instruction No 22 of 15 April 2011 of the Ministry for National Development on the Organisational and Operational Rules of the National Transport Authority as follows:

2.7 Road Vehicle Transport Office

2.7.1 Vehicle Methodology Division

- 2.7.2.1 Vehicle Roadworthiness Tests Division
- 14. It performs the regulatory market surveillance tasks in the area of road vehicles.

In 2013, in respect of **coordination and information exchange**, the NKH appointed a contact person at the request of the national market surveillance authority in order to join the ICSMS system. The responsibilities and competences have not been allocated in the Statutes and within the Organisational and Operational Rules of the NKH until the current supply of data.

Information on total resources available for market surveillance activities

Due to the regulatory deficiency described above, there are no targeted resources available; therefore, the figures show the value of zero for the period after 18 January 2013, except for the product groups of vehicles and their accessories and parts. Considering the fact that according to the guideline, other activities undertaken by the authorities, which do not relate to the implementation of product legislation, should be excluded from the calculations, the display of data relating to the market surveillance of services is not relevant here. The implementation legislation, the Government decree on market surveillance procedures and market surveillance fines, has not been published until the present provision of data, therefore, the funds required for performance of the activities are not provided.

	National Transport Authority	2010	2011	2012	2013
1.1.	Budget available to market surveillance	0	0	0	0
	authorities in nominal terms (EUR)				
1.2.	Budget available to market surveillance	0	0	0	0
	authorities in relative terms (percentage				
	of total national budget)				
2.	Staff available to market surveillance	0	0	0	0
	authorities (full-time equivalent units)				
3.	Number of inspectors available to	0	0	0	0
	market surveillance authorities (full-time				
	equivalent units)				

B. Assessment of the functioning of market surveillance activities

The evaluation of the operation of the market surveillance activities cannot be carried out in detail in the absence of budget data on the activities. The budget figure has to include all financial resources that are assigned by the authorities to market surveillance and enforcement activities (including related infrastructures) as well as to projects and measures aimed at ensuring compliance of economic operators with **product legislation**.

9. <u>Directorate for Industrial Safety and Labour of the National Labour Office</u> (the 'NMH MMI')

A. Review of general market surveillance activities

Information on the general market surveillance organisation and infrastructures in place for the 2010–2013 period

The regulatory market surveillance tasks in respect of individual protective equipment and work equipment (machinery) were performed by the National Inspectorate General for Industrial Safety and Labour (the 'OMMF') and its regional inspectorates until 31 December 2010, then by the legal successor of the OMMF, the Directorate for Industrial Safety and Labour of the National Labour Office (the 'NMH MMI') and the industrial safety and labour administration bodies of the metropolitan/county government offices.

In the period reviewed, pursuant to the provisions of Act XCIII of 1993 on industrial safety ('Act XCIII of 1993'), Government Decree No 295 of 23 December 2006 on the National Inspectorate General for Industrial Safety and Labour and, later, of Government Decree No 323 of 28 December 2011 on the National Employment Office and the responsibilities and competence of the administration bodies coming under its profession direction, the industrial safety authority examined compliance with the rules relating to the safety and conformity of individual protective equipment and machinery within its own competence, as part of the official inspection of the performance of organised work.

If the machinery and individual protective equipment used during the performance of organised work are non-conforming, the findings reached by the industrial safety authority could be construed only in respect of the equipment used at the workplace and in relation to the employer, and the authority checked only the existence of the certificates of conformity. Pursuant to Act XCIII of 1993, the sanction that may be applied by the industrial safety authority could be the suspension of the operation or use of the device used at the workplace, which is, however, not a sanction under Act LXXXVIII of 2012 on the market surveillance of products ('Act LXXXVIII of 2012').

In the period reviewed, the industrial safety authority informed the Hungarian Authority for Consumer Protection about the products that did not meet the safety requirements, however, did not order any other market surveillance measure (e.g. withdrawal or recall from distribution). The industrial safety inspectorates could initiate alarms via the OMMF or the NMH MMI with regard to restrictive or prohibitive measures taken in the case of products not meeting the safety requirements, which were found during workplace inspections performed by industrial safety inspectors.

Information on total resources available for market surveillance activities

		2010	2011	2012	2013
1.1	Budget available to market surveillance				
	authorities in nominal terms (EUR)				
1.2	Budget available to market surveillance				
	authorities in relative terms				
	(percentage of total national budget)				
2.	Staff available to market surveillance	239 persons	196	164 persons	166 000000
	authorities (full-time equivalent units)	2.59 persons	100 persons	104 persons	roo persons

3.	Number of inspectors available to				
	market surveillance authorities (full-	149 persons	124 persons	100 persons	105 persons
	time equivalent units)				

Notes for interpreting the figures in the table:

To points 1.1 and 1.2: Among the tasks of the industrial safety authority, the performance of market surveillance tasks is a partial activity, therefore, it does not have a budget established specifically for this activity.

To points 2 and 3: The figures represent average headcount, which is based on time actually spent at work (leave, sick leave, in-service trainings and other authorised absences were deducted).

B. Assessment of the functioning of market surveillance activities

Industrial safety inspectorates were not suitable for performing general (i.e. performed not only during inspections conducted in workplaces) regulatory market surveillance tasks in the period reviewed, and the industrial safety authority was not prepared either for this shortage of human resources due to the lengthy trainings required and the lack of budgetary funds (tests by measurements).

In the period between 2010 and 2013, the market surveillance activities of the authority were confined to KPIR alarms initiated by the industrial safety inspectorates via the OMMF and the NMH-MMI. In addition, the information provided by the authorities of the Member States to the RAPEX system were forwarded to the industrial safety inspectorates.

In 2010, we initiated an alarm in the case of a piece of individual protective equipment on one occasion. The ear muffs did not have the conformity markings and information brochure specified in Decree No 18 of 3 December 2008 of the Minister of Welfare and Labour. The protective equipment did not have a CE marking, an EC declaration of conformity or a CE type certificate, its protective ability could not be identified, and no user manual was provided with it either.

In the same year, a KPIR alarm relating to work equipment was given also on one occasion, in the case of a two-chamber compacting press. The non-conformity of the warning notices on the machine and the incompleteness of the user manual could be related to a serious work accident involving amputation.

In 2012, we provided data to the KPIR system as a result of a serious work accident involving amputation, which took place on a plastic bundle cutting machine. The alarm was warranted by the non-conforming design of the protective housing of the machine.

In 2013, we arranged for a KPIR alarm after the suspension of the use of a firewood splitting machine. Reaching into the dangerous inner space of the machine was not prevented by a technical solution, resulting in the risk of hand amputation.

10. National Media and Infocommunications Authority (the 'NMHH')

A. Review of general market surveillance activities

Information on the general market surveillance organisation and infrastructures in place for the 2010–2013 period

In the Hungarian system of the market surveillance of products, the National Media and Infocommunications Authority (the 'NMHH') is responsible for enforcing legislation representing the national implementation of regulations associated with two harmonised areas, Directive 1999/5/EC on electronic terminal communications equipment and radio equipment (the 'RTTE Directive') and Directive 2004/108/EC on electromagnetic compatibility (EMC) (the 'EMC Directive'), within its competence. These are Act C of 2003 on electronic communication ('Act C of 2003'), Decree No 5 of 13 April 2004 of the Minister for Information Technology and Communications on radio equipment and electronic terminal communications equipment and the mutual recognition of the conformity thereof ('Decree No 5 of 2004'), and Decree No 62 of 30 August 2006 of the Ministry of the Economy and Transport on electromagnetic compatibility ('Decree No 62 of 2006'). In respect of the RTTE, the authority performs the market surveillance tasks as an independent responsible agency, while in the case of the EMC, its competence extends only to electronic terminal communications equipment, radio equipment and high frequency electrical or electronic terminal communications equipment in the period reported on, until February 2013, the Hungarian Trade Licensing Office (the 'MKEH') also participated in the performance of market surveillance tasks relating to the EMC.

		2010	2011	2012	2013
1.1.	Budget available to market surveillance				
	authorities in nominal terms (EUR)				
1.2.	Budget available to market surveillance				
	authorities in relative terms (percentage				
	of total national budget)				
2.	Staff available to market surveillance	493.75	514.25	560.85	569.4
	authorities (full-time equivalent units)				
3.	Number of inspectors available to	10	10	10	10
	market surveillance authorities (full-time				
	equivalent units)				

Information on total resources available for market surveillance activities

B. Assessment of the functioning of market surveillance activities

In the period reported on, the equipment surveillance activities performed by the NMHH were characterised by continuous change, following trends in the market of terminal communications equipment, radio equipment, and equipment generating high frequency signals and side effects. The digitalisation of electronic communications networks, the progressing convergence of terminal communications equipment and IT devices resulted in a decrease in the importance of dedicated terminal telecommunications equipment, including analogue devices (telephones, faxes, numeral displays, etc.) and the disappearance of certain equipment categories from the market. At the same time, the number and diversity of devices communicating through radio transmission has increased to an extent that could not be forecast previously, and this process is still ongoing today. With regard to the limited nature of the radio spectra and the inherent sensitivity of radio applications to interference, compliance and ensuring compliance with the fundamental requirements for radio equipment are given increasing importance.

However, it is similarly important also to closely monitor the enforcement of the provisions originally applicable to electromagnetic compatibility, because equipment not designed for radio communication at all and generating radio frequency signals only during its operation often causes interference, which is difficult to discover and eliminate subsequently during normal use. With the development of technology, other important trends in the period reported on were a change in the group of market players and the transformation of the relations between them. A large part of the devices available on the internal market come from third countries (typically from China) today, thus it has become much more difficult for the market surveillance authorities to ensure compliance with the obligations applicable to manufacturers.

Sales schemes have also undergone significant changes: In addition to the previous conventional sales in shops, an outstanding role is given to Internet trade, even surpassing sales in shops in certain cases, where in many cases all of the participants in the distribution chain are established in a country outside the Community. This represents a particularly serious challenge, because the Directives falling within the responsibilities and competence of the NMHH essentially contain provisions for placement on the market, distribution and, in certain cases, commencement of use, while the activities of end users do not belong to the competence of the market surveillance authority. The multitude and diversity of equipment available on the market as well as its often very short life cycle require appropriate decisions to be made also in the management of resources. In response to these main processes, the NMHH, firstly, continuously developed its technical and measurement competencies required for market surveillance inspections and, secondly, enhanced its participation also in the area of cooperation existing with foreign partner authorities with similar responsibilities. Thus, it became possible to learn European best practices and, if warranted, they can be integrated into the work of the Hungarian authority. During the planning of inspections, the principle of risk-based market surveillance increasingly prevailed, thus the majority of the resources could be spent on the inspection of risky equipment types, which had been proven to be problematic previously or newly appeared on the market. At the same time, the figures stated in the Report also show that these principles need to be followed consistently also in the future in order to achieve the goals of public interest of market surveillance at the highest level possible.

11. <u>National Directorate-General for Disaster Management of the Ministry of</u> <u>Interior (the 'BM OKF')</u>

A. Review of general market surveillance activities

Information on the general market surveillance organisation and infrastructures in place for the 2010–2013 period

The National Directorate-General for Disaster Management of the Ministry of Interior (the 'BM OKF') has been participating in the market surveillance system of Hungary by inspecting construction products, firefighting technical equipment and flammable or explosive apparatuses, machinery and equipment since 2004. Until 1 January 2013, one of the divisions of the BM OKF conducted market surveillance inspections and procedures with national competence. As of 1 January 2013, 65 local disaster management offices were given competence to conduct on-site market surveillance inspections; however, conducting market surveillance procedures and making decisions and imposing sanctions in relation to products continued to remain in the competence of the BM OKF.

The BM OKF cooperates with other market surveillance authorities in specific cases, depending on the case. It participates in the general information exchange between authorities via the Central Market Surveillance Information System (the 'KPIR') and the Market Surveillance Information and Communication System (the 'ICSMS'). Possible RAPEX notices are sent and received via the Hungarian Authority for Consumer Protection. The BM OKF provided data for the sectoral market surveillance programme every year.

		2010	2011	2012	2013
1.1.	Budget available to market surveillance authorities in nominal terms (EUR)	63 506*	61714*	64357*	50811*
1.2.	Budget available to market surveillance authorities in relative terms (percentage of total national budget)	0.00013%	0.00013%	0.00012%	0.00009%
2.	Staff available to market surveillance authorities (full-time equivalent units)	6	6	6	5
3.	Number of inspectors available to market surveillance authorities (full-time equivalent units)	6**	6**	6**	5**

Information on total resources available for market surveillance activities

* Estimated value. In connection with the market surveillance activities of the BM OKF, the costs incurred may be separated in part in relation to the remuneration of the personnel, considering the fact that the staff assigned to market surveillance tasks are also engaged in other activities associated with disaster management and fire protection. Other material costs (office supplies, fuel, etc.) are accounted for in connection with the other activities of the BM OKF.

** The number of personnel available to the market surveillance authority (2nd row) also includes the number of available inspectors (3rd row).

In 2013, the local disaster management offices also carried out on-site market surveillance inspections, but this did not entail an increase in headcount. The task was carried out by the existing staff of the local offices.

B. Assessment of the functioning of market surveillance activities

The BM OKF exercises market surveillance competence regarding construction products, firefighting technical products (e.g. portable fire extinguishers, fire blankets, fire engines and firefighting protective clothing), as well as flammable or explosive apparatuses, machinery and equipment. Only the designated administrators of the BM OKF performed market surveillance activities between 2004 and 2013. The number of inspections was lower at that time, but the market surveillance inspections and procedures revealed more irregularities, especially in the case of firefighting technical products. In 2013, the local disaster management bodies (65) were also given competence to conduct on-site market surveillance inspections, without decision-making competence, which facilitated the increase of the number of inspections and the increased presence of the authority.

The administrators of the BM OKF essentially perform the coordination and evaluation of inspections. After evaluation, in the case of an irregularity, they decide on launching a market surveillance procedure or, in the case of insufficient information, request the submission of additional data, information and documents as part of a repeated market surveillance inspection, or close the case in the absence of a breach of law.

Products falling within its competence are seldom tested, because no separate cover is available for it in the budget. Products are usually tested if the expected result of the test will reveal an irregularity, where the costs of the test can be charged to the client. Decisions are essentially made on the basis of the available documents and on-site inspections.

12. National Police Headquarters (the 'ORFK')

A. Review of general market surveillance activities

Information on the general market surveillance organisation and infrastructures in place for the 2010–2013 period

Government Decree No 173 of 24 August 2011 on pyrotechnical activities for civilian purposes regulates the market surveillance measures and procedures of the Police.

No classical market surveillance measures were taken by the Police in the past years, considering the fact that no measures specified in legislation were required. The Police regularly conducted inspections in connection with the authorisation of the performance of pyrotechnical activities, which, however, did not warrant the initiation of technical tests.

Information on total resources available for market surveillance activities

No data are at our disposal.

		2010	2011	2012	2013
1.1.	Budget available to market surveillance				
	authorities in nominal terms (EUR)				
1.2.	Budget available to market surveillance				
	authorities in relative terms (percentage				
	of total national budget)				
2.	Staff available to market surveillance				
	authorities (full-time equivalent units)				
3.	Number of inspectors available to				
	market surveillance authorities (full-time				
	equivalent units)				

B. Assessment of the functioning of market surveillance activities

No market surveillance measures and procedures set forth in Government Decree No 173 of 24 August 2011 on pyrotechnical activities for civilian purposes were taken and initiated, respectively, thus the Police did not perform any market surveillance activity.

13. National Food Chain Safety Office (the 'NÉBIH-NTAI')

A. Review of general market surveillance activities

Information on the general market surveillance organisation and infrastructures in place for the 2010–2013 period

The National Food Chain Safety Office (the 'NÉBIH') was established on 15 March 2012. Government Decree No 22 of 29 February 2012 on the National Food Chain Safety Office provides for its establishment. As a support institute of the Ministry for Rural Development, the Office oversees compliance with the food chain safety rules in national competence, bearing in mind the high-level protection of people and the interests of fair businesses. The NÉBIH is responsible for the professional direction of agricultural administration bodies. The NÉBIH comprises the following directorates:

- Veterinary and Animal Protection Directorate
- Veterinary Diagnostic Directorate
- Veterinary Products Directorate
- Animal Husbandry Directorate
- Oenology Directorate
- Forestry Directorate
- Food Safety Risk Assessment Directorate
- Food and Animal Feed Safety Directorate
- Agricultural Directorate
- System Organisation and Surveillance Directorate
- Crop Production and Horticultural Directorate
- Plant Protection, Soil Conservation and Agricultural Environmental Protection Directorate
- Legal and Human Resources Directorate
- IT Directorate
- Budget Directorate
- Asset Management and Operation Directorate
- Internal Control Directorate
- Supervisory Fees and Distributor Inspection Directorate
- Secretariat of the President
- Priority Issues Directorate

Pursuant to Section 37(2)(b) of Act XLIV of 2008, the Plant Protection, Soil Conservation and Agricultural Environmental Protection Directorate of the National Food Chain Safety Office (the 'NÉBIH-NTAI') is responsible for the verification of compliance with the registration, marking, packaging, transport, placement on the market, storage, best before date and application regulations of EC fertilisers as well as the verification of the existence of premises, fixtures and equipment used for their purposes and of safety data sheets. The inspections are carried out by plant protection and soil conservation inspectors working at the Plant Protection and Soil Conservation Directorates of the county Government Offices under coordination by the NÉBIH-NTAI. The NÉBIH-NTAI gathers and evaluates the national inspection data. Laboratory analyses are carried out by the Szolnok Soil Conservation Laboratory, the Tanakajd Soil Conservation Laboratory and the Velence Soil Conservation Laboratory. Our laboratories hold accreditation from the Hungarian Accreditation Board.

		2010	2011	2012	2013
1.1.	Budget available to market surveillance	59969	61762	78005	81 604
	authorities in nominal terms (EUR)				
1.2.	Budget available to market surveillance	0.00012%	0.00012%	0.00014%	0.00014%
	authorities in relative terms (percentage				
	of total national budget)				
2.	Staff available to market surveillance	1.58	1.58	3.16	3.16
	authorities (full-time equivalent units)				
3.	Number of inspectors available to	1.58	1.58	1.58	1.58
	market surveillance authorities (full-time				
	equivalent units)				

Information on total resources available for market surveillance activities

B. Assessment of the functioning of market surveillance activities

As parts of its market surveillance activities, the NÉBIH NTAI inspects only EC fertilisers, and has no other market surveillance activities covered by the Report.

