

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

## **PORTUGAL**

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## **Scope of the report**

This report covers the market-surveillance activities carried out by the Portuguese market-surveillance authorities for some of the products covered by Community harmonisation legislation.

A list of the various sectors concerned is given in Annex 1 to this document.

The action carried out by border control authorities can be found in a document attached to this report.

# **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.**

In Portugal, responsibility for market-surveillance under Article 18 of Regulation (EC) No 765/2008 of 9 July 2008 lies with eight authorities, two of which are based in Azores and in Madeira.

The names of the above-mentioned authorities are as follows:

- **ASAE**— Authority for Food and Economic Safety;
- **INFARMED** – National Authority for Medicines and Health Products;
- **ICP-ANACOM** – National Communications Authority;
- **IMT**— Mobility and Land Transport Institute, I. P.;
- **DGRM**— Directorate-General for Natural Resources, Safety and Maritime Services;
- **DNPSP** — National Directorate for the Public Security Police (DAE)
- **IRAE Azores**— The Regional Inspectorate for Economic Activities — Azores;
- **IRAE Madeira**— The Regional Inspectorate for Economic Activities — Madeira

Under national law, external border control is assigned to the Portuguese Tax and Customs Authority (**AT**), which is not considered a market-surveillance authority.

Decree Law No 23/2011 of 11 February provided for the enforcement of the obligations arising from Regulation (EC) No 765/2008 of 9 July 2008.

This aims to ensure that all products placed on or made available on the EU market comply with legal requirements, so that they do not pose a risk to the health and safety of consumers or users.

In order to achieve the intended goals, the Decree-Law provides for the organisation of market-surveillance at national level and sets out provisions related to the responsibilities assigned to the market-surveillance authorities.

This legislation also stipulates that, if a product poses a serious risk to consumers or users, the ASAE or any of the other market-surveillance authorities responsible for surveillance relating to the type of product in question has the power to prohibit, restrict the availability of, withdraw or recall it throughout the supply chain.

The responsibilities assigned to each of the market-surveillance authorities are described in an annex to this report, as are the shared responsibilities under the national legislative framework for the transposition of EU harmonisation legislation.

### **AUTHORITY FOR FOOD AND ECONOMIC SAFETY (ASAE)**

Central administrative department address: Rua Rodrigo da Fonseca, n.º 73; 1269-274 Lisbon;

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The ASAE is a department of the criminal police with headquarters in Lisbon, led by an Inspector-General

assisted by two Deputy Inspectors-General.

It is a central direct administration office of the State within the framework of the Ministry of Economic Affairs and it has administrative autonomy. It is tasked with conducting surveillance and prevention to ensure compliance with legislation governing the pursuit of economic activities in the food and non-food sectors. It is also tasked with evaluating and notifying risks within the food chain and operates as the national body for liaison with equivalent bodies at European and international level.

Covering all mainland Portugal, the ASAE has various decentralised units that carry out market-surveillance inspections. These are based in Porto, Mirandela, Coimbra, Castelo Branco, Lisbon, Santarém, Évora and Faro and are referred to as Regional Units (UR).

The central offices are organised in the following units:

- a) Department of Food Risks and Laboratories,
- b) National Operations Unit,
- c) National Criminal Intelligence and Investigation Unit,
- d) Department of Administration and Logistics,
- e) Department of Legal Affairs and Administrative Offences.

The ASAE is a market-surveillance authority within the meaning of Article 17 of Regulation (EC) No 765/2008 of 9 July 2008 for the majority of European Union harmonisation legislation, except for the Directives on explosives for civil uses, medical devices and cableway installations designed to carry persons. As such, the ASAE is a member of a total of 17 different Administrative Cooperation groups (ADCO groups). In addition, it is a competent authority and surveillance authority within the scope of Regulation (EC) No 764/2008 of 9 July 2008.

The tasks of the ASAE include the following:

- a) surveillance of economic activities;
- b) developing, implementing and regularly disseminating the market-surveillance programme, in accordance with Regulation (EC) No 765/2008 of the European Parliament and the Council of 9 July 2008, in addition to taking restrictive prohibition measures, restricting products being made available on the market and recalling products that have been made available on the market;
- c) surveillance of the sale of products and services with a view to ensuring the health and safety of consumers, as well as surveillance of compliance with the legal obligations of economic operators;
- d) performing the functions of a coordinating authority and National Contact Point in the framework of the general information support system (ICSMS system);
- e) directly or indirectly collaborating in the exchange of information on products placed or made available on the market that present a serious risk, through the EU rapid alert system (RAPEX);
- f) investigating and applying sanctions in administrative offence proceedings within the area for which it is responsible.

With regard to financial resources, the ASAE has a budget from appropriations allocated to it from the State Budget.

In addition, the ASAE retains income from own revenue relating to amounts collected for the provision of services within the area for which it is responsible, as well as income assigned to it from any fines .

There is excellent cooperation between the ASAE and the AT regarding the control of products entering the EU market for the purposes of meeting the requirements of Articles 27 to 29 of Regulation (EC) No 765/2008 of 9 July.

Whenever there is any suspicion relating to the requirements of Article 27 of the above-mentioned Regulation, the AT suspends the release of products for free circulation and reports to the ASAE. The market-surveillance authority then states its views and intervenes in the matter, particularly with regard to the conformity of the products and the analysis of all accompanying documentation, in accordance with Article 28 of the Regulation.

Market-surveillance inspection activity has two key components:

- proactive work, based on a central schedule including appropriate regional operations, as part of which inspections are planned and carried out according to predetermined criteria, regional specificities, structural and cyclical situations and the requirements of interinstitutional cooperation;
- reactive work, based on complaints and reports in specific situations detected on the ground and also based on requests for cooperation from other entities.

The operational methodology is described in market-surveillance procedures that cover visual inspection and documentary inspection.

Proactive operational activity is planned. For each surveillance action undertaken, a numbered document known as an Operations Order (OP) is drawn up, describing the aim of the inspection and the type of products targeted. The OP includes the above-mentioned procedures, a table setting out the types of infringement and another containing the legal requirements.

This document is distributed at national level (mainland Portugal) to all the Regional Units, no later than 48 hours before the date of the scheduled inspection.

The visual inspection and documentary inspection procedures involve different stages. The first stage is verification of the product acquisition documents (invoices) in order to verify the date on which the products were placed on the market or made available on the market.

Once this data has been collected, the traceability mechanism (identification of the operator from whom the products were acquired) is activated.

Following this, surveillance starts with visual inspection of the labelling of the product, warnings, instructions, Portuguese language and conformity markings, e.g. CE marking and Pi marking, amongst others.

The next stage relates to documentary inspection, focusing on the declaration of conformity and technical documentation.

If the documents are not in the possession of the economic operators concerned, the ASAE notifies them that they are required to provide the documents within a time limit of 5 or 10 days (as set out in the VAT — Value Added Tax — Code and the Code of Administrative Procedure, respectively), as appropriate.

Failure to submit these documents is sufficient grounds for the economic operator concerned to be found guilty of an infringement. In this case, the products should be prevented from being made available in the supply chain, as there is no evidence that they comply with the essential safety requirements.

A different methodology is adopted in the reactive inspections, which are carried out in response to RAPEX notifications that concern Portuguese economic operators, in accordance with Article 12 of the General Product Safety Directive (Directive 2001/95/EC).

When the National Contact Point makes the ASAE aware of the notification and the grounds on which it is based, the ASAE sends a letter to each of the operators involved, ordering them to refrain from marketing the product concerned and informing them that if they do market it they will be guilty of infringing the law.

At the same time, the ASAE draws up an OP, with a view to confirming on the premises indicated in the notification whether or not the products are being made available.. This entire process takes place within a maximum of 5 days after submission of the notification. Normally, the product is no longer available on the market.

If the economic operator is found to have not followed the order given by the ASAE, it will be found guilty of an infringement and the products are immediately seized.

Another kind of reactive inspection which takes place as a result of cooperation with the AT, in accordance with Articles 27 to 29 of Regulation (EC) No 765/2008 of 9 July 2008.

As the process in question needs to be completed rapidly to comply with the three-day time limit



set by law, requests from the customs authority may be made in two ways: by fax or email.

## **INFARMED – NATIONAL AUTHORITY OF MEDICINES AND HEALTH PRODUCTS**

INFARMED - National Authority of Medicines and Health Products, I. P., is a public institute integrated under the indirect administration of the State, with administrative and financial autonomy and its own assets, exercising the powers of the Ministry of Health, under the supervision and guidance of the respective ministry.

It is a central body, headquartered in Lisbon, with jurisdiction over the entire national territory, and may collaborate with the bodies of the Autonomous Regions, in accordance with its powers.

Pursuant to Decree Law No 46/2012 of 24 February, the mission of INFARMED, I. P. is to regulate and supervise the sectors of medicines for human use and health products (medical devices and cosmetic and personal hygiene products), according to the highest standards of public health protection, and to ensure that health professionals and citizens have access to quality, effective and safe medicines and health products.

This mission is accomplished through the implementation of powers in the fields of policy definition and execution, regulations, compliance, assessment, authorisation, post-marketing surveillance, investigation monitoring and enforcement, production, distribution and marketing, consumption and use of medicines, medical devices and cosmetic and personal hygiene products.

In addition to the above, other powers of INFARMED, I.P. include the promotion of access for health professionals and citizens to the information necessary for the rational use of medicines, medical devices and cosmetic and personal hygiene products, and the promotion and support of study and research in the fields of science and pharmaceutical technology, biotechnology, pharmacology and pharmacoepidemiology.

At European Union level it forms part of, and participates in, committees, commissions and working groups of the Council of the European Union, the European Commission and the European Medicines Agency, promoting initiatives within the scope of the European System for the Assessment and Supervision of Medicines and Health Products, the European Network of Medicines and Health Products Authorities and the European Network of Official Medicines Control Laboratories. With regard to cooperation, initiatives have been put in place with Portuguese-speaking countries (Cape Verde, Brazil and Angola), Macau and third countries, namely with countries in the Maghreb and Latin America.

