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*Ministry of Economic Development*

Directorate General for the Market, Competition, Consumers, Surveillance and Technical Standards  
Division XVI Product Safety and Conformity

*Ministry of Economic Development*

Department for Enterprise and  
Internationalisation

Structure: DG-MCCVNT

**OFFICIAL REGISTER**

**File No 0193631 - 03/11/2014 - OUTGOING**

TO THE EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR  
ENTERPRISE AND INDUSTRY

BB-1049 BRUSSELS

entr.c.1@ec.europa.eu

giuseppina.bitonto@ec.europa.eu

stamatia.vounasi@ec.europa.eu

THE PERMANENT  
REPRESENTATION OF ITALY TO THE EUROPEAN UNION

BRUSSELS

(references: 5087 of 22 May 2014 and 10966 of 3 November 2014)

normtec@rpue.esteri.it

THE MINISTRY OF FOREIGN AFFAIRS

D.G.U.E OFFICE I

dgue1@esteri.it

a.villa@governo.it

**Subject: Review and assessment of the functioning of market surveillance activities pursuant to Article 18(6) of Regulation (EC) No 765/2008**

With regard to Article 18 of the above-mentioned Regulation, please find enclosed the four-year report on the functioning of surveillance activities in the national market

We remain at your disposal for any further clarification needed.

Yours sincerely.

THE OFFICE HEAD

*(Rita Novelli)*

[signed]

**Review and assessment of the functioning of market surveillance activities  
pursuant to Article 18(6) of Regulation (EC) No 765/2008 - 2010-2013**

**Overview of general market surveillance activities**

**A. Review of general market surveillance activities**

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

**MINISTRY OF THE ENVIRONMENT**

**INSTITUTE FOR ENVIRONMENTAL PROTECTION AND RESEARCH (ISPRA)  
PHYSICAL AGENT SERVICE**

**MINISTRY OF HEALTH**

**DIRECTORATE GENERAL FOR PREVENTIVE HEALTHCARE  
OFFICE IV  
DIRECTORATE GENERAL FOR MEDICAL DEVICES AND PHARMACEUTICAL  
SERVICE  
OFFICE III AND OFFICE VII**

**MINISTRY OF INFRASTRUCTURE AND TRANSPORT**

**COAST GUARD AND HARBOUR MASTER CORPS  
GENERAL COMMAND  
UNIT VI - MARITIME SAFETY - II OFFICE TECHNICAL SAFETY SERVICES AND DANGEROUS GOODS  
SECRETARIAT  
DEPARTMENT FOR TRANSPORT, NAVIGATION AND IT AND STATISTICAL  
SYSTEMS  
DIRECTORATE GENERAL FOR VEHICLE REGISTRATION**

**MINISTRY OF THE ECONOMY AND FINANCE**

**CUSTOMS AND STATE MONOPOLY AGENCY  
DIRECTORATE GENERAL FOR EXCISE DUTIES  
DIRECTORATE GENERAL FOR FRAUD PREVENTION AND CONTROLS  
CUSTOMS CONTROL OFFICE**

**MINISTRY OF THE INTERIOR**

**DEPARTMENT OF THE FIRE SERVICE, PUBLIC RESCUE AND CIVIL PROTECTION  
CENTRAL DIRECTORATE FOR PREVENTION AND TECHNICAL SAFETY  
DEPARTMENT OF PUBLIC SECURITY  
GENERAL ADMINISTRATION OFFICE  
OFFICE FOR ADMINISTRATIVE AND SOCIAL POLICE - WEAPONS AND EXPLOSIVES  
AREA**

**FINANCIAL POLICE**

**SPECIAL UNIT FOR MARKET PROTECTION**

GROUP FOR TRADEMARKS, PATENTS AND INTELLECTUAL PROPERTY

**MINISTRY OF LABOUR AND WELFARE POLICIES**

**DIRECTORATE GENERAL FOR INSPECTION ACTIVITY**

DIVISION III CO-ORDINATION OF ORDINARY AND TECHNICAL SURVEILLANCE

**MINISTRY OF ECONOMIC DEVELOPMENT**

**DIRECTORATE GENERAL FOR THE PLANNING AND MANAGEMENT OF THE  
RADIOELECTRICAL SPECTRUM**

DIVISION II CONTROL OF RADIOELECTRICAL EMISSIONS TECHNICAL  
MANAGEMENT LOCAL INSPECTORATES FOR SURVEILLANCE  
OF THE RADIOELECTRICAL EQUIPMENT MARKET. GENERAL AFFAIRS

**DIRECTORATE GENERAL FOR THE MARKET, COMPETITION, CONSUMERS,  
SURVEILLANCE AND TECHNICAL STANDARDS**

DIVISION XV MEASUREMENT INSTRUMENTS AND PRECIOUS METALS  
DIVISION XVI PRODUCT SAFETY AND CONFORMITY

**DIRECTORATE GENERAL FOR INDUSTRIAL POLICY, COMPETITIVENESS AND  
SMALL AND MEDIUM-SIZED ENTERPRISES**

DIVISION XI POLICIES FOR THE SUPPORT AND PROMOTION OF INDUSTRIAL  
SECTORS AND ITALIAN GOODS

**Information on total resources available for market surveillance activities (subject to availability)**

[This section should contain information on total resources allocated to market surveillance authorities by a Member State for all necessary activities (enforcement, communications) at either general or sectoral level. ]

		2010	2011	2012	2013
1.1	Budget available to market surveillance authorities in nominal terms <sup>1</sup> (EUR)	1 490 000	1 588 985	1 579 812	1 586 694
1.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	0.005%	0.005%	0.005%	0.005%

<sup>1</sup> The budget figure should cover all financial resources which are assigned by public 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.

These measures range from communication activities (consumer/business information and education) to pure enforcement and market surveillance activities. They include the remuneration of staff, direct costs of inspections, laboratory tests, training and office equipment cost. Enforcement activities at regional/local level should also be reported. Other activities undertaken by these authorities not related to the enforcement of product legislation should be excluded from the calculation.

2	Staff available to market surveillance authorities (full-time equivalent units)	192 including 100 Customs Agency (estimate)	194.5 including 100 Customs Agency (estimate)	199.5 including 100 Customs Agency (estimate)	198.5 including 100 Customs Agency (estimate)
3	Number of inspectors available to market surveillance authorities (full-time equivalent units)	916 including 500 Financial Police and 275 Chambers of Commerce	916 including 500 Financial Police and 275 Chambers of Commerce	918 including 500 Financial Police and 275 Chambers of Commerce	918 including 500 Financial Police and 275 Chambers of Commerce

### ***B. Assessment of the functioning of market surveillance activities***

[This section contains a Member State's exclusive assessment of the information provided in Section A. It could point, among other things, to horizontal difficulties, if any, encountered by authorities in carrying out their activities (and.g. lack of traceability information, problems with distribution of competences, lack of resources, insufficient deterrence of penalties, etc.).]

The entry into force of Regulation No 765/2008 has fostered improved development of surveillance activity in the Italian national territory over the period 2010-2013. In particular, several specific sectoral programmes have been implemented pursuant to Article 18 of the above mentioned Regulation by State authorities but also by Chambers of Commerce, the Customs Agency and (public or private) bodies and entities responsible to the performance of technical tests. In this field, the national surveillance authorities have committed themselves fully to ensure the market circulation of safe products focusing checks on goods intended for use by especially sensitive consumer groups, such as children and the elderly. More specifically, the control activity has focused on toys, electrical [appliances] and childcare items and has resulted in the adoption of a number of restrictive measures, either voluntary or mandatory.

Moreover, surveillance on medical devices was strengthened further by setting up a "data bank and registry of medical devices" which enable the sharing of information and data by the public healthcare structures and sector businesses.

Overall, we believe that surveillance activities in the period in question have produced positive impacts also thanks to the deterrent effect of the system of penalties put in place by the national legislation and to the *ad hoc* training delivered to inspectors. This notwithstanding, on account of the complexity and vast range of the product market, continuity of training delivery should be ensured, to provide staff with ongoing refresher courses and ensure uniform standards of control across the national territory. The present weakness in the uniformity and continuity of training is compounded by the scarcity of financial resources, which limits significantly the number of inspections and laboratory tests on products and, albeit in limited cases, even the planning of proactive surveillance.