CHAPTER I: OVERVIEW OF GENERAL MARKET SURVEILLANCE ACTIVITIES (A) Review of general market surveillance activities Information on all resources available for market surveillance activities (subject to availability)

	Information on all re	esources available f	or market surveilla	nce activities (subje	ect to availability)	
1(a)	Budget available to market surveillance authorities in nominal terms, EUR	2010	2011	2012	2013	Approved by:
						László Koszorús
	National Office of the Chief Medical Officer of the National Public Health and Medical Officer Service (the 'ÁNTSZ OTH')	0	5.186.801	5.361.560	3.869.582	
	Office of Health Authorisations and Administrative Procedures (the 'EEKH')	0	0	0	0	
	Lifts and Escalators Inspectorate of ÉMI Építésügyi Minőségellenőrző Innovációs	0	0	0	60.000	
	National Institute for Quality and Organisational Development in Healthcare and Medicine (the	41.414	32.471	40.794	97.480	
	Hungarian Office for Mining and Geology (the 'MBFH')	173.544	440.635	532.680	299.517	
	Hungarian Trade Licensing Office (the 'MKEH')	128.993	325.098	310.963	296.116	
	Hungarian Authority for Consumer Protection (the 'NFH')	1.330.062	2.131.214	1.975.866	1.855.328	
	National Transport Authority (the 'NKH')	0	0	0	0	
	Directorate for Industrial Safety and Labour of the National Labour Office (the 'NMH')	0	0	0	0	
	National Media and Infocommunications Authority (the 'NMHH')	0	0	0	0	
	National Directorate-General for Disaster Management of the Ministry of Interior (the	63.506	61.714	64.357	50.811	
	'BM OKF') National Police Headquarters (the 'ORFK')	0	0	0	0	
	National Food Chain Safety Office (the 'NÉBIH')	59.969	61.762	78.005	81.604	
	Total (EUR):	1.797.488	8.239.695	8.364.225	6.610.438	
1(b)	Budget available to market surveillance authorities in relative terms (percentage of total national budget)					
	Grand total of annual budget, HUF million	13.533.027	13.838.618	14.917.107	16.155.651	
	Grand total of annual budget, EUR	49.735.490.628	49.423.635.714	55.557.195.531	57.006.531.404	
	Relative value (percentage), % Relative value, rounded off, %	0,003614095 0.0035 %	0,016671568 0.0166 %	0,015055161 0.0150 %	0,011595931 0.0114 %	
2.	Staff available to market surveillance authorities (full-time equivalent units)					
	National Office of the Chief Medical Officer of the National Public Health and Medical Officer Service (the 'ÁNTSZ OTH')	0	628,21	597,81	574,8	
	Office of Health Authorisations and Administrative Procedures (the 'EEKH')	1	1	1	1	
	Lifts and Escalators Inspectorate of ÉMI	0	0	0	10	
	National Institute for Quality and Organisational Development in Healthcare and Medicine (the 'GYEMSZI')	1	1	1	1	
	Hungarian Office for Mining and Geology (the 'MBFH')	24	24	22	21	
	Hungarian Trade Licensing Office (the 'MKEH')	5,12	6,81	11,52	8,46	
	Hungarian Authority for Consumer Protection (the 'NFH')	131	143	120	137	

(the 'NFH')

National Transport Authority (the 'NKH')

	Directorate for Industrial Safety and Labour of the National Labour Office (the 'NMH')	239	186	164	166	
	National Media and Infocommunications Authority (the 'NMHH')	493,75	514,25	560,85	569,4	
	National Directorate-General for Disaster Management of the Ministry of Interior (the 'BM OKF')	6	6	6	5	
	National Police Headquarters (the 'ORFK')	0	0	0	0	
	National Food Chain Safety Office (the 'NÉBIH')	1,58	1,58	3,16	3,16	
	Total (persons)	902,45	1511,85	1487,34	1496,82	
3.	Number of inspectors available to market surveillance authorities (full-time equivalent units)					
	National Office of the Chief Medical Officer of the National Public Health and Medical Officer Service (the 'ÁNTSZ OTH')	0	319,59	324,41	332,72	
	Office of Health Authorisations and Administrative Procedures (the 'EEKH')	1	1	1	1	
	Lifts and Escalators Inspectorate of ÉMI	0	0	0	10	
	National Institute for Quality and Organisational Development in Healthcare and Medicine (the 'GYEMSZI')	0	0	0	0	
	Hungarian Office for Mining and Geology (the 'MBFH')	18	18	18	17	
	Hungarian Trade Licensing Office (the 'MKEH')	4,13	5,82	10,65	7,51	
	Hungarian Authority for Consumer Protection (the 'NFH')	85	93	79	89	
	National Transport Authority (the 'NKH')	0	0	0	0	
	Directorate for Industrial Safety and Labour of the National Labour Office (the 'NMH')	149	124	100	105	
	National Media and Infocommunications Authority (the 'NMHH')	10	10	10	10	
	National Directorate-General for Disaster Management of the Ministry of the Interior (the 'BM OKF')	6	6	6	5	
	National Police Headquarters (the 'ORFK')	0	0	0	0	
	National Food Chain Safety Office (the 'NÉBIH')	1,58	1,58	1,58	1,58	
	Total (persons):	274,71	578,99	550,64	568,81	

REPORT

ON THE REVIEW AND EVALUATION OF THE OPERATION OF MARKET SURVEILLANCE ACTIVITIES IN HUNGARY (2010 TO 2013)

CHAPTER II: MARKET SURVEILLANCE ACTIVITIES IN SPECIFIC SECTORS

1. Medical devices

1.A. Review of market surveillance activities in the sector

In connection with the evaluation of this chapter and, in general, the data of the table provided by the Health Licensing and Public Administration Office (the 'EEKH'), it is to be noted that the EEKH performs market surveillance activities only with respect to medical devices, thus it is our position that in our case, the separation of general and sectoral activities can be construed with certain reservations or cannot be construed at all. With regard to this, the reader is also requested to take into account the explanations provided in Chapter I for the examination of the issues in Chapter II.

		2010	2011	2012	2013
1.	Number of product-related accidents/consumer complaints	800	142	363	526
2.	Number of substantiated complaints by industry concerning unfair competition				
3.	Number of inspections (total)	33	58	41	26
3.1	number of reactive inspections	33	40	41	26
3.2	number of inspections on the market surveillance authorities' own initiative	0	18	0	0
3.3	number of inspections prompted by the customs authorities	0	0	0	1
4.	Number of inspections based on:				
4.1	tests performed in laboratories	0	0	1	0
4.2	physical testing of products	33	58	40	26
5.	Number of inspections resulting in:				
5.1	finding of non-compliance	9	3	17	8
5.2	corrective actions taken by economic operators ('voluntary actions')	0	0	0	0
5.3	restrictive measures taken by market surveillance authorities	9	3	17	8
5.4	sanctions/penalties applied	0	0	0	3
6.	Number of inspections where other Member States were also invited to	0	11	2	0

Information on the implementation activities performed in the 2010–2013 period

	· · · · · · · · · · · · · · · · · · ·		
collaborate			

Information on communication activities carried out in the 2010-2013 period (optional)

The efficiency of market surveillance activities and the practices of manufacturers relating to the devices are fundamentally determined by the extent of awareness by end users in their decisions made on devices; therefore, the EEKH lays increased emphasis on trainings in, and the provision of information about, product requirements. The Medical Engineering Division of the EEKH takes an active part in trainings in medical devices. In 2011 to 2013, it continuously sought opportunities to provide the widest possible range of information on the legislative provisions relating to medical devices to the parties concerned. The following are listed as examples also in connection with market surveillance activities:

- 11 April 2011, In-service Training of Hygienists, Medical University of Debrecen: Demonstration of Medical Devices
- 24 May 2011, MAGYOTT (Hungarian Regulatory Affairs Society): Demonstration of Medical Devices
- 27 July 2011, ETT TUKEB (Scientific and Research Ethics Committee of the Medical Research Council), at the request of the new Presidency: Demonstration of Medical Devices, Clinical Trials
- 11 October 2011, Concept of Medical Devices to the Officials of ETT TUKEB
- 13 December 2011, MAGYOTT: Border Area Between Medical Devices and Medicines
- Medicine Conference: The Role of Medical Engineering and Medical Technology in Patient Care in Hungary and Germany, September 2012, Péter Bunyitai
- Informa Conference: Clinical Trials, October 2012, Péter Bunyitai
- Technical Documentation of Medical Devices, Training in Rudiments, November 2012, Dr Péter Bunyitai, Eszter Solymár and Gábor Molnár

In order to provide information to end users, information materials are posted and continually updated on the website of the EEKH, which include general information on the distribution and other statutory requirements for medical devices, aimed at increasing consumer awareness, as well as public notices and information relating to certain issues or specific products (medical devices), perhaps also affecting 'consumer' safety.

In other respects, it is a statutory obligation to post excerpts of the decisions of market surveillance procedures ending in certain specific market surveillance measures on the website of the EEKH.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance	0	0	0	0
	authorities in nominal terms (EUR)				
7.2	Budget available to market surveillance	0	0	0	0
	authorities in relative terms (percentage				
	of total national budget)				
8.	Staff available to market surveillance	1	1	1	1
	authorities (full-time equivalent units)	1	1	1	1
9.	Number of inspectors available to				
	market surveillance authorities (full-time	1	1	1	1
	equivalent units)				

1.B. Assessment of the functioning of market surveillance activities in the sector

With regard to responsibilities in the sector, the framework provided by Act LXXXVIII of 2012 on the market surveillance of products is filled with content by two further decrees. Pursuant to Section 5(4) of Decree No 4 of 17 March 2009 of the Minister of Health on medical devices and Section 4(5) of Decree No 8 of 13 March 2003 of the Minister of Health, Welfare and Family Affairs on in vitro medical diagnostic devices, the Authority may, during its market surveillance procedure, verify compliance with the provisions relating to the placement on the market or commencement of use of devices as well as the implementation of the regulations applicable to commercially available devices or devices provided for use.

On the basis of the authorisation granted in the legislation referred to above, the EEKH performs market surveillance activities in four ways:

- 1. By official inspection launched at the manufacturer of the device or its authorised representative or distributor on the basis of customer filings (complaints, unexpected incidents or accidents) or deceptive advertising; If the filing relates to a device that has been made available by a non-health care provider or it has been used outside a health care institution (e.g. at home), the Medical Engineering Division notifies the National Consumer Protection Authority in order to take the measures set out in separate legislation.
- 2. On the basis of a preliminary market surveillance plan prepared annually or within ad hoc official inspections launched *ex officio*.
- 3. By compiling a system of criteria which helps the national institutes and county public health administration bodies of the National Public Health and Medical Officer Service (the 'ÁNTSZ') carrying out the inspections of health care providers in examining whether the user meets the requirements for the intended and safe functionality of the individual devices. On the initiative of the national institutes and county public health administration bodies of the ÁNTSZ, the Medical Engineering Division may, pursuant to Section 14(2) of the Decree, order the withdrawal of IVD devices from use.
- 4. On the basis of inquiries made by partner authorities (National Consumer Protection Authority, Hungarian Competition Authority, Customs and Excise Office, National Tax and Customs Administration and EU partner authorities).

In many cases, market surveillance procedures are generated by official inspection procedures performed for other reasons or other regulatory tasks performed by the staff of the Division, for irregularities found during them warrant deeper market surveillance procedures that may also end in the possible restriction of the distribution of the product.

The Medical Engineering Division carries out official verification in the following subject areas:

- verification of the medical engineering nature and category of the device (if the question is simply whether the product qualifies as a medical device);
- inspection of the manufacturers of devices made on order;
- verification of the performance of the registration obligation of the manufacturer and the entity responsible for placement on the market and the correctness of the reported data;
- inspection in the case of filings relating to any malfunction of the device, the deterioration of its parameters or efficiency as well as any deficiency or inadequacy of its labelling or user manual;
- authorisation of clinical trials not involving an intervention.

In the period reviewed, market surveillance procedures launched in response to filings by the partner authorities and individual complainants or *ex officio* accounted for a significant part of the inspection activities of the Medical Engineering Division. In 2011, a list of about 20 products was prepared on the basis of questionable data found during the uploading of the EUDAMED database for the purposes of planned market surveillance. These items formed the backbone of planned market surveillance in 2012. Afterwards, no planned market surveillance was carried out up until 2014, which falls outside the period reviewed, due to a higher commitment rate resulting from an increasing workload on the scarce human resources available and the increasing number of procedures launched by the partner authorities.

With regard to the changed statutory environment, the form of publication of decisions of the Authority restricting distribution, issued as a result of market surveillance procedures launched after 1 September 2012, has changed. Pursuant to Section 17 of Act LXXXVIII of 2012 on the market surveillance of products, the decisions published on the website of the EEKH also contain excerpts from the decisions.

The competence of the Authority relating to market surveillance was clearly defined in 2013; the legislature also passed the missing authorisation provision, and Section 2(1)(b) of Government Decree No 6 of 18 January 2013 on the detailed rules of market surveillance activities, which entered into force in addition to Government Decree No 295 of 28 October 2004 and the relevant ministerial decrees, also contains that the EEKH is a body with market surveillance competence.

The specimen documents relating to market surveillance were amended accordingly. In addition to the amendments generated by changes in legislation, several new checklists were introduced for the inspection of user manuals and labels with the intent not to miss the checking of any condition during the procedures. Market surveillance procedures are based on collaboration within staff. In market surveillance procedures, the 'inside cover' aims at providing a trackable method for this, on which it can be followed which staff member performed what tasks in the given procedure.

Medical devices affected by sanctions represent a very high risk source due to their deficiencies; applying the compulsory publication form of legislation, excerpts from the decisions are also stated on the website of the EEKH. (In the case of IVD and MDD devices, they are uniformly published on the EEKH's own website.) In addition, decisions restricting distribution also have to be reported through the Central Market Surveillance and Information System (the 'KPIR').

Finally, it is to be noted that one of the main (but not only) responsibilities of the Medical Engineering Division of the EEKH is conducting market surveillance inspections. The Division with a staff of nine performs tasks relating to Free Sales Certificates and EUDAMED; the evaluation and registration of the efficiency of MDD and IVD medical devices; the management of the database of accident officers; authorisation for periodic review; the operation of the Central Implants Register; regulatory tasks relating to designated organisations; participation in the Joint Assessment Programme; liaison with the Ministry of Human Resources and other official bodies (responding to domestic legal aid applications, inquiries, etc.); verification of compliance by the manufacturers of devices made on order with the decision of the National Health Insurance Fund; regulatory tasks relating to clinical trials; research in medical science not resulting in interventions; management of unexpected incidents (vigilance); provision of expert opinions on the issue of the categorisation and classification of medical devices; tasks of expert authorities; issue of specific permits of use; international liaison; devising concepts associated with regulations and falling within its responsibilities; participation in the preparation and review and comment on of bills and draft legislation; and performance of customer service tasks as responsibilities referred to its competence by legislation.

Even with this incomplete list, it can be seen that the Medical Engineering Division of the EEKH performs its market surveillance responsibilities referred to its competence by law even with the very

scarce personal and material conditions compared to its statutory obligations and the resulting workload. Therefore, the modest figures provided in the tables are to be evaluated by taking into account the foregoing.

2. <u>Cosmetic products</u>

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010-2013 period

(We note that the ÁNTSZ did not provide any data for 2010, only the Consumer Protection Authority [the 'NHF'] did.)

		r	,		1
		2010	2011	2012	2013
1.	Number of product-related accidents/consumer complaints	22	24	17	23
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total)	7278	9 668	30257	2204
3.1	number of reactive inspections	107	78	36	45
3.2	number of inspections on the market surveillance authorities' own initiative	6 281	6 508	3088	2 303
3.3	number of inspections prompted by the customs authorities	0	1	1	0
4.	Number of inspections based on:				
4.1	tests performed in laboratories	264	277	161	64
4.2	physical testing of products	7 224	8 3 5 2	3136	2675
5.	Number of inspections resulting in:				
5.1	finding of non-compliance	349	423	193	296
5.2	corrective actions taken by economic operators ('voluntary actions')	2	2	4	1
5.3	restrictive measures taken by market surveillance authorities	76	78	101	80
5.4	sanctions/penalties applied	74	44	87	46
6.	Number of inspections where other Member States were also invited to collaborate	0	0	0	0

Information on communication activities carried out in the 2010–2013 period (optional)

In its communication activities, the NFH gives priority to communicating product safety information to the consumers and economic operators. The Authority continuously publishes news, information and changes in legislation relating to market surveillance and individual product groups as well as dangerous products prohibited by the Authority on its website and Facebook account. In addition, news about the market surveillance activities of the Authority is regularly published in various media (national and local television and radio stations, Internet and written press), and information is also provided about these in its official journal and newsletter. Furthermore, the Authority tries to draw the attention of the public to products posing a risk with laboratory open days, roadshows and campaigns.

Information on resources (subject to availability)

(""	we note that the ministration provide any data for 2010, only the ministration						
		2010	2011	2012	2013		
7.1	Budget available to market surveillance	63 508	129112	107017	111929		
	authorities in nominal terms (EUR)						
7.2	Budget available to market surveillance						
	authorities in relative terms (percentage	0.000127	0.000261	0.000192	0.000196		
	of total national budget)						
8.	Staff available to market surveillance	6	634	603	581		
	authorities (full-time equivalent units)						
9.	Number of inspectors available to						
	market surveillance authorities (full-time	4	323	328	336		
	equivalent units)						

(We note that the ÁNTSZ did not provide any data for 2010, only the NFH did.)

1.B. Assessment of the functioning of market surveillance activities in the sector

The NFH:

During its market surveillance inspections conducted between 2010 and 2013, the consumer protection authority inspected cosmetic product groups that it had not yet tested in previous years.

The group of cosmetic products tested for the first time was as follows:

- child and baby care cosmetics
- eyelash brushes
- tanning products
- face and body compresses
- make-up for children.

The thematic reviews included the compliance of the labelling of product samples with legislation and checking the parameters of the products important from the point of view of human health (pH value, microbiological purity, heavy metal content and preservative content) and quality parameters (in the case of tanning agents, e.g. light absorption and absorbability).

During the thematic reviews conducted in the past four years, some kind of labelling deficiency was established for 22.6% of the products. The most frequent deficiencies were the lack of stating batch numbers, use before dates and ingredients.

On the basis of the analytical results, all test samples but one product sample met the safety requirements from the point of view of microbiological purity. On the basis of the measurement results of the laboratory analyses aimed at determining the heavy metal content of the cosmetic products sampled, it can be stated that the measured metal contents were significantly lower in all samples than the recommended allowable upper limits. The complaint ratio of the cosmetic products can be considered low compared to other products groups.

The ÁNTSZ

The majority of the inspections carried out as part of market surveillance activities took place on the authorities' own initiative, on the basis of annual work plans specified by the National Office of the Chief Medical Officer (the 'OTH'). Compared to the total number of inspections, complaints are lodged in an insignificant number, and are not even well-founded in many cases or result from the misuse of the cosmetic product/chemical.

The market surveillance activities relating to **cosmetic products** fundamentally changed after 13 July 2013, after the mandatory application of Regulation (EC) No 1223/2009. The domestic registration of products placed on the market ceased to exist and was replaced by registration with the European Union, thus a much greater emphasis is laid on subsequent inspections at the national level. The inspectors inspect both cosmetic manufacturers and commercially available cosmetics. The fact of product registration and the existence and contents of labels in Hungarian are verified as well as chemical and microbiological tests are conducted at the laboratory.

A significant change took place also in the area of product information documentation, which is inspected by the National Institute for Food and Nutrition Science (the 'OÉTI') designated as the national authority for cosmetics. According to the practice in Hungary, in the case of non-conformity, the OTH having regulatory powers takes measures on the basis of the expert opinion of the OÉTI. At present, 23 procedures are pending due to the non-conformity of product information documentation.

It has been possible to report serious undesirable effects caused by cosmetic products since July 2013, which are investigated by the OÉTI. In the past one year, four filings were received, of which any relationship between the use of the cosmetic product and health impairment was out of the question in two cases, and a relationship between the use of the cosmetic product and health impairment was likely in two cases. The OÉTI forwarded the results of the investigations into the filings to the Commission of the European Union via the ICSMS system.

In our experience, during the inspection of both cosmetic products and chemicals, most industrial players and distributors are cooperative, but in many cases, they are uninformed about the legislative provisions or cannot interpret them; therefore, some of the market surveillance activities comprise the provision of information to customers. The principle of gradualness is applied in the measures taken by the Authority, but if human health is endangered, the product is withdrawn from commercial distribution or, if warranted, a health fine or a chemical load fine is imposed.

3. <u>Toys</u>

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product-related accidents/consumer complaints	21	25	25	31
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total)	1153	1 510	1015	1043
3.1	number of reactive inspections	465	571	352	393
3.2	number of inspections on the market surveillance authorities' own initiative	683	926	656	641
3.3	number of inspections prompted by the customs authorities	5	13	7	9
4.	Number of inspections based on:				
4.1	tests performed in laboratories	76	55	62	90
4.2	physical testing of products	1 422	2 6 9 5	2476	2094
5.	Number of inspections resulting in:				
5.1	finding of non-compliance	207	305	479	512
5.2	corrective actions taken by economic operators ('voluntary actions')	4	3	2	1
5.3	restrictive measures taken by market surveillance authorities	161	237	223	230
5.4	sanctions/penalties applied	130	197	153	137
6.	Number of inspections where other Member States were also invited to collaborate	0	0	0	0

Information on communication activities carried out in the 2010-2013 period (optional)

In its communication activities, the NFH gives priority to communicating product safety information to the consumers and economic operators. The Authority continuously publishes news, information and changes in legislation relating to market surveillance and individual product groups as well as dangerous products prohibited by the Authority on its website and Facebook account. In addition, news about the market surveillance activities of the Authority is regularly published in various media (national and local television and radio stations, Internet and written press), and information is provided about these in its official journal and newsletter. Furthermore, the Authority tries to draw the attention of the public to products posing a risk with laboratory open days, roadshows and campaigns.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance	317 192	522807	465263	461 052
	authorities in nominal terms (EUR)				
7.2	Budget available to market surveillance				
	authorities in relative terms (percentage	0.000637	0.00105	0.000837	0.0008
	of total national budget)				
8.	Staff available to market surveillance	32	35	30	34
	authorities (full-time equivalent units)				
9.	Number of inspectors available to				
	market surveillance authorities (full-time	21	23	19	22
	equivalent units)				

1.B. Assessment of the functioning of market surveillance activities in the sector

The consumer protection authority examined the following types of toys between 2010 and 2013:

- **Dolls/doll kits:** according to experience, 90% of the products analysed have a high phthalic ester-type softener content in the heads of dolls. Instead of the heads of dolls, the softener is mostly located in the bodies of dolls and other accessories. 18% of the labelling are incomplete, 4% of the products do not have conformity documentation. The complaint ratios were nearly equal in all three years.
- **Projectile toys:** their most typical defect is the separation of the suction disc and the higher than permitted phthalic ester-type softener content of the suction disc. This product group was also inspected as part of sample testing/individually every year; the Authority increasingly often encountered phthalic-free products in 2013 and this year. Projectiles are already made of different materials, thus they do not contain any softener and the design of projectiles has been changed: they consist of a piece cast in one mould, thus they have no small part that can get separated. In terms of labelling, 25% of them are inadequate, and 3% do not have conformity documentation.
- Toys for children under the age of three: Of the baby toys tested in 2012, 112 types or 388 toys (20.9%) were complained about due to inadequate markings, labels and warnings. During the inspections, samples were taken from 14 toys presumed to be suspicious from a safety point of view. On the basis of the results of laboratory tests, two baby toys proved to be dangerous. A baby chew toy represents a serious risk to small children from the point of view of choking hazard, while a pram rattle poses a high risk in terms of eye injuries. In 2013, the product group was examined as part of laboratory tests, where dangerous softeners were found also to a small proportion. In the case of this product group, manufacturers pay higher attention to hazards posed by small parts and pull cords. The documentation was conforming in the case of 85.7% of the toys.
- **Bubble blowers/replenishers:** In the case of the product group, microbiological analyses were carried out on several occasions. In 25% of the cases, microbiological infections were found, in one case due to a specific defect of the product.