The internal organisation of INFARMED, I.P. was determined through Implementing Order (Portaria) No 267/2012 of 31 August, and consists of the following bodies and organic units:

- a) Advisory Board
- b) Specialist Technical Commissions
- c) National Medicines Advertising Board
- d) Sole Auditor

These Business Functions are supported by the following organic units:

- Medicines Evaluation Department (DAM)
- Medicines Risk Management Department (DGRM)
- Health Products Department (DPS) – Responsible for market supervision/surveillance activities, in order to ensure the compliance of health products made available, including desk-review and physical control processes, the customs clearance processes for health products and the handling of complaints, campaigns aimed at surveillance, amongst other activities.
- Inspection and Licensing Department (DIL) – Responsible for inspection actions on agents and products, handling complaints and claims connected to entities or products including their physical control, and imposing sanctions/penalties (along with the GJC).
- Quality Control Department (DCQ) – Responsible for laboratory tests on health products, within the scope of campaigns and other internal/external requests.
- Economic Assessment and Market Observation Department (DAEOM)

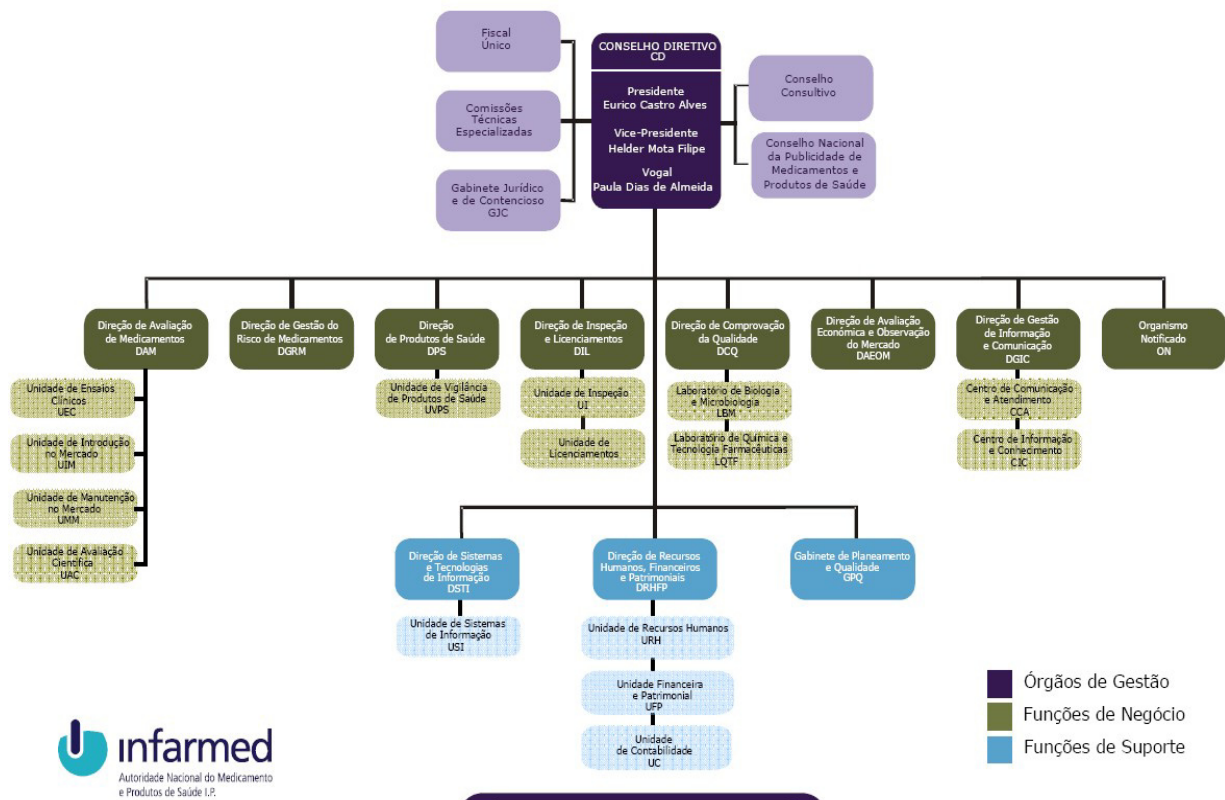
- Information and Communication Management Department (DGIC)
- Regulatory and Scientific Advice Authority (GARC)
- Notified Body (ON), within the scope of the Medical Devices Directive.

The Support Functions are organised in the following organic units:

- Information Systems and Technologies Department (DSTI)
- Human, Financial and Physical Resources Department (DRHFP)
- Planning and Quality Office (GPQ)
- Legal and Litigation Office (GJC) – Responsible for providing support functions for the activities of the other Departments of a legal nature, such as the DPS and DIL, within the scope of INFARMED, I.P.'s activity, and for imposing sanctions/penalties (instigation of administrative proceedings).

Note: The Departments mentioned are those which most actively participate in surveillance of the health products market.

This structure is summarised in the figure below:



Key to diagram	
PT	EN
Fiscal único	Sole Auditor
Comissões Técnicas especializadas	Specialised Technical Committees
Gabinete Jurídico e de contencioso (GJC)	Legal and litigation office (GJC)
Conselho Diretivo (CD)	Governing Board (CD)
Presidente Eurico Castro Alves	President Eurico Castro Alves
Vicepresidente Helder Mota Filipe	Vice-president Helder Mota Filipe
Vogal Paula Dias de Almeida	Member Paula Dias de Almeida
Conselho Consultivo	Consultative Board
Conselho Nacional da Publicidade de Medicamentos e Produtos da Saúde	National Advertising Board for Medicines and Health Products
Direção de Avaliação de Medicamentos (DAM)	Medicine Evaluation Directorate (DAM)
Unidade de Ensaios Clínicos (UEC)	Clinical Trials Unit (UEC)
Unidade de Introdução no Mercado (UIM)	Market Introduction Unit (UIM)
Unidade de Manutenção no Mercado (UMM)	Market Maintenance Unit (UMM)
Unidade de Avaliação Científica (UAC)	Scientific Evaluation Unit (UAC)
Direção de Gestão do Risco de Medicamentos (DGRM)	Medicine Risk Management Directorate (DGRM)
Direção de Produtos de Saúde (DPS)	Health Products Directorate (DPS)
Unidade de Vigilância de Produtos de Saúde (UVPS)	Health Products Surveillance Unit (UVPS)
Direção de Inspeção e Licenciamentos (DIL)	Licensing and Inspection Directorate (DIL)
Unidade de Inspeção (UI)	Inspection Unit (UI)
Unidade de Licenciamentos (UL)	Licensing Unit (UL)
Direção da Comprovação da Qualidade (DCQ)	Quality Confirmation Directorate (DCQ)
Laboratório de Biologia e Microbiologia (LBM)	Biology and Microbiology Laboratory (LBM)
Laboratório de Química e Tecnologia Farmacêuticas (LQTF)	Chemistry and Pharmaceutical Technology Laboratory (LQTF)
Direção de Avaliação Económica e Observação do Mercado (DAEOM)	Economic Evaluation and Market Observation Directorate (DAEOM)
Direção de Gestão de Informação e Comunicação (DGIC)	Information and Communication Management Directorate (DGIC)
Centro de Comunicação e Atendimento (CCA)	Communication and Service Centre (CCA)
Centro de Informação e Conhecimento (CIC)	Information and Knowledge Centre (CIC)
Organismo Notificado (ON)	Notified Body (ON)
Direção de Sistemas e Tecnologias de Informação (DSTI)	Information Technology Systems Directorate (DSTI)
Unidade de Sistemas de Informação (USI)	Information Systems Unit (USI)
Direção de Recursos Humanos, Financeiros e Patrimoniais (DRHFP)	Human Resources, Financial and Property Directorate (DRHFP)
Unidade de Recursos Humanos (URH)	Human Resources Unit (URH)
Unidade Financeira e Patrimonial (UFP)	Financial and Property Unit (UFP)
Unidade de Contabilidade (UC)	Accountancy Unit (UC)
Gabinete de Planeamento e Qualidade (GPQ)	Planning and Quality Office (GPQ)
Orgãos de Gestão	Management Bodies
Funções de Negócio	Business Duties
Funções de Suporte	Support Duties

### **National Directorate of the Public Security Police (DNPSP)**

The National Directorate of the Public Security Police (DNPSP), through its Arms and Explosives Department (DAE), carries out market-surveillance activities at national level, in those product sectors listed as numbers 14 and 15 in Annex 1, relating to pyrotechnics and explosives for civilian use, respectively.

The DAE carries out market-surveillance activities on those products referred to in the previous paragraph both independently or in internal and external cooperation with other bodies: internal cooperation is established between the DAE and the Arms and Explosives Centres (NAE) of each Command (Regional, Metropolitan and District) of the PSP and covers all areas of surveillance concerned. On the other hand, external cooperation mainly takes place with the AT services and with the ASAE, when surveillance activities are involved that relate to imports or exports respectively, or when handling irregularities relating to the CE marking of the products concerned.

Furthermore, the DAE is represented in various working parties coordinated by the COM, within the scope of pyrotechnics, explosives and their precursors. The DAE representatives on the aforementioned working parties contribute, in terms of information-sharing, to a greater harmonisation at Community level in terms of the surveillance activities carried out.

### **Directorate-General for Natural Resources, Security and Maritime Services (DGRM)**

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The DGRM took over the powers of the IPTM - Port and Maritime Transport Institute, I. P., in the field of regulation, supervision and surveillance of the maritime, port and pleasure-sailing sector, assuming the authority to exercise the duties of surveillance that were previously held by the IPTM, namely in the sectors of recreational craft and marine equipment.

The DGRM is led by a director-general assisted by two deputies directors, and is structured into the following units, with each of these led by a services director:

- a) Maritime Administration Services Department;
- b) Natural Resources Services Department;
- c) Marine Environment and Sustainability Services Department;
- d) Inspection, Monitoring and Control of Maritime Activities Services Department;
- e) Planning, Information and Structures Services Department;
- f) Legal Services Department;
- g) General Administration Services Department.

### **THE REGIONAL INSPECTORATE FOR ECONOMIC ACTIVITIES — AZORES (IRAE Azores)**

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Email: [irae@azores.gov.pt](mailto:irae@azores.gov.pt)

The IRAE's headquarters are in Ponta Delgada and it has delegations on the islands of Terceira, Faial, Pico and S. Jorge.

**Structure:** The IRAE Azores is led by a Regional Inspector, a Director of Services and a Head of Division. The island of São Miguel and the island of Terceira each have a Coordinator, while Pico and São Jorge are coordinated by the Faial delegation.

The IRAE Azores has 35 members of staff, 23 of whom are inspectors. It has a central structure, which means that the remainder of the staff are based at its headquarters. Their role is to ensure that all the administrative aspects of the procedures adopted are completed.

The competences of the IRAE Azores and control of products entering the EU market are identical to those described for the ASAE, except in that they apply to the Azores.

### **THE REGIONAL INSPECTORATE FOR ECONOMIC ACTIVITIES — MADEIRA (IRAE Madeira)**

Address: Rua Direita nº 27, 3º andar; 9050-450 Funchal

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The IRAE Madeira is the Service of the Regional Secretariat for Social Affairs with the powers and competences to supervise and ensure compliance throughout the Autonomous Region of Madeira with legislation regulating the exercise of economic activities in the food and non-food sectors, in order to ensure compliance with the legal standards governing the exercise of economic activity in the Autonomous Region of Madeira. In terms of surveillance of product sectors, the competences of IRAE Madeira are similar in scope to those of the ASAE.

The IRAE Madeira consists of the following bodies and services:

- a) Regional Inspector;
- b) Inspection Services Department;
- c) Administrative Services.

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

<b>ASAE</b>		2010	2011	2012	2013
1.1	Budget available to market-surveillance authorities in nominal terms (€)	25 300 439	23 290 616	19 944 754	20 952 564
1.2	Budget available to market-surveillance authorities in relative terms (% of total national budget)	n.a.	n.a.	n.a.	n.a.
2	Staff available to market-surveillance authorities (full-time equivalent units )	526	498	503	500
3	Number of inspectors available to market-surveillance authorities (full-time equivalent units)	277	256	271	249
<b>ICP-ANACOM</b>		2010	2011	2012	2013
1.1	Budget available to market-surveillance authorities in nominal terms (€)	1 369 726	1.435230	1 570 629	1 618 101
1.2	Budget available to market-surveillance authorities in relative terms (% of total national budget)	n.a.	n.a.	n.a.	n.a.