## Market surveillance activities in specific sectors

### **Ministry of the Environment - Institute for Environmental Protection and Research - Physical Agent Service (ISPRA)**

#### **Sector 12. Noise emission in the environment by equipment for use outdoors - Directive 2000/14/EC**

##### *12.A. Review of market surveillance activities in the sector*

**Information on the activities carried out to apply the law in the period 2010-2013 by the Ministry of the Environment - Institute for Environmental Protection and Research - Physical Agent Service (ISPRA)**

		2010	2011	2012	2013
1	Number of product related accidents / user complaints				
2	Number of substantiated complaints by industry concerning unfair competition				
3	Number of inspections (total number)		<b>54</b>	<b>164</b>	<b>186</b>
3.1	Number of reactive inspections				
3.2	Number of self-initiated inspections				
3.3	number of inspections prompted by the customs				
4	Number of inspections based on:				
4.1	tests performed in laboratories				
4.2	physical checks of products			<b>10</b>	<b>10</b>
5	Number of inspections resulting in:				
5.1	finding of non-compliance				
5.2	corrective actions taken by economic operators (“voluntary measures”)				
5.3	restrictive measures taken by market surveillance authorities				
5.4	application of sanctions/penalties				
6	Number of inspections where other Member States were invited to collaborate				

#### **Information on communication activities carried out in the period 2010-2013**

In the period in question, particular attention was paid to the manufacturers of/agents for the machines/equipment listed in Annex I to Directive 2000/14/EC the aim being to make them aware of the need to comply with the regulatory requirements. This activity involves:

- annual meetings with the machinery manufacturers' associations;
- annual meetings with the Notified Bodies;
- organisation of seminars and participation in workshops organised by industry associations at the time of the main sectoral exhibitions and/or national trade fairs;
- web dissemination of information by devoting to surveillance activity specific sections in the

official website of ISPRA's Physical Agent Services.  
namely <http://agentifisici.isprambiente.it/rumore/macchine-and-attrezzature-funzionanti-allaperto.html> where the following may be consulted:

- the relevant legislation;
- replies to questions submitted formally;
- information brochure on application of Legislative Decree No 262/2002
- data on market control;
- and e-mail address [infomacchine@isprambiente.it](mailto:infomacchine@isprambiente.it) used for contacts with enterprises (in 2013 alone, more than **200** contacts were handled).

#### Information on resources

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (EUR)			<b>2,500.00*</b>	<b>2,500.00*</b>
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	-	-	-	-
8	Staff available to market surveillance authorities (full-time equivalent units)	<b>3</b>	<b>3</b>	<b>5</b>	<b>5</b>
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	<b>7</b>	<b>7</b>	<b>10</b>	<b>10</b>

**\* These resources are not allocated *ad hoc*, but are instead used on the basis of the budget available to the competent inspection authority (ISPRA).**

## 12.B. Assessment of the functioning of market surveillance activities in the sector

The market surveillance activity is supported by the MARA database, prepared *ad hoc*. The database has two sections:

- The first is devoted to the company (manufacturer/agent), and contains its identification details, location, types of machines manufactured, company contact persons etc.;
- The second contains information on each model of machine manufactured and contains the data and main information entered in the CE conformity declarations.

MARA also maintains the results of the investigations as well as the reports of the inspection activities carried out pursuant to the Ministerial Decree of 4 October 2011.

The companies on the MARA database as at 31 December 2013 are 585, broken down by Region as follows:

Region	Number of companies	Percentage distribution of companies by Region  [Illegible chart]
EMILIA-ROMAGNA	155	
LOMBARDY	125	
VENETO	108	
PIEDMONT	49	
TUSCANY	26	
PUGLIA	22	
LAZIO	15	
MARCHE	15	
CAMPANIA	15	
FRIULI-VENEZIA GIULIA	11	
UMBRIA	10	
TRENTINO-ALTO ADIGE	9	
SICILY	7	
ABRUZZO	7	
BASILICATA	5	
MOLISE	3	
LIGURIA	1	
SARDINIA	1	
CALABRIA	1	
<b>Total</b>	<b>585</b>	

The breakdown of companies by type is as follows:

Type of company	%
Manufacturer	81
Agent	15
Manufacturer/Agent	4

**Ministry of Health - Department of Public Health and Innovation -  
Directorate General for Prevention - Office IV**

**Sector 3 and Sector 30 toys and consumer products pursuant to the  
General Product Safety Directive (GSPD)**

**A. Overview of general market surveillance activities**

**Overview of the resources available for the market surveillance activities implemented by the  
Ministry of Health - Department of Public Health and Innovation - Directorate General for  
Prevention - Office IV**

		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 (%age 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)	100 (NAS)			

***B. Assessment of the functioning of market surveillance activities***

Following the RAPEX alerts on microbiological or chemical issues relating to consumer products (toys and other), under the competence of the Ministry of Health, NAS (the Health Protection Unit of the Carabinieri) launched a review on the national market. The main issues reported include the lack of detailed information as to the distribution network, imports via unofficial channels and the lack of documentation and invoices showing the origin of the products. The lack of resources restricts significantly the possibility of performing control tests.



### 3.A and 30.A. Review of market surveillance activities in the sector

#### Information on enforcement activities carried out in the period 2010-2013

		2010	2011	2012	2013
1	Number of product related accidents / user complaints	Accidents 205 Complaints 13	Accidents 229 Complaints 13	Accidents 96 Complaints 11	Accidents 275 Complaints 7
2	Number of substantiated complaints by industry concerning unfair competition				
3	Number of inspections (total number)	1 168	1 305	547	1 567
3.1	number of reactive inspections	218	450	259	372
3.2	number of self-initiated inspections				
3.3	number of inspections prompted by the customs				
4	Number of inspections based on:				
4.1	tests performed in laboratories		ISS safe toy Project years 2011-2014 and RAPEX activities total test performed 415		
4.2	physical checks of products				
5	Number of inspections resulting in:				
5.1	finding of non-compliance		Years 2011-2014: 228		
5.2	corrective actions taken by economic operators (“voluntary measures”)				
5.3	restrictive measures taken by market surveillance authorities		Measures adopted by the Ministry of Health 2011-2014 :185		
5.4	application of sanctions/penalties				
6	Number of inspections where other Member States were invited to collaborate				

## Information on resources

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (EUR)	n.a.	n.a.	n.a.	n.a.
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	n.a.	n.a.	n.a.	n.a.
8	Staff available to market surveillance authorities (full-time equivalent units)	7	7	11	10
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	n.a.	n.a.	n.a.	n.a.

## Sector 1 - Medical devices

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

The Ministry of Health - Directorate General for Medical Devices, the Pharmaceutical Service and Treatment Safety, in its capacity as competent authority for medical devices monitors implementation of the national legislation (Legislative Decrees No 46/97, 507/92 and 332/2000) implementing a programme of continuing checks on the various links of the medical device supply chain (manufacturers, distributors and users). This activity, described in all EU documents and fora as market surveillance, in those areas not covered by a system of prior authorisation by the public authorities is one of the main pillars of the system in the absence of the CE marking system for medical devices. In the same EU context, surveillance on the other hand means the management of information concerning deterioration of the devices or incidents, i.e. adverse events linked to the characteristics or performance of the medical devices.

Surveillance activity involves various checks aimed at verifying the activities of manufacturers, distributors, sellers and importers, to safeguard the health of the public and of end users. To perform checks on medical devices, the Ministry of Health may order checks directly at the product manufacturing and/or storage sites, either acquiring all the information necessary for each check, or, where thought to be appropriate and useful in the specific case, by temporary collection of a sample of the device to be checked, for performing tests and checks.

Surveillance actions are initiated subsequent to reports or checks carried out in the course of routine monitoring (inspections, database of medical devices, issue of the certificates for free placing on the market, management of withdrawn or suspended CE marking certificates, etc.). Of key importance are also the reports from local-level agencies (local health services, the Ministry's maritime and border health offices, Health Protection Units of the Carabinieri, etc.). Last but not least ongoing and prompt communication with the other competent European authorities and participation in the activities coordinated by the European Commission constitute further sources of information for the purposes of market surveillance.

### Information on enforcement activities carried out in the period 2010-2013

		2010	2011	2012	2013
1	Number of product related accidents / user complaints	1600	1500	1850	1792
2	Number of substantiated complaints by industry concerning unfair competition	n.a.	n.a.	n.a.	n.a.
3	Number of inspections (total number)	n.a.	n.a.	n.a.	125 (**)
3.1	number of reactive inspections				15 (***)
3.2	number of self-initiated inspections				110 (***)
3.3	number of inspections prompted by the customs				
4	Number of inspections based on:				
4.1	tests performed in laboratories				
4.2	physical checks of products				
5	Number of inspections resulting in:				
5.1	finding of non-compliance				
5.2	corrective actions taken by economic operators ("voluntary measures")				
5.3	restrictive measures <sup>3</sup> taken by market surveillance authorities.				
5.4	application of sanctions/penalties				
6	Number of inspections where other Member States were invited to collaborate				

(\*\*) Inspections ordered by the Ministry of Health. These do not include the inspections arranged independently by the Carabinieri Health Protection Unit (NAS), by the judicial authorities and by other control authorities.