- **Tricycles and scooters:** The majority of the products did not meet the requirements set for load-bearing capacity, brakes, stability, burr and sticking. With regards to labelling, product-specific warning notices were incomplete or completely missing.
- Textile puppets (2013) and textile doll clothes (2012): The Authority analysed these products for their azo-dye content (in specific analyses); in two analyses, one product did not meet the requirements.
- **Expanding toys:** A very small group of toys belongs to the group of expanding toys: In 20% of these products, they expand too much (several fold in size). The Authority checked these products, too, in its own laboratory tests and sampling tests every year.
- Make-up kits: They were not subjected to independent thematic reviews, but about 10 of them were tested (randomly and through consumer complaints) every year. In terms of microbiological and heavy metal content, the products meet the requirements.
- Toy books: During the inspection of children's books, a total of 20 products were sampled, of which deficiencies relating to the conditions of distribution were established in the case of 12 (60%), and non-conformity affecting product safety, which represents a medium risk, was established in the case of one (5%). It can be stated from the experience gained that the manufacturers and importers are not aware of the fact that they have to meet not only the requirements set for books, but also those set for children's toys. They do not know the boundary between books and toys. In many cases, therefore, conformity markings were not shown either.
- Toy mobile phones: The Authority inspected these product groups as part of independent thematic reviews in 2111 and 2012. On both occasions, the Authority established that the volume emitted was too high in nearly 82% of the products, 30% did not conform to the structural specifications, and 17% were malfunctioning.

On the basis of experience of the past period, it can be stated that it is a frequent problem in the case of toys that the documentation certifying the conformity of the product is incomplete or inadequate. In the case of EC declarations of conformity, the most frequent errors are the name and ID number of the registered organisation. The inspection of a significant part of the products is carried out by an (unregistered) Chinese subsidiary of a registered organisation. Another error is the ambiguous identifiability (lack/quality of photograph, difference in identification markings). It is an error that occurs less frequently, but so much the more significant, that the product is examined in accordance with inappropriate standards/conformity with the required regulations is not examined, thus not all hazards arising during normal use are taken into account by the manufacturer.

4. Personal protective equipment

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product-related accidents/consumer complaints	7	7	3	2
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total)	298	233	109	87
3.1	number of reactive inspections	11	53	23	25
3.2	number of inspections on the market surveillance authorities' own initiative	285	176	83	50
3.3	number of inspections prompted by the customs authorities	2	4	3	12
4.	Number of inspections based on:	0	0	0	0
4.1	tests performed in laboratories	0	7	0	0
4.2	physical testing of products	359	262	111	135
5.	Number of inspections resulting in:	0	0	0	0
5.1	finding of non-compliance	209	69	15	49
5.2	corrective actions taken by economic operators ('voluntary actions')	1	2	2	1
5.3	restrictive measures taken by market surveillance authorities	194	70	15	49
5.4	sanctions/penalties applied	172	56	10	0
6.	Number of inspections where other Member States were also invited to collaborate	0	0	0	0

Information on communication activities carried out in the 2010-2013 period (optional)

In its communication activities, the NFH gives priority to communicating product safety information to the consumers and economic operators. The Authority continuously publishes news, information and changes in legislation relating to market surveillance and individual product groups as well as dangerous products prohibited by the Authority on its website and Facebook account. In addition, news about the market surveillance activities of the Authority is regularly published in various media (national and local television and radio stations, Internet and written press), and information is provided about these in its official journal and newsletter. Furthermore, the Authority tries to draw the attention of the public to products posing a risk with laboratory open days, roadshows and campaigns.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance	37 894	62807	55789	55087
	authorities in nominal terms (EUR)				
7.2	Budget available to market surveillance				
	authorities in relative terms (percentage	0.0001	0.000127	0.0001	0.0001
	of total national budget)				
8.	Staff available to market surveillance	4	4	3	4
	authorities (full-time equivalent units)				
9.	Number of inspectors available to				
	market surveillance authorities (full-time	2	2	2	2
	equivalent units)				

1.B. Assessment of the functioning of market surveillance activities in the sector

The NFH:

The purpose of the official inspections was to verify the existence and conformity in content of the labels and purchase information brochures belonging to personal protective equipment used by a wide range of consumers, with special regard to warning notices referring to the safe use of the products, and to filter out any inadequately certified personal protective equipment, which may not meet certain safety considerations, from commercial distribution.

The lack of any information provided by the manufacturer or its unavailability in Hungarian was general problems associated with the fulfilment of the individual safety requirements of the protective equipment inspected. The inspectors complained about conformity regarding the content of information brochures in a very high number in the case of protective gloves and reflective vests, while the complaint ratio was lower in this respect in the case of individual protective equipment worn during skiing. In the case of protective equipment used for leisure activities, the missing information, such as warning notices relating to the limits of protection and information referring to the importance of storage conditions and maintenance inspections, draws the attention of consumers to the hazards of circumstances affecting the level of protection and safe use, therefore, the provision of such information would be very important.

In the case of ski goggles, laboratory tests showed that the products sampled met the safety requirements and, while being used, they did not pose a hazard to the health and safety of users. In the case of sunglasses, the laboratory tests for UV protection and Ni dissolution performed year after year showed good results also in respect of sunglasses, similar to those of ski goggles.

The tests threw light on the fact that the product group reviewed was well regulated by statutory regulations and standard specifications, but such provisions and specifications were not sufficiently known among those engaged in commercial activities. With the change of consumer habits, increasing focus will be placed on personal safety, therefore, it is expected that the market of the products inspected will pick up in the future. Considering all the above and due to the high complaint ratio found in the area of meeting the individual requirements, it will be warranted to carry out new inspections of certain groups of these products also in the coming years.

Directorate for Industrial Safety and Labour of the National Labour Office (the 'NMH MMI')

On the basis of what was set out in the general part, in the case of the non-conformity of individual protective equipment 'intended for targeted economic use', pursuant to Act XCIII of 1993 on industrial safety ('Act XCIII of 1993'), the industrial safety authority suspended the use of individual protective equipment used during the performance of organised work. As a market surveillance measure, the industrial safety authority provided information to the consumer protection authority (KPIR alarm), and did not order withdrawal from distribution, recall from distribution, etc.

The industrial safety inspectorate initiated an alarm regarding a restrictive or prohibitive measure taken in the case of a product found during the inspection at a workplace conducted by industrial safety inspectors and not conforming to the safety requirements on one occasion via the National General Inspectorate for Industrial Safety (the 'OMMF') in the period between 2010 and 2013. The use of an objected piece of individual protective equipment was suspended immediately because the ear muffs did not have the conformity markings and information brochure specified in Decree No 18 of 3 December 2008 of the Minister of Welfare and Labour. The protective equipment did not have a CE marking, a EC declaration of conformity or a CE type certificate, its protective ability could not be identified, and no user manual was provided with it either.

5. Construction products

The NFH:

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product-related accidents/consumer complaints	12	32	40	41
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	2	1
3.	Number of inspections (total)	458	538	357	128
3.1	number of reactive inspections	44	84	51	29
3.2	number of inspections on the market surveillance authorities' own initiative	414	953	306	99
3.3	number of inspections prompted by the customs authorities	0	1	0	0
4.	Number of inspections based on:	0	0	0	0
4.1	tests performed in laboratories	6	10	0	0
4.2	physical testing of products	1 002	1 245	1 282	408
5.	Number of inspections resulting in:	0	0	0	0
5.1	finding of non-compliance	817	921	660	87
5.2	corrective actions taken by economic operators ('voluntary actions')	21	8	3	4
5.3	restrictive measures taken by market surveillance authorities	741	686	170	62
5.4	sanctions/penalties applied	433	126	42	2
6.	Number of inspections where other Member States were also invited to collaborate	0	0	0	0

Information on communication activities carried out in the 2010–2013 period (optional)

In its communication activities, the NFH gives priority to communicating product safety information to the consumers and economic operators. The Authority continuously publishes news, information and changes in legislation relating to market surveillance and individual product groups as well as dangerous products prohibited by the Authority on its website and Facebook account. In addition, news about the market surveillance activities of the Authority is regularly published in various media (national and local television and radio stations, Internet and written press), and information is provided about these in its official journal and newsletter. Furthermore, the Authority tries to draw the attention of the public to products posing a risk with laboratory open days, roadshows and campaigns.

		2010	2011	2012	2013
7.1	Budget available to market surveillance	63 508	104 561	92982	91 929
	authorities in nominal terms (EUR)				
7.2	Budget available to market surveillance				
	authorities in relative terms (percentage	0.000127	0.000211	0.000167	0.000161
	of total national budget)				
8.	Staff available to market surveillance	6	7	6	7
	authorities (full-time equivalent units)				
9.	Number of inspectors available to				
	market surveillance authorities (full-time	4	4	4	4
	equivalent units)				

Information on resources (subject to availability)

1.B. Assessment of the functioning of market surveillance activities in the sector

With regard to products used for construction, the conditions of distribution of a number of construction product categories were inspected in the past four years. During the inspections, the consumer protection inspectorates verified whether the distribution of construction products made in Hungary and abroad had complied with the legislative provisions. The selection of the product group was warranted by the fact, firstly, that the Authority had experienced a high number of irregularities during previous inspections affecting the selected product group (primarily in the area of certificates of conformity), while in other cases, it targeted areas that had not yet been inspected previously.

The consumer protection authority verified compliance with the technical requirements prescribed in the relevant legislation, the existence of the certificates of conformity applicable to the product and the well-foundedness of the reference made to the technical specification forming the basis of the certificates of conformity.

Mystery shopping performed revealed major professional deficiencies. During mystery shopping, failure to hand over certificates of conformity occurred in a relatively high number of cases, which can be considered significant despite our continuous inspections. It can be stated in the case of all product groups that during the inspections, the most frequent irregularity was content deficiencies in the declarations of conformity of suppliers handed over to the inspectors. However, these were usually deficiencies in data content, which did not question the well-foundedness of the certificates of conformity.

In summary, it can be stated that compliance with the provisions of the legislation on the distribution of construction products is a cause for concern year after year for the manufacturers in making out declarations of conformity and for merchants in selling the products. Despite the deficiencies found, the positive effect of inspections focusing on the provision of information and notices could be felt in the past years, for instead of passing on liability, the inspectors found maximum readiness to cooperate by both manufacturers and distributors.

In addition to the above, radioactivity tests were also carried out as part of the thematic reviews in 2010. The tests mainly covered softwood lumber products, but a few hardwood products were also

measured. During the review, 348 wood products were tested, which came from Ukraine, Norway, Russia and Belarus. During dose rate measurements, it was established that no value exceeding the natural background radiation could be found in any of the tested of products.

National Directorate-General for Disaster Management of the Ministry of the Interior (the 'BM OKF')

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product-related accidents/consumer complaints	1	3	2	4
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total)	23	23	91	418
3.1	number of reactive inspections	1	3	2	4
3.2	number of inspections on the market surveillance authorities' own initiative	22	20	89	414
3.3	number of inspections prompted by the customs authorities	0	0	0	0
4.	Number of inspections based on:				
4.1	tests performed in laboratories	0	0	0	0
4.2	physical testing of products	23	23	91	418
5.	Number of inspections resulting in:				
5.1	finding of non-compliance	9	7	9	3
5.2	corrective actions taken by economic operators ('voluntary actions')	0	0	0	0
5.3	restrictive measures taken by market surveillance authorities	5	6*	8**	3
5.4	sanctions/penalties applied	4	4*	5**	0
6.	Number of inspections where other Member States were also invited to collaborate	0	0	0	0

* In three cases, the BM OKF applied both restrictive measures and sanctions; therefore, the decisions are included in both rows.

** In four cases, the BM OKF applied both restrictive measures and sanctions; therefore, the decisions are included in both rows.

Information on communication activities carried out in the 2010-2013 period (optional)

The heads and administrators of the organisation unit of the BM OKF pursuing market surveillance activities (Fire Protection Division) gave presentations at conferences and professional events in the period reviewed, primarily in connection with the changes of 1 July 2013, and those interested were continuously informed by telephone, email and post. In order to apply legislation uniformly, the BM OKF gave several presentations and held several in-service trainings in, changes in the rules relating to

the distribution and installation of construction products in the second half of 2013 for the regional and local bodies of the disaster management organisation.

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (EUR)	63 506*	61714*	64357*	50811*
7.2	Budget available to market surveillance authorities in relative terms (percentage of total national budget)	0.00013%	0.00013%	0.00012%	0.00009%
8.	Staff available to market surveillance authorities (full-time equivalent units)	6	6	6	5
9.	Number of inspectors available to market surveillance authorities (full-time equivalent units)	6**	6**	6**	5**

Information on resources (subject to availability)

* Estimated value. In connection with the market surveillance activities of the BM OKF, the costs incurred may be separated in part in relation to the remuneration of the personnel, considering the fact that the staff assigned to market surveillance tasks are also engaged in other activities associated with disaster management and fire protection. Other material costs (office supplies, fuel, etc.) are accounted for in connection with the other activities of the BM OKF.

** The number of personnel available to the market surveillance authority (2nd row) also includes the number of available inspectors (3rd row).

In 2013, the local disaster management offices also carried out on-site market surveillance inspections, but this did not entail an increase in headcount. The task was carried out by the existing staff of the local offices.

1.B. Assessment of the functioning of market surveillance activities in the sector

The Hungarian legal framework allows the BM OKF and the local disaster management office to examine the conformity of the products with the fire protection and safety requirements not only during distribution, but also during installation. Thus, it can be verified that indeed the product placed on the market is installed and the product is not changed during construction or installation.

The disaster management bodies are not engaged in the examination of circumstances relating to the market of construction products (market size, number of distributors, import, etc.). Market surveillance includes the examination of the conformity of the products placed on the market and installed, essentially on the basis of the available documents (declarations of performance, certificates, test reports and technical documentation).

On the basis of market surveillance inspections, procedures, consultations, presentations given at conferences and information brochures issued, both the bodies performing regulatory tasks, including partner authorities (consumer protection authority, construction authority and construction surveillance authority) and the manufacturers, distributors, contractors and service providers became widely familiar with the statutory conditions of the distribution and installation of construction products. On the basis of the experience of these actions held in 2013, manufacturers and distributors prepared for the application of the new Decree. The market surveillance inspections found minor deficiencies in declarations of performance, which were corrected within a short time.

On the basis of the high number of market surveillance inspections in 2013 and due to the considerable time spent on the evaluation of a large number of documents certifying the conformity of the various products subjected to inspection, the BM OKF specifies specific products, product groups and inspection periods in 2014. With this, the transparency and level of the coordination of market surveillance inspections are improved, and the inspections are spread out throughout the year.

6. <u>Aerosols</u>

No market surveillance inspections were carried out for the period of 2010 to 2013.

7. Simple pressure vessels and pressure equipment (PED)

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product-related accidents/consumer complaints	0	1	1	2
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total)	5	15	36	51
3.1	number of reactive inspections	0	1	1	2
3.2	number of inspections on the market surveillance authorities' own initiative	5	14	35	49
3.3	number of inspections prompted by the customs authorities	0	0	0	0
4.	Number of inspections based on:				
4.1	tests performed in laboratories	0	2	1	0
4.2	physical testing of products	5	13	35	51
5.	Number of inspections resulting in:				
5.1	finding of non-compliance	0	12	18	13
5.2	corrective actions taken by economic operators ('voluntary actions')	0	0	0	0
5.3	restrictive measures taken by market surveillance authorities	0	2	0	1
5.4	sanctions/penalties applied	0	0	0	0
6.	Number of inspections where other Member States were also invited to collaborate	0	0	0	0

Information on communication activities carried out in the 2010–2013 period (optional)

Our most important means of communication is our website (www.mkeh.gov.hu), on which important information on the market surveillance activities of the Hungarian Trade Licensing Office (the 'MKEH') can be found. We publish a market surveillance newsletter on current market surveillance topics in the fresh news column of the website. After preliminary registration, newsletters are automatically sent to the registered electronic addresses. We published a total of six newsletters in the period in question.

We drew the attention of distributors and users to dangerous products found during the inspections in announcements on the website.

In addition to non-governmental organisations, we regularly communicate with a number of partner authorities on the basis of contractual relationships. We exchange experience and information with the measurement and technical and safety authorities of government offices, the National Consumer Protection Authority and the National Tax and Customs Administration. We publish public information brochures regarding our annual activities, with the aid of which those interested are given comprehensive information on all areas falling within our competence.

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (EUR)	4006	17004	11 534	22676
7.2	Budget available to market surveillance authorities in relative terms (percentage of total national budget)	0.00001%	0.00003%	0.00002%	0.00005%
8.	Staff available to market surveillance authorities (full-time equivalent units)	0.21	0.39	0.47	0.65
9.	Number of inspectors available to market surveillance authorities (full-time equivalent units)	0.12	0.30	0.40	0.58

Information on resources (subject to availability)

1.B. Assessment of the functioning of market surveillance activities in the sector of simple pressure vessels and pressure equipment

The regulatory market surveillance tasks of the Hungarian Trade Licensing Office are performed at first instance by the Market Surveillance Department with national jurisdiction. Of the simple pressure vessels and pressure equipment (PED, SPV) intended for targeted economic use, coming under Directive 2009/105/EC and Directive 97/23/EC, the following product categories were inspected:

- air reservoirs, safety valves,
- unheated pressure vessels,
- reactor vessels, heat exchangers, air coolers,
- cryogenic vessels and evaporators,
- pipes and tubes,
- sand blasters,
- dry powder fire extinguishers, breathing cylinders and cylinder valves,
- boilers burning solid fuels,
- dust filters, manometers.

During the inspections, the documentation (EC declaration of conformity, operating manual, CE type test certificate where appropriate, selected parts of the technical documentation) was reviewed and the products were subjected to physical checks and, in a few cases, laboratory tests were also carried out.

Experience of inspections:

In many cases, the documentation was not available at the place of inspection; however, ensuring that the missing information is supplemented was successful in every case and conformity was certified.

Just a few non-conformities can be found with regard to equipment used in the chemical industry (tanks, liquefied gas storage tanks, heat exchangers, air coolers and pipes). Both the manufacturers and the users are aware of the requirements, the equipment has the required documentation and markings, and the equipment is designed and manufactured in accordance with the relevant harmonised standards.

Of the cylinder types of composite breathing apparatuses, the use of one type was prohibited, because the use of the product type had become life-threatening as a result of a defect in its material.

The valve of the cylinder of another type of breathing apparatus broke off during use, but did not cause an accident. We had the damaged cylinder and valve tested by a laboratory. An expert established that the equipment had met the requirements and the damage to the valve could be caused by inappropriate use.

It was typical among companies manufacturing low-performance boilers burning solid fuels that they did not know and apply the legislation applicable to the design, manufacture and placement on the market of pressure vessels, did not carry out the conformity assessment of the products, and did not mark the equipment appropriately. If more than one directive applied to a piece of equipment, the manufacturers did not carry out the certification of the product in accordance with all relevant directives on several occasions. At the request of the Authority, the manufacturers brought the inspected product types into compliance, made up for the missing documentation and corrected the inadequate data plates.

In the case of the high performance boilers inspected, no deviation requiring an intervention was found.

In the case of manometers, it represented a deficiency that certain distributors did not provide a user manual in Hungarian or did not display any data or marking on one product type inspected.

We had one type of dry powder fire extinguishers tested by the laboratory after an inspection launched in response to a filing. As a result, the placement of the product type on the market and its distribution were prohibited in the decision due to the non-conformity of its wall thickness and the recall of the product was ordered. The non-conformity of the product was entered in the RAPEX system, and the market surveillance authority of the manufacturing country was also notified.