2	Staff available to market-surveillance authorities (full-time equivalent units )	9	9	10	10
3	Number of inspectors available to market-surveillance authorities (full-time equivalent units)	6	6	7	7
	<b>INFARMED</b>	2010	2011	2012	2013
1.1	Budget available to market-surveillance authorities in nominal terms (€)	1 598 602	1 393 711	1 292 605	1 151 089
1.2	Budget available to market-surveillance authorities in relative terms (% of total national budget)	n.a.	n.a.	n.a.	n.a.
2	Staff available to market-surveillance authorities (full-time equivalent units )	23.5	24.5	22	22
3	Number of inspectors available to market-surveillance authorities (full-time equivalent units)	22.5	23	20.5	19.5
	<b>DNPS (DAE)</b>	2010	2011	2012	2013
1.1	Budget available to market-surveillance authorities in nominal terms (€)	Amounts available for inspection purposes are not accounted for individually or per activity as, owing to the way in which services are structured, most of the personnel involved in market inspection also carry out other tasks, very often associated with the field but not exclusively			
1.2	Budget available to market-surveillance authorities in relative terms (% of total national budget)				
2	Staff available to market-surveillance authorities (full-time equivalent units )	55 <sup>1</sup>	55	55	55
3	Number of inspectors available to market-surveillance authorities (full-time equivalent units)	22 <sup>2</sup>	22	22	22
	<b>DGRM<sup>3</sup></b>	2010	2011	2012	2013
1.1	Budget available to market-surveillance authorities in nominal terms (€)	0	0	0	0
1.2	Budget available to market-surveillance authorities in relative terms (% of total national budget)	0	0	0	0

<sup>1</sup> Only DAE staff exclusively involved in inspection were accounted for. Other personnel (more than one hundred) which carry out inspections on a district and regional level were not included (note, applicable for all years).

<sup>2</sup> Same as footnote (1)

<sup>3</sup> The problems shown in this table are being resolved by the government.

2	Staff available to market-surveillance authorities (full-time equivalent units )	0	0	0	0
3	Number of inspectors available to market-surveillance authorities (full-time equivalent units)	0	0	0	0
	<b>IRAE Madeira</b>	2010	2011	2012	2013
1.1	Budget available to market-surveillance authorities in nominal terms (€)	n.a.	n.a.	n.a.	n.a.
1.2	Budget available to market-surveillance authorities in relative terms (% of total national budget)	n.a.	n.a.	n.a.	n.a.
2	Staff available to market-surveillance authorities (full-time equivalent units )	18	18	17	16
3	Number of inspectors available to market-surveillance authorities (full-time equivalent units)	18	18	17	16
	<b>IRAE Azores</b>	2010	2011	2012	2013
1.1	Budget available to market-surveillance authorities in nominal terms (€)	a)	1 427 242 a)	1 416 591 a)	1 316 576 a)
1.2	Budget available to market-surveillance authorities in relative terms (% of total national budget)	a)	a)	a)	a)
2	Staff available to market-surveillance authorities (full-time equivalent units )	a)	a)	a)	a)
3	Number of inspectors available to market-surveillance authorities (full-time equivalent units)	29 a)	25 a)	28 a)	23 a)
a) These figures are the totals for all sectors. IRAE has no staff or budget dedicated exclusively to this sector - Regulation (EC) No 765/2008					



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

**[ASAE]** In terms of available budget, staff and the number of available inspectors, it is important to note that this is not possible with regard to the ASAE structure, given that there is no separation at the level of either human or financial resources between surveillance in the food and non-food areas.

One of the difficulties for this surveillance authority was connected with the fact that the rules for implementing Regulation (EC) No 765/2008 had been published on 11 February 2011, by means of Decree Law No 23/2011, which resulted in a failure to monitor the requirements regarding affixation of the CE marking during 2010.

There are also other difficulties which are related to economic operators failing to provide declarations of conformity and conformity assessment reports, etc.

Furthermore, financial resources are limited, especially with regard to the participation of this Authority in administrative cooperation groups (ADCO group).

With regard to sanctions, there is disproportionality between those relating to aspects of product safety and those relating to waste management.

**[INFARMED]** In the exercise of their surveillance activities, the INFARMED, I.P. Departments involved in these activities mainly encountered difficulties connected with the lack and turnover (in some areas) of human resources, while in other areas a greater and clearer division of competences between different entities (which sometimes overlap) would be useful, with the current boundaries in place proving to be inadequate.

Another difficulty encountered relates to the clear lack of deterrent power of sanctions, particularly the low value of fines to be applied in accordance with Decree Law No 145/2009 (amounts between €2 000 and € 45 000).

**[DGRM]** No surveillance actions were carried out with regard to the Directives on recreational craft and marine equipment.

**[DNPSP (DAE)]** In spite of there being some constraints on the surveillance activities carried out by the DAE (mainly related to a lack of resources), there was a reduction in violations of the legal provisions applicable to the sectors under review. This fact enables us to conclude, in light of the continuing nature of surveillance activities, that these activities have achieved their overall targets, given that compliance with the applicable standards has been on the increase.

**[IRAE Azores]** In view of its reduced team of inspectors and owing to its small budget, the IRAE Azores was unable to allocate resources solely to the surveillance of Regulation (EC) 765/2008, with this being handled along with other matters that also lie within the competence of this Inspectorate.

The IRAE Azores concluded a cooperation protocol with the ASAE for the surveillance of all product sectors, including the matter of training for inspectors.

**[IRAE Madeira]** There is a need for greater intercommunication between the competent entities, namely the AT and IRAE Madeira, in order to prevent the entry of products from third countries that have not been duly traced or that do not comply with the legal requirements.

The IRAE Madeira does not have data by sector at its disposal. The analysis of its surveillance activities therefore appears in number 40, all product sectors.

Finally, it is important to underline the fact that, when accessing the functioning of surveillance activities by sector, it is impossible to provide an estimate of the size of the domestic market for most products, to take into account the context in which market-surveillance takes place in each product sector, that is to say by legislative instrument.

In order for these estimates to be as close as possible to reality, it is necessary to construct a matrix in order to equate those products which are subject to a certain legislative act with the REV.3 Classification of Economic Activities (CEA) and vice-versa.

For example, construction products are split between various CEAs, whilst one CEA may include various products covered by different legislative acts. This diversity can also be seen with regard to businesses that are subject to a certain CEA.

The same is also true in the internal trade sector (distribution).

The AT also does not have a record of the number of importers for each directive, as any natural or legal person may act as an importer.

## Market-surveillance activities in specific sectors

### Sector 1: Medical devices

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

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

	<b>INFARMED</b>	2010	2011	2012	2013
1.	Number of product-related accidents / user complaints	83	132	198	110
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total number)	2 661	2 884	2 992	3 118
3.1	Number of reactive inspections	2 350	2 434	2 778	2 819
3.2	Number of self-initiated inspections	303	435	198	289
3.3	Number of inspections prompted by the customs	8	15	16	10
4	Number of inspections based on:				
4.1	Tests performed in laboratories	130	95	106	56
<p>The reports on the laboratory tests of medical devices are available at:  <a href="http://www.infarmed.pt/portal/page/portal/INFARMED/MONITORIZACAO_DO_MERCADO/COMPROVACAO_DA_QUALIDADE/CONTROLO_LABORATORIAL/DISPOSITIVOS_MEDICOS">http://www.infarmed.pt/portal/page/portal/INFARMED/MONITORIZACAO_DO_MERCADO/COMPROVACAO_DA_QUALIDADE/CONTROLO_LABORATORIAL/DISPOSITIVOS_MEDICOS</a></p>					
4.2	Physical checks of products	5 820	6 741	5 429	5 849
		(790 + 30% of 16 766)	(835 + 30% of 19 688)	(254 + 30% of 17 250)	(348 + 30% of 18 338)
		<p>The figures result from the sum of the actual physical control of products (e.g. whistleblowing processes, contribution, etc.), and an estimate of the checks resulting from the validation of register information, which we estimate to be around 30% of validated registration.</p>			
5	Number of inspections resulting in:				

5.1	Finding of non-compliance	1 000	673	343	372
	▪ Products	134	335	48	19
	▪ Economic operators (Manufacturers and Distributors)	These figures are less than actual figures as non-compliance information is not registered in the manner requested. These numbers are not the result of an estimate but of the recording of actions (which do not include all inspection actions) in which non-compliance is accounted for in terms of the number of non-conforming products			
5.2	Corrective actions taken by economic operators ('voluntary measures')	867	864	940	1 090
		These figures refer only to measures resulting from specific inspection actions (e.g. corrective actions within the scope of surveillance). However, the fact should be considered that almost all detections of non-compliances (5.1) led to corrective measures being implemented by the economic agents involved.  However, the number of products and operators in non-compliance does not relate directly to the number of measures.			
5.3	Restrictive measures taken by market-surveillance authorities.	4	0	0	0
5.4	Application of sanctions/penalties	2	17	7	3
6	Number of inspections where other Member States were invited to collaborate	32	56	31	23

On an additional note, it is important to mention that the transposition into the domestic legal system of Directive 2007/47/EC of the European Parliament and of the Council of 5 September (amending Council Directive 90/385/EEC of 20 June on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market) by means of Decree Law No 145/2009, of 17 June, led to an opportunity to include supplementary provisions to those included in the Directives within the domestic legislation in the area, thereby enabling a greater degree of enforcement/surveillance of agents and products.

By means of the aforementioned Decree-Law, the manufacture and wholesale distribution of medical devices became subject to notification of the competent authority and to the obligation of the party in question to have a technical manager to ensure the quality of the activities carried out, and the suitability of facilities and equipment, in order to ensure that safety requirements and device-performance requirements are upheld. This document also introduced specific articles relating to the regulation of the advertising of medical devices.

Provisions relating to vigilance, manufacturing, wholesale distribution, advertising, confidentiality and surveillance are also understood to apply to in vitro diagnostic (IVD) medical devices. In addition, specific articles were included for IVDs which serve to restrict the use and availability of certain IVDs, specifically those intended for the detection, confirmation and quantification of infection markers for HIV, HTLV, Hepatitis B, C or D, the determination of tumour markers, the diagnosis of hereditary diseases, blood groups or genetic testing. Requirements/rules were also created regarding the public availability of IVDs for self-diagnosis.

The Competent Portuguese Authority (INFARMED, I.P.) has also been working on coding for medical devices, resulting in each medical device (each brand, model and manufacturer reference) being assigned a code enabling it to be clearly identified (unique device

identification), and which will resemble the static part of the device information, that is the device identifier (as indicated in Commission Recommendation (2013/172/EU) of 5 April 2013 regarding the UDI). In addition, this coding also takes into account the Portuguese nomenclature for Medical Devices, which enables devices to be grouped according to their purposes and technical characteristics, resulting in a significant improvement in the identification and handling of information relating to Medical Devices. Work is also taking place in tandem in order to implement standards and other mechanisms that will pave the way for tools to be established, in the short/medium-term, to enable the effective implementation of a UDI system with the necessary impact in terms of product traceability (MDs identified not only by the MD identifier information, but also by product information, batch identification, etc.).