(\*\*\*) Estimate.

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

[This section should contain information on guidance, training courses and other initiatives carried out by market surveillance authorities for businesses, consumers, users or other stakeholders, namely with the objective of enhancing businesses' understanding of product rules and facilitating compliance, enhancing consumers'/users' awareness of product hazards and rules, meaning of markings, prevention of accidents, etc. ]

In the period 2010-2013, the annual editions of the National Conference on Medical Devices were organised. This is an event designed for all sector stakeholders, during which special attention is focused on the supervision and surveillance of medical devices.

Link to the section of the Ministry of Health's portal where the proceedings of all the editions of the Conference are published.

[http://www.salute.gov.it/portale/temi/p2\\_6.jsp?lingua=italiano&id=2561&area=dispositivi-medici&menu=vuoto](http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=2561&area=dispositivi-medici&menu=vuoto)

Furthermore, in 2010, when transposing Directive 2007/47/EC which amended the basic Medical Device Directives (Directives 93/42/EEC, 98/79/EC and 90/385/EEC) the second edition of a publication drafted by the competent Directorate General of the Ministry of Health was released, entitled *Regulatory and Operational Aspects of Medical Devices*

[http://www.salute.gov.it/imgs/C\\_17\\_pubblicazioni\\_1238\\_allegato.pdf](http://www.salute.gov.it/imgs/C_17_pubblicazioni_1238_allegato.pdf)

### Information on resources

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (EUR)	n.a.	n.a.	n.a.	n.a.
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	n.a.	n.a.	n.a.	n.a.
8	Staff available to market surveillance authorities (full-time equivalent units)	7	7	11	10
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	n.a. (*)	n.a. (*)	n.a. (*)	n.a. (*)

(\*) Part of the inspection activity is carried out under *ad hoc* agreements signed with the National Institute of Health.

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

The market for medical devices includes a broad range of products. Up to the recent past, only approximate figures could be provided on the number of medical devices available for use in the national territory. Today, more accurate information is available: we know that medical devices number several hundred thousand, and we are aware of their characteristics: from the more traditional ones with low degree of technological innovation (and.g. plasters) up to highly innovative devices, such as implantable devices provided with an energy source.

Moreover, the medical devices sector is not a single entity but encompasses a highly varied mix of sectors and markets and comprises various enterprises, which produce different products to meet different needs.

EUDAMED, the European database on medical devices, established to strengthen market surveillance and improve the sector's transparency, has established a mandatory platform for the exchange of information between the Member States and the European Commission providing that, starting from May 2011, the information would be inputted into the EU database directly by the Member States. However, as of today the inputting process is yet to be completed, even though Italy contributes in an ongoing and systematic manner, having made choices and investments to comply with the European Commission's request.

To achieve these goals, since 2007 Italy has embarked on an information and data sharing process, by setting up a central database and Register of medical devices.

The use of the registration number issued by the single register of the health authorities' management information systems has been the first step in a process of change which has generated significant positive effects in the overall governance of medical devices by the public healthcare centres within the National Health Service and by the companies themselves, which are required to update regularly the data concerning their products.

In this regard, we should stress the strong effort made by all stakeholders to harmonise the legal and business needs of the sector's businesses with the strictly regulatory aspects of medical devices. To date, management of the updating of the data already entered in the database and Register of medical devices is a complex and specific activity, entrusted to the business sector.

The publication on the Ministry of Health's website, starting from December 2011, of the identification details of the devices on the database and register of medical devices has without doubt facilitated the sharing of information, which has been useful to enable accurate checks which include the monitoring/validation of the inputted data.

The growing interest by the competent authorities of the other EU Member States for the data acquisition system put in place by Italy leads us to believe that the Italian database is absolutely unique, especially with regard to the amount and quality of the information entered, compared with those of other European countries.

As of 31 December 2013 the system's register included **548 195** medical devices placed on the market in Italy. At the same date, the manufacturers and the European representatives of manufacturers not established in the EU numbered **11 386**. Of these manufacturers, **3 285**, or about 29% of the total, are based in Italy.

In view of the complexity and vastness of the medical devices market, we stress the need to maintain a continuing training system for both users and monitoring and surveillance personnel, to ensure the ongoing updating of their knowledge, not least to ensure uniform assessment criteria nationwide. This critical requirement is all the more important in consideration of the scarcity of

resources.

Moreover, in Italy healthcare providers are subject to more extensive reporting obligations for incidents with medical devices than in many other European countries. This ensures that even where the manufacturer fails to comply with its obligations, the Ministry of Health can be informed of adverse events, measure them and assess their relevance.

Despite the lack of reliable data on the total use of devices, the presence of a centralised database collecting incident report data allows better assessment of the risk of individual incidents and of the remedial actions taken, by using all the information available, including, for example, the extent of the potentially exposed population and the likelihood of incident recurrence.

At the end of 2011 initial implementation was completed of a new IT system strengthening the collection and analysis of surveillance data. The database is accessible via the web also by healthcare providers and has improved functions for statistical processing.

Moreover, the Ministry of Health publishes on its website the safety notices issued by manufacturers to report their corrective actions. Whenever publication of the manufacturers' notices on the Ministry's website is felt to provide insufficient dissemination, as was the case for breast and hip implants, the Ministry also issues circulars to reach the parties concerned more directly and rapidly.

## **Sector 2 - Cosmetics**

### **Overview of general market surveillance activities**

#### ***A. Review of general market surveillance activities***

#### **Information on the general market surveillance organisation and infrastructures in place for the period 2010-2013**

The Ministry of Health - Directorate General for medical devices, pharmaceutical service and treatment safety, is the competent authority for the surveillance of cosmetic products. This activity is performed through Office VII of the Directorate General for medical devices, pharmaceutical services and treatment safety (DGDFSC), with the support of the authorities having local competence, i.e. the Regions/Local Health Authorities and the Carabinieri Health Protection Units. Further surveillance activities are handled by the maritime, air and border health offices (USMAF). Prior to 11 July 2013 the reference national legislation was Law No 713 of 11 October 19/86 as amended and supplemented. The operational procedures are described in Document No 4275 of 4 February 2010 forwarded to Division XVI of the Ministry of Economic Development.

As specified in said document, prior legislation did not contemplate performance by the Ministry of Health of monitoring and verification of the activities carried out by the competent authorities.

From 11 July 2013 Regulation (EC) No 1223/2009 on cosmetic products has become fully applicable. The Regulation has updated the reference framework, including surveillance activity, now expressly provided for by Article 22:

“Member States shall monitor compliance with this Regulation via in-market controls of the cosmetic products made available on the market. They shall perform appropriate checks of cosmetic products and checks on the economic operators on an adequate scale, through the product information file and, where appropriate, physical and laboratory checks on the basis of adequate samples.

Member States shall entrust to market surveillance authorities the necessary powers, resources and knowledge in order for those authorities to properly perform their tasks.

Member States shall periodically review and assess the functioning of their surveillance activities. Such reviews and assessments shall be carried out at least every four years and the results thereof shall be communicated to the other Member States and the Commission and be made available to the public, by way of electronic communication and, where appropriate, by other means."

As provided for by Article 16 of Law No 97 of 6 August 2013: "Provisions for fulfilling the obligations arising from Italy's membership of the European Union - European Law 2013", a Ministerial Decree currently being drafted will regulate the procedures for monitoring the national market for cosmetic products, including checks on the products, the sector's operators and good manufacturing practices. The Decree will also contain rules on the formalities and notices required of sector operators under the surveillance activity pursuant to Regulation No 1223.

A separate Decree on sanctions has been drafted and is currently undergoing approval.

We provide below the data on the document checks performed by Office VII of DGFDMS, competent for cosmetic products.

Regional-level checks have been carried out by the Regions (or by the bodies delegated by them via *ad-hoc* Regional legislation) according to their plans. However, there was no obligation to report this activity to the Ministry of Health.

For data on the checks carried out by the USMAF offices, please see the Ministry's website at:

[http://www.salute.gov.it/portale/temi/p2\\_6.jsp?lingua=italiano&id=3065&area=usmaf&menu=vuoto](http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=3065&area=usmaf&menu=vuoto).