8. Transportable pressure vessels (TPED)

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product-related accidents/consumer complaints	0	0	0	0
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	1	0
3.	Number of inspections (total)	0	0	338	175
3.1	number of reactive inspections	0	0	1	0
3.2	number of inspections on the market surveillance authorities' own initiative	0	0	337	175
3.3	number of inspections prompted by the customs authorities	0	0	0	0
4.	Number of inspections based on:				
4.1	tests performed in laboratories	0	0	0	0
4.2	physical testing of products	0	0	338	175
5.	Number of inspections resulting in:				
5.1	finding of non-compliance	0	0	19	7
5.2	corrective actions taken by economic operators ('voluntary actions')	0	0	0	0
5.3	restrictive measures taken by market surveillance authorities	0	0	11	7
5.4	sanctions/penalties applied	0	0	0	0
6.	Number of inspections where other Member States were also invited to collaborate	0	0	0	0

Information on communication activities carried out in the 2010-2013 period (optional)

Our most important means of communication is our website (<u>www.mkeh.gov.hu</u>), on which important information on the market surveillance activities of the MKEH can be found. We publish a market surveillance newsletter on current market surveillance topics in the fresh news column of the website. After preliminary registration, newsletters are automatically sent to the registered electronic addresses. We published a total of six newsletters in the period in question.

We gave a presentation on the inspection experience of transportable pressure vessels at a session of the Hungarian Industrial Gas Association and also organised a meeting for smaller industrial gas distributors to discuss technical issues.

In addition to non-governmental organisations, we regularly communicate with a number of partner authorities on the basis of contractual relationships. We exchange experience and information with the measurement and technical and safety authorities of government offices, the Hungarian Authority for Consumer Protection and the National Tax and Customs Administration. We publish our public information brochures regarding our annual activities, with the aid of which those interested are given comprehensive information on all areas falling within our competence.

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (EUR)	0	0	108 293	77808
7.2	Budget available to market surveillance authorities in relative terms (percentage of total national budget)	0%	0%	0.00022%	0.00016%
8.	Staff available to market surveillance authorities (full-time equivalent units)	0.15	0.13	3.79	2.05
9.	Number of inspectors available to market surveillance authorities (full-time equivalent units)	0.06	0.04	3.71	1.97

Information on resources (subject to availability)

1.B. Assessment of the functioning of market surveillance activities in the sector

The regulatory market surveillance tasks of the Hungarian Trade Licensing Office are performed at first instance by the Market Surveillance Department with national jurisdiction.

At the beginning of the baseline period, preparation for the inspections formed the essential part of the activities. As part of this, the following tasks were carried out:

1. Devising and correction of the ME 721-01PO ('Market surveillance procedure') quality management procedure and related specimen documents, checklists and product-specific data sheets within the ISO 9001 certified quality system.

2. Exchange of experience in inspection, review and procedure issues in accordance with the provisions of the cooperation agreement concluded with the consumer protection authority in 2005, the industrial safety authority in 2007 and the mining authority in 2003.

3. Monitoring and processing of the information entered in the database of the Central Market Surveillance and Information System (the 'KPIR') and participation in the professional forums of the sector concerned in Hungary and possibly in the European Union.

With respect to the product group of transportable pressure equipment (TPED) intended for targeted economic use, coming under Directive 2010/35/EC, the following product categories were inspected under the market surveillance programme:

- periodic inspection of gas cylinders,
- industrial gas cylinders, gas cylinder bundles and gas barrels.

The subject-matter of the inspection is the product itself, its CE marking, the accompanying documentation, the EC declaration of conformity and, if necessary, the technical documentation compiled in accordance with legislation, in whole or in part.

Experience of inspections:

Non-conformity was established in the case of 5% of the 513 inspected industrial gas cylinders.

About 20 products were found to have expired test periods. At our instruction, the distributor had the defective products returned to the cylinder filling plant, where the mandatory periodic tests were carried out and certified.

The distributors corrected the defects found (inappropriate colour marking, rusting, illegible marking or expired test dates).

On cylinders filled for food and medical purposes, what are called 'batch labels' allowing misunderstanding were found during on-site inspections, on which the use before date extended beyond the test period of the pressure vessel stamped on the cylinder. Since the data shown on the 'batch label' mandatorily are prescribed by other decrees, the contradiction can be resolved by the amendment of the regulation applicable to the filling of cylinders. Such amendment is initiated by the Authority.

One distributor distributed industrial gases in gas cylinders owned by another company. Considering the fact that it could not present the documentation of the third party cylinders, we ordered the prohibition of the distribution of these cylinders.

9. Machinery

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product-related accidents/consumer complaints	13	10	7	8
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total)	418	625	599	636
3.1	number of reactive inspections	182	211	159	183
3.2	number of inspections on the market surveillance authorities' own initiative	234	414	438	448
3.3	number of inspections prompted by the customs authorities	2	0	2	5
4.	Number of inspections based on:				
4.1	tests performed in laboratories	3	18	1	10
4.2	physical testing of products	342	641	572	617
5.	Number of inspections resulting in:				
5.1	finding of non-compliance	13	70	28	15
5.2	corrective actions taken by economic operators ('voluntary actions')	0	0	1	1
5.3	restrictive measures taken by market surveillance authorities	18	76	37	20
5.4	sanctions/penalties applied	12	47	23	9
6.	Number of inspections where other Member States were also invited to collaborate	0	0	0	0

Information on communication activities carried out in the 2010-2013 period (optional)

The NFH:

In its communication activities, the NFH gives priority to communicating product safety information to the consumers and economic operators. The Authority continuously publishes news, information and changes in legislation relating to market surveillance and individual product groups as well as dangerous products prohibited by the Authority on its website and Facebook account. In addition, news about the market surveillance activities of the Authority is regularly published in various media (national and local television and radio stations, Internet and written press), and information is provided about these in its official journal and newsletter. Furthermore, the Authority tries to draw the attention of the public to products posing a risk with laboratory open days, roadshows and campaigns.

The MKEH:

Our most important means of communication is our website (www.mkeh.gov.hu), on which important information on the market surveillance activities of the MKEH can be found. We publish a market surveillance newsletter on current market surveillance topics in the fresh news column of the website. After preliminary registration, newsletters are automatically sent to the registered electronic addresses. We published a total of six newsletters in the period in question.

Of the market surveillance programs performed in a wider scope and commanding higher interest, we shared the experience of inspections with interested distributors and users in longer studies in two areas, which were published on the website.

At request, we gave presentations on the market surveillance of machines primarily in in-service trainings organised by the SAASCO Consulting and Engineering Office for small and medium-sized enterprises.

In addition to non-governmental organisations, we regularly communicate with a number of partner authorities on the basis of contractual relationships. We exchange experience and information with the measurement and technical and safety authorities of government offices, the Hungarian Authority for Consumer Protection and the National Tax and Customs Administration.

We publish our public information brochures regarding our annual activities, with the aid of which those interested are given comprehensive information on all areas falling within our competence.

		2010	2011	2012	2013
7.1	Budget available to market surveillance	74035	154736	159649	169122
	authorities in nominal terms (EUR)				
7.2	Budget available to market surveillance				
	authorities in relative terms (percentage	0.000148	0.000313	0.000287	0.000296
	of total national budget)				
8.	Staff available to market surveillance	7	8	9	9
	authorities (full-time equivalent units)				
9.	Number of inspectors available to				
	market surveillance authorities (full-time	4	5	6	6
	equivalent units)				

Information on resources (subject to availability)

1.B. Assessment of the functioning of market surveillance activities in the sector

The NFH:

During the inspection of machines, the consumer protection authority examined whether the conditions of distribution of the most widespread, commercially available hand tools with an electric

motor, imported primarily from third countries (drilling machines, angle grinders, circular saws and planers) and small garden machines (lawn mowers and grass trimmers), comply with the relevant legislative provisions, with special regard to the markings, warning notices, conformity assessments and user manuals of such products.

The inspections involved units of department store chains/commercial chains, units engaged in both wholesale and retail as well as fairs and markets, on a country-wide basis in the case of hand tools, while six counties in connection with small garden machines. Taking into account the inspection criteria specified in the inspection guidelines, the inspectors established some kind of non-conformity at nearly half (about 46%) of the commercial units distributing and selling hand tools, while at nearly one-quarter (about 22%) of the distributors of small garden machines.

The experience relating to product inspection criteria were very favourable in the case of small garden machines: a deficiency was found in the case of only one or two products with a minimum complaint ratio of a few percentages. Although the experience was also similar about hand tools, in the case of one inspection criterion (lack of product name), the highest complaint ratio reached 20%, which can still not be considered critical in itself.

In addition to the foregoing, it can be evaluated as a positive result that the merchants did not find any commercially available product that had been previously prohibited or included in a RAPEX report during any of the thematic reviews.

Therefore, in summary, it can be established that the above-mentioned thematic reviews were closed with better results than previously expected, and product sales practices complying with the law appear to be implemented with respect to the product groups concerned.

The MKEH:

The regulatory market surveillance tasks of the Hungarian Trade Licensing Office are performed at first instance by the Market Surveillance Department with national jurisdiction. With respect to the product groups intended for targeted economic use, coming under Directive 2006/42/EC on the safety requirements for machines and certification of conformity, the following product types were subjected to inspection under the market surveillance programme:

- earth-moving machinery,
- mobile road construction machinery,
- machine tools
- slow lifts,
- vehicle hoisting equipment,
- access control gates, lifting gates and industrial garage doors,
- agricultural and forestry machinery, woodworking machinery,
- construction machinery,
- forklift trucks,
- printing and paper-making machinery,
- rubber and plastic machinery,
- high pressure water jet cutters,
- compressors,
- packaging machinery,
- food machinery,

- public works machinery,
- lifting accessories.

The subject-matter of the inspection is the product itself, its CE marking, the accompanying documentation, the EC declaration of conformity and, if necessary, the technical documentation compiled in accordance with legislation, in whole or in part.

According to the experience of inspections, it transpires from the relationship of the product categories compared to each other that the highest rate of non-conformity can be found among general mechanical and construction machinery.

In the case of the inspected products, it is a frequent error to have an EC declaration of conformity with incorrect contents and to display text in foreign languages (while lacking a Hungarian description) on the machinery. In several cases, the data plate, the CE marking or a user manual in Hungarian was also missing. In respect of cranes, except for a few cases where the manufacturer referred to standards that had ceased to be in force in the EC declaration of conformity, it can be stated about the market players that they strictly comply with the legislative provisions. Furthermore, imported used equipment of uncertain origin, lacking documentation (e.g. forklift trucks) is a frequent problem. As a result of the notification from the National Tax and Customs Administration (the 'NAV') in respect of machinery (pallet production line, yoghurt making equipment, industrial sewing machine), the placement on the market of the latter two products was prohibited. It can be stated in general that the information provision work is successful in most cases, and the customers subsequently meet the requirements applicable to them for the documentation and safety regulations prescribed by legislation. Experience shows that there is a relatively low number of striking irregularities in the area of machine tools and food machinery. However, inspections must be continued at agricultural machinery manufacturers. Meeting user demand, Hungarian manufacturers often manufacture 'specially' designed equipment without carrying out a minimum risk analysis.

The NMH MMI

On the basis of what was set out in the general part, in the case of the non-conformity of machinery, the industrial safety authority suspended the use of a machine (work equipment) used during the performance of organised work pursuant to Act XCIII of 1993. As a market surveillance measure, the industrial safety authority provided information to the consumer protection authority (KPIR alarm), and did not order withdrawal from distribution, recall from distribution, etc. The industrial safety inspectorates initiated alarms regarding restrictive or prohibitive measures taken in the case of machinery not conforming to the safety requirements, which was found during work site inspections by the industrial safety inspectors via the OMMF and the NMH MMI on a total of three occasions in the period between 2010 and 2013.

In 2010, a KPIR alarm was given in the case of a two-chamber compacting press. The non-conformity of the warning notices on the machine and the incompleteness of the user manual could be related to a serious work accident involving amputation.

In 2012, data were supplied to the KPIR system as a result of a serious work accident involving amputation, which took place on a plastic bundle cutting machine. The alarm was warranted by the non-conforming design of the protective housing of the machine.

In 2013, we arranged for a KPIR alarm after the suspension of the use of a firewood splitting machine. Reaching into the dangerous inner space of the machine was not prevented by a technical solution; therefore, there was a risk of hand amputation.

<u>10. Lifts</u>

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product-related				1
	accidents/consumer complaints				L
2.	Number of substantiated complaints by				0
	industry concerning unfair competition				0
3.	Number of inspections (total)				97
3.1	number of reactive inspections				1
3.2	number of inspections on the market				96
	surveillance authorities' own initiative				90
3.3	number of inspections prompted by				0
	the customs authorities				0
4.	Number of inspections based on:				
4.1	tests performed in laboratories				0
4.2	physical testing of products				94
5.	Number of inspections resulting in:				
5.1	finding of non-compliance				10
5.2	corrective actions taken by economic				1
	operators ('voluntary actions')				1
5.3	restrictive measures taken by market				9
	surveillance authorities				,
5.4	sanctions/penalties applied				1
6.	Number of inspections where other				
	Member States were also invited to				0
	collaborate				

Information on communication activities carried out in the 2010–2013 period (optional)

In 2013, two staff members of the Lifts and Escalators Inspectorate of ÉMI Építésügyi Minőségellenőrző Innovációs Nonprofit Kft. (ÉMI Not-for-profit Company for Quality Control and Innovation in Construction) (the 'ÉMI FMF') attended the spring meeting of ADCO in Brussels. The representatives of the ÉMI FMF operated a customer service for market surveillance cases throughout the year, handled complaint cases and received clients who came forward in connection with appeals. The experts of the ÉMI FMF took part in the commissioning test of a total of 87 new pieces of equipment from February 2013 to the end of the year, taking into account market surveillance considerations. One of the representatives of the ÉMI FMF participated in a several-day consumer protection training offered by the ICSMS during the year. The representatives of the ÉMI FMF handled the electronic correspondence on the IMI, ICSMS and ADCO Internet interfaces throughout the year.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance				60 000

	authorities in nominal terms (EUR)		
7.2	Budget available to market surveillance		
	authorities in relative terms (percentage		
	of total national budget)		
8.	Staff available to market surveillance		10
	authorities (full-time equivalent units)		10
9.	Number of inspectors available to		
	market surveillance authorities (full-time		10
	equivalent units)		

1.B. Assessment of the functioning of market surveillance activities in the lift sector

The text of the assessment is the same as that written in Chapter I.B. (due to the altogether one type of regulatory market surveillance activity).

11. <u>Ropeways</u>

No market surveillance inspections were carried out for the period of 2010 to 2013.

12. Noise emissions for outdoor equipment

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product-related accidents/consumer complaints	2	2	2	2
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total)	14	23	64	96
3.1	number of reactive inspections	0	0	1	0
3.2	number of inspections on the market surveillance authorities' own initiative	13	23	63	95
3.3	number of inspections prompted by the customs authorities	1	0	0	1
4.	Number of inspections based on:				
4.1	tests performed in laboratories	0	0	2	0
4.2	physical testing of products	17	26	67	99
5.	Number of inspections resulting in:				
5.1	finding of non-compliance	4	21	32	23
5.2	corrective actions taken by economic operators ('voluntary actions')	0	20	7	4
5.3	restrictive measures taken by market surveillance authorities	4	20	27	12
5.4	sanctions/penalties applied	2	20	25	10
6.	Number of inspections where other Member States were also invited to collaborate	0	0	0	0

Information on communication activities carried out in the 2010-2013 period (optional)

The NFH:

In its communication activities, the NFH gives priority to communicating product safety information to the consumers and economic operators. The Authority continuously publishes news, information and changes in legislation relating to market surveillance and individual product groups as well as dangerous products prohibited by the Authority on its website and Facebook account. In addition, news about the market surveillance activities of the Authority is regularly published in various media (national and local television and radio stations, Internet and written press), and information is provided about these in its official journal and newsletter. Furthermore, the Authority tries to draw the attention of the public to products posing a risk with laboratory open days, roadshows and campaigns.

The MKEH:

Our most important means of communication is our website (www.mkeh.gov.hu), on which important information on the market surveillance activities of the MKEH can be found. We publish a market surveillance newsletter on current market surveillance topics in the fresh news column of the website. After preliminary registration, newsletters are automatically sent to the registered electronic addresses. We published a total of six newsletters in the period in question.

In addition to non-governmental organisations, we regularly communicate with a number of partner authorities on the basis of contractual relationships. We exchange experience and information with the measurement and technical and safety authorities of government offices, the National Consumer Protection Authority and the National Tax and Customs Administration.

We publish our public information brochures regarding our annual activities, with the aid of which those interested are given comprehensive information on all areas falling within our competence.

		2010	2011	2012	2013
7.1	Budget available to market surveillance	12666	22105	20350	28947
	authorities in nominal terms (EUR)				
7.2	Budget available to market surveillance				
	authorities in relative terms (percentage	0.0000254	0.0000447	0.0000366	0.0000507
	of total national budget)				
8.	Staff available to market surveillance	2	2	2	2
	authorities (full-time equivalent units)				
9.	Number of inspectors available to				
	market surveillance authorities (full-time	1	1	1	1
	equivalent units)				

Information on resources (subject to availability)

1.B. Assessment of the functioning of market surveillance activities in the sector

The NFH:

The consumer protection authority did not conduct specific inspections relating to the noise emissions of equipment designed for outdoor use; the Authority checked the tests relating to the product group in the case of electrical products and machinery. As part of this, the Authority did not conduct laboratory tests; it examined the fulfilment of the labelling requirements and the documentation in the case of equipment subject to noise emissions standards.

The market surveillance authorities are requested to provide information on all sectors where they conducted market surveillance activities in the period between 2010 and 2013. A list of reference sectors is annexed to this template. Naturally, Member States authorities may also provide information at a much more detailed level than the one proposed in the reference list of sectors if this is appropriate in view of the characteristics of a specific sector.

The MKEH:

The regulatory market surveillance tasks of the Hungarian Trade Licensing Office are performed at first instance by the Market Surveillance Department with national jurisdiction.

At the beginning of the baseline period, preparation for the inspections formed the essential part of the activities. As part of this, the following tasks were carried out:

1. Devising and correction of the ME 721-01PO ('Market surveillance procedure') quality management procedure and related specimen documents, checklists and product-specific data sheets within the ISO 9001 certified quality system.

2. Exchange of experience in inspection, review and procedure issues in accordance with the provisions of the cooperation agreement concluded with the consumer protection authority in 2005, the industrial safety authority in 2007 and the mining authority in 2003.

3. Monitoring and processing of the information entered in the database of the Central Market Surveillance and Information System (the 'KPIR') and participation in the professional forums of the sector concerned in Hungary and possibly in the European Union.

Government Decree No 140 of 8 August 2001 on the noise emission requirements for, and the certification of conformity of, certain outdoor equipment ('Government Decree No 140 of 2001') is the decree transposing Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors into the Hungarian legal system.

We did not have any task relating to the obligations set forth in Section 10(2) and Section 11(1) and (2) of Government Decree No 140 in 2010 to 2013. No inquiry was received from the European Commission or the competent authorities of Member States, and no manufacturer or authorised representative established in the European Economic Area sent a copy of an EC declaration of conformity relating to an equipment type coming under the Decree to the Hungarian Trade Licensing Office.

Experience of inspections:

In 2010, the number of inspections in respect of the product group intended for targeted economic use, falling under the Noise Directive under the market surveillance programme, was still low, but increased over the subsequent years. We would additionally point out, however, that in the case of outdoor equipment inspected pursuant to the Machinery Directive, to which the Noise Directive also applied, compliance with the legislation was also sometimes verified without independent inspection minutes being taken.

No laboratory test (sound power level measurements) was performed in the area. Inspections involving visual examination and document inspection were carried out in the areas of both equipment with noise emission standards and equipment only subject to the indication of noise.

Products coming under the Directive had the appropriate noise labels and CE markings on, the manufacturers made out EC declarations of conformity (which were made out, in the case of equipment with noise emission standards, by involving an organisation registered for conformity assessment procedures).

More than half of the inspected product types fully met the relevant requirements at the time of the onsite inspections. After the inspections, market players made up for the non-conformities (reference made to an inoperative directive or inoperative standards) voluntarily or at request. No serious nonconformities were found, and no obligation or sanction was imposed by the Authority in the area.

Among the equipment inspected in 2010 to 2013, there was none that should have been notified by the manufacturer or its authorised representative to the Hungarian Trade Licensing Office or, on the initiative of our Authority, should have been entered in the database operated by the European Commission.