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

**[INFARMED]** Over 150 training actions were carried out between 2010 and 2013 which encompassed:

- On-site training provided to health professionals in Hospitals and professional Associations;
- Training aimed at businesses, professional associations and entities overseen by INFARMED I.P., in areas such as Distribution Best Practices and distribution of medical devices, amongst others;
- Information mornings/clarification sessions and workshops aimed at economic agents in the sector, aimed at disseminating information on the legislation applying to the area of medical devices;
- Lessons/lectures in higher education establishments (domestic and international) for students in the health and regulatory areas;
- Training in the form of courses and workshops aimed at other stakeholders, and training for colleagues in other European and African Competent Authorities;
- Participation in domestic and international conferences.

238 Notes and Information Circulars were also published and disseminated between 2010 and 2013, aimed at the general public, economic agents and health professionals (available at [http://www.infarmed.pt/portal/page/portal/INFARMED/MAIS\\_ALERTAS/ALERTAS\\_DE\\_QUALIDADE](http://www.infarmed.pt/portal/page/portal/INFARMED/MAIS_ALERTAS/ALERTAS_DE_QUALIDADE) and [http://www.infarmed.pt/portal/page/portal/INFARMED/DISPOSITIVOS\\_MEDICOS/NOTAS\\_INFORMATIVAS](http://www.infarmed.pt/portal/page/portal/INFARMED/DISPOSITIVOS_MEDICOS/NOTAS_INFORMATIVAS)) with relevant information relating to the dissemination of key aspects of the legislation applying to medical devices, as well as on their conformity, and the performance of manufacturers and distributors in the sector (including guidelines for compliance with legal provisions).

### Information on resources (subject to availability)

	INFARMED	2010	2011	2012	2013
7.1	Budget available to market-surveillance authorities in nominal terms (€)	1 070 397	960 153	918 315	823 315
7.2	Budget available to market-surveillance authorities in relative terms (% of total national budget)	n.a.	n.a.	n.a.	n.a.
8	Staff available to market-surveillance authorities (full-time equivalent units)	16.75	17.75	16.25	16.25
9	Number of inspectors available to market	14.75	15.25	13.75	13.25

	surveillance authorities (full-time equivalent units)				
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## ***1.B. Assessment of the functioning of market-surveillance activities in the sector***

**[INFARMED]** In terms of the market, it is worth noting that in 2013 there were 218 registrations relating to domestic manufacturers in the field of medical devices, and 1 007 relating to domestic distributors. These numbers reflect the reality in Portugal, given that in this area, wholesale distribution clearly plays a prominent role, which is the main reason why this Authority always channels its efforts into ensuring the registration of these agents, and the products marketed by them, as a supplement to the provisions laid down in European Directives.

In spite of the legislation that led to the compulsory notification of the manufacturing and wholesale distribution of medical devices dating back only to 2010 (Decree-Law No 145/2009 of 17 June), more than 500 entities have already been licensed and inspected.

At the end of 2013, almost 640 000 references of medical devices (MDs and IVDs) placed on the domestic market had been registered by national distributors (which corresponds to almost 187 995 registrations\*).

The approximate total market value of devices, based on the volume of sales determined by the applicable sales tax, is around 1 billion euros.

\* Note: All information relating to the number of devices supervised should be understood in terms of registrations and not in terms of references.

## **Sector 2: Cosmetics**

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

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

	<b>ASAE</b>	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)	57	6	0	82
3.1	Number of reactive inspections	0	0	0	0
3.2	Number of self-initiated inspections	57	6	0	82
3.3	Number of inspections prompted by the customs	—	—	—	—
4	Number of inspections based on:				
4.1	Tests performed in laboratories	0	0	0	0

4.2	Physical checks of products	876	1 800	876	1 907
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	7	2	0	20
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	0	0	0	0
5.4	Application of sanctions/penalties	2	2	0	18
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0
	<b>INFARMED</b>	2010	2011	2012	2013
1.	Number of product-related accidents / user complaints	46	54	88	139
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total number)	907	1 176	1 252	1 673
3.1	Number of reactive inspections	546	689	762	972
3.2	Number of self-initiated inspections	7	11	20	8
3.3	Number of inspections prompted by the customs	354	476	470	693
4	Number of inspections based on:				
4.1	tests performed in laboratories	141	161	158	110
The reports on the laboratory tests of cosmetics are available at: <a href="http://www.infarmed.pt/portal/page/portal/INFARMED/MONITORIZACAO_DO_MERCADO/COMPROVACAO_DA_QUALIDADE/CONTROLO_LABORATORIAL/PRODUTOS_COSMETICOS_E_DE_HIGIENE_CORPORAL">http://www.infarmed.pt/portal/page/portal/INFARMED/MONITORIZACAO_DO_MERCADO/COMPROVACAO_DA_QUALIDADE/CONTROLO_LABORATORIAL/PRODUTOS_COSMETICOS_E_DE_HIGIENE_CORPORAL</a>					
4.2	Physical checks of products	12 936	95 76	6 850	7 936
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	239	632	60	35
5.2	Corrective actions taken by economic operators ('voluntary measures')	49	69	11	2
5.3	Restrictive measures taken by market-surveillance authorities	1	1	0	0

5.4	Application of sanctions/penalties	30	25	16	15
6	Number of inspections where other Member States were invited to collaborate	5	31	21	7
	<b>IRAE Azores</b>	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)	5	5	5	6
3.1	Number of reactive inspections	5	5	5	6
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	0	0	0	0
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 2010-2013 period (optional)

**[INFARMED]** Between 2010 and 2013, various training activities were carried out in the field of Cosmetics in the form of conferences and lectures aimed at students in higher education, stakeholders and internships. It is worth highlighting the annual employee visits as part of the 'EXCHANGE OF OFFICIALS – NON FOOD PRODUCT SAFETY 2010, 2011, 2012 and 2013 programme', internships within the scope of the cooperation protocol with PALOP countries and training in the regulatory and cosmetics surveillance fields which forms part of the Masters course syllabus at Portuguese universities.

Information Notes and Information Circulars were also published and disseminated on safety and guidelines for compliance with the legal requirements applying to cosmetic products, aimed at consumers, economic operators and health professionals, as well as general information on the regulatory aspects of cosmetics productd available at:



[http://www.infarmed.pt/portal/page/portal/INFARMED/MAIS\\_NOVIDADES](http://www.infarmed.pt/portal/page/portal/INFARMED/MAIS_NOVIDADES)

[http://www.infarmed.pt/portal/page/portal/INFARMED/MAIS\\_ALERTAS](http://www.infarmed.pt/portal/page/portal/INFARMED/MAIS_ALERTAS)

<http://www.infarmed.pt/portal/page/portal/INFARMED/COSMETICOS>

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

	INFARMED	2010	2011	2012	2013
7.1	Budget available to market-surveillance authorities in nominal terms (€)	528 204	433 558	374 290	327 774
7.2	Budget available to market-surveillance authorities in relative terms (% of total national budget)	n.a.	n.a.	n.a.	n.a.
8	Staff available to market-surveillance authorities (full-time equivalent units)	6.75	6.75	5.75	5.75
9	Number of inspectors available to market-surveillance authorities (full-time equivalent units)	7.75	7.75	6.75	6.25

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

**[ASAE]** Inspection actions related to distributors and retailers and the infringements detected due to the absence of a Portuguese translation and the lack of mandatory information

**[INFARMED]** In terms of the market, it is worth noting that in 2013 there were 218 domestic manufacturers registered in the field of cosmetic products, with 552 entities registered as domestic distributors and 232 as importers. (72 (2010), 63 (2011), 52 (2012) and 45 (2013)).

We can also point out that 1 288 documents of conformity were issued between 2010 and 2013 (350 (2010); 329 (2011); 324 (2012); 285 (2013)) for 30 940 products.

**[IRAE Azores]** During the period in question, the IRAE Azores participated in a seminar on safe trade promoted by the DNPS (DAE), during which this and other topics relevant to Regulation (EC) No 765/2008 were covered.

## **Sector 3: Toys**

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

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

	ASAE	2010	2011	2012	2013
1.	Number of product-related accidents / user complaints	10	60	15	24

2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total number)	50	30	442	319
3.1	Number of reactive inspections	43	30	122	175
3.2	Number of reactive inspections	7	0	320	144
3.3	Number of inspections prompted by the customs	Please see the document attached to this report from the Tax Authority			
4	Number of inspections based on:				
4.1	Tests performed in laboratories	0	0	59	0
4.2	Physical checks of products	7	0	320	144
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	7	0	68	33
5.2	Corrective actions taken by economic operators ('voluntary measures')	n.a.	n.a.	n.a.	n.a.
5.3	Restrictive measures <sup>1</sup> taken by market-surveillance authorities	0	0	0	2
5.4	Application of sanctions/penalties	0	0	53	26
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0
	<b>IRAE Azores</b>	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)	0	0	11	86
3.1	Number of reactive inspections	0	0	11	86
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	0	0	7	1
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	0	0	6	0

<sup>1</sup> Compulsory measures to prohibit or restrict the product being made available on the national market, to withdraw it or to recall it. These measures are taken when the economic operators did not follow up on previous request of market-surveillance authorities to take corrective action or where authorities have to intervene urgently.

6	Number of inspections where other Member States were invited to collaborate	-	-	-	-
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### Information on communication activities carried out in the 2010-2013 period (optional)

**[ASAE]** With the publication of Directive 2009/48/EC, internal training activities were held for its inspectors, in which they were made aware of changes to the legislation on toy safety.

Documentary inspection procedures, checklists and sample collection procedures have been drawn up, so as to cover various types of toys, with the aim of creating an operating methodology for all cases covered by legislation.

The ASAE held an information session for secondary school pupils in February 2011. The session covered toys typical of the carnival season, with specific focus on their labelling and general principles of the CE marking and its meaning.

Following an invitation from Toy Industries of Europe (TIE), the ASAE participated as a speaker in the seminar on toy safety held in Madrid in October 2012. This event, funded by the European Commission, was organised by TIE in collaboration with the Spanish Association of Toy Manufacturers (AEFJ). It was mainly aimed at Portuguese and Spanish economic operators representing various parts of the supply chain (manufacturers, importers and distributors) and testing laboratories.

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

**[ASAE]** The ASAE participated in a joint action called Joint Action 2010 'Children's Fancy Dress Project' organised by PROSAFE (Product Safety Forum of Europe) and supported by the European Commission. During this action, it collected 59 samples of Halloween and Carnival costumes.

The greatest difficulty encountered related directly to the transitional period provided for in the legislation. The main difficulty regarded not impeding the making available on the market of toys which are in accordance with Directive 88/378/EEC and which were placed on the market before 20 July 2011.

However, in Portugal, there are virtually no toy manufacturers and the number of importers is not significant, and so inspection actions related to distributors and retailers.