As to the checks carried out by the Carabinieri's Health Protection Unit (NAS), it should be noted that the NAS units, besides operating autonomously or via delegation as judicial police, are also entrusted by the Ministry of Health to perform *ad hoc* nationwide checks in respect of every alert from the "Rapex" platform. The Ministry of Health may also request the assistance of NAS in cases of ordinary surveillance activity.

### 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)	NA	NA	NA	NA
1.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	NA	NA	NA	NA
2	Staff available to market surveillance authorities (full-time equivalent units)	10	10	10	10
3	Number of inspectors available to market surveillance authorities (full-time equivalent units)	NA	NA	NA	NA

In budget terms there is at national level no specific line item on cosmetic products, nor are the line items of local authorities available; therefore we are unable to estimate the budget resources (which also include indirect costs such as staff salaries or surveillance expenses).

The estimate of ten units under the heading "Staff available to market surveillance authorities" refers to the Ministry of Health's staff tasked with document checks, who however also have other duties and are thus not engaged full time in this task. Within the Ministry of Health there are also USMAF staff members, with competence on the entry of cosmetic products into the EU territory. The relevant data is published on website

[http://www.salute.gov.it/portale/temi/p2\\_6.jsp?lingua=italiano&id=3065&area=usmaf&menu=vuoto](http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=3065&area=usmaf&menu=vuoto)

As to the number of the Carabinieri's Health Protection Unit officers, see the data on their website (<http://www.carabinieri.it/Internet/Arma/Curiosita/Non+tutti+sanno+che/N/11+N.htm>).

We are unable to estimate the number of inspectors available, as the staff is employed across various sectors and by different authorities (local authorities, judicial police bodies).

### ***B. Assessment of the functioning of market surveillance activities***

In the period 2010-2013 surveillance activity was supplied by different-level authorities (the central government through the Ministry of Health, the Regions through the bodies appointed by them under Regional legislation), as well as through ongoing cooperation with the judicial police bodies and research entities (National Health Institute, Regional Agencies for Environmental Protection).

The national legislation is currently being updated to comply with Regulation (EC) No 1223/2009, attempting to maintain continuity with the positive experiences of previous years.



## 2.A. Review of market surveillance activities in the sector

### Information on enforcement activities carried out in the period 2010-2013

		2010	2011	2012	2013
1	Number of product related accidents / user complaints	NA	NA	NA	NA
2	Number of substantiated complaints by industry concerning unfair competition	NA	NA	NA	NA
3	Number of inspections (total number)	1 658	1 768	1 025	1 090
3.1	number of reactive inspections	66	104	74	92
3.2	number of self-initiated inspections	1592	1664	951	988
3.3	number of inspections prompted by the customs	NA	NA	NA	NA
4	Number of inspections based on:				
4.1	tests performed in laboratories	NA	NA	NA	NA
4.2	physical checks of products	NA	NA	NA	NA
5	Number of inspections resulting in:				
5.1	finding of non-compliance	669	243	250	118
5.2	corrective actions taken by economic operators (“voluntary measures”)	NA	NA	NA	NA
5.3	restrictive measures taken by market surveillance authorities .	NA	NA	NA	NA
5.4	application of sanctions/penalties	NA	NA	NA	NA
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

Since 2013 a system for the receipt of incident reports concerning cosmetics has been in force in accordance with Article 23 of Regulation No 1223/2009. The figure concerns the reports received by the Ministry of Health and does not include reports made at Regional level. No estimate is possible for the previous years.

We are unable to estimate the complaints received for unfair competition; they mostly posed no health hazard but concerned market distortion (infringement of competition rules, misleading advertising) subjected to proceedings by competent agencies or the judicial authorities, hence bodies not linked to the Ministry of Health as their competences do not always fall under its remit. The number of inspections was calculated by adding to those carried out on behalf of the Ministry of Health the inspections performed by the Regional bodies, calculated by taking as a sample the Veneto and Emilia Romagna Regions and considering the data in proportion to the national population on the basis of the latest national population census performed by ISTAT. The same technique was used to calculate the non-conformities, then adding the data directly held by the Ministry of Health.

We are unable to supply separate data for the customs authorities.

No distinction can be made between inspections based on laboratory tests and physical checks in Italy with regard to cosmetic products, because the same inspection may well concern either or both types of checks; hence no sharp distinction is possible.

As to the distinction between voluntary corrective measures and coercive restrictive measures, the corrections are often made in the course of the investigation; therefore here too no sharp distinction can be made. The application of sanctions does not fall under the competence of the Ministry of Health, and the Regions have no exclusive competence over the matter, since cases

involving criminal offence fall under the competence of the judicial authorities. Therefore we are unable to estimate the penalties applied.

We are aware of no inspections where other Member States were invited to collaborate.

### **Information on communication activities carried out in the period 2010-2013**

During the four-year period 2010-2013 training courses and seminars on cosmetic product legislation were delivered to authorities/public agencies such as the Regions, the Carabinieri for Health Protection, universities, customs and local offices of USMAF.

2010: 2 courses

2011: 2 courses

2012: 2 courses

One of the aims of this training was to assist in the fight against the counterfeiting of cosmetic products: in 2012 and 2013 this was a key objective for the Ministry of Health.

### **Information on resources**

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (EUR)	NA	NA	NA	NA
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	NA	NA	NA	NA
8	Staff available to market surveillance authorities (full-time equivalent units)	4	4	4	4
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	NA	NA	NA	NA

There is no specific deployment to training activity on cosmetics surveillance; the data on the staff available to surveillance authorities concern the Ministry of Health's staff who deliver training but not on a full-time basis.

## ***2.B. Assessment of the functioning of market surveillance activities in the sector***

On the basis of the data collected under the earlier legislative framework, the cosmetics market involves thousands of manufacturers and/or parties that place these products on the market in the national territory, plus the chain of distributors, which raises exponentially the number of operators in the sector.

Given the sheer size of the market, surveillance is of necessity also performed via document checks which, however, are flanked by checks (also by judicial police or on the basis of reports) conducted directly on the market.

Surveillance also covers the cosmetics production phase.

In accordance with Article 16 of Law No 97 of 6 August 2013, decrees are being drafted to regulate surveillance activity in accordance with Regulation (EC) No 1223/2009, trying to preserve the internal allocation of competences which is felt to be satisfactory.

**Ministry of Transport - General Command of the Italian Coast Guard and Harbour Masters - 6<sup>th</sup> Unit - Maritime Safety - Office II Technical safety services dangerous goods**

**Sector 26 Maritime equipment**

**Overview of general market surveillance activities**

***A. Review of general market surveillance activities***

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

See the list previously provided in the template on the planning of the national market surveillance activities for the year 2014

**Information on total resources available for market surveillance activities (subject to availability)**

		2010	2011	2012	2013
1.1	Budget available to market surveillance authorities in nominal terms <sup>4</sup> (EUR)	0	0	0	0
1.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	0	0	0	0
2	Staff available to market surveillance authorities (full-time equivalent units)	0.20	0.20	0.20	0.20
3	Number of inspectors available to market surveillance authorities (full-time equivalent units)	0	0	0	0

***B. Assessment of the functioning of market surveillance activities***

The current organisation of the infrastructure and resources available for surveillance of the national market only allow the relevant authority to perform reactive surveillance actions. In its capacity as the authority responsible for market surveillance for maritime equipment, in the immediate future the 6<sup>th</sup> Unit - Market Security of this authority would hope to engage in proactive market surveillance which, based on the statistics from the on-board checks carried out on national and EU ships, is able to identify the equipment at higher risk. However this activity would require additional funds and a dedicated budget heading, to manage the planned actions.

**Market surveillance activities in specific sectors**

**Sector 26 Maritime equipment**

***26.A. Review of market surveillance activities in the sector***

**Information on enforcement activities carried out in the period 2010-2013**

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

#### **Information on communication activities carried out in the period 2010-2013**

In the four years in question, no communication activities were implemented, owing to the lack of funds.

#### **Information on resources**

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms <sup>5</sup> (EUR)	0	0	0	0
7.2	Budget available to market surveillance authorities in relative terms (%age 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

#### ***26.B. Assessment of the functioning of market surveillance activities in the sector***

As also described in the the national market surveillance planning template submitted annually, to date, despite several requests, no funds have been allocated nor have staff and/or appropriate infrastructure been selected to enable the sampling of products and the selection, purchase and testing of maritime equipment.

Consequently, our checks are purely of a reactive nature and comprise exclusively document analyses on products identified through reports from private parties or other Member States.