13. Equipment and protective systems intended for use in potentially explosive atmospheres

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product-related accidents/consumer complaints	0	0	0	0
2.	Number of substantiated complaints by industry concerning unfair competition	0	1	0	0
3.	Number of inspections (total)	10	9	5	16
3.1	number of reactive inspections	0	1	0	1
3.2	number of inspections on the market surveillance authorities' own initiative	10	8	5	15
3.3	number of inspections prompted by the customs authorities	0	0	0	0
4.	Number of inspections based on:				
4.1	tests performed in laboratories	0	0	0	0
4.2	physical testing of products	10	9	5	13
5.	Number of inspections resulting in:				
5.1	finding of non-compliance	5	6	3	11
5.2	corrective actions taken by economic operators ('voluntary actions')	0	0	0	0
5.3	restrictive measures taken by market surveillance authorities	1	3	0	0
5.4	sanctions/penalties applied	0	0	0	0
6.	Number of inspections where other Member States were also invited to collaborate	0	0	0	0

Information on communication activities carried out in the 2010-2013 period (optional)

Our most important means of communication is our website (<u>www.mkeh.gov.hu</u>), on which important information on the market surveillance activities of the MKEH can be found. We publish a market surveillance newsletter on current market surveillance topics in the fresh news column of the website. After preliminary registration, newsletters are automatically sent to the registered electronic addresses. We published a total of six newsletters in the period in question.

In addition to non-governmental organisations, we regularly communicate with a number of partner authorities on the basis of contractual relationships. We exchange experience and information with the measurement and technical and safety authorities of government offices, the National Consumer Protection Authority and the National Tax and Customs Administration.

We publish our public information brochures regarding our annual activities, with the aid of which those interested are given comprehensive information on all areas falling within our competence.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (EUR)	8012	10203	1 602	7114
7.2	Budget available to market surveillance authorities in relative terms (percentage of total national budget)	0.00002%	0.00002%	0.00000%	0.00001%
8.	Staff available to market surveillance authorities (full-time equivalent units)	0.33	0.27	0.13	0.26
9.	Number of inspectors available to market surveillance authorities (full-time equivalent units)	0.24	0.18	0.05	0.18

1.B. Assessment of the functioning of market surveillance activities in the sector

The regulatory market surveillance tasks of the Hungarian Trade Licensing Office are performed at first instance by the Market Surveillance Department with national jurisdiction. Subject to Directive 94/9/EC on the equipment and protective systems intended for use in potentially explosive atmospheres, the following product categories were inspected under annual market surveillance programmes:

- explosion-proof electric motors,
- E 85 fuel pumps,
- explosion-proof measuring devices,
- explosion-proof fans,
- explosion-proof detectors, switches, junction boxes and control units,
- explosion-proof pumps.

Of the products intended for potentially explosive environments, the competence of the Authority extends to the inspection of equipment falling within application group II (for purposes other than mining), intended for targeted economic use. During the inspections, the products were subjected to physical checks and the documentation (CE declaration of conformity, operating manual, CE type test certificate where appropriate, selected parts of the technical documentation) was reviewed. No laboratory tests were carried out in the given period.

Experience of inspections:

It can be stated in connection with the ATEX products that in many cases, the manufacturer or the distributor does not keep finished products in stock, thus we could inspect a specimen of the inspected product type only at the operator. However, there were products (e.g. pumps), where only the documentation could be checked, because no sale of the given model has been realised yet (and it was not in stock either) or the product sold was put into service abroad. It was frequent mainly in the case of distributors that some of the requested documentation was not available (e.g. EC declaration of conformity, operating manual in Hungarian, CE type test certificate), thus the clients were requested to make up for them in the inspection minutes or the order.

In 2010, we participated in a joint inspection action initiated by the ATEX ADCO, in which 10 EU Member States, including Hungary, and Turkey took part.

The number of serious non-conformities are very few in the area of ATEX. The manufacturers and distributors know the regulations, and the products more or less comply with the provisions of the

Directive and the transposing Hungarian Decree. It occurred in the case of a fan product line made in Hungary that Hungarian standards withdrawn several years ago had been applied and the conformity of the model line could not be proven with appropriate test records.

In the case of foreign-made products, the lack of an operating manual in Hungarian is a frequent nonconformity. They usually make up for them at request. In the case of two fuel pumps, one of the reasons for the prohibition of distribution was that the operating manual in Hungarian was available only in part and was not made up for.

In a few cases, withdrawn standards were referred to in the EC declaration of conformity, and they included product types where a type testing supplement conforming to the new standards was not available.

14-Pyrotechnics

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product-related				
	accidents/consumer complaints				
2.	Number of substantiated complaints by				
	industry concerning unfair competition				
3.	Number of inspections (total)				
3.1	number of reactive inspections				
3.2	number of inspections on the market surveillance authorities' own initiative				
3.3	number of inspections prompted by the customs authorities	0	0	0	0
4.	Number of inspections based on:				
4.1	tests performed in laboratories	0	0	0	0
4.2	physical testing of products	0	0	1075*	1 218*
5.	Number of inspections resulting in:				
5.1	finding of non-compliance	0	0	0	0
5.2	corrective actions taken by economic operators ('voluntary actions')				
5.3	restrictive measures taken by market surveillance authorities	0	0	0	0
5.4	sanctions/penalties applied	0	0	0	0
6.	Number of inspections where other Member States were also invited to collaborate	0	0	0	0

* The Police regularly conducted inspections in connection with the authorisation of the performance of pyrotechnical activities; as part of such inspections, they check product labels and the presence of warning notices and information by visual examination.

Information on communication activities carried out in the 2010-2013 period (optional)

The National Police Headquarters did not engage in communication activities.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance				
	authorities in nominal terms (EUR)				
7.2	Budget available to market surveillance				
	authorities in relative terms (percentage				

	of total national budget)		
8.	Staff available to market surveillance		
	authorities (full-time equivalent units)		
9.	Number of inspectors available to		
	market surveillance authorities (full-time		
	equivalent units)		

1.B. Assessment of the functioning of market surveillance activities in the sector

The Police did not engage in market surveillance activities, thus no evaluation of those was received from them.

15. Explosives for civil uses

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010–2013 period

		2010	2011	2012	2013
1.	Number of product-related accidents/consumer complaints	0	0	0	0
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total)	59	88	83	109
3.1	number of reactive inspections	0	0	0	0
3.2	number of inspections on the market surveillance authorities' own initiative	59	88	83	109
3.3	number of inspections prompted by the customs authorities	0	0	0	0
4.	Number of inspections based on:	0	0	0	0
4.1	tests performed in laboratories	0	0	0	0
4.2	physical testing of products	49	74	62	78
5.	Number of inspections resulting in:	0	0	0	0
5.1	finding of non-compliance	3	8	4	2
5.2	corrective actions taken by economic operators ('voluntary actions')	1	4	2	2
5.3	restrictive measures taken by market surveillance authorities	2	3	3	0
5.4	sanctions/penalties applied	0	1	0	0
6.	Number of inspections where other Member States were also invited to collaborate	0	1	0	0

Information on communication activities carried out in the 2010-2013 period (optional)

The mining supervisory authority did not engage in communication activities in the period reviewed while exercising its market surveillance competence.

Information on resources

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (EUR)	0	0	0	0
7.2	Budget available to market surveillance authorities in relative terms (percentage of total national budget)	0	0	0	0
8.	Staff available to market surveillance authorities (full-time equivalent units)	0	0	0	0
9.	Number of inspectors available to market surveillance authorities (full-time equivalent units)	0	0	0	0

1.B. Assessment of the functioning of market surveillance activities in the sector

On the whole, it can be stated that it is difficult to separate the exercise of the market surveillance competence during inspections from the exercise of the technical and safety and industrial safety competences of the Authority. Nonetheless, the inspections and cases where the mining supervisory authority examined whether the machinery, equipment and protective equipment used during the performance of mining activities met the safety and conformity certification requirements prescribed in the relevant legislation are included in this Report in part as inspections carried out within market surveillance competence. This is also supported by the number of inspections carried out within market surveillance competence (paragraph 3).

Comparing the numbers of inspections carried out within market surveillance competence, set forth in paragraph 3, to <u>the total number of inspections</u> carried out by the mining supervisory authority, the following figures are obtained:

3.	Total number of market surveillance inspections per year, Table 2, 3rd row	59	88	83	109
	Total number of inspections by the mining supervisory authority	1932	2038	1 689	3644
	Proportion of inspections conducted within market surveillance competence	3.05%	4.3%	4.9%	3.0%

to the total number of inspections		

For the above reasons, the exercise of market surveillance powers do not appear, or do not appear with clear boundaries, in the shift records in many cases. A more precise <u>breakdown</u> of this, <u>to a level of detail corresponding to the daily tasks</u> (inspections) <u>completed</u>, <u>appears as a goal to be achieved</u> later under any circumstances.

It must be pointed out that no specific and segregated resources to be used for this purpose are set aside in the budget of the mining supervisory authority in connection with the market surveillance activities. The costs incurred in respect of the activities performed within market surveillance competence may be calculated in proportion to the inspections.

16. Appliances burning gaseous fuels

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product-related accidents/consumer complaints	5	2	7	4
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total)	8	18	55	11
3.1	number of reactive inspections	2	0	3	2
3.2	number of inspections on the market surveillance authorities' own initiative	6	18	52	8
3.3	number of inspections prompted by the customs authorities	0	0	0	1
4.	Number of inspections based on:				
4.1	tests performed in laboratories	0	0	0	0
4.2	physical testing of products	14	18	55	13
5.	Number of inspections resulting in:				
5.1	finding of non-compliance	1	7	46	5
5.2	corrective actions taken by economic operators ('voluntary actions')	0	0	2	0
5.3	restrictive measures taken by market surveillance authorities	3	0	1	3
5.4	sanctions/penalties applied	1	0	0	0
6.	Number of inspections where other Member States were also invited to collaborate	0	0	0	0

Information on communication activities carried out in the 2010-2013 period (optional)

The NFH:

In its communication activities, the NFH gives priority to communicating product safety information to the consumers and economic operators. The Authority continuously publishes news, information and changes in legislation relating to market surveillance and individual product groups as well as dangerous products prohibited by the Authority on its website and Facebook account. In addition, news about the market surveillance activities of the Authority is regularly published in various media (national and local television and radio stations, Internet and written press), and information is provided about these in its official journal and newsletter. Furthermore, the Authority tries to draw the attention of the public to products posing a risk with laboratory open days, roadshows and campaigns.

The MKEH:

Our most important means of communication is our website (www.mkeh.gov.hu), on which important information on the market surveillance activities of the MKEH can be found. We publish a market surveillance newsletter on current market surveillance topics in the fresh news column of the website. After preliminary registration, newsletters are automatically sent to the registered electronic addresses. We published a total of six newsletters in the period in question.

We drew the attention of distributors and users to dangerous products found during the inspections in announcements on the website.

In addition to non-governmental organisations, we regularly communicate with a number of partner authorities on the basis of contractual relationships. We exchange experience and information with the measurement and technical and safety authorities of government offices, the Hungarian Authority for Consumer Protection and the National Tax and Customs Administration.

We publish our public information brochures regarding our annual activities, with the aid of which those interested are given comprehensive information on all areas falling within our competence.

		2010	2011	2012	2013
7.1	Budget available to market surveillance	38 596	74035	55789	70526
	authorities in nominal terms (EUR)				
7.2	Budget available to market surveillance				
	authorities in relative terms (percentage	0.0000776	0.000149	0.0001	0.000123
	of total national budget)				
8.	Staff available to market surveillance	4	4	4	4
	authorities (full-time equivalent units)				
9.	Number of inspectors available to				
	market surveillance authorities (full-time	2	2	3	2
	equivalent units)				

Information on resources (subject to availability)

1.B. Assessment of the functioning of market surveillance activities in the sector

The NFH:

Since primarily the MKEH has competence to inspect products coming under Directive 2009/142/EC relating to appliances burning gaseous fuels (GAD), the consumer protection authority did not carry out any comprehensive thematic review for the product group. The Authority verified only the fulfilment of the labelling requirements and the existence of the documentation in a few cases on the basis of submissions by consumers received in the case of products intended for consumers.

The MKEH:

The regulatory market surveillance tasks of the Hungarian Trade Licensing Office are performed at first instance by the Market Surveillance Department with national jurisdiction.

In 2010, preparation for the inspections formed the essential part of the market surveillance activities in the sector. As part of this, the following tasks were carried out:

1. Devising and correction of the ME 721-01PO ('Market surveillance procedure') quality management procedure and related specimen documents, checklists and product-specific data sheets within the ISO 9001 certified quality system.

2. Exchange of experience in inspection, review and procedure issues in accordance with the provisions of the cooperation agreement concluded with the consumer protection authority in 2005, the industrial safety authority in 2007 and the mining authority in 2003.

3. Monitoring and processing of the information entered in the database of the Central Market Surveillance and Information System (the 'KPIR') and participation in the professional forums of the sector concerned in Hungary and possibly in the European Union.

With respect to the product group intended for targeted economic use, coming under Directive 2009/142/EC relating to appliances burning gaseous fuels (GAD), the following product categories were inspected under the market surveillance programme:

- large kitchen gas appliances,
- baking machines,
- absorption refrigerators,
- bakery product and milk breed bakers,
- water heaters.

The subject-matter of the inspection is the product itself, its CE marking, the accompanying documentation, the EC declaration of conformity and, if necessary, the technical documentation compiled in accordance with legislation, in whole or in part.

Experience of inspections:

- the declaration of conformity contains a repealed directive;
- warning notices or ones in a language other than Hungarian missing on the equipment or packaging;
- target country not shown;
- documentation not available in Hungarian.

Two inspections with significant effects were carried out in this area of inspections:

- testing of gas convectors from outside the European Union and

- inspection of ('home' made) chimney cake ovens; in respect of the majority of the products, the manufacturers did not assess conformity and a distributor [sic] discontinued manufacturing the products.

In the case of a large kitchen gas appliance from a third country (the procedure was initiated upon notice received from the NAV), its placement on the market was prohibited. Furthermore, a bathroom water heater having caused fatal carbon monoxide poisoning was subjected to inspection: the

information label on the equipment was misleading; as a consequence of our investigations, we filed a criminal report with the competent police station.

17. Measuring instruments, non-automatic weighing instruments and prepackaged products

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product-related accidents/consumer complaints	24	30	31	32
2.	Number of substantiated complaints by industry concerning unfair competition	2	4	6	3
3.	Number of inspections (total)	102	171	361	223
3.1	number of reactive inspections	23	22	223	26
3.2	number of inspections on the market surveillance authorities' own initiative	79	149	338	197
3.3	number of inspections prompted by the customs authorities	0	0	0	0
4.	Number of inspections based on:				
4.1	tests performed in laboratories	33	23	14	69
4.2	physical testing of products	83	134	61	91
5.	Number of inspections resulting in:				
5.1	finding of non-compliance	55	65	27	81
5.2	corrective actions taken by economic operators ('voluntary actions')	0	0	0	1
5.3	restrictive measures taken by market surveillance authorities	15	23	22	45
5.4	sanctions/penalties applied	13	14	18	37
6.	Number of inspections where other Member States were also invited to collaborate	0	0	0	0

Information on communication activities carried out in the 2010–2013 period (optional)

The NFH:

In its communication activities, the NFH gives priority to communicating consumer protection and product safety information to the consumers and economic operators. The Authority continuously publishes news, information and changes in legislation relating to consumer protection, market surveillance and the individual product groups as well as dangerous products prohibited by the Authority on its website and Facebook account. In addition, news about the consumer protection and

market surveillance activities of the Authority is regularly published in various media (national and local television and radio stations, Internet and written press), and information is provided about these in its official journal and newsletter. The Authority regularly publishes its inspection experience relating to checking the weight of pre-packaged products and food, since the public always pays attention to this area.

The MKEH:

Our most important means of communication is our website (www.mkeh.gov.hu), on which important information on the market surveillance activities of the MKEH can be found. We publish a market surveillance newsletter on current market surveillance topics in the fresh news column of the website. After preliminary registration, newsletters are automatically sent to the registered electronic addresses. We published a total of six newsletters in the period in question.

In addition to non-governmental organisations, we regularly communicate with a number of partner authorities on the basis of contractual relationships. We exchange experience and information with the measurement and technical and safety authorities of government offices, the Hungarian Authority for Consumer Protection and the National Tax and Customs Administration.

We publish our public information brochures regarding our annual activities, with the aid of which those interested are given comprehensive information on all areas falling within our competence.

		2010	2011	2012	2013
7.1	Budget available to market surveillance	16175	27929	29122	21 929
	authorities in nominal terms (EUR)				
7.2	Budget available to market surveillance				
	authorities in relative terms (percentage	0.0000325	0.0000565	0.0000524	0.0000383
	of total national budget)				
8.	Staff available to market surveillance	2	3	3	3
	authorities (full-time equivalent units)				
9.	Number of inspectors available to				
	market surveillance authorities (full-time	1	2	2	2
	equivalent units)				

Information on resources (subject to availability)

1.B. Assessment of the functioning of market surveillance activities in the sector

The NFH:

On the basis of its previous inspection experience gained in food trade and consumer complaints, the consumer protection authority regularly checked the weight of pre-packaged food in the past period in order to filter out regularly appearing misleading trading practices and to facilitate that the nominal quantity stated on the packaging corresponds to the actual quantity of the product.

During the measurement of sample items, it occurred in a number of cases that although the laboratory measures less than the net weight value shown on the label of the product, the weight shortage did not

exceed the still acceptable rate of negative difference. In addition, it must also be mentioned that during the measurement of 20 sample items per product sample, it occurred with regard to a few items that a quantity larger than the net weight shown was packaged.

In connection with the items complained about, it can be stated that mostly foodstuffs that may be considered essential (flour, rice, wheat meal, salt and castor sugar) did not comply with the relevant legislative provisions, which raises serious concerns, since the highest number of consumers and, together with this, perhaps those in the most vulnerable financial situation, become concerned persons through these very products.

In addition, however, it must also be noted that in addition to a weight shortage, the Authority found overfill in the case of some 1000 g product sample items (1029.17 and 1089.95 g).

The MKEH:

The regulatory market surveillance tasks of the Hungarian Trade Licensing Office are performed at first instance by the Market Surveillance Department with national jurisdiction. With respect to products coming under Directive 2004/22/EC on measuring instruments (MID) and Directive 2009/23/EC on non-automatic weighing instruments (NAWI), the following product categories were inspected under the market surveillance programme:

- heat meters,
- taximeters,
- gas meters,
- dimensional measuring instruments,
- water meters,
- measuring systems for liquids other than water,
- exhaust gas analysers,
- electricity meters,
- material measures,
- non-automatic weighing instruments.

The subject-matter of the inspection is the product itself, its CE marking, the accompanying documentation, the EC declaration of conformity and, if necessary, the technical documentation compiled in accordance with legislation, in whole or in part.

Experience of inspections:

The lack of product documentation was typical; the manufacturer or the distributor made up for it. Deficiencies occurring in the case of non-automatic weighing instruments were non-conforming markings, missing labels, inadequate sealing of the measuring device and reference made to an old directive in the EC declaration of conformity.

With regard to non-automatic weighing instruments (NAWI Directive), a comprehensive test program was launched in connection with one of the models of the inspected weighing instruments, which was closed with a test report completed in April 2013. On the basis of this, the Authority called upon the distributors and the manufacturer to place only measuring devices conforming to EC type examination certificate on the market, and jointly with the MKEH Metrology Authority, notified the measurement and technical safety authorities of government offices in connection with certification (EC verification).

In the case of water meters, certification of the inspected equipment and its documentation were satisfactory. The manufacturer or distributor presented the documentation certifying conformity.

18. Radio and telecommunications equipment, EMC

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product-related accidents/consumer complaints	35	22	30	44
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	1
3.	Number of inspections (total)	98	89	104	128
3.1	number of reactive inspections	12	9	12	12
3.2	number of inspections on the market surveillance authorities' own initiative	84	77	85	95
3.3	number of inspections prompted by the customs authorities	2	3	7	21
4.	Number of inspections based on:				
4.1	tests performed in laboratories	80	73	78	91
4.2	physical testing of products	90	82	91	102
5.	Number of inspections resulting in:				
5.1	finding of non-compliance	18	7	22	28
5.2	corrective actions taken by economic operators ('voluntary actions')	0	0	0	1
5.3	restrictive measures taken by market surveillance authorities	20	8	21	29
5.4	sanctions/penalties applied	12	2	6	9
6.	Number of inspections where other Member States were also invited to collaborate	0	0	0	2

Information on communication activities carried out in the 2010-2013 period (optional)

The NFH:

In its communication activities, the NFH gives priority to communicating product safety information to the consumers and economic operators. The Authority continuously publishes news, information and changes in legislation relating to market surveillance and individual product groups as well as dangerous products prohibited by the Authority on its website and Facebook account. In addition, news about the market surveillance activities of the Authority is regularly published in various media (national and local television and radio stations, Internet and written press), and information is also provided about these in its official journal and newsletter. Furthermore, the Authority tries to draw the attention of the public to products posing a risk with laboratory open days, roadshows and campaigns.