The infringements detected related to the lack of labelling in Portuguese, the absence of a CE marking, non-compliance with distributor's duties, violation of the requirements relating to the EC declaration, violation of the rules and conditions on affixing the CE marking and the refusal of economic operators to submit documentation, information requested by the market-surveillance authority.

## **Sector 4: Personal protective equipment**

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

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

	ASAE	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)	61	1	24	124
3.1	Number of reactive inspections	7	1	1	80
3.2	Number of self-initiated inspections	54	0	23	44

3.3	Number of inspections prompted by the customs	Please see the document attached to this report from the Tax Authority			
4	Number of inspections based on:				
4.1	Tests performed in laboratories	0	0	6	0
4.2	Physical checks of products	201	0	310	1 487
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	15	0	0	13
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	0	0	0	0
5.4	Application of sanctions/penalties	11	0	0	9
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

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

[ASAE] The ASAE participated in seminars promoted by an association representing the sector where clarifications were given on the implementation of legislation.

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

[ASAE] The ASAE participated in a joint action called Joint Action 2010 'Visibility Clothing and Accessories' organised by PROSAFE (Product Safety Forum of Europe) and supported by the European Commission. During this action, it collected three samples of jackets for non-professional use and three samples of accessories.

However, in Portugal, there are virtually no personnel protection equipment (PPE) manufacturers and the number of importers is not significant, therefore Inspection actions related to distributors and retailers.

The infringements detected related to the lack of labelling in Portuguese, the absence of a CE marking, lack of an EC declaration of conformity, and the refusal of economic operators to submit documentation, information requested by the market-surveillance authority.

## **Sector 5: Construction products**

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

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

	<b>ASAE</b>	2010	2011	2012	2013
1.	Number of product-related accidents / user complaints	3	19	0	7
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total number)	155	1	34	1
3.1	Number of reactive inspections	5	1	3	1

3.2	Number of self-initiated inspections	154	0	31	0
3.3	Number of inspections prompted by the customs	Please see the document attached to this report from the Tax Authority			
4	Number of inspections based on:				
4.1	Tests performed in laboratories	0	0	0	0
4.2	Physical checks of products	1 350	922	155	1
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	25	0	0	0
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	0	0	0	0
5.4	Application of sanctions/penalties	17	0	0	0
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0
	<b>IRAE Azores</b>	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)	1	1	1	108
3.1	Number of reactive inspections	1	1	1	108
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	1	1	1	0
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	0	0	0	0
6	Number of inspections where other Member States were invited to collaborate	-	-	-	-

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

**[ASAE]** With the publication of Regulation (EU) No 305/2011, various internal training activities were held for its inspectors, in which they were made aware of amendments to Community harmonisation legislation for construction products, as well as the application of Regulation (EC) No 764/2008, for those construction products only covered by national provisions, as well as procedures for the application of certain national technical rules to products lawfully marketed in another Member State.

Documentary inspection procedures, checklists and sample collection procedures have been drawn up, so as to cover the various construction products covered by Community harmonisation legislation, with the aim of creating an operating methodology for all cases covered by legislation, as well as for those construction products that constitute a national technical rule.

Participated in seminars promoted either by associations representing the various construction products sectors, or by Portuguese Notified Bodies where clarifications were given on the implementation of legislation.

It is an invited member, along with the AT, of the Portuguese Group of Notified Bodies, where all domestic Notified Bodies have a seat.

**[IRAE Azores]** During the period in question, the IRAE Azores participated in a seminar on construction products where this and other relevant topics relating to Regulation (EC) 765/2008 were covered.

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

**[ASAE]** Inspection actions related to distributors and retailers.

In accordance with Directive 89/106/EEC, in effect until 30 June 2013, the infringements detected related to the absence of a CE marking, the lack of an EC declaration of conformity and the lack of an EC certificate of conformity.

After 1 July 2013, the major difficulty encountered was directly linked to the late publication of national rules for implementing the Regulations, which led to surveillance activities not being carried out in this field, due to the absence of a penalty system.

## **Sector 6: Aerosol dispensers**

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

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

	<b>ASAE</b>	2010	2011	2012	2013
1.	Number of product-related accidents / user complaints	0	0	2	1
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total number)	0	77	3	2
3.1	Number of reactive inspections	0	4	3	1
3.2	Number of self-initiated inspections	0	73	0	1
3.3	Number of inspections prompted by the customs	Please see the document attached to this report from the Tax Authority			

4	Number of inspections based on:				
4.1	Tests performed in laboratories	0	0	0	0
4.2	Physical checks of products	0	77	19	1
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	0	15	0	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	0	0	0	0
5.4	Application of sanctions/penalties	0	13	0	1
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

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

[ASAE] Documentary inspection procedures have been drawn up with the aim of creating an operating methodology for all cases covered by legislation.

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

[ASAE] Inspection actions related to distributors and retailers.

The infringements detected related to the introduction for free circulation and consumption of aerosol dispensers lacking the mandatory inscriptions, and to the affixation of the CE marking to products for which this mark is not intended.

## **Sector 7: Pressure equipment**

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

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

	<b>ASAE</b>	2010	2011	2012	2013
1.	Number of product-related accidents / user complaints	0	0	3	0
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	1
3.	Number of inspections (total number)	133	39	11	114
3.1	Number of reactive inspections	91	6	11	25
3.2	Number of self-initiated inspections	42	33	0	89
3.3	Number of inspections prompted by the customs	Please see the document attached to this report from the Tax Authority			
4	Number of inspections based on:				



4.1	Tests performed in laboratories	0	0	0	0
4.2	Physical checks of products	43	19	22	88
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	8	0	0	15
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	0	0	0	0
5.4	Application of sanctions/penalties	7	0	0	10
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

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

[ASAE] Visual and documentary inspection procedures and a checklist have been drawn up with the aim of creating an operating methodology for all cases covered by legislation.

Participated in seminars promoted by an association representing the sector where clarifications were given on the implementation of legislation

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

[ASAE] Inspection actions related to distributors and retailers.

The infringements detected related to the lack of an identification number from the notified body, the absence of an EC declaration of conformity, and the refusal of economic operators to submit documentation, information requested by the market-surveillance authority.

## **Sector 9: Machinery**

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

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

	<b>ASAE</b>	2010	2011	2012	2013
1.	Number of product-related accidents / user complaints	0	6	2	3
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total number)	64	27	105	10
3.1	Number of reactive inspections	30	17	11	5
3.2	Number of self-initiated inspections	34	10	94	5
3.3	Number of inspections prompted by the customs	Please see the document attached to this report from the Tax Authority			
4	Number of inspections based on:				

4.1	Tests performed in laboratories	0	0	0	3
4.2	Physical checks of products	24	15	27	6
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	19	6	13	3
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	0	0	1	0
5.4	Application of sanctions/penalties	9	4	12	2
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

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

**[ASAE]** With the publication of Directive 2006/42/EC, which came into effect on 29 December 2009, internal training activities were held for its inspectors, in which they were made aware of amendments to legislation relating to machinery, as well as the application of Regulation (EC) No 764/2008, for machinery covered only by national provisions, as well as procedures for the application of certain national technical rules to products lawfully marketed in another Member State.

Documentary inspection procedures, checklists and sample collection procedures have been drawn up so as to cover the various types of machinery covered by Community harmonisation legislation, with the aim of creating an operating methodology for all cases covered by legislation, as well as for machinery that constitutes a national technical rule.

In 2011, it secured the Presidency of *Machinery ADKO group*.

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

**[ASAE]** The ASAE participated in a joint action called Joint Action 2011 'Lawnmowers' organised by PROSAFE (Product Safety Forum of Europe) and supported by the European Commission. During this action, it collected three samples of lawnmowers.

Inspection actions related to manufacturers, importers, distributors and retailers.

In accordance with Directive 2006/42/EC, the infringements detected related to the absence of a CE marking, the failure to translate the instruction manual into Portuguese, lack of the manufacturers name and address, non-compliance with the conformity assessment procedures, availability on the market of machinery that fails to comply with the legal provisions and a failure to indicate the guaranteed sound power level.

## Sector 11: Cableway installations

### 11.A. Review of market-surveillance activities in the sector

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

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

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market-surveillance authorities in nominal terms (€)	n.d	n.d	n.d	n.d

7.2	Budget available to market-surveillance authorities in relative terms (% of total national budget)	n.d	n.d	n.d	n.d
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)	2	2	2	2

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

The Institute for Mobility and Transport (IMT) is a body which, within the sector comprising cableway installations for passenger transport, is essentially responsible for licensing.

The activities undertaken that may be regarded as falling within the scope of market surveillance are restricted to the performance of inspections (most of which are provided for by law) prior to the granting of authorisation for entry into service and, subsequently, once the installations are in operation.

The inspections performed by the IMT on passenger-carrying cableway installations are specified in Decree-Law No 313/2002 of 23 December 2002, which transposed into Portuguese law Directive 2000/9/EC of 20 March 2000.

The purpose of the inspections is to check how safe the installations are with regard to passengers, workers and third parties. The installation is considered as a whole and due account is also taken of the technical capacity of the body and the staff who operate it.

To date, no inspections have been carried out on specific products, subsystems or safety components. Checks (essentially of documents) are, however, carried out on product conformity where a new installation is concerned or a subsystem or safety component has been replaced.

Cooperation with counterpart bodies in other Community countries has been established through attendance at the meetings of the ADCO Group (a group set up by the European Commission to bring together representatives from national bodies responsible for market surveillance).

As a result of involvement in the aforementioned group, occasional e-mails have been received from other, similar bodies that have detected safety problems in certain products. Since the products in question are not installed on Portuguese territory and are unlikely to be so on account of their obsolescence, no action has been taken in response to the e-mails.

Finally, it should be pointed out that the sector within Portugal is on a very small scale, with barely two dozen installations and no major manufacturers; virtually all the products concerned are imported from the major European manufacturers.

## Sector 12: Noise emissions for outdoor equipment

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

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

	ASAE	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	60	0	89
3.1	Number of reactive inspections	0	0	0	0
3.2	Number of self-initiated inspections	0	60	0	89
3.3	Number of inspections prompted by the customs	Please see the document attached to this report from the Tax Authority			
4	Number of inspections based on:				
4.1	Tests performed in laboratories	0	0	0	3
4.2	Physical checks of products	0	124	0	27
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	0	28	0	11
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	0	0	0	0
5.4	Application of sanctions/penalties	0	14	0	11
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

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

[ASAE] Carried out internal training for inspectors which informed on the most relevant aspects of legislation on noise emission for outdoor equipment.

Documentary inspection procedures and checklists have been drawn up so as to cover various types of equipment.

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

[ASAE] Inspection actions related to distributors and retailers.

The infringements detected related to the failure to indicated the guaranteed sound power level, the absence of a CE marking, the absence of an EC declaration of conformity, placing on the market or entry into service of machinery that fails to comply with the legal provisions, a failure to translate the instruction manual into Portuguese and a refusal by the economic operator to submit documentation, information requested by the market-surveillance authority.

## Sector 13: Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres

### 13.A. Review of market-surveillance activities in the sector

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

	ASAE	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	0
3.1	Number of reactive inspections	0	0	0	0
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	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 2010-2013 period (optional)

[ASAE] Carried out internal training for inspectors which informed on the most relevant aspects of legislation on ATEX.