## Customs and Monopoly Agency

### Overview of general market surveillance activities

#### Sector 31- Tobacco products-cigarettes

##### *31.A. Review of market surveillance activities in the sector*

##### Information on enforcement activities carried out in the period 2010-2013

		2010	2011	2012	2013
1	Number of product related accidents / user complaints		0	0	0
2	Number of substantiated complaints by industry concerning unfair competition				
3	Number of inspections (total number)		0	0	0
3.1	number of reactive inspections		0	0	0
3.2	number of self-initiated inspections		2	129	268
3.3	number of inspections prompted by the customs		0	0	0
4	Number of inspections based on:				
4.1	tests performed in laboratories		2	129	268
4.2	physical checks of products				
5	Number of inspections resulting in:				
5.1	finding of non-compliance		0	0	4 (***)
5.2	corrective actions taken by economic operators (“voluntary measures”)		0	0	0
5.3	restrictive measures taken by market surveillance authorities.		0	0	4 (***)
5.4	application of sanctions/penalties		0	0	0
6	Number of inspections where other Member States were invited to collaborate		0	0	0

**(\*\*\*\*) these findings of non-compliance were made during preventive monitoring, which is performed prior to registering in the price list new cigarette brands to allow their sale in the national territory. In the case in question, the relevant brands cannot be marketed.**

##### Information on resources

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (EUR)		131,889	76,716	88,834
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)				
8	Staff available to market surveillance authorities (full-time equivalent units)		1.5	1.5	1.5
9	Number of inspectors available to		0	0	0

market surveillance authorities (full-time equivalent units)				
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## Overview of general market surveillance activities

### *A. Review of general market surveillance activities*

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

See the information provided in letters No 44752/RU of 6 April 2012 and 22257/RU of 25 February 2014.

**Sectors 1. 2. 3. 4. 5. 6. 7. 8. 9.13.14.15.16.17.18.19. 20. 21. 22. 23. 26. 27. 29. 30.**

### *A. Review of market surveillance activities in the sector*

#### Information on enforcement activities carried out in the period 2010-2013

		2010	2011	2012	2013
1	Number of product related accidents / user complaints				
2	Number of substantiated complaints by industry concerning unfair competition				
3	Number of inspections (total number)				
3.1	number of reactive inspections				
3.2	number of self-initiated inspections				
3.3	number of inspections prompted by the customs			<b>187</b>	<b>274</b>
4	Number of inspections based on:				
4.1	tests performed in laboratories				
4.2	physical checks of products				
5	Number of inspections resulting in:				
5.1	finding of non-compliance				
5.2	corrective actions taken by economic operators ("voluntary measures")				
5.3	restrictive measures taken by market surveillance authorities.				
5.4	application of sanctions/penalties				
6	Number of inspections where other Member States were invited to collaborate				



## Ministry of the Interior

### Department of Public Security

#### Sector 14. Pyrotechnic articles – Directive 2007/23/EC

##### *14. Review of market surveillance activities in the sector.*

##### Information on enforcement activities carried out in the period 2010-2013

		2010	2011	2012	2013
1	Number of product related accidents / user complaints	0	0	0	0
2	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3	Number of inspections (total number)	0	0	0	<b>65</b>
3.1	number of reactive inspections	0	0	0	0
3.2	number of self-initiated inspections	0	0	0	<b>65</b>
3.3	number of inspections prompted by the customs	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 checks of products	0	0	0	0
5	Number of inspections resulting in:	0	0	0	0
5.1	finding of non-compliance	0	0	0	0
5.2	corrective actions taken by economic operators (“voluntary measures”)	0	0	0	0
5.3	restrictive measures taken by market surveillance authorities.	0	0	0	0
5.4	application of sanctions/penalties	0	0	0	0
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

##### Information on communication activities carried out in the period 2010-2013

The Ministry of the Interior, Department of Public Security, in its capacity as National Surveillance Authority for the market of pyrotechnic articles with CE marking, has published on the State Police's official website a guide for users entitled "**Guides on fireworks**".

One section is entitled: "**Fireworks - let's make things clear**" <http://poliziadistato.it/articolo/644/>,

another: "**Prohibited fireworks**" <http://poliziadistato.it/articolo/642/>.

Additional information is provided in the following guides:

"**Advice on fireworks**" <http://www.poliziadistato.it/articolo/view/10261/>

"**How to use them correctly. Safety tips**" <http://www.poliziadistato.it/articolo/view/641/>

"**For children. Beware of...**" <http://www.poliziadistato.it/articolo/view/636/>

All police agencies also have reserved access to an Intranet platform via the address: <http://application.cedinterforze.interno.it/polam/index.php>. This platform has a number of publications including circular, statistics and national and EU legislation on the sector (both pyrotechnic articles and explosives for civil use).

#### 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 (%age 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

#### ***14.B Assessment of the functioning of market surveillance activities in the sector***

The greatest difficulty encountered by market surveillance in the sector of explosives (both pyrotechnic articles and explosives for civil use) is that of selecting laboratories for tests to ascertain the products' conformity. The laboratories contacted have pointed out that there are costs to be borne. The lack of national funds earmarked for these activities prevent implementation of the checks. Action by the EU also in the form of funding would be more than welcome.

Funding would also be useful for the training of staff performing checks on documents and on product labelling (e.g. law enforcement, customs and administrative authorities). The working group (ADCO) should draft as soon as possible the guidelines to be used when executing the checks, in order to ensure that surveillance activities are performed uniformly and harmoniously throughout the EU.

Possible comparisons with other countries, via the participation of inspectors from other Member States in the checks, or information on the tests they perform, would be another opportunity to standardise and raise the bar of surveillance activities within the EU.

## Sector 15. Explosives for civil use – Directive 93/15/EC

### 15.A Review of market surveillance activities in the sector

#### Information on enforcement activities carried out in the period 2010-2013

		2010	2011	2012	2013
1	Number of product related accidents / user complaints	0	0	0	0
2	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3	Number of inspections (total number)	0	23	30	0
3.1	number of reactive inspections	0			0
3.2	number of self-initiated inspections	0	23	30	0
3.3	number of inspections prompted by the customs	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 checks of products	0	0	0	0
5	Number of inspections resulting in:	0	0	0	0
5.1	finding of non-compliance	0	0	0	0
5.2	corrective actions taken by economic operators (“voluntary measures”)	0	0	0	0
5.3	Restrictive measures taken by market surveillance authorities.	0	0	0	0
5.4	Application of sanctions/penalties	0	0	0	0
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

#### Information on communication activities carried out in the period 2010-2013

All police agencies also have reserved access to an Intranet platform via the address: <http://application.cedinterforze.interno.it/polam/index.php>. This platform has a number of publications including circular, statistics and national and EU legislation in the sector (both pyrotechnic articles and explosives for civil use).

### 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 (%age 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

#### ***15.B Assessment of the functioning of market surveillance activities in the sector***

The greatest difficulty encountered by market surveillance in the sector of explosives (both pyrotechnic articles and explosives for civil use) is that of selecting laboratories for tests to ascertain the products' conformity. The laboratories contacted have pointed out that there are costs to be borne. The lack of national funds earmarked for these activities prevent implementation of the checks. Action by the EU also in the form of funding would be welcome. Funding would also be useful for the training of staff performing checks on documents and on product labelling (e.g. law enforcement, customs and administrative authorities). The working group (ADCO) should draft as soon as possible the guidelines to be used when executing the checks, in order to ensure that surveillance activities are performed uniformly and harmoniously throughout the EU.

Possible comparisons with other countries, via the participation of inspectors from other Member States in the checks, or awareness of the tests they perform, would be another opportunity to standardise and raise the bar of surveillance activities within the EU.

## Financial Police

### Overview of general market surveillance activities

#### *A. Review of general market surveillance activities*

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

The Financial Police is engaged in the surveillance of product safety and conformity through a network of local and special units, specifically:

- a. the local units comprise about 700 "ordinary" departments, consisting of the fiscal police units (with their groups "Protection of the market, goods and services, which gather together the best qualified investigative unit in each Province), and by the various subunits which are the backbone of the Financial Police's activities;
- b. the special component is under the Special Unit Command, to which the Special Unit for Market Protection reports.

The latter unit:

- performs risk analysis by cross-checking internal and external databases, studying fraud systems, drawing up operational methodologies and providing specialist technical support to the local Commands, also by creating comprehensive inspection plans targeting selected parties;
- through its local offices, it monitors the correct enforcement of restrictive measures (import bans, notices to conform, marketing bans, withdrawal from the market, etc.) issued by the Ministry of Economic Development.
- is equipped with two "MS creator" stations through which it uploads onto GRAS-RAPEX (RAPID ALERT SYSTEM FOR ALL DANGEROUS CONSUMER PRODUCTS), the information supplied by the Financial Police Units on the dangerous goods identified in the national territory, and monitors any releases of dangerous products into the market through the same stations.