The MKEH:

Our most important means of communication is our website (www.mkeh.gov.hu), on which important information on the market surveillance activities of the MKEH can be found. We publish a market surveillance newsletter on current market surveillance topics in the fresh news column of the website. After preliminary registration, newsletters are automatically sent to the registered electronic addresses. We published a total of six newsletters in the period in question.

In addition to non-governmental organisations, we regularly communicate with a number of partner authorities on the basis of contractual relationships. We exchange experience and information with the measurement and technical and safety authorities of government offices, the Hungarian Authority for Consumer Protection and the National Tax and Customs Administration.

We publish our public information brochures regarding our annual activities, with the aid of which those interested are given comprehensive information on all areas falling within our competence.

		2010	2011	2012	2013
7.1	Budget available to market surveillance	25263	42807	38245	36842
	authorities in nominal terms (EUR)				
7.2	Budget available to market surveillance				
	authorities in relative terms (percentage	0.0000507	0.0000866	0.0000688	0.0000646
	of total national budget)				
8.	Staff available to market surveillance	13	13	13	13
	authorities (full-time equivalent units)				
9.	Number of inspectors available to				
	market surveillance authorities (full-time	12	12	12	12
	equivalent units)				

Information on resources (subject to availability)

1.B. Assessment of the functioning of market surveillance activities in the sector

The NFH:

The consumer protection authority did not conduct specific inspections relating to electromagnetic compatibility. The Authority checked the tests relating to the product group in the case of electrical products and machinery.

As part of this, the Authority did not conduct laboratory tests; it examined the fulfilment of the labelling requirements and the documentation in the case of products intended for consumers and subject to the relevant legislation.

The MKEH

The regulatory market surveillance tasks of the Hungarian Trade Licensing Office are performed at first instance by the Market Surveillance Department with national jurisdiction. Products intended for

targeted economic use, coming under Directive 2004/108/EC relating to electromagnetic compatibility (EMC) were subjected to inspections. The market surveillance under the EMC was removed from the responsibilities of the MKEH as of 2 February 2013.

The subject-matter of the inspection is the product itself, its CE marking, the accompanying documentation, the EC declaration of conformity and, if necessary, the technical documentation compiled in accordance with legislation, in whole or in part.

Experience of inspections:

At the beginning of the baseline period, preparation for the inspections formed the essential part of the activities. As part of this, the following tasks were carried out:

1. Devising and correction of the ME 721-01PO ('Market surveillance procedure') quality management procedure and related specimen documents, checklists and product-specific data sheets within the ISO 9001 certified quality system.

2. Exchange of experience in inspection, review and procedure issues in accordance with the provisions of the cooperation agreement concluded with the consumer protection authority in 2005, the industrial safety authority in 2007 and the mining authority in 2003.

3. Monitoring and processing of the information entered in the database of the Central Market Surveillance and Information System (the 'KPIR') and participation in the professional forums of the sector concerned in Hungary and possibly in the European Union.

According to the data shown in the table, a low number of product types were inspected only in accordance with the EMC Directive. However, in the case of the products tested in accordance with the LVD Directive (to which the EMC Directive also applied), compliance with the EMC Directive was also checked as part of the given inspection.

Among the products examined primarily in accordance with the EMC Directive, frequency changers with LED light sources proved to be conforming during the inspections. In the case a fixed electronic speed sign, the distributor had to be called upon to bring the product into compliance, which the client carried out.

National Media and Infocommunications Authority (the 'NMHH'):

The primary goal of the inspections was, in addition to the protection of consumers, to protect manufacturers that place their equipment on the market in accordance with the relevant standards and requirements. Other goals are to maintain the safety of public electronic communication networks and to protect the eligible and regular users of radio frequencies against interference generated by equipment not conforming to the regulations. This is to be achieved by filtering out non-conforming equipment placed on the market and applying sanctions against offenders. The inspections are planned and the tested equipment is selected from the offerings available in shops, department stores and other distributors by taking into account many years of market surveillance experience and equipment types and models found to be non-conforming in the previous years (risk-based market surveillance).

The EMC tests affected mostly light sources, electrically driven machine tools and power supply units for various electronic devices in the period reported on, but attention was also paid to the immunity testing of terminal telecommunications equipment. The market surveillance organisation closely cooperates with the organisational unit belonging to the organisation of the Authority and investigating radio frequency interferences. In the case of interferences occurring due to high-frequency signals or a side effect indicated by them, we check whether the equipment causing it is available in the domestic market. The inspections and the restrictive measures taken against non-conforming equipment and economic operators distributing them had a proper effect on the market. The situation improved in the area of inadequately designed terminal telecommunications equipment and tested light sources, DIY devices and household appliances in the period reported on. The manufacturers try to eliminate the defects found, and the willingness of the traders and distributors to cooperate in the procedures of the authorities also shows an improving trend.

19. Radio and telecommunications equipment, RTTE

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product-related accidents/consumer complaints	0	0	0	0
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total)	141	182	160	197
3.1	number of reactive inspections	0	0	0	0
3.2	number of inspections on the market surveillance authorities' own initiative	141	182	160	190
3.3	number of inspections prompted by the customs authorities	0	0	0	7
4.	Number of inspections based on:	141	182	160	197
4.1	tests performed in laboratories	141	182	160	190
4.2	physical testing of products	141	182	160	197
5.	Number of inspections resulting in:	38	50	34	49
5.1	finding of non-compliance	38	50	34	49
5.2	corrective actions taken by economic operators ('voluntary actions')	0	0	0	0
5.3	restrictive measures taken by market surveillance authorities	0	0	0	0
5.4	sanctions/penalties applied	38	50	34	51
6.	Number of inspections where other Member States were also invited to collaborate	0	0	0	2

Information on communication activities carried out in the 2010–2013 period (optional)

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance				
	authorities in nominal terms (EUR)				
7.2	Budget available to market surveillance				
	authorities in relative terms (percentage				
	of total national budget)				
8.	Staff available to market surveillance				
	authorities (full-time equivalent units)				
9.	Number of inspectors available to				
	market surveillance authorities (full-time				
	equivalent units)				

1.B. Assessment of the functioning of market surveillance activities in the sector

The primary goal of the equipment surveillance activities was, in addition to the protection of consumers, to protect manufacturers that place their equipment on the market in accordance with the relevant standards and requirements. Other goals are to maintain the safety of public electronic communication networks and to protect the eligible and regular users of radio frequencies against interference generated by equipment not conforming to the regulations. The Authority wishes to achieve this by filtering out non-conforming equipment placed on the market and applying sanctions against offenders.

The inspections are planned and the tested equipment is selected from the offerings available in shops, department stores and other distributors by taking into account many years of market surveillance experience and equipment types and models found to be non-conforming in the previous years (riskbased market surveillance). In addition to conventional shop retail, the Authority also pays special attention to equipment sold on the Internet, in Hungarian webshops. In coordination with partner authorities operating in other Member States of the European Economic Area, international campaigns are also held regularly, which focus on individual equipment types or problems that can be felt in several Member States. It is also increasingly frequent that the Authority examines equipment to be imported through the external customs borders of the Union as indicated by the customs agencies. The market surveillance organisation closely cooperates with the organisational unit integrated with the Authority investigating radio frequency interferences. In the case of interferences attributable to nonconforming radio equipment indicated by them, we check whether the equipment causing it is available in the domestic market. In addition to FM transmitters and wireless doorbells and gate openers, which have been subjected to increased inspection for years, e.g. WLAN routers operating at 5 GHz sold in the domestic market were tested so in 2013 within international cooperation, with special regard to the fact whether they apply the protective measures prescribed by the standards in order to avoid interference by weather radars. The inspection was closed with a positive result: such equipment available in the domestic market met the specifications of the standards.

The inspections and the restrictive measures taken against non-conforming equipment and economic operators distributing them had a proper effect on the market. Among terminal telecommunications equipment, the number of non-conforming models has been very low for years and, therefore, there is a decreasing number of new equipment in this market anyway. In the case of radio equipment, generalisation is more difficult due to its great variety. It can be stated in general that the situation improved in the period reported on. The manufacturers try to eliminate the defects found, and the willingness of the traders and distributors to cooperate in the procedures of the authorities also shows an improving trend. At the same time, e.g. the proportion of non-conforming equipment continues to be very high, 60% to 80%, among FM transmitters or PMR (Personal Mobile Radio) transceivers. Similarly, there are also many issues with wireless doorbells and gate openers: in their case, too, 50% of the tested equipment proved to be non-conforming in the period reported on. Therefore, it is warranted to continue their inspections under any circumstances.

20. Electrical appliances and equipment coming under the Low Voltage Directive (LVD)

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product-related accidents/consumer complaints	111	67	80	125
2.	Number of substantiated complaints by industry concerning unfair competition	2	1	1	6
3.	Number of inspections (total)	2080	2 3 2 6	1963	1 892
3.1	number of reactive inspections	711	700	491	520
3.2	number of inspections on the market surveillance authorities' own initiative	1 362	1 620	1 452	1 340
3.3	number of inspections prompted by the customs authorities	7	6	20	32
4.	Number of inspections based on:	0	0	0	0
4.1	tests performed in laboratories	192	179	150	133
4.2	physical testing of products	4140	4 008	3 6 2 0	3 0 2 6
5.	Number of inspections resulting in:	0	0	0	0
5.1	finding of non-compliance	508	618	471	512
5.2	corrective actions taken by economic operators ('voluntary actions')	4	0	6	3
5.3	restrictive measures taken by market surveillance authorities	322	480	372	398
5.4	sanctions/penalties applied	250	350	271	318
6.	Number of inspections where other Member States were also invited to collaborate	0	0	1	0

Information on communication activities carried out in the 2010-2013 period (optional)

The NFH:

In its communication activities, the NFH gives priority to communicating product safety information to the consumers and economic operators. The Authority continuously publishes news, information and changes in legislation relating to market surveillance and individual product groups as well as dangerous products prohibited by the Authority on its website and Facebook account. In addition, news about the market surveillance activities of the Authority is regularly published in various media (national and local television and radio stations, Internet and written press), and information is also provided about these in its official journal and newsletter. Furthermore, the Authority tries to draw the attention of the public to products posing a risk with laboratory open days, roadshows and campaigns.

The MKEH:

The most important means of communication is the website (www.mkeh.gov.hu), on which important information on the market surveillance activities of the MKEH can be found. A market surveillance newsletter is published on current market surveillance topics in the fresh news column of the website. After preliminary registration, newsletters are automatically sent to the registered electronic addresses. A total of six newsletters were published in the period in question.

At the beginning of the reporting period, ultraviolet radiation emitted by sunbeds had an often hazardous level for users in Hungary, similarly to other Member States. To tackle the problem, the European Commission established the joint Sunbeds 1 and 2 action coordinated by Prosafe, which was joined by the MKEH. During the market surveillance work, the Market Surveillance Department established a close communication relationship with the two Hungarian sunbed organisations. A number of meetings and consultations were held with the representatives of other trades (UV lamp distributors and a UV lamp manufacturer). At the end of February 2010, a market surveillance forum was held on the joined market surveillance inspection of sunbeds in the EU for the representatives of the sunbed profession. Nearly 100 persons attended the forum. We could directly address the economic operators and users concerned by means of the websites of the organisations and at the forums and meetings organised by the organisations (to which the representative of our Authority was regularly invited).

A study of the SCCP scientific committee on the biological effect of ultraviolet radiation on human health, with special regards to sunbeds used for cosmetic purposes, was translated into Hungarian and published on their website.

The purpose and results of the joint action were regularly published as newsletters on the official website of the MKEH. During the action, a press release was issued, and with regard to the high interest of the media, the Head of the Market Surveillance Department gave radio and TV interviews on a number of occasions.

We continue to give presentations regularly on the legislation relating to the current issue in other areas coming under the LVD at the conferences and in-service trainings of professional organisations. For example, a written material – an interview – about the distribution requirements for electrical products was published in the Journal entitled '*Villanyszerelők Lapja*' (Electricians' Journal).

In addition to non-governmental organisations, we regularly communicate with a number of partner authorities on the basis of contractual relationships. We exchange experience and information with the measurement and technical and safety authorities of government offices, the Hungarian Authority for Consumer Protection and the National Tax and Customs Administration.

They publish their public information brochures regarding their annual activities, with the aid of which those interested are given comprehensive information on all areas falling within our competence.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance	633228	709 403	749578	671754
	authorities in nominal terms (EUR)				
7.2	Budget available to market surveillance				
	authorities in relative terms (percentage	0.00127	0.00143	0.00134	0.00117
	of total national budget)				
8.	Staff available to market surveillance	36	38	35	39
	authorities (full-time equivalent units)				
9.	Number of inspectors available to				
	market surveillance authorities (full-time	30	32	29	32
	equivalent units)				

1.B. Assessment of the functioning of market surveillance activities in the sector

The NFH:

In the 2010 to 2013 period, the consumer protection Authority launched nearly 20 thematic reviews for the verification of compliance with the provisions of the LVD Directive (and Decree No 79 of 31 December 1997 of Minister of Industry, Trade and Tourism on the safety requirements for certain electrical products adapting it and the assessment of conformity thereto), and conducted investigations as part of inspections other than thematic reviews (e.g. alarms received from the customs authority).

It can be stated that the Authority conducted inspections regarding almost all electrical products found in households. The Authority found the highest number of non-conformities posing a serious hazard to consumers in the case of lighting engineering products, of which lighting chains, rechargeable torches and lighting fittings that help night-time orientation (directional lights) are to be specifically pointed out.

It is typical that in the case of inspected non-conforming products, conformity assessment procedures were not conducted or were not appropriately conducted and, therefore, as a result of their nature, they posed an electrical shock hazard to users, but due to the use of parts with parameters considerably inferior to those prescribed (e.g. a wire core diameter less than prescribed), they also posed a risk of burns, among others.

The Authority also found a number of deficiencies in respect of the marking requirements for the inspected products set by harmonised standards. It continues to be typical in commerce that products even without markings allowing their basic identification (manufacturer, identification marking of the product) are also available commercially. CE conformity markings are mostly shown on electrical products (unlawfully in the case of non-conforming products), however, on the basis of experience, it continues to be a problem in countless cases in respect of complying with the formal design prescribed by legislation and the minimum size prescribed.

In the case of the EC declarations of conformity and the technical documentation, the Authority found on a high number of occasions that they were not available, did not relate to the inspected products or could not be accepted for some other reason (e.g. the parts or design of a certified product do(es) not match the inspected product).

The MKEH:

The regulatory market surveillance tasks of the Hungarian Trade Licensing Office are performed at first instance by the Market Surveillance Department with national jurisdiction.

With respect to the product group intended for targeted economic use, coming under Directive 2006/95/EC (LVD) on low-voltage electrical equipment, the following product groups were subjected to inspection under the market surveillance programme:

- devices used for the ultraviolet irradiation of the skin,
- commercial dispensers and vending machines,
- switching cabinets,
- infra panels, radiators,
- LED lamps and lighting fittings,
- city lights,
- grills,
- multimeters,
- swimming pool hair dryers,
- electric car chargers.

The subject-matter of the inspection is the product itself, its CE marking, the accompanying documentation, the EC declaration of conformity and, if necessary, the technical documentation compiled in accordance with legislation, in whole or in part.

The Authority participated in the 2nd joint sunbed action organised under the management of the Netherlands, which began in January 2010 and lasted until the end of 2011. The campaign took place in cooperation with 12 Member States and with the co-financing of the EU Commission. As a result of the action, a perceptible improvement was achieved in the area of sunbeds in Hungary with respect to the conformity of ultraviolet radiation and the information provided to customers. The testing of sunbeds for UV radiation also continued after the action, and according to the results, the proportion of equipment emitting high radiation continued to decrease. However, the number of non-conformities is still significant, because the majority of operators use tubes that have radiation values higher than permitted or operate their equipment provided with tubes with permitted radiation levels at higher output levels. The Department continues to pay special attention to the inspection and testing of this product type.

The inspections of imported electrical equipment launched at the request of the NAV (meat grills, copiers, LED street lamps) were closed with the prohibition of the placement of the product on the market on one occasion.

Within the inspected electrical switching cabinet and main distributor product type, several models proved to be non-conforming. The smaller manufacturers do not know the relevant legislation, did not apply the prescribed conformity assessment procedure in several cases, did not place CE markings on the products, and did not prepare user manuals.

On the basis of the results, it can be seen on the basis of the results that it is still necessary to inspect and test products coming under the LVD Directive. During the inspections, special importance should be attached, in addition to the physical testing of the products, to the existence of documentation demonstrating compliance and its review in detail.

21. Electrical and electronic equipment and batteries coming under the Directive on the restriction of the use of certain hazardous substances (RoSH) and the Directive on the waste of television sets (WEEE)

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010–2013 period

		2010	2011	2012	2013
1.	Number of product-related accidents/consumer complaints	4	6	8	5
2.	Number of substantiated complaints by industry concerning unfair competition	1	0	0	0
3.	Number of inspections (total)	30	23	16	27
3.1	number of reactive inspections	14	1	2	2
3.2	number of inspections on the market surveillance authorities' own initiative	17	22	14	25
3.3	number of inspections prompted by the customs authorities	0	0	0	0
4.	Number of inspections based on:	0	0	0	0
4.1	tests performed in laboratories	0	0	0	0
4.2	physical testing of products	21	26	27	12
5.	Number of inspections resulting in:	0	0	0	0
5.1	finding of non-compliance	3	16	5	18
5.2	corrective actions taken by economic operators ('voluntary actions')	2	0	1	1
5.3	restrictive measures taken by market surveillance authorities	3	16	7	3
5.4	sanctions/penalties applied	2	1	6	2
6.	Number of inspections where other Member States were also invited to collaborate	0	0	0	0

Information on communication activities carried out in the 2010-2013 period (optional)

The NFH:

In its communication activities, the NFH gives priority to communicating product safety information to the consumers and economic operators. The Authority continuously publishes news, information and changes in legislation relating to market surveillance and individual product groups as well as dangerous products prohibited by the Authority on its website and Facebook account. In addition, news about the market surveillance activities of the Authority is regularly published in various media (national and local television and radio stations, Internet and written press), and information is also provided about these in its official journal and newsletter. Furthermore, the Authority tries to draw the attention of the public to products posing a risk with laboratory open days, roadshows and campaigns.

The MKEH:

Our most important means of communication is our website (www.mkeh.gov.hu), on which important information on the market surveillance activities of the MKEH can be found. We publish a market surveillance newsletter on current market surveillance topics in the fresh news column of the website. After preliminary registration, newsletters are automatically sent to the registered electronic addresses. We published a total of six newsletters in the period in question.

In addition to non-governmental organisations, we regularly communicate with a number of partner authorities on the basis of contractual relationships. We exchange experience and information with the measurement and technical and safety authorities of government offices, the Hungarian Authority for Consumer Protection and the National Tax and Customs Administration.

We publish our public information brochures regarding our annual activities, with the aid of which those interested are given comprehensive information on all areas falling within our competence.

		2010	2011	2012	2013
7.1	Budget available to market surveillance	27012	45964	43612	41 637
	authorities in nominal terms (EUR)				
7.2	Budget available to market surveillance				
	authorities in relative terms (percentage	0.0000543	0.0000930	0.0000784	0.0000730
	of total national budget)				
8.	Staff available to market surveillance	2	2	2	3
	authorities (full-time equivalent units)				
9.	Number of inspectors available to				
	market surveillance authorities (full-time	1	1	1	2
	equivalent units)				

Information on resources (subject to availability)

1.B. Assessment of the functioning of market surveillance activities in the sector

The NFH:

The consumer protection authority did not conduct comprehensive inspections and laboratory tests in the past period in connection with the RoHS 1 and RoHS 2 Directives. In combination with the thematic review of electrical products, the Authority verified whether the products coming under the directives met the relevant labelling requirements (RoHS) and had the appropriate documentation. In addition, the Authority also examined the fulfilment of the requirements in a few cases of consumer complaints about this product group.

It is important to point out, furthermore, that the environmental protection authority had a more comprehensive competence in relation to the RoHS 1 Directive, thus this Authority may also possess relevant laboratory results.

The MKEH:

The regulatory market surveillance tasks of the Hungarian Trade Licensing Office are performed at first instance by the Market Surveillance Department with national jurisdiction. In the European Union, the previous Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) was replaced by Directive 2011/65/EU at the beginning of 2013, pursuant to which Government Decree No 374 of 18 December 2012 entered into force also in Hungary on 3 January 2013. According to the new regulation, RoHS conformity was included in the scope of the CE regulation. Consequently, compliance with the restriction on hazardous substances is verified by the market surveillance authorities in the future (previously, this task was performed by the environmental protection authorities).