Documentary inspection procedures and checklists have been drawn up so as to combine the legal requirements with the various types of products covered by ATEX.

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

[ASAE]. These products were not found on the market and as such, no inspections were conducted.

## **Sector 14: Pyrotechnics**

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

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

	<b>ASAE</b>	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	10
3.1	Number of reactive inspections	0	0	0	0
3.2	Number of self-initiated inspections	0	0	0	9
3.3	Number of inspections prompted by the customs	Please see the document attached to this report from the Tax Authority			
4	Number of inspections based on:				
4.1	Tests performed in laboratories	0	0	0	10
4.2	Physical checks of products	0	0	0	10
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 measures')	n.a.	n.a.	n.a.	n.a.
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

**ASAE** Market-surveillance in this field is shared with another surveillance authority (DNPSP- DAE). However, the verification of legal requirements, in matters relating to the affixation of the CE marking and the respective conformity assessment is the responsibility of the ASAE.

Documentary inspection procedures, sample collection procedures and checklists have been drawn up.

It participated in a seminar, promoted by the University of Coimbra in partnership with the Spanish Notified Body AIDICO, in which clarifications were provided on the application of legislation.

	<b>DNPSP- DAE<sup>4 and 5</sup></b>	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)	402 (partial)	3 921	4 672	5 986
3.1	number of reactive inspections				
3.2	number of self-initiated inspections	402 (partial)	3 921	4 672	5 986
3.3	number of inspections prompted by the customs	Please see the document attached to this report from the Tax Authority			
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	238 (partial)	238 (partial)	6 832	5 039
5.2	Corrective actions taken by economic operators ('voluntary measures')				
5.3	Restrictive measures taken by market-surveillance authorities	Proceedings brought: 190 PCO <sup>6</sup> 48 PC <sup>7</sup>	Proceedings brought: 190 PCO <sup>8</sup> 48 PC <sup>9</sup>	Proceedings brought: 6 591 PCO PC 241	Proceedings brought: 4 899 PCO 144 PC
5.4	Application of sanctions/penalties	Different	Different	Different	Different

<sup>4</sup> Data on pyrotechnic products sector for DNPSP/DAE are combined with data from the sector for civil use explosives.

<sup>5</sup> The figures in the table above on control activities were collated from annual statistical reports by the DAE Investigation and Inspection Department and other competent divisions.

<sup>6</sup> Partial value due to only having calculated those relating to DAE

<sup>7</sup> Value calculated as in previous note.

<sup>8</sup> PCO – Infraction Proceedings

<sup>9</sup> PC – Criminal Proceedings



		administrative and criminal penalties where applied. Exact number not available	administrative and criminal penalties where applied. Exact number not available	administrative and criminal penalties where applied. Exact number not available	administrative and criminal penalties where applied. Exact number not available
6	Number of inspections where other Member States were invited to collaborate				

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

	DNPSP-DAE	2010	2011	2012	2013
7.1	Budget available to market-surveillance authorities in nominal terms (€)	Amounts available for inspection are not accounted for individually or per activity as, due to the way services are structured, most of the personnel involved in market-surveillance also carry out other tasks, very often associated to the field but not exclusively. As such, the budget made available to the authorities which conduct inspections, is also for other activities.			
7.2	Budget available to market-surveillance authorities in relative terms (% 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)				

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

**[ASAE]** The ASAE participated in a joint action called Joint Action 2011 'Fireworks' organised by PROSAFE (Product Safety Forum of Europe) and supported by the European Commission. During this action, it collected ten samples of pyrotechnics.

Sample collection was carried out on economic operators with importer status.

The major difficulty in participating in the aforementioned activity was directly linked to the fact that there are technical rules in both Portugal and Spain, which makes it hard for ASAE to participate in cooperative action as they constitute a barrier to the free circulation of goods. However, the most negative aspect was the difficulty in sending samples to the AIDICO laboratory, which only took place six months after sample collection, which meant that the results of ASAE participation were not positive.

In reality, Directive 2007/23/EC and its amendments equate to Community harmonisation legislation on products that benefit from the free circulation of goods.

However, the reality is very different, as in this case the technical rules continue to overlap with the Community

harmonisation legislation.

**[DNPSP-DAE]** During the period under review, there was a noticeable development in surveillance activities which were enhanced, widened and increased in number, expanding into other areas somehow linked to the arms and explosives sector.

As a result of this increase in inspections, there was a natural reduction in the number of cases of non-conformity detected, which reflects the effort and care with which these actions are planned and carried out.

The sector is also in the process of adapting to the new rules and seeking to comply with that which has been established.

## Sector 15: Explosives for civil uses.

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

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

Please see note 5 on DNPSP-DAE in Sector 14: pyrotechnical items.

## Sector 16: Appliances burning gaseous fuels

### 16.A. Review of market-surveillance activities in the sector

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

	ASAE	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	104
3.1	Number of reactive inspections	0	0	0	0
3.2	Number of self-initiated inspections	0	0	0	104
3.3	Number of inspections prompted by the customs	Please see the document attached to this report from the Tax Authority			
4	Number of inspections based on:				
4.1	Tests performed in laboratories	0	0	0	
4.2	Physical checks of products	0	0	0	78
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	0	0	0	23
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	0	0	0	0
5.4	Application of sanctions/penalties	0	0	0	16
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

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

[ASAE] Documentary inspection procedures have been drawn up so as to cover the various types of gas appliances.

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

[ASAE] Inspection actions related to manufacturers, importers, distributors and retailers.

The infringements detected related to the absence of mandatory inscriptions in a visible, legible and indelible form, failure to comply with the general principles related to the CE marking and the rules relating to graphics, placement or availability on the market of gas appliances and equipment that fail to comply with the applicable provisions, absence of a CE marking and the refusal of the economic operators to submit documentation, information requested by the market-surveillance authority.

## **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 2010-2013 period

	ASAE	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)	434	257	30	164
3.1	Number of reactive inspections	5	0	0	6
3.2	Number of self-initiated inspections	429	257	30	158
3.3	Number of inspections prompted by the customs	Please see the document attached to this report from the Tax Authority			
4	Number of inspections based on:		1		
4.1	Tests performed in laboratories	0	0	0	4

4.2	Physical checks of products	434	257	30	164
5	Number of inspections resulting in:				
5.1	Finding of non-compliance				10
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	0	0	0	0
5.4	Application of sanctions/penalties	106	95	9	7
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

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

**[ASAE]** Carried out internal training for inspectors which informed on the most relevant aspects of legislation on Measuring instruments, Non-automatic weighing instruments and Pre-packaged products.

Documentary inspection procedures, sample collection procedures and checklists have been drawn up.

Participated in seminars promoted by laboratories and notified bodies where clarifications were given on the implementation of legislation.

Cooperation with market-surveillance authorities in third countries, Turkey, Algeria and Tunisia, where they were made aware of the operational methodology adopted with regard to surveillance in these sectors.

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

**[ASAE]** Surveillance activities with regard to the marketing of some measuring instruments and non-automatic weighing instruments were focused on distributors and retailers, whilst for pre-packaged products they also focused on distributors and retailers.

Only four sample collections of frozen fish products were carried out, given that this operation was made extremely difficult for the market-surveillance authorities due to the fact that each sample had to be made of up of twenty strictly equal units, from the brand, name, firm or business name appearing on the pre-packaging label, batch, ...

The infringements detected related to the failure to comply with rules relating to mandatory inscriptions and the failure of the packer or importer to comply with their obligations.

## **Sector 18: Electromagnetic compatibility**

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

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

	<b>ASAE</b>	2010	2011	2012	2013
1.	Number of product-related accidents / user complaints	0	0	0	0
2.	Number of substantiated complaints by	0	0	0	0

	industry concerning unfair competition				
3.	Number of inspections (total number)	1	1	46	16
3.1	Number of reactive inspections	1	1	1	0
3.2	Number of self-initiated inspections	0	0	45	16
3.3	Number of inspections prompted by the customs	Please see the document attached to this report from the Tax Authority			
4	Number of inspections based on:				
4.1	Tests performed in laboratories	0	0	0	9
4.2	Physical checks of products	0	0	45	13
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	0	0	46	9
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	0	0	0	0
5.4	Application of sanctions/penalties	0	0	24	3
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

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

[ASAE] Documentary inspection procedures and sample collection procedures have been drawn up with regard to the CEM:

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

[ASAE] Market-surveillance in this field is shared with another surveillance authority (ICP- ANACOM). Cooperative actions were thereby carried out between these two surveillance authorities, especially in 2013.

Sample collections were carried out on nine pieces of equipment.

The infringements detected related to the absence of a CE marking, the lack of a Portuguese translation, failure on the part of the manufacturer to indicate, where necessary, the compatibility conditions with interfaces and subsets and the failure to identify the person responsible for demonstrating conformity.

## **Sector 19: R&TTE**

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

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

	ICP-ANACOM	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)	371	281	273	362
3.1	Number of reactive inspections	0	0	0	0
3.2	Number of self-initiated inspections	371	281	273	362
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	124	105	133	163
4.2	Physical checks of products	618 <sup>10</sup>	445	1 623	663
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	248 <sup>11</sup>	330	263	146
5.2	Corrective actions taken by economic operators ('voluntary measures')	n.d	n.d	n.d	n.d
5.3	Restrictive measures taken by market-surveillance authorities	216 <sup>12</sup>	178	1274	357
5.4	Application of sanctions/penalties	9 Processes: Total of 205 443 62	8 Processes: Total of 38 850 00	42 Processes: Total of 446 750 00	30 Processes: Total of 151 293 99
6	Number of inspections where other Member States were invited to collaborate	2	19	39	101

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

**[ICP-ANACOM]** The '[Report on Regulation, Supervision and Other Activities](#)'<sup>13</sup> is published on an annual basis, detailing information relating to surveillance of the R&TTE directive, transposed into national legislation by Decree-Law No 192/2000, of 18 August, which establishes the framework for the free circulation, placing on the market and putting in service of radiocommunications equipment and telecommunications terminal equipment within national territory.

A significant degree of non-conformity with the requirements stipulated in the applicable legislation can be seen in the R&TTE equipment placed on the market, with the failure to provide technical documentation being particularly noteworthy (particularly reports from tests to prove their conformity), as well as the

<sup>10</sup> Number of items of equipment inspected. Idem for all years.

<sup>11</sup> Number of items of equipment inspected. Idem for all years.

<sup>12</sup> Number of items of equipment inspected. Idem for all years.

<sup>13</sup> <http://www.anacom.pt/render.jsp?categoryId=343168#horizontalMenuArea>

absence of an EC declaration of conformity or manuals in Portuguese.

Market monitoring also requires the use of laboratory tests (carried out in the ICP-ANACOM laboratory) and the analysis of technical documentation in order to verify the conformity of equipment.

ANACOM regularly collaborates with the Tax and Customs Authority in the surveillance of products that enter the community market, and in 2013 they analysed 18 jammers (electronic communication blockers) whose authorisation for entry to the market was suspended.