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 (%age 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)	2	2	2	2

## *B. Assessment of the functioning of market surveillance activities*

**Lack of economic resources for the performance of laboratory tests aimed at assessing the hazards posed by products**

### *Review of market surveillance activities in the sector*

Information on enforcement activities carried out in the period 2010-2013

The data entered in this table refer solely to the Financial Police's RAPEX activity

		<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>
1	Number of product related accidents / user complaints				
2	Number of substantiated complaints by industry concerning unfair competition				
3	Number of inspections (total number)				
3.1	number of reactive inspections	36	16	25	6
3.2	number of self-initiated inspections			3	21
3.3	number of inspections prompted by the customs				
4	Number of inspections based on:				
4.1	tests performed in laboratories				
4.2	physical checks of products				
5	Number of inspections resulting in:				
5.1	a finding of non-compliance				
5.2	corrective actions taken by economic operators (“voluntary measures”)				
5.3	restrictive measures taken by market surveillance authorities.				
5.4	application of sanctions/penalties				
6	Number of inspections where other Member States were invited to collaborate				

### Information on resources

		<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>
7.1	Budget available to market surveillance authorities in nominal terms (EUR)				
7.2	Budget available to market surveillance authorities in relative terms (%age 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)	2	2	2	2

**Ministry of Labour and Social Policies**  
**Directorate General for Inspection Activity - DIV III**  
**Sector 9 - Machinery – Directive 2006/42/EC**  
*A. Review of general market surveillance activities*

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

Under Article 6 of Legislative Decree No 17/2010, the Ministry of Labour is the market surveillance authority together with the Ministry of Economic Development for machines and partly completed machines, for conformity checking. Surveillance activities are coordinated by the Directorate General for inspection and are performed by the local offices present in each Province (DTL).

The local offices have no services dedicated exclusively to market surveillance. This activity is performed by the technical inspectors as part of their monitoring of workplace health and safety.

The surveillance activity involves checks on the conformity of machines or partly completed machines at the manufacturer's plant where campaigns on certain products seem advisable or where, under Article 6(3), the health and safety surveillance bodies find that a machine with CE marking or a partly completed machine fails to satisfy partly or entirely one or more essential health and safety requirements.

In the period in question (2010-2013) the activity carried out by this Directorate General was determined by the reports submitted by the surveillance bodies, and was implemented in the manner agreed with the Ministry of Economic development - D.G.M.C.C.V.N.T - DIV XVIII in accordance with the Interministerial Decree of 14 December 2004 and with circulars No 1067 of 30 September 1999 and No 2182 of 20 December 2000. In particular:

The local offices (DTL) are responsible for performing checks on:

- 1) machines for which the manufacturer has failed to comply with the formal notice to comply with the essential safety requirements served on it by the Ministry of Economic Development after technical checks carried out by INAIL;
- 2) machines on which the manufacturer has declared it has remedied the non-compliance with essential safety requirements and has aligned those machines already on the market.

**Information on total resources available for market surveillance activities**

Market surveillance activities are performed, in the manner specified above, by the technical inspectors manning each local office. There are no plans to set up in local offices sections dedicated exclusively to market surveillance. Therefore, market surveillance inspections cannot be distinguished in economic terms from official inspections (workplace health and safety in the areas under the Ministry's competence). Consequently, the financial values requested in the table cannot be calculated.



		2010	2011	2012	2013
1.1	Budget available to market surveillance authorities in nominal terms <sup>7</sup> (EUR)	n.a.	n.a.	n.a.	n.a.
1.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	n.a.	n.a.	n.a.	n.a.
2	Staff available to market surveillance authorities (full-time equivalent units)	5	6	5	5
3	Number of inspectors available to market surveillance authorities (full-time equivalent units)	2	2	i	1

### ***B. Assessment of the functioning of market surveillance activities***

On the basis of the information provided, the procedure in force reveals no specific difficulties in performance of market surveillance, including in terms of human resources. However, we wish to point out that the penalties under Article 15 of Legislative Decree No 17/2010 may be applied only in the absence of a criminal offence. Since the placing of non-conforming machines on the market constitutes a criminal offence, Article 15 of Legislative Decree No 17/2010 is not applicable.

### ***9.A Review of market surveillance activities in the sector***

#### **Information on enforcement activities carried out in the period 2010-2013**

		2010	2011	2012	2013
1	Number of product related accidents / user complaints	122	117	110	118
2	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3	Number of inspections (total number)	143	123	79	66
3.1	number of reactive inspections				
3.2	number of self-initiated inspections				
3.3	number of inspections prompted by the customs				
4	Number of inspections based on:				
4.1	tests performed in laboratories				
4.2	physical checks of products				
5	Number of inspections resulting in:				
5.1	finding of non-compliance	279	252	242	200
5.2	corrective actions taken by economic operators (“voluntary measures”)				
5.3	restrictive measures taken by market surveillance authorities	Figure not available as it falls under the competence of the Ministry of Economic	Figure not available as it falls under the competence of the Ministry of Economic	Figure not available as it falls under the competence of the Ministry of Economic	Figure not available as it falls under the competence of the Ministry of Economic

		Developme nt	Developme nt	Developme nt	Developme nt
5.4	application of sanctions/penalties	Figure not available	Figure not available	Figure not available	Figure not available
6	Number of inspections where other Member States were invited to collaborate				

***9.B. Assessment of the functioning of market surveillance activities in the sector***

On the basis of the information provided, the procedure in force reveals no specific difficulties in performance of market surveillance, including in terms of human resources. However, we point out that the penalties under Article 15 of Legislative Decree No 17/2010 may be applied only in the absence of a criminal offence. Since the placing of non-conforming machines on the market constitutes a criminal offence, Article 15 of Legislative Decree No 17/2010 is not applicable.

## Ministry of Economic Development

### Overview of general market surveillance activities

#### *A. Review of general market surveillance activities*

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

Reference to the national sectoral market surveillance programme (2014)
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#### **Information on total resources available for market surveillance activities**

		2010	2011	2012	2013
1.1	Budget available to market surveillance authorities in nominal terms <sup>8</sup> (EUR)	1 490/000	1 440/000	1 480/000	1 470/000
1.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	0.05%	0.05%	0.05%	0.05%
2	Staff available to market surveillance authorities (full-time equivalent units)	63	63	63	63
3	Number of inspectors available to market surveillance authorities (full-time equivalent units)	30	30	30	30

#### *B. Assessment of the functioning of market surveillance activities*

The performance of market surveillance activities is often hampered by the lack of traceability information and by the serious lack of - especially financial - resources. These budgetary constraints have limited the number of pro-active inspections.
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#### *A. Review of market surveillance activities in the sector*

##### **Information on enforcement activities carried out in the period 2010-2013**

		2010	2011	2012	2013
1	Number of product related accidents / user complaints	n.a.	n.a.	n.a.	n.a.
2	Number of substantiated complaints by industry concerning unfair competition	n.a.	n.a.	n.a.	n.a.
3	Number of inspections (total number)	<b>43</b>	<b>265</b>	<b>204</b>	<b>63</b>
3.1	number of reactive inspections	3	4	2	2
3.2	number of self-initiated inspections	40	261	202	61
3.3	number of inspections prompted by the customs	n.a.	n.a.	n.a.	n.a.
4	Number of inspections based on:				
4.1	tests performed in laboratories	<b>9</b>	<b>78</b>	<b>80</b>	<b>26</b>
4.2	physical checks of products	<b>43</b>	<b>265</b>	<b>204</b>	<b>63</b>
5	Number of inspections resulting in:				

5.1	finding of non-compliance	<b>13</b>	<b>38</b>	<b>45</b>	<b>24</b>
5.2	corrective actions taken by economic operators (“voluntary measures”)	n.a.	n.a.	n.a.	n.a.
5.3	restrictive measures taken by market surveillance authorities	n.a.	n.a.	n.a.	n.a.
5.4	application of sanctions/penalties	n.a.	n.a.	n.a.	n.a.
6	Number of inspections where other Member States were invited to collaborate	n.a.	n.a.	n.a.	n.a.