In 2013, of the product groups included in the 10 categories under the Directive, the Authority inspected:

- 9. Monitoring and control instruments, including industrial monitoring and control instruments,
- 10. Automatic dispensers, and
- Other electrical and electronic equipment not covered by any of these 10 categories.

Last year, equipment belonging to the product group of automatic dispensers was inspected. The vast majority of Hungarian manufacturers did not apply this piece of legislation, in fact, they did not make their products comply with the old RoHS Directive either. Even the vast majority of other European manufacturers, too, still refer to the old RoHS directive in their RoHS declarations attached to their products.

22. Chemicals

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010-2013 period

	· · · · · · · · · · · · · · · · · · ·	2010	2011	2012	2013
1.	Number of product-related accidents/consumer complaints	13	13	16	13
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total)	4782	3907	3374	2711
3.1	number of reactive inspections	36	40	29	23
3.2	number of inspections on the market surveillance authorities' own initiative	4586	3869	3 3 5 6	2688
3.3	number of inspections prompted by the customs authorities	0	0	0	0
4.	Number of inspections based on:	0	0	0	0
4.1	tests performed in laboratories	64	35	49	37
4.2	physical testing of products	5126	4410	4739	3753
5.	Number of inspections resulting in:	0	0	0	0
5.1	finding of non-compliance	311	665	319	876
5.2	corrective actions taken by economic operators ('voluntary actions')	0	1	0	0
5.3	restrictive measures taken by market surveillance authorities	59	146	71	108
5.4	sanctions/penalties applied	45	49	50	38
6.	Number of inspections where other Member States were also invited to collaborate	0	0	0	0

(We note that the ÁNTSZ did not provide any data for 2010, only the NFH did.)

Information on communication activities carried out in the 2010-2013 period (optional)

In its communication activities, the NFH gives priority to communicating product safety information to the consumers and economic operators. The Authority continuously publishes news, information and changes in legislation relating to market surveillance and individual product groups as well as dangerous products prohibited by the Authority on its website and Facebook account. In addition, news about the market surveillance activities of the Authority is regularly published in various media (national and local television and radio stations, Internet and written press), and information is also provided about these in its official journal and newsletter. Furthermore, the Authority tries to draw the attention of the public to products posing a risk with laboratory open days, roadshows and campaigns.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (EUR)	50771	103 859	92982	85964
7.2	Budget available to market surveillance	0.000102	0.00021	0.000167	0.00015
	authorities in relative terms (percentage	0.000102	0.00021	0.000107	0.00015
	of total national budget)				
8.	Staff available to market surveillance	3	631	601	577
	authorities (full-time equivalent units)				
9.	Number of inspectors available to	2	221	227	224
	market surveillance authorities (full-time	2	321	327	334
	equivalent units)				

(We note that the ÁNTSZ did not provide any data for 2010, only the NFH did.)

1.B. Assessment of the functioning of market surveillance activities in the sector

The NFH:

In the past period, the consumer protection authority examined the following product groups:

- paints and lacquers
- detergents
- household chemical products.

In the case of **paints and lacquers**, the Authority examined the organic solvent content of commercially available paint products every year due to an EU commitment. In the past four years, all but a few of the test samples met the requirements for VOC content. In 2013, 50% of the test samples, in 2012, 30% and in 2011, 41% were found unsatisfactory in respect of labelling and special markings. A significant proportion of the deficiencies found during the inspections affected product safety (e.g. tactile warning labels, hazard symbols and lack of R and S phrases).

The experience of the inspections shows that despite regular inspections, there has been no drop in the complaint ratio in the case of this product group.

In the case of **detergents**, the concentrations of phosphates and other phosphorus compounds were limited in consumer detergents in 2012. During the market surveillance inspections of detergents, the Authority firstly examined the performance of statutory obligations relating to the labelling and dose of the products and, secondly, performed laboratory analyses to determine the total phosphorus content of the commercially available detergents as well as the total surfactant content and the net weight certified on the label of the products in order to establish to what extent the quality of the products conformed to the information given on the packaging. Relatively few deficiencies (complaint ratio: 17.8%) can be found in respect of the distribution conditions and labelling of commercially available detergents. Most deficiencies occurred in connection with the display of website addresses, accessibility of websites and the downloadability of the list of components.

On the basis of the laboratory tests, in all except four cases the laboratory found the measured composition data of the inspected products to be equal to the values claimed by the manufacturers on the label. The manufacturers of the sampled products fully complied with the restrictions of the Union applicable to the phosphorous content of household detergents. During our laboratory analyses, the

laboratory also measured the common salt content of seven detergent samples, in which common salt was detected in quantities ranging between 50.7% and 87.4%.

During the thematic reviews relating to **household chemical products,** the Authority verified compliance with the statutory obligations relating to the labelling, marking and closing method of the products as well as the fulfilment of the distribution conditions of products classified as hazardous. All sampled products (including products not classified as hazardous) had safety data sheets. The labelling of 15.6% of the products did not meet the relevant legislative provisions (the most frequent deficiency was the inadequate display of R and S phrases and the non-conformity of hazard markings and the Hungarian name of the hazard). In the case of certain samples, the deficiencies found were even cumulative.

On the basis of the laboratory test results, the closing of the original packaging of the examined samples but one met the regulations and can be said safe in all cases. 3% of the products (221) classified as 'corrosive' and inspected in the past period were not fitted with child-resistant fastening as prescribed by legislation, and no palpable hazard sign was found on the packaging of 1.9% of the products (138) classified as 'harmful'. During the thematic reviews, of the sampled products, quantities smaller than the nominal fill values were measured in the case of three products, and the difference was larger than the permitted negative difference.

The results show that the commercially available household chemical products can be said to be conforming in terms of product safety. At the same time, it can be established that the manufacturers pay greater attention to the assumed quality of the products than to complying with the legislative provisions applicable to labelling.

<u>The ÁNTSZ</u>

The majority of the inspections carried out as part of market surveillance activities took place on the authorities' own initiative, on the basis of annual work plans specified by the OTH. Compared to the total number of inspections, complaints are lodged in an insignificant number, and are not even well-founded in many cases or result from the misuse of the cosmetic product/chemical.

During the market surveillance activities relating to **chemicals**, the inspectors examine the reporting of activities performed with hazardous substances and mixtures and the chemical risk assessment documentation relating to the chemicals and mixtures used, with special regard to its hazard identification and risk management chapters. Important checklist items are the verification of the risk communication interfaces of hazardous substances and mixtures as well as the verification of the proper content and format of safety data sheets and labels, taking into account the provisions of the relevant Community legislation. The verification of the mandatory reporting of hazardous substances/mixtures in terms of toxin monitoring applicable to manufacturers, importers and distributors placing the product on the Hungarian market is also a high priority consideration.

With regard to the specific features of the product group, the market surveillance activity relating to biocide products must be pointed out. As part of this, the National Office of the Chief Medical Officer is conducting licensing procedures in the case of most biocide products affecting the population. Among the considerations of the official inspection of biocide products, the verification of the marketability considerations affecting the biocide product and its active ingredient/ingredients as well as the verification of compliance with special regulations applicable to usability, special labelling requirements and the product itself must be mentioned in addition to ensuring compliance with the above-mentioned general chemical safety regulations.

In our experience, during the inspection of both cosmetic products and chemicals, most industrial players and distributors are mostly cooperative, but in many cases, they are uninformed about the legislative provisions or cannot interpret them; therefore, some of the market surveillance activities comprise the provision of information to customers. The principle of gradualness is applied in the measures taken by the Authority, but if human health is endangered, the product is withdrawn from commercial distribution or, if warranted, a health fine or a chemical load fine is imposed.

23. Ecodesign and energy labelling

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product-related accidents/consumer complaints	2	3	3	3
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total)	5	31	33	112
3.1	number of reactive inspections	0	2	2	1
3.2	number of inspections on the market surveillance authorities' own initiative	5	30	31	55
3.3	number of inspections prompted by the customs authorities	0	0	0	0
4.	Number of inspections based on:	0	0	0	0
4.1	tests performed in laboratories	0	0	0	0
4.2	physical testing of products	10	35	37	181
5.	Number of inspections resulting in:	0	0	0	0
5.1	finding of non-compliance	0	22	12	14
5.2	corrective actions taken by economic operators ('voluntary actions')	0	0	0	0
5.3	restrictive measures taken by market surveillance authorities	0	22	12	14
5.4	sanctions/penalties applied	0	9	1	7
6.	Number of inspections where other Member States were also invited to collaborate	0	0	0	0

Information on communication activities carried out in the 2010–2013 period (optional)

The NFH:

In its communication activities, the NFH gives priority to communicating product safety information to the consumers and economic operators. The Authority continuously publishes news, information and changes in legislation relating to market surveillance and individual product groups as well as dangerous products prohibited by the Authority on its website and Facebook account. In addition, news about the market surveillance activities of the Authority is regularly published in various media (national and local television and radio stations, Internet and written press), and information is also provided about these in its official journal and newsletter. Furthermore, the Authority tries to draw the attention of the public to products posing a risk with laboratory open days, roadshows and campaigns.

The MKEH:

Our most important means of communication is our website (<u>www.mkeh.gov.hu</u>), on which important information on the market surveillance activities of the MKEH can be found. We publish a market surveillance newsletter on current market surveillance topics in the fresh news column of the website. After preliminary registration, newsletters are automatically sent to the registered electronic addresses. We published a total of six newsletters in the period in question.

The Authority liaises with professional organisations manufacturing illuminating devices, consults them on professional issues and has given presentations at their events on several occasions (Lighting Technology Association, Association of Electrical Contractors).

Our Authority takes part in the work of the joint ECOPLIANT market surveillance consortium of the EU. We regularly report on the goal, events and results of the action on the website of the Authority.

In addition to non-governmental organisations, we regularly communicate with a number of partner authorities on the basis of contractual relationships. We exchange experience and information with the measurement and technical and safety authorities of government offices, the Hungarian Authority for Consumer Protection and the National Tax and Customs Administration.

We publish our public information brochures regarding our annual activities, with the aid of which those interested are given comprehensive information on all areas falling within our competence.

		2010	2011	2012	2013
7.1	Budget available to market surveillance	25368	48877	107403	124 596
	authorities in nominal terms (EUR)				
7.2	Budget available to market surveillance				
	authorities in relative terms (percentage	0.000051	0.0000988	0.000193	0.000218
	of total national budget)				
8.	Staff available to market surveillance	1	1	2	2
	authorities (full-time equivalent units)				
9.	Number of inspectors available to				
	market surveillance authorities (full-time	1	1	1	1
	equivalent units)				

Information on resources (subject to availability)

1.B. Assessment of the functioning of market surveillance activities in the sector

The NFH:

Energy efficiency and ecodesign

1. Energy efficiency

In 2011, the consumer protection authority inspected the energy efficiency labelling of a total of 3283 types of 67008 electrical products in 33 commercial units on the basis of 52 different aspects. On the whole, it can be stated about the inspection results that 333 types of 829 products were objected to, which represents a complaint ratio of 10.1% (1.2%) on average. The highest number of non-conformities occurred in the case of refrigerators (complaint ratio: 12.5%), washing machines (complaint ratio: 15.0%), dishwashers (complaint ratio: 14.5%) and washing and drying machines (complaint ratio: 22.2%). In terms of non-conformities, the lack of labels (an average complaint ratio of 6.7% for the product type) as well as the formal design and appropriate language of the labels (an average complaint ratio of 3.9%) were prominent.

In 2013, the county/metropolitan consumer protection inspectorates checked the energy efficiency labelling of a total of 1871 types of electrical products in 93 commercial units on the basis of 29 different aspects. On the whole, it can be stated about the inspection results that 236 types of products were objected to, which represents a complaint ratio 12.61% on average. It was characteristic to the trade in the products subjected to inspection that only one or two household appliances were available per shop.

The relatively high complaint ratio (29.02%) of electric ovens is presumed to have been caused by the fact that the product group was inspected for the first time. It must be pointed out in connection with the non-conformity of the contents of energy efficiency labels of certain product groups that in the case of refrigerators, an error whereby the shop displayed its own article number instead of the supplier's type designation of the appliance was encountered in higher numbers only at the metropolitan inspectorate (in the case of nine appliances). In the case of electric ovens, the lack or non-conformity of almost all content elements occurred, but the highest number of deficiencies appeared in providing the model (33), size (28) and noise emission values (48) of the ovens. In the case of washing machines, only the staff of the inspectorates of Pest and Veszprém Counties found products (9) where the noise emission values during washing and centrifuging were missing from the energy efficiency labels as primary deficiency in marking.

2. Ecodesign

In 2012, the purpose of the inspections was to establish whether the power of distributed simple settop boxes measurable in standby mode complied with the relevant legislative provisions after one or three years following the entry into force of Commission Regulation (EC) No 107/2009 on 25 February 2009 (i.e. after 25 February 2010 and 25 February 2012). The investigation affected eight units belonging to department store chains/commercial chains. The Consumer Protection Inspectorate of the Pest County Government Office participating in the inspection did not find any simple set-top box suitable for sampling in any units belonging to a department store chain/commercial chain. The reason for this was that the set-top boxes placed out for sale did not qualify as simple set-top boxes (since they already contained a USB connector, i.e. they were capable of a recording function that was based on a removable data carrier of a conventional directorate format and/or ecolabels and/or a second tuner and/or a hard disk). All this reflects that the set-top boxes are in a very fast development phase, which is attributable to the fact that they have a prominent role in combining information technology and communications equipment. The thematic review also drew attention to the following two obstacles to the efficient inspection of energy-related products:

- In the sampling period, no legislation in force existed yet that would have allowed free sampling also in the case of laboratory tests other than product safety inspections;
- Even the units of larger department store chains/commercial chains did not have a stock large enough that would have been sufficient to comply with the stipulation of the relevant implementation decrees whereby in the case of non-conformity, power measurements also have to be taken on three additional samples. In total, this means four samples and four control

samples, which should be available in the commercial unit subjected to inspection in order to appropriately evaluate the test results in accordance with the legislative provisions.

In 2013, the inspections affected 11 units belonging to department store chains/commercial chains and nine retail units. The staff of the Consumer Protection Inspectorates of the Government Office of the Capital City of Budapest and the Government Office of Pest County participating in the inspections found television sets that met the sampling conditions (placed on the market after 07 January 2010, at least four available products without control samples) in two cases out of 105 various types of television sets. According to the tests conducted by the accredited Mechanical and Electrical Laboratory of the National Consumer Protection Authority, each of the sampled products met the energy consumption requirements prescribed for standby mode in the relevant implementation decree.

The MKEH:

The regulatory market surveillance tasks of the Hungarian Trade Licensing Office are performed at first instance by the Market Surveillance Department with national jurisdiction.

At the beginning of the baseline period, preparation for the inspections formed the essential part of the activities. As part of this, the following tasks were carried out:

1. Devising and correction of the ME 721-01PO ('Market surveillance procedure') quality management procedure and related specimen documents, checklists and product-specific data sheets within the ISO 9001 certified quality system.

2. Exchange of experience in inspection, review and procedure issues in accordance with the provisions of the cooperation agreement concluded with the consumer protection authority in 2005, the industrial safety authority in 2007 and the mining authority in 2003.

3. Monitoring and processing of the information entered in the database of the Central Market Surveillance and Information System (the 'KPIR') and participation in the professional forums of the sector concerned in Hungary and possibly in the European Union.

In the European Union, the ecodesign requirements for, and energy labelling of, energy-related products are set by Directive No 2009/125/EC and Directive No 2010/30/EU. Under the market surveillance programs, the following product categories intended for targeted economic use were subjected to inspection:

- simple set-top boxes,

- external power supply units,
- electric motors,
- circulating pumps,
- electrical and electronic household and office equipment,

- installed fluorescent tubes without front pieces, high intensity discharge lamps, and front pieces and lighting fittings of such lamps,

– fans,

- television sets.

The subject-matter of the inspection is the product itself, its CE marking, the technical parameters, the accompanying documentation, the EC declaration of conformity and, if necessary, the whole technical documentation. Our Authority joined the action called ECOPLIANT, financed by the European Commission, within which the market surveillance authorities of the European Union are jointly devising new inspection methods. The 'best practices' arising as a result of the project can be utilised for the market surveillance inspection of products coming under the Ecodesign Directive. The action has been ongoing for three years; it was launched in 2012 and operates with the participation of 10 countries. The purpose of the project is to cut energy use and CO_2 emissions, thereby increasing energy efficiency in the Union.

In 2011, gas-fired hot-water boilers and electric motors were subjected to inspection. During the inspections, deficiencies concerning markings and documentation were found.

In 2012, among other things, the following product types were subjected to market surveillance inspection in accordance with the legislation in force: electric motors, electric household appliances, electric office equipment and set-top boxes. The experience of the inspections showed that the distributors and manufacturers were only little informed about the relevant legislation.

In 2013, we performed the inspection of circulating pumps and fans as priority under the Ecopliant market surveillance project of the European Union. Within the action, 40 products were inspected and a high number of deficiencies concerning the fulfilment of product information requirements were found.

Fans: In almost all cases, the documentation was incomplete, and the reviewed fan models did not meet the product information requirements.

Circulating pumps: Within a comprehensive inspection campaign, we checked a number of manufacturers and distributors, and took control measurements with our own testing equipment. Typically, stating the ecodesign requirements in the documentation was missing. In most cases, this meant the non-fulfilment of the product information requirements. The manufacturers certified the values of the energy efficiency indices shown on the products by submitting measurement records. The Market Surveillance Department's own measurement results confirmed the manufacturers' values. The labelling and documentation of the inspected equipment models were conforming.

24. Efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product-related	0	0	0	0
	accidents/consumer complaints	0	0	0	0
2.	Number of substantiated complaints by	0	0	0	0
	industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total)	0	4	20	3
3.1	number of reactive inspections	0	0	0	0
3.2	number of inspections on the market surveillance authorities' own initiative	0	4	20	3
3.3	number of inspections prompted by the customs authorities	0	0	0	0
4.	Number of inspections based on:				
4.1	tests performed in laboratories	0	0	0	0
4.2	physical testing of products	0	4	20	3
5.	Number of inspections resulting in:				
5.1	finding of non-compliance	0	3	9	0
5.2	corrective actions taken by economic operators ('voluntary actions')	0	0	0	0
5.3	restrictive measures taken by market surveillance authorities	0	0	0	0
5.4	sanctions/penalties applied	0	0	0	0
6.	Number of inspections where other				
	Member States were also invited to	0	0	0	0
	collaborate				

Information on communication activities carried out in the 2010-2013 period (optional)

Our most important means of communication is our website (www.mkeh.gov.hu), on which important information on the market surveillance activities of the MKEH can be found. We publish a market surveillance newsletter on current market surveillance topics in the fresh news column of the website. After preliminary registration, newsletters are automatically sent to the registered electronic addresses. We published a total of six newsletters in the period in question.

In addition to non-governmental organisations, we regularly communicate with a number of partner authorities on the basis of contractual relationships. We exchange experience and information with the measurement and technical and safety authorities of government offices, the Hungarian Authority for Consumer Protection and the National Tax and Customs Administration.

We publish our public information brochures regarding our annual activities, with the aid of which those interested are given comprehensive information on all areas falling within our competence.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (EUR)	0	4534	6 408	1 334
7.2	Budget available to market surveillance authorities in relative terms (percentage of total national budget)	0%	0.00001%	0.00001%	0.00000%
8.	Staff available to market surveillance authorities (full-time equivalent units)	0.15	0.17	0.30	0.11
9.	Number of inspectors available to market surveillance authorities (full-time equivalent units)	0.06	0.08	0.22	0.03

1.B. Assessment of the functioning of market surveillance activities in the sector

The regulatory market surveillance tasks of the Hungarian Trade Licensing Office are performed at first instance by the Market Surveillance Department with national jurisdiction.

At the beginning of the baseline period, preparation for the inspections formed the essential part of the activities. As part of this, the following tasks were carried out:

1. Devising and correction of the ME 721-01PO ('Market surveillance procedure') quality management procedure and related specimen documents, checklists and product-specific data sheets within the ISO 9001 certified quality system.

2. Exchange of experience in inspection, review and procedure issues in accordance with the provisions of the cooperation agreement concluded with the consumer protection authority in 2005, the industrial safety authority in 2007 and the mining authority in 2003.

3. Monitoring and processing of the information entered in the database of the Central Market Surveillance and Information System (the 'KPIR') and participation in the professional forums of the sector concerned in Hungary and possibly in the European Union.