In addition to participating in all meetings held by the TCAM group and ADCO R&TTE, ANACOM has also ensured that information is provided to the ADCO R&TTE group on a yearly basis regarding its R&TTE surveillance activities, as well as participating in the various European market-surveillance campaigns<sup>14</sup> (from 2002-2013, five European surveillance campaigns were held).

### Information on resources (subject to availability)

	<b>ICP-ANACOM</b>	2010	2011	2012	2013
7.1	Budget available to market-surveillance authorities in nominal terms (€)	1 369 726	1 435 230	1 570 629	1 618 101
7.2	Budget available to market-surveillance authorities in relative terms (% of total national budget)	n.a.	n.a.	n.a.	n.a.
8	Staff available to market-surveillance authorities (full-time equivalent units)	9	9	10	10
9	Number of inspectors available to market-surveillance authorities (full-time equivalent units)	6	6	7	7

## 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 2010-2013 period

	<b>ASAE</b>	2010	2011	2012	2013
1.	Number of product-related accidents / user complaints	36	28	6	21
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total number)	95	68	115	319
3.1	Number of reactive inspections	17	34	62	53

<sup>14</sup> [http://ec.europa.eu/enterprise/sectors/rtte/documents/state-of-play/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/rtte/documents/state-of-play/index_en.htm)

3.2	Number of self-initiated inspections	72	6	47	245
3.3	Number of inspections prompted by the customs	Please see the document attached to this report from the Tax Authority			
4	Number of inspections based on:				
4.1	Tests performed in laboratories	0	0	0	6
4.2	Physical checks of products	209	111	188	225
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	56	14	10	29
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	0	0	0	0
5.4	Application of sanctions/penalties	40	8	9	20
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

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

**[ASAE]** Carried out internal training for inspectors which informed on the most relevant aspects of legislation on equipment under LVD.

Documentary inspection procedures, sample collection procedures and checklists have been drawn up.

The ASAE participated in seminars, promoted by Laboratories and notified bodies where clarifications were given on the implementation of legislation.

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

**[ASAE]** Participated in the following cooperation actions promoted by PROSAFE (*Product Safety Forum of Europe*) and supported by the European Commission:

- *Joint Action 2011 'Battery Chargers'*.  
In order to carry out this action, six samples of battery chargers were collected.
- *Joint Market-surveillance Action on Sunbeds II*.  
In order to carry out this action, training activities were held, so as to establish the requirements for the measures to be taken on the sunbeds at the tanning centres.

Currently, it participates in the *Joint Action 2012 'CO and smoke detectors'*, promoted by PROSAFE (*Product Safety Forum of Europe*) and supported by the European Commission.

Inspection actions related to distributors and retailers.

The infringements detected related to the absence of a CE marking, failure to translate the instruction manual into Portuguese and the refusal of economic operators to submit documentation, information requested by the market-surveillance authority.



## Sector 21: Waste Electrical and Electronic Equipment

### 21.A. Review of market-surveillance activities in the sector

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

	ASAE	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)	344	68	0	71
3.1	Number of reactive inspections	0	0	0	0
3.2	Number of self-initiated inspections	344	68	0	71
3.3	Number of inspections prompted by the customs	Please see the document attached to this report from the Tax Authority			
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	139	18	0	17
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	0	0	0	0
5.4	Application of sanctions/penalties	89	16	0	12
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

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

[ASAE] Carried out internal training for inspectors which informed on the most relevant aspects of this legislation.

Documentary inspection procedures have been drawn up.

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

[ASAE] The infringements detected related to non-compliance with the information obligations by WEEE operators, non-compliance with the information obligations by WEEE operators, the failure to deposit WEEE in a suitable location for its selective collection, failure to adhere to an integrated system or the placement of

prohibited substances onto the EEE market.

## Sector 26: Marine equipment

### 26.A. Review of market-surveillance activities in the sector

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

	ASAE	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)	19	35	0	0
3.1	Number of reactive inspections	0	0	0	0
3.2	Number of self-initiated inspections	19	35	0	0
3.3	Number of inspections prompted by the customs				
4	Number of inspections based on:				
4.1	Tests performed in laboratories	0	0	0	0
4.2	Physical checks of products	59	108	0	0
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	2	3	0	0
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	0	0	0	0
5.4	Application of sanctions/penalties	2	3	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 2010-2013 period (optional)

[ASAE] Market-surveillance in this field is shared with another surveillance authority (DGRM). Documentary and visual inspection procedures have been drawn up.

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

[ASAE] Inspection actions related to retailers.
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## **Sector 27 – Motor vehicles and tyres**

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

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

The Institute for Mobility and Transport (IMT) is a body which, within this sector, is essentially responsible for type-approval.

The performance of market-surveillance activities at public sales outlets is not one of the Institute's tasks. The IMT activities that may be regarded as falling within the scope of market surveillance are restricted to granting approval and checking product conformity.

The data provided relate to the activities undertaken by the IMT in the field shown.

		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	n.d.	n.d.	n.d.	n.d.
3	Number of inspections (total number)	2	3	3	1
3.1	Number of reactive inspections	0	0	0	0
3.2	Number of self-initiated inspections	2	3	3	1
3.3	Number of inspections prompted by the customs	n.d.	n.d.	n.d.	n.d.
4	Number of inspections based on:	-	-	-	-
4.1	Tests performed in laboratories	0	0	0	0
4.2	Physical checks of products	2	3	4	1
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 measures')	n.d.	n.d.	n.d.	n.d.
5.3	Restrictive measures taken by market-surveillance authorities	n.d.	n.d.	n.d.	n.d.
5.4	Application of sanctions/penalties	n.d.	n.d.	n.d.	n.d.
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market-surveillance authorities in nominal terms (€)	(*)	(*)	(*)	(*)
7.2	Budget available to market-surveillance authorities in relative terms (% of total national budget)	n.d.	n.d.	n.d.	n.d.
8	Staff available to market-surveillance authorities (full-time equivalent units)	3	3	3	3
9	Number of inspectors available to market-surveillance authorities (full-time equivalent units)	1,5	1,5	1,5	1,5

## ***27.B. Review of market-surveillance activities in the sector***

As stated, the Institute for Mobility and Transport (IMT) is a body that, in this sector, is essentially responsible for type-approval.

The EU type-approvals for road vehicles and components thereof that are granted by the IMT under harmonised EU legislation relate to motor vehicles (Directive 2007/46/EC) and to two-wheel motor vehicles, three-wheel motor vehicles and quadricycles (Directive 2002/24/EC).

The aforementioned market-surveillance activities are detailed below.

### 1 – Motor vehicles

Directive 2007/46/EC of 5 September 2007 establishes a framework for the approval of motor vehicles and their trailers, and of systems and components intended for such vehicles.

Under the Directive, the market-surveillance activities undertaken by the IMT in respect of the vehicles, components and systems for which it has granted EU type-approvals are:

a) Granting of type-approval

Type-approval for motor vehicles (or for their components and systems) is granted in accordance with the technical and safety requirements laid down in Directive 2007/46/EC and in the relevant EU and UNECE Directives and Regulations.

b) Initial assessment of the production plant

Before type-approval is granted, the production plant is subjected to an initial assessment for the purpose of verifying that satisfactory arrangements and procedures are in place that will enable effective checks to be carried out, so as to ensure that the vehicles, components, systems or technical units produced are compliant with the approved model or type. Such verification is carried out in accordance with Annex X to the Directive.

c) Periodic assessments of production plants

Periodic assessments are carried out in order to ensure that the vehicles, components, systems or technical units produced and subsequently placed on the market are always compliant with the approved model or type.

For this purpose and whenever deemed necessary by the IMT, the latter verifies the conformity-control methods applied within each production unit and checks that the procedures laid down in paragraph 1.2 of Annex X (initial assessment and product conformity) continue to be effective.

If production-conformity verification activities have been carried out by an approved or recognised certifying body, those activities are accepted as constituting the periodic procedure checks referred to in this section.

2 - Two-wheel motor vehicles, three-wheel motor vehicles and quadricycles

Directive 2002/24/EC of 18 March 2002 establishes a framework for the type-approval of two- or three-wheel motor vehicles and quadricycles, and of systems and components intended for such vehicles.

With regard to the vehicles, components and systems for which EU type-approvals have been granted by the IMT, the market-surveillance activities undertaken by the IMT pursuant to the Directive are as follows:

a) Granting of type-approval

Type-approval for motor vehicles (or for their components and systems) is granted in accordance with the technical and safety requirements laid down in Directive 2007/46/EC and in other relevant Directives.

b) Periodic assessments of production plants

With regard to the EU type-approvals that it grants, the IMT carries out periodic checks at each production plant in accordance with the provisions laid down in Annex VI to Directive 2002/24/EC. The purpose of the checks is to establish whether the methods used are capable of ensuring production conformity. In order to do so, the IMT analyses production and test records.

If non-compliant procedures or outcomes are observed in the course of inspections, the IMT ensures that the requisite corrective action is taken in order to render the production of type-approved models compliant.

4 – Withdrawal of products that are faulty or not compliant with the approved model

As regards the withdrawal of products that are faulty or not compliant with the approved model (recall), the IMT receives notifications under Article 32 of Directive 2007/46/EC from the approval authorities of the Member States that approved the products in question.

Such notifications describe the shortcomings detected and the corrective action proposed by the manufacturer. The IMT informs the manufacturer's representative in Portugal regarding the non-compliant products. If there are any vehicles in the country that are covered by the campaign, the representative notifies the relevant remedial plan, the effective implementation of which will be monitored by the IMT.

## **Sector 29: Fertilisers**

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

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

	<b>ASAE</b>	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)	10	42	25	80
3.1	Number of reactive inspections	0	0	0	0
3.2	Number of self-initiated inspections	10	42	25	80
3.3	Number of inspections prompted by the customs	Please see the document attached to this report from the Tax Authority			
4	Number of inspections based on:				
4.1	Tests performed in laboratories	0	0	0	0
4.2	Physical checks of products	181+6 907kg	1 790 kg	252	455
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	5	8	11	10
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	0	0	0	0
5.4	Application of sanctions/penalties	4	5	8	7
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0
	<b>IRAE Azores<sup>15</sup></b>	2010	2011	2012	2013
1.	Number of product-related accidents / user complaints	-	-	-	-
2.	Number of substantiated complaints by industry concerning unfair competition	-	-	-	-

<sup>15</sup>

Data relating to IRAE Azores also include data on phytopharmaceuticals, as they were supplied to us combined

3.	Number of inspections (total number)	1	0	3	4
3.1	Number of reactive inspections	1	0	3	4
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	0	0	2	2
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	0	0	0	0
6	Number of inspections where other Member States were invited to collaborate	-	-	-	-

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

**[ASAE]** With the publication of Regulation (EC) No 2003/2003, internal training activities were held for its inspectors, in which they were made aware of amendments to legislation relating to fertilisers and fertilising materials, as well as the application of Regulation (EC) No 764/2008, for those fertilisers only covered by national provisions, as well as procedures for the application of certain national technical rules to products lawfully marketed in another Member State.

Documentary inspection procedures and checklists have been drawn up so as to cover the various types of fertilisers covered by Community harmonisation legislation, with the aim of creating an operating methodology for all cases, as well as for fertilisers that constitute a national technical rule.