## **Sector 4. PERSONAL PROTECTIVE EQUIPMENT**

### *4.A. Review of market surveillance activities in the sector*

#### **Information on enforcement activities carried out in the period 2010-2013**

		<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>
1	Number of product related accidents / user complaints	n.a.	n.a.	n.a.	n.a.
2	Number of substantiated complaints by industry concerning unfair competition	n.a.	n.a.	n.a.	n.a.
3	Number of inspections (total number)	<b>6</b>	<b>78</b>	<b>39</b>	<b>18</b>
3.1	number of reactive inspections	0	0	1	0
3.2	number of self-initiated inspections	6	78	38	18
3.3	number of inspections prompted by the customs	n.a.	n.a.	n.a.	n.a.
4	Number of inspections based on:				
4.1	tests performed in laboratories	<b>2</b>	<b>9</b>	<b>2</b>	<b>5</b>
4.2	physical checks of products	<b>6</b>	<b>78</b>	<b>39</b>	<b>18</b>
5	Number of inspections resulting in:				
5.1	finding of non-compliance	<b>3</b>	<b>18</b>	<b>2</b>	<b>7</b>
5.2	corrective actions taken by economic operators (“voluntary measures”)	n.a.	n.a.	n.a.	n.a.
5.3	restrictive measures taken by market surveillance authorities.	n.a.	n.a.	n.a.	n.a.
5.4	application of sanctions/penalties	n.a.	n.a.	n.a.	n.a.
6	Number of inspections where other Member States were invited to collaborate	n.a.	n.a.	n.a.	n.a.

## Sector 20. ELECTRICAL APPLIANCES AND EQUIPMENT UNDER LVD

### *20.A. Review of market surveillance activities in the sector*

#### Information on enforcement activities carried out in the period 2010-2013

		2010	2011	2012	2013
1	Number of product related accidents / user complaints	n.a.	n.a.	n.a.	n.a.
2	Number of substantiated complaints by industry concerning unfair competition	n.a.	n.a.	n.a.	n.a.
3	Number of inspections <sup>9</sup> (total number)	<b>36</b>	<b>176</b>	<b>128</b>	<b>77</b>
3.1	number of reactive inspections	8	7	5	3
3.2	number of self-initiated inspections	28	169	123	74
3.3	number of inspections prompted by the customs	n.a.	n.a.	n.a.	n.a.
4	Number of inspections based on:				
4.1	tests performed in laboratories	<b>10</b>	<b>40</b>	<b>29</b>	<b>34</b>
4.2	physical checks of products				
5	Number of inspections resulting in:				
5.1	finding of non-compliance	<b>13</b>	<b>29</b>	<b>25</b>	<b>22</b>
5.2	corrective actions taken by economic operators ("voluntary measures")	n.a.	n.a.	n.a.	n.a.
5.3	restrictive measures taken by market surveillance authorities.	n.a.	n.a.	n.a.	n.a.
5.4	application of sanctions/penalties	n.a.	n.a.	n.a.	n.a.
6	Number of inspections where other Member States were invited to collaborate	n.a.	n.a.	n.a.	n.a.

## Sector 23. Energy labelling and eco-design

### Overview of general market surveillance activities

#### *A. Review of general market surveillance activities*

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

		2010	2011	2012	2013
1.1	Budget available to market surveillance authorities in nominal terms (EUR)	<b>n.a.</b>	<b>17 096.00</b>	<b>20 596.00</b>	<b>25 360.00</b>
1.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	n.a.	n.a.	n.a.	n.a.
2.	Staff available to market surveillance authorities (full-time equivalent units)	n.a.	n.a.	n.a.	n.a.
3	Number of inspectors available to market surveillance authorities (full-time equivalent units)	n.a.	n.a.	n.a.	35

## 1 data relating solely to direct inspection costs and laboratory tests

### *B. Assessment of the functioning of market surveillance activities*

Lack of resources;  
High costs for sampling the products and performing laboratory tests; difficulties in locating local test laboratories.

## Sector 23. Ecodesign and Energy labelling

### *23.A. Review of market surveillance activities in the sector*

#### Information on enforcement activities carried out in the period 2010-2013

		2010	2011	2012	2013
1	Number of product related accidents / user complaints	n.a.	n.a.	n.a.	n.a.
2	Number of substantiated complaints by industry concerning unfair competition	n.a.	n.a.	n.a.	n.a.
3	Number of inspections (total number)	n.a.	11	12	55
3.1	number of reactive inspections	n.a.	n.a.	n.a.	n.a.
3.2	number of self-initiated inspections	n.a.	11	12	55
3.3	number of inspections prompted by the customs	n.a.	n.a.	n.a.	n.a.
4	Number of inspections based on:				
4.1	tests performed in laboratories	n.a.	n.a.	n.a.	2
4.2	physical checks of products	n.a.	82	111	292
5	Number of inspections resulting in:				
5.1	a finding of [non]-conformity	n.a.	6	9	26
5.2	corrective actions taken by economic operators (“voluntary measures”)	n.a.	0	0	21
5.3	restrictive measures taken by market surveillance authorities.	n.a.	0	0	0
5.4	application of sanctions/penalties	n.a.	6	9	5
6	Number of inspections where other Member States were invited to collaborate	n.a.	n.a.	n.a.	n.a.

#### Information on communication activities carried out in the period 2010-2013

No communication activity was materially carried out. Training activity for the inspectors attached to the Chambers of Commerce was solely planned, and will be delivered over the period 2014-2015.

#### Information on resources (subject to availability)

### *23.B. Assessment of the functioning of market surveillance activities in the sector*

Lack of resources;  
High costs for sampling the products and performing laboratory tests;  
Difficulties in locating local testing laboratories.

Surveillance activity is based on the estimates made locally by each Chamber of Commerce, under their autonomous control powers.

## Sector 30. OTHER CONSUMER PRODUCTS UNDER GPSD

### 30.A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the period 2010-2013

		2010	2011	2012	2013
1	Number of product related accidents / user complaints	n.a.	n.a.	n.a.	n.a.
2	Number of substantiated complaints by industry concerning unfair competition	n.a.	n.a.	n.a.	n.a.
3	Number of inspections (total number)	13	28	43	9
3.1	number of reactive inspections	2	2	0	1
3.2	number of self-initiated inspections	11	26	43	8
3.3	number of inspections prompted by the customs	n.a.	n.a.	n.a.	n.a.
4	Number of inspections based on:				
4.1	tests performed in laboratories	0	2	5	6
4.2	physical checks of products	13	28	43	9
5	Number of inspections resulting in:				
5.1	finding of non-compliance	5	10	10	4
5.2	corrective actions taken by economic operators ("voluntary measures")	n.a.	n.a.	n.a.	n.a.
5.3	restrictive measures taken by market surveillance authorities.	n.a.	n.a.	n.a.	n.a.
5.4	application of sanctions/penalties	n.a.	n.a.	n.a.	n.a.
6	Number of inspections where other Member States were invited to collaborate	n.a.	n.a.	n.a.	n.a.

## Sector 32. LABELLING OF TEXTILE PRODUCTS

### 32.A. Review of market surveillance activities in the sector

Information on enforcement activities carried out in the period 2010-2013

		2010	2011	2012	2013
1	Number of product related accidents / user complaints	n.a.	n.a.	n.a.	n.a.
2	Number of substantiated complaints by industry concerning unfair competition	n.a.	n.a.	n.a.	n.a.
3	Number of inspections (total number)	155	210	121	2
3.1	number of reactive inspections	4	3	1	0
3.2	number of self-initiated inspections	151	207	120	2

3.3	number of inspections prompted by the customs	n.a.	n.a.	n.a.	n.a.
4	Number of inspections based on:				
4.1	tests performed in laboratories	30	98	55	2
4.2	physical checks of products				
5	Number of inspections resulting in:				
5.1	finding of non-compliance	28	50	28	2
5.2	corrective actions taken by economic operators (“voluntary measures”)	n.a.	n.a.	n.a.	n.a.
5.3	restrictive measures taken by market surveillance authorities.	n.a.	n.a.	n.a.	n.a.
5.4	application of sanctions/penalties	n.a.	n.a.	n.a.	n.a.
6	Number of inspections where other Member States were invited to collaborate	n.a.	n.a.	n.a.	n.a.

## Sector 33. FOOTWEAR LABELLING

### *33.A. Review of market surveillance activities in the sector*

#### **Information on enforcement activities carried out in the period 2010-2013**

		<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>
1	Number of product related accidents / user complaints	n.a.	n.a.	n.a.	n.a.
2	Number of substantiated complaints by industry concerning unfair competition	n.a.	n.a.	n.a.	n.a.
3	Number of inspections (total number)	38	97	53	3
3.1	number of reactive inspections				
3.2	number of self-initiated inspections	38	97	53	3
3.3	number of inspections prompted by the customs	n.a.	n.a.	n.a.	n.a.
4	Number of inspections based on:				
4.1	tests performed in laboratories	0	42	15	2
4.2	physical checks of products	38	97	53	3
5	Number of inspections resulting in:				
5.1	finding of non-compliance	6	13	4	1
5.2	corrective actions taken by economic operators (“voluntary measures”)	n.a.	n.a.	n.a.	n.a.
5.3	restrictive measures taken by market surveillance authorities	n.a.	n.a.	n.a.	n.a.
5.4	application of sanctions/penalties	n.a.	n.a.	n.a.	n.a.
6	Number of inspections where other Member States were invited to collaborate	n.a.	n.a.	n.a.	n.a.