The efficiency of hot-water boilers was checked under the market surveillance program with respect to the product group intended for targeted economic use, coming under Council Directive 92/42/EEC on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels in the European Union. The subject-matter of the inspection is the product itself, its CE marking, the accompanying documentation, the EC declaration of conformity and, if necessary, the technical documentation compiled in accordance with legislation, in whole or in part.

Experience of inspections:

- about half of the equipment types had incomplete documentation (the EC declaration of conformity did not contain reference to the relevant directive, the documentation did not contain a quantified efficiency value, the efficiency was marked by stars under a regulation no longer in force) or was not available at the distributor;

- the documentation was not available at the distributor, but was submitted subsequently at request.

25. Hobby watercraft

No market surveillance inspections were carried out for the period of 2010 to 2013.

26. Marine equipment

No market surveillance inspections were carried out for the period of 2010 to 2013.

27. Motor vehicles and tyres

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010-2013 period

With regard to the responsibilities of the National Transport Authority and the Transport Inspectorates, Section 4(5)(22) of Government Decree No 263 of 20 December 2006 on the National Transport Authority regulates the task of 'Conducting the authentication procedure under Regulation (EC) No 1222/2009 of the European Parliament and of the Council of 25 November 2009 on the labelling of tyres with respect to fuel efficiency and other essential parameters and the verification of compliance with the provisions of Articles 4 to 6 of Regulation (EC) No 1222/2009 of the European Parliament and of the Council of 25 November 2009 on the labelling of tyres with respect to fuel efficiency and other essential parameters with respect to fuel efficiency and other essential parameters are to fuel efficiency and other essential parameters in the introduction of the market surveillance organisation, the National Transport Authority involved the bodies of first instance in the implementation of the task, which took part, in addition to their other regulated tasks, in the activities in accordance with the resources available to them as follows:

Of the county transport inspectorates, the Transport Inspectorates of the Government Offices for Fejér County, Győr-Moson Sopron County, Baranya County, Szabolcs-Szatmár-Bereg County, Bács-Kiskun County and Jász-Nagykun-Szolnok County reviewed the operation of tyre repair shops (motor vehicle maintenance shops) as targeted inspections in 2013, and typically found that they operated in accordance with the rules.

On the basis of feedback received from the Transport Inspectorates of the Government Offices, the distribution of the number of inspections is not even, typically due to the lack of available resources and staff capacity, therefore, it was signalled several times that the staff size and resources required for performing the task referred to above were not planned and provided in the same way at the government offices. A summary of the data available to the Road Vehicle Transport Office are set forth in this table:

		2010	2011	2012	2013
1.	Number of product-related	0	0	1	1
	accidents/consumer complaints				
2.	Number of substantiated complaints by	1	1	1	1
	industry concerning unfair competition				
3.	Number of inspections (total)	4	1	33	24
3.1	number of reactive inspections	2	3	4	3
3.2	number of inspections on the market	0	0	31	23
	surveillance authorities' own initiative				
3.3	number of inspections prompted by	0	0	0	0
	the customs authorities				
4.	Number of inspections based on:	0	0	31	230
4.1	tests performed in laboratories	0	0	0	0
4.2	physical testing of products	37	138	186	312
5.	Number of inspections resulting in:	0	0	0	0
5.1	finding of non-compliance	17	8	11	5
5.2	corrective actions taken by economic	17	7	11	4

	operators ('voluntary actions')				
5.3	restrictive measures taken by market surveillance authorities	0	1	0	1
5.4	sanctions/penalties applied	0	0	0	0
6.	Number of inspections where other	0	0	0	0
	Member States were also invited to				
	collaborate				

Information on communication activities carried out in the 2010-2013 period (optional)

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance				
	authorities in nominal terms (EUR)				
7.2	Budget available to market surveillance				
	authorities in relative terms (percentage				
	of total national budget)				
8.	Staff available to market surveillance				
	authorities (full-time equivalent units)				
9.	Number of inspectors available to				
	market surveillance authorities (full-time				
	equivalent units)				

1.B. Assessment of the functioning of market surveillance activities in the sector

On the basis of the report on the market surveillance activities, it is clear that it is necessary to devise rules for the responsibilities and competence of the market surveillance organisation overseeing the product and to provide conditions of implementation in the case of the National Transport Authority as partner authority. This task requires the immediate coordination of the legislation preparation, strategic and inspection, and market surveillance program planning tasks. On the basis of the remarks shown above, it is recommended to review Section 2(1)(h) of Government Decree No 6 of 18 January 2013 on the detailed rules of market surveillance activities, the amendment of legislation aimed at further specifying the designation and regulating responsibilities, competence and measures, and, if necessary, to issue and amend a public law instrument for organisation regulation.

The Ministry responsible for transport is preparing a draft proposal on Government decrees relating to market surveillance procedures associated with certain road vehicles subject to approval and the amendments of Acts and Government decrees in connection with Regulation (EU) 167/2013 of the European Parliament and of the Council of 5 February 2013 and Regulation (EU) 168/2013 of the European Parliament and of the Council of 15 January 2013.

The relevant market surveillance activity and the draft proposal being prepared for that would introduce new regulation, in addition to the statutory designations currently in force in order to transpose:

– Regulation (EU) 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles;

– Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles;

- Commission Delegated Regulation (EU) No 3/2014 of 24 October 2013 supplementing Regulation (EU) No 168/2013 of the European Parliament and of the Council with regard to vehicle functional safety requirements for the approval and market surveillance of two- or three-wheel vehicles and quadricycles;

- Commission Delegated Regulation (EU) No 44/2014 of 21 November 2013 supplementing Regulation (EU) No 168/2013 of the European Parliament and of the Council with regard to the vehicle construction and general requirements for the approval of two- or three-wheel vehicles and quadricycles;

– Commission Delegated Regulation (EU) 134/2014 of 16 December 2013 supplementing Regulation (EU) 168/2013 of the European Parliament and of the Council with regard to vehicle functional safety requirements for the approval and market surveillance of two- or three-wheel vehicles and quadricycles.

28. Non-road mobile machinery

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product-related accidents/consumer complaints	4	3	4	3
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total)	2	2	3	3
3.1	number of reactive inspections	1	0	1	0
3.2	number of inspections on the market surveillance authorities' own initiative	1	2	2	3
3.3	number of inspections prompted by the customs authorities	0	0	0	0
4.	Number of inspections based on:				
4.1	tests performed in laboratories	0	0	0	0
4.2	physical testing of products	5	5	6	6
5.	Number of inspections resulting in:				
5.1	finding of non-compliance	1	0	1	0
5.2	corrective actions taken by economic operators ('voluntary actions')	0	0	0	0
5.3	restrictive measures taken by market surveillance authorities	2	0	1	0
5.4	sanctions/penalties applied	1	0	0	0
6.	Number of inspections where other Member States were also invited to collaborate	0	0	0	0

Information on communication activities carried out in the 2010-2013 period (optional)

In its communication activities, the NFH gives priority to communicating product safety information to the consumers and economic operators. The Authority continuously publishes news, information and changes in legislation relating to market surveillance and individual product groups as well as dangerous products prohibited by the Authority on its website and Facebook account. In addition, news about the market surveillance activities of the Authority is regularly published in various media (national and local television and radio stations, Internet and written press), and information is also provided about these in its official journal and newsletter. Furthermore, the Authority tries to draw the attention of the public to products posing a risk with laboratory open days, roadshows and campaigns.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance	12666	20912	18596	18421
	authorities in nominal terms (EUR)				
7.2	Budget available to market surveillance				
	authorities in relative terms (percentage	0.0000254	0.0000423	0.0000334	0.0000323
	of total national budget)				
8.	Staff available to market surveillance	1	1	1	1
	authorities (full-time equivalent units)				
9.	Number of inspectors available to				
	market surveillance authorities (full-time	1	1	1	1
	equivalent units)				

1.B. Assessment of the functioning of market surveillance activities in the sector

In the area of the market surveillance of non-road mobile machinery, the National Transport Authority does not have considerable experience, it has conducted only a few inspections to date on the basis of consumer filings. In 10 inspections conducted, the Authority established non-conformity only in two cases, on the basis of which it arranged for making distribution lawful.

29. Fertilisers

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010–2013 period

		2010	2011	2012	2013
1.	Number of product-related	2	3	3	9
	accidents/consumer complaints				
2.	Number of substantiated complaints by	0	0	0	0
	industry concerning unfair competition				
3.	Number of inspections (total)	197	150	161	335
3.1	number of reactive inspections				9
3.2	number of inspections on the market	197	150	161	326
	surveillance authorities' own initiative				
3.3	number of inspections prompted by	0	0	0	0
	the customs authorities				
4.	Number of inspections based on:				
4.1	tests performed in laboratories	99	126	81	129
4.2	physical testing of products	197	150	161	335
5.	Number of inspections resulting in:				
5.1	finding of non-compliance	7	8	15	28
5.2	corrective actions taken by economic	0	1	1	2
	operators ('voluntary actions')				
5.3	restrictive measures taken by market	2	0	9	18
	surveillance authorities				
5.4	sanctions/penalties applied	0	0	9	18
6.	Number of inspections where other	0	0	0	1
	Member States were also invited to				
	collaborate				

Information on communication activities carried out in the 2010–2013 period (optional)

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance	59969	61762	78005	81 604
	authorities in nominal terms (EUR)				
7.2	Budget available to market surveillance	1.21	1.25	1.4	1.43
	authorities in relative terms (percentage				
	of total national budget)				
8.	Staff available to market surveillance	1.58	1.58	3.16	3.16
	authorities (full-time equivalent units)				
9.	Number of inspectors available to	1.58	1.58	1.58	1.58
	market surveillance authorities (full-time				
	equivalent units)				

1.B. Assessment of the functioning of market surveillance activities in the sector

In 2010 to 2013, no substantiated complaints by industry concerning unfair competition was lodged with the National Food Chain Safety Office (the 'NÉBIH'), and no proceedings were instituted on the initiative of the customs authority. The staff working with the county crop protection and soil conservation directorates launched 98% of the inspections on their own initiative. Inspections launched in response to complaints accounted for the remaining 2%. Inspections are carried out with an inspection plan issued by the NÉBIH. It occurred for the first time in 2013 that the NÉBIH launched inspections on the basis of a RAPEX notice.

During the physical testing of fertilizers from the EC, the county crop protection and soil conservation directorate examined compliance with the registration, marking, packaging, transport, distribution, storage and application regulations; the premises, devices and equipment used for their purposes; and the existence of safety data sheets. If the product meets the above-mentioned conditions, laboratory tests were also carried out in certain cases. The laboratory tests were aimed at content values; it is examined whether the content values of EC fertilisers correspond to the values stated on the label or in the accompanying document.

Since the accession of Hungary to the European Union, the number of EC fertilisers placed on the market in Hungary has been continuously increasing; a lot of fertilisers provided with national licenses previously are placed on the market today as EC fertilisers. Therefore, this trend also applies to the period of 2010 to 2013. In 2013, the county crop protection and soil conservation directorates inspected EC fertilisers on 335 occasions. The proportion of fertilisers showing deficiencies at the inspections is increasing, but the proportion of non-conforming products still does not reach 10%. Due to the non-conforming items, it is warranted to increase the number of inspections. Of the deficiencies, the most important is that yield-increasing materials the composition of which shown on the label does not meet the requirements set forth in Regulation (EC) No 2003/2003, e.g. they also contain an organic component, are placed on the market as EC fertilisers. On the basis of content analyses, the active ingredient contents did not correspond to the values declared on the label in the case of a few products.

30. General Product Safety Directive

1.A. Review of market surveillance activities in the sector

Information on the implementation activities performed in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product-related accidents/consumer complaints	33	54	46	62
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	1
3.	Number of inspections (total)	1710	2775	2134	2 506
3.1	number of reactive inspections	725	963	517	568
3.2	number of inspections on the market surveillance authorities' own initiative	983	1 805	1613	1 921
3.3	number of inspections prompted by the customs authorities	2	7	4	17
4.	Number of inspections based on:	0	0	0	0
4.1	tests performed in laboratories	81	41	123	132
4.2	physical testing of products	7 458	17 451	8979	11954
5.	Number of inspections resulting in:	0	0	0	0
5.1	finding of non-compliance	706	570	828	843
5.2	corrective actions taken by economic operators ('voluntary actions')	0	0	4	7
5.3	restrictive measures taken by market surveillance authorities	332	426	614	711
5.4	sanctions/penalties applied	360	294	465	441
6.	Number of inspections where other Member States were also invited to collaborate	0	0	0	1

Information on communication activities carried out in the 2010-2013 period (optional)

In its communication activities, the NFH gives priority to communicating product safety information to the consumers and economic operators. The Authority continuously publishes news, information and changes in legislation relating to market surveillance and individual product groups as well as dangerous products prohibited by the Authority on its website and Facebook account. In addition, news about the market surveillance activities of the Authority is regularly published in various media (national and local television and radio stations, Internet and written press), and information is also provided about these in its official journal and newsletter. Furthermore, the Authority tries to draw the attention of the public to products posing a risk with laboratory open days, roadshows and campaigns.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance	88877	146 561	130280	129122
	authorities in nominal terms (EUR)				
7.2	Budget available to market surveillance				
	authorities in relative terms (percentage	0.000178	0.000296	0.000234	0.000226
	of total national budget)				
8.	Staff available to market surveillance	7	6	6	7
	authorities (full-time equivalent units)				
9.	Number of inspectors available to				
	market surveillance authorities (full-time	4	3	3	4
	equivalent units)				

1.B. Assessment of the functioning of market surveillance activities in the sector

In the past period, the Authority inspected a number of product groups coming under the General Product Safety Directive. A high complaint ratio can be typically found in the case of product groups that had not been inspected previously by the Authority; in the case of the already inspected products groups, the complaint ratios have been decreasing year after year.

The consumer protection authority subjected the following product groups to inspection, among others:

- children's clothing,
- products intended for children under the age of three,
- scooters, skateboards,
- clothing accessory products, small fashion articles,
- footwear,
- products that can be mistaken for food,
- laser pointers,
- electric hand tools,
- playground equipment,
- showman's equipment,
- children's bicycles,
- garden furniture.

On the basis of the experience of the past years, it can be stated that the Authority found the most deficiencies in terms of product safety in the case of children's clothing products. The product safety deficiencies typically arose from the fact that in the case of children under the age of seven, serious accidents may be caused primarily by cords in the hoods attached to their clothing or around their necks getting caught by playground equipment (e.g. slides). In the case of children aged between seven and 14, serious injuries or even a fatal accidents may be caused by cords and drawstrings at the waistline and the lower edges of the clothing getting caught on moving vehicles (such as bus doors, ski lifts and bicycles).

In the case of children's clothing, the Authority found it as an additional product safety deficiency that in many cases, the products contained prohibited azo-dyes. It was established in the past years that prohibited azo-dyes were used in quantities harmful to human health in 25% of the tested samples.

The Authority also found the same deficiency in the case of clothing accessory products, for on the basis of laboratory analyses, the Authority found that prohibited azo-dyes had been used in quantities harmful to human health (significantly exceeding the limit) in the case of two products.

The Authority found, furthermore, a number of product safety deficiencies in respect of inadequately fastened beads, flitters as well as hanging parts, fringes and cords on children's footwear. On the basis of the inspections carried out in the past period, it was established that out of 19 pairs of children's footwear inspected, the ornaments used came off the product upon the application of a very small force in the case of 16 pairs, while the design was objected to in the case of six pairs of footwear, therefore, they did not meet the safety requirements.

In addition to the above, the experience gained during the inspection of scooters and skateboards is to be pointed out, for 50% of the 821 scooters and 538 skateboards inspected in the past years did not meet the relevant regulations. With regard to the information required for safe use, the most frequent deficiency was the failure to state information on weight limits (complaint ratio: 40%). In addition, the experience of the thematic review pointed out that the overlap currently existing between toy scooters intended for bigger children and those sold as sporting goods on the basis of a weight limit may cause issues during the inspections, because in certain cases, it is difficult to determine whether the given product is distributed as a toy or sporting goods. However, it is to be mentioned as a positive finding that the experience of the last inspection showed that the contents of user manuals showed a definitely improving trend compared to the previous years, and the safety tests carried out in the laboratory also gave better results.

In the case of bicycles intended for children, the Authority established some deficiency in 37% of 258 types of a total of 567 bicycles made for young children and inspected by the Authority in 2011, while in 31% of 216 types of 510 bicycles in inspections conducted in 2013. Most complaints were lodged about the non-conformity of the contents of the information brochure helping safe use (35% in 2011 and 12% in 2013). It can also be stated here that the number of complaints about user manuals showed considerable improvement compared to the inspections carried out in 2011. The complaint ratio previously found in this respect decreased by more than half, which is probably the result of previous inspections. It can be established that the manufacturers and importers pay more attention today to displaying the information required for safe use. During the inspections in 2011 and 2013, seven and two children's bicycles were sampled, respectively, for the purpose of laboratory testing. None of the children's bicycles met the safety requirements; therefore, they pose a hazard to the health and safety of children during their use. The most typical source of defect was that the chain guard covered the outer edge of the chain not in compliance with the regulations, which poses an accident hazard. Simultaneously, there were issues with the non-conformity of the diameter of the handlebar grips, the location of side wheels, and the static strength of the brakes and the saddle in the case of several bicycles.

Finally, the Authority also conducted inspections among products that might be mistaken for food and garden furniture in the past period. Experience also shows in this case too, that it is necessary to conduct intensive inspections of both private groups also in the future, for the Authority established some products safety deficiency in the case of about 50% of the products.

31. Medicines

1.A. Review of market surveillance activities in the sector

		2010	2011	2012	2013
1.	Number of product-related				
	accidents/consumer complaints				
2.	Number of substantiated complaints by				
	industry concerning unfair competition				
3.	Number of inspections (total)	94	115	112	329
3.1	number of reactive inspections				
3.2	number of inspections on the market				
	surveillance authorities' own initiative				
3.3	number of inspections prompted by	94	115	112	329
	the customs authorities				
4.	Number of inspections based on:				
4.1	tests performed in laboratories	56	43	55	140
4.2	physical testing of products	94	115	112	329
5.	Number of inspections resulting in:				
5.1	finding of non-compliance	94	115	112	329
5.2	corrective actions taken by economic				
	operators ('voluntary actions')				
5.3	restrictive measures taken by market				
	surveillance authorities				
5.4	sanctions/penalties applied				
6.	Number of inspections where other				
	Member States were also invited to				
	collaborate				

Information on the implementation activities performed in the 2010–2013 period

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance				
	authorities in nominal terms (EUR)	41 41 4	32471	40794	97 480
7.2	Budget available to market surveillance				
	authorities in relative terms (percentage				
	of total national budget)				
8.	Staff available to market surveillance	2+1	2+1	2+1	4+2
	authorities (full-time equivalent units)				
9.	Number of inspectors available to	1	1	1	1
	market surveillance authorities (full-time				
	equivalent units)				

1.B. Assessment of the functioning of market surveillance activities in the sector

With the development of technology, the Internet has recently become the primary scene for the distribution of fake or counterfeit medicines and ones from uncontrolled sources. With their activities, merchants operating without a licence want to shortchange and damage patients who seek low cost and simple purchase opportunities, do not want to see a doctor with their problems or perhaps feel

ashamed of their illness. The vast majority of these medicines or therapeutic preparations that are not medicinal arrive in the territory of Hungary via postal home delivery services, and the customs authorities become aware of them in such a way. Furthermore, the above-mentioned circumstances also justify an increase in the number of inquiries received from the customs authorities found in the past years.

The counterfeiting of medicines and the cross-border distribution of, and trade in, fake medicines involve a serious public health risk and cause financial and legal damage to the population of both Hungary and the European Union. As detailed above, the National Institute of Pharmacy of the National Institute for Quality and Organisational Development in Healthcare and Medicine (the 'GYEMSZI-OGYI'), as the pharmaceutical administrative body, was designated as market surveillance body with regard to its expertise and assets, which participates in the procedures of the customs authorities to determine whether the products concerned may be released to free circulation or not.

In order to prevent the counterfeiting of medicines, to ensure the success of the fight against the counterfeiting of medicines and to coordinate quick and efficient action, the expansion of the bilateral agreement made between the customs authority and the GYEMSZI-OGYI, referred to above, into a trilateral agreement through the involvement of the National Police Headquarters is currently under way. Due to this, the efficiency of the information exchange between the parties and the utilisation rate of the existing resources have considerably improved.

These bi- and trilateral agreements as well as the cooperation set forth in them are essential in the fight against the counterfeiting of medicines to ensure that the action taken against medicine counterfeiters can be successful and the cross-border distribution of, and trade in, fake medicines can be prevented to the greatest possible extent in the interest of the protection of public health, also by ensuring that the Parties thwart access by unsafe goods to the Community markets and minimise the risk of the same accessing the Community market.