## Sector 17 - Measuring instruments, non-automatic weighing instruments and pre-packaged products

### *17.A. Review of market surveillance activities in the sector*

#### Information on enforcement activities carried out in the period 2010-2013 <sup>23</sup>

		2010	2011	2012	2013
1	Number of product related accidents / user complaints	n.a.	n.a.	n.a.	n.a.
2	Number of substantiated complaints by industry concerning unfair competition	n.a.	n.a.	n.a.	n.a.
3	Number of inspections (total number)				
3.A	Measuring instruments (MID)	217 (aggregated figure for the four years)			
3.B	Prepackaged	198 (aggregated figure for the four years)			
3.1	Number of reactive inspections	n.a.	n.a.	n.a.	n.a.
3.2	Number of self-initiated inspections	n.a.	n.a.	n.a.	n.a.
3.3	Number of inspections prompted by the customs	n.a.	n.a.	n.a.	n.a.
4	Number of inspections based on:				
4.1.A	lab tests performed (MID)	7 (aggregated figure for the four years)			
4.1.B	lab tests performed (prepackaged products)	0			
4.2.A	physical checks of products 10 (MID)	217 (aggregated figure for the four years)			
4.2.B	physical checks of products 101 (prepackaged products)	198 (aggregated figure for the four years)			
5	Number of inspections resulting in:				
5.1.A	finding of non-compliance (MID)	6 (aggregated figure for the four years)			
5.2	corrective actions taken by economic operators ("voluntary measures")	n.a.	n.a.	n.a.	n.a.
5.3	restrictive measures taken by market surveillance authorities	n.a.	n.a.	n.a.	n.a.

## Radio and telecom equipment under the RTTE Directive (radio and telecommunications terminal equipment)

### *19.A. Review of market surveillance activities in the sector*

<sup>2</sup> This refers to visual examination of the product in order to verify the existence of markings, warnings and information and determining obvious technical shortcomings of the product according to the requirements of applicable Union legislation.

<sup>3</sup> This refers to visual examination of the product in order to verify the existence of markings, warnings and information and determining obvious technical shortcomings of the product according to the requirements of the applicable Union legislation.

**Information on enforcement activities carried out in the period 2010-2013**

		2010	2011	2012	2013
1	Number of product related accidents / user complaints	367	285	349	340
2	Number of substantiated complaints by industry concerning unfair competition	11	15	18	18
3	Number of inspections (total number)	378	300	367	358
3.1	number of reactive inspections	362	300	367	367
3.2	number of self-initiated inspections	20	25	27	30
3.3	number of inspections prompted by the customs	4	3	3	3
4	Number of inspections based on:				
4.1	tests performed in laboratories	130	103	126	123
4.2	physical checks of products	248	197	241	235
5	Number of inspections resulting in:				
5.1	finding of non-compliance	171	135	166	162
5.2	corrective actions taken by economic operators (“voluntary measures”)	0	0	0	0
5.3	restrictive measures taken by market surveillance authorities.	0	1	0	0
5.4	application of sanctions/penalties	171	135	166	162
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

***19.B. Assessment of the functioning of market surveillance activities in the sector***

In the four years in question, the market surveillance activities for the products covered by Directive 1999/05/EC found that about 90% of non-conformities relate to products from third countries, in particular from the People's Republic of China.

## Sector 34 - Control equipment in the road transport sector

### *34.A. Review of market surveillance activities in the sector*

#### **Information on enforcement activities carried out in the period 2010-2013**

		2010	2011	2012	2013
1	Number of product related accidents / user complaints				
2	Number of substantiated complaints by industry concerning unfair competition				
3	Number of inspections (total number)	1013	1028	1134	1233
3.1	number of reactive inspections				
3.2	number of self-initiated inspections				
3.3	number of inspections prompted by the customs				
4	Number of inspections based on:				
4.1	tests performed in laboratories				
4.2	physical checks of products				
5	Number of inspections resulting in:				
5.1	finding of non-compliance				
5.2	corrective actions taken by economic operators (“voluntary measures”)				
5.3	restrictive measures taken by market surveillance authorities.				
5.4	application of sanctions/penalties				
6	Number of inspections where other Member States were invited to collaborate				

## Annex 1: Reference list of sectors

<b>Product sectors</b>	<b>Relevant legislation<sup>4 5</sup></b>	<b>Included in this report? (Y/N)</b>
1. Medical devices (including In vitro diagnostic medical devices and Active implantable medical devices)	Directives 93/42/EEC, 98/79/EC and 90/385/EEC	<b>Yes</b>
2. Cosmetics	Regulation No 1223/2009	<b>Yes</b>
3. Toys	Directive 2009/48/EC	<b>Yes</b>
4. Personal protective equipment	Directive 89/686/EEC	<b>Yes</b>
5. Construction products	Regulation No 305/2011	
6. Aerosol dispensers	Directive 75/324/EEC	
7. Simple pressure vessels and pressure equipment	Directives 2009/105/EC and 97/23/EC	
8. Transportable pressure equipment	Directive 2010/35/EC	
9. Machinery	Directive 2006/42/EC	<b>Yes</b>
10. Lifts	Directive 1995/16/EC	
11. Cableways	Directive 2000/9/EC	
12. Noise emissions for outdoor equipment	Directive 2000/14/EC	<b>Yes</b>
13. Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	Directive 1994/9/EC	
14. Pyrotechnics	Directive 2007/23/EC	<b>Yes</b>
15. Explosives for civil uses	Directive 93/15/EEC	<b>Yes</b>
16. Appliances burning gaseous fuels	Directive 2009/142/EC	
17. Measuring instruments, non-automatic weighing instruments and pre-packaged products	Directives 2004/22/EU, 2009/23/EU and 2007/45/EC	<b>Yes</b>
18. Radio and telecom equipment under the EMC Directive (electromagnetic compatibility)	Directive 2004/108/EC	
19. Radio and telecom equipment under the RTTE Directive (radio and telecommunications terminal equipment)	Directive 1999/5/EC	<b>Yes</b>

<b>Product sectors</b>	<b>Relevant legislation<sup>4, 5</sup></b>	<b>Included in this report? (Y/N)</b>
20. Electrical appliances and equipment under LVD	Directive 2006/95/EC	<b>Yes</b>

<sup>4</sup> For ease of reference this table indicates established EU legislation. New legislation having replaced or amended that listed in the table should also be taken into account for the relevant period to which it applies.

<sup>5</sup> For ease of reference in some cases (and. g. eco-design, energy labelling), this table only indicates EU framework legislation, but is intended to cover also product specific EU legislative acts.

21. Electrical and electronic equipment under RoHS, WEEE and batteries	Directives 2011/65/EU, 2002/96/EU and 2006/66/EC	
22. Chemicals (Detergents, Paints, Persistent organic pollutants) <sup>6</sup>	Regulation No 648/2004 Directive 2004/42/CE Regulation No 850/2004	
23. Ecodesign and Energy labelling	Directives 2009/125/EC and 2010/30/EU	<b>Yes</b>
24. Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	Directive 1992/42/EEC	
25. Recreational craft	Directive 1994/25/EC	
26. Marine equipment	Directive 96/98/EC	<b>Yes</b>
27. Motor vehicles and tyres	Directives 2002/24/EC and 2007/46/EC, and Regulation (EC) No 1222/2009	
28. Non-road mobile machinery	Directive 97/68/EC	
29. Fertilisers	Regulation No 2003/2003	
30. Other consumer products under GPSD (optional)	Directive 2001/95/EC	<b>Yes</b>
31. Tobacco products and cigarettes	Directive 2014/40/EC	
32. Labelling of textile products	Regulation (EU) No 1007/2011	<b>Yes</b>
33. Footwear labelling		<b>Yes</b>
34. Control equipment in the road transport sector	Regulation No 3821/85/EEC and Regulation No 432/2004/EC	<b>Yes</b>

<sup>6</sup> This section focuses on chemicals other than those falling under REACH and CLP Regulations. Market surveillance activities conducted under REACH and CLP Regulations fall within the scope of Regulation 765/2008, however, since they are already the subject of specific reports available to the public, they may be excluded from the current report. It is nevertheless requested that Member states include in this section a link to the REACH and CLP reports for the relevant period.