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

**[ASAE]** Inspection actions related to distributors and retailers.

In accordance with Regulation (EC) No 2003/2003 the infringements detected were related to the failure to indicate 'EC fertiliser' and the failure to observe the rules on market placement.

## **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 2010-2013 period**

	<b>ASAE</b>	2010	2011	2012	2013
1.	Number of product-related accidents / user complaints	12	10	16	10
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total number)	258	211	235	464
3.1	Number of reactive inspections	28	87	34	88
3.2	Number of self-initiated inspections	230	124	171	376
3.3	Number of inspections prompted by the customs	Please see the document attached to this report from the Tax Authority			
4	Number of inspections based on:				
4.1	Tests performed in laboratories	4	8	0	0
4.2	Physical checks of products	155	113	185	400
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	59	29	88	42
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	0	0	0	0
5.4	Application of sanctions/penalties	35	36	40	28
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

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

**[ASAE]** Documentary inspection procedures and sample collection procedures have been drawn up.

Cooperation with the market-surveillance authorities in France, Slovakia and Lithuania, specifically in those aspects related to operational methodology, involved in employee exchange projects promoted by the European Commission.

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

**[ASAE]** Participated in the following cooperative actions promoted by PROSAFE (*Product Safety Forum of Europe*) and supported by the European Commission:

- *Joint Action 2010 'Baby Walkers'.*  
In order to carry out this action, four samples of baby walkers were collected.
- *Joint Action 2011 'Laser pointers'.*  
In order to carry out this action, eight samples of laser pointers were collected. It secured the role of group Task Leader.

Currently, it participates in the Joint Action 2013 '*Cords and Drawstrings on Children's Clothing II*', promoted by



PROSAFE (*Product Safety Forum of Europe*) and supported by the European Commission.

Surveillance actions in the field of general product security have focused on manufacturers, importers, distributors and retailers.

The infringements detected related to the supply of products, which the producer or distributor is aware, or should be aware, in accordance with the information at their disposal, do not comply with the general safety obligations and a lack of labelling in Portuguese.

## Sector 31: Labelling of textile products

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

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

	<b>ASAE</b>	2010	2011	2012	2013
1.	Number of product-related accidents / user complaints	25	29	14	46
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total number)	141	158	164	226
3.1	Number of reactive inspections	25	29	14	46
3.2	Number of self-initiated inspections	146	129	150	180
3.3	Number of inspections prompted by the customs	Please see the document attached to this report from the Tax Authority			
4	Number of inspections based on:				
4.1	Tests performed in laboratories	0	50	0	0
4.2	Physical checks of products	369	386	294	84
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	49	40	44	33
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	0	0	0	0
5.4	Application of sanctions/penalties	26	20	31	22
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0
	<b>IRAE Azores</b>	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)	0	0	0	5
3.1	Number of reactive inspections	0	0	0	5
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	0	0	0	0
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	0	0	0	0
6	Number of inspections where other Member States were invited to collaborate	-	-	-	-

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

[ASAE] Documentary and visual inspection procedures and checklists have been drawn up.

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

[ASAE] Inspection actions related to manufacturers, importers, distributors and retailers.

The infringements detected related to the failure to translate labelling into Portuguese, the absence of pictograms, a lack of labelling, or the placing of a '100%', 'pure' or 'all' label or mark on products that are not made entirely from the same fibre.

In accordance with Regulation (EU) No 1007/2011 of the European Parliament and of the Council of 27 September 2011, the greatest difficulty encountered related directly to the transitional period provided for in the legislation. The main difficulty regarded not impeding the making available on the market of textile products which were placed on the market before 8 May 2012.

## **Sector 32: Labelling of footwear**

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

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

	ASAE	2010	2011	2012	2013
1.	Number of product-related accidents / user	12	8	5	6

	complaints				
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total number)	12	8	5	197
3.1	Number of reactive inspections	12	8	5	6
3.2	Number of self-initiated inspections	0	0	0	191
3.3	Number of inspections prompted by the customs	Please see the document attached to this report from the Tax Authority			
4	Number of inspections based on:				
4.1	Tests performed in laboratories	0	0	0	0
4.2	Physical checks of products	78	89	202	337
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	0	0	0	44
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	0	0	0	0
5.4	Application of sanctions/penalties	0	0	0	31
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

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

[ASAE] Documentary and visual inspection procedures have been drawn up.

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

[ASAE] Inspection actions related to distributors and retailers.

The infringements detected related to a lack of labelling on at least one of the shoes, a lack of pictograms, failure to translate the written inscriptions into Portuguese, and the absence or poor labelling of the shoes (outer, inner and sole).

## **Sector 33: Biocidal products**

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

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

	<b>ASAE</b>	2010	2011	2012	2013
1.	Number of product-related accidents / user	0	0	0	0

	complaints				
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total number)	0	110	0	0
3.1	Number of reactive inspections	0	0	0	0
3.2	Number of self-initiated inspections	0	110	0	0
3.3	Number of inspections prompted by the customs				
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	24	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	n.a.	n.a.	n.a.	n.a.
5.4	Application of sanctions/penalties	0	21	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 2010-2013 period (optional)

[ASAE] Documentary and visual inspection procedures have been drawn up.

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

[ASAE] Inspection actions related to distributors and retailers.

The infringements detected related to the lack of authorisation or registration, and the lack of a Portuguese translation.

## **Sector 34: Food imitating products**

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

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

	<b>ASAE</b>	2010	2011	2012	2013
1.	Number of product-related accidents / user	0	0	0	0

	complaints				
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total number)	32	40	52	20
3.1	Number of reactive inspections	0	0	0	0
3.2	Number of self-initiated inspections	32	40	52	20
3.3	Number of inspections prompted by the customs				
4	Number of inspections based on:				
4.1	Tests performed in laboratories	0	0	52	0
4.2	Physical checks of products	280	827	909	111
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	14	9	6	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	0	0	0	0
5.4	Application of sanctions/penalties	14	9	6	2
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

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

[ASAE] Documentary inspection procedures and sample collection procedures have been drawn up.

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

[ASAE] The ASAE participated in a joint action called Joint Action 2011 'Food Imitation Products' organised by PROSAFE (Product Safety Forum of Europe) and supported by the European Commission. During this action, it collected 52 samples of products.

The infringements detected related to the manufacturing, marketing, importing or exporting of dangerous imitations.

## **Sector 35: Misuse of the CE marking**

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

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

	<b>ASAE</b>	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)				
3.1	Number of reactive inspections	0	0	0	0
3.2	Number of self-initiated inspections	0	58	142	0
3.3	Number of inspections prompted by the customs				
4	Number of inspections based on:	0	58	142	0
4.1	Tests performed in laboratories	0	0	0	0
4.2	Physical checks of products	0	2 586	19 068	0
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	0	51	70	0
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	0	0	0	0
5.4	Application of sanctions/penalties	0	37	59	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 2010-2013 period (optional)**

**[ASAE]** Documentary inspection procedures and sample collection procedures have been drawn up.

Cooperation with third countries, Moldavia, Libya and Brazil, with regard to the application of Community harmonisation legislation covered by Regulation (EC) No 765/2008 together with Decision No 768/2009/EC.

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

**[ASAE]** The CE marking rules are very clear, yet there are still products made available on the market that have opted to place a CE marking on their labelling, without being covered by Union harmonisation legislation that provides for this.

Under national legislation, Decree-Law No 23/2011 of 11 February, which ensures the enforcement of obligations arising from Regulation (EC) No 765/2008 of 9 July, which sets out the requirements for accreditation and market-surveillance relating to the marketing of products, this type of situation shall constitute a punishable offence.

In addition to the above, various other products can also be found on the market that have opted to place graphics on their labelling that do not correspond to the CE marking, due to including various circles with inscriptions around the CE graphic.

However, Decree-Law No 23/2011 of 11 February, which ensures the enforcement of the obligations arising from Regulation (EC) No 765/2008 of 9 July, determines that the affixation of these types of markings, signs or inscriptions which are likely to mislead third parties regarding the meaning or form, or both, of the CE marking shall constitute a punishable offence.

## Sector 36: Plant protection products

### 36.A. Review of market-surveillance activities in the sector

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

	ASAE	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	70	2	80
3.1	Number of reactive inspections	0	0	0	0
3.2	Number of self-initiated inspections	0	70	2	80
3.3	Number of inspections prompted by the customs				
4	Number of inspections based on:				
4.1	Tests performed in laboratories	0	0	0	0
4.2	Physical checks of products	0	430	2	80
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	0	13	1	10
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	0	0	0	0
5.4	Application of sanctions/penalties	0	12	1	7
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

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

[ASAE] Internal training activities were held for its inspectors, in which they were made aware of amendments to legislation relating to phytopharmaceutical products, as well as the application of Regulation (EC) No 764/2008, for those types of products only covered by national provisions, as well as procedures for the application of certain national technical rules to products lawfully marketed in another Member State.

Documentary inspection procedures and checklists have been drawn up so as to cover the

various types of phytopharmaceutical products for professional use covered by Community harmonisation legislation, with the aim of creating an operating methodology for all cases, as well as for those phytopharmaceutical products for non-professional use that constitute a national technical rule.

Participated in seminars where clarifications were given on the implementation of legislation.

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

**[ASAE]** Inspection actions related to distributors and retailers.

The infringements detected related to the failure to register the sale of the phytopharmaceutical product or incorrect registration of commercial documents, marketing without authorisation for sale and the unauthorised exercise of marketing or sales activity.

## **Sector 37: Labelling and Energy efficiency**

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

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

	<b>ASAE</b>	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)				
3.1	Number of reactive inspections	0	0	0	0
3.2	Number of self-initiated inspections	21	5	6	190
3.3	Number of inspections prompted by the customs				
4	Number of inspections based on:				
4.1	Tests performed in laboratories	0	0	0	0
4.2	Physical checks of products	58	25	133	761
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	5	0	0	30
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	0	0	0	0
5.4	Application of sanctions/penalties	5	0	0	24
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0



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

[ASAE] Internal training activities were held for their inspectors, in which they were made aware of amendments relating to energy efficiency labelling

Documentary and visual inspection procedures have been drawn up.

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

[ASAE] Inspection actions related to distributors and retailers.

The infringements detected related to the failure to advertise the energy efficiency classification of the product, the use of labels in an unauthorised manner, and the affixation of labels, markings, symbols or inscriptions which do not comply with the established requirements

## **Sector 38: Dangerous Substances and Preparations**

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

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

	<b>ASAE</b>	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)	19	0	0	0
3.1	Number of reactive inspections	0	0	0	0
3.2	Number of self-initiated inspections	19	0	0	0
3.3	Number of inspections prompted by the customs				
4	Number of inspections based on:				
4.1	Tests performed in laboratories	0	0	0	0
4.2	Physical checks of products	109	0	0	0
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	13	0	0	0
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	19	0	0	0

5.4	Application of sanctions/penalties	10	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 2010-2013 period (optional)**

[ASAE] Documentary and visual inspection procedures have been drawn up.

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

[ASAE] Inspection actions related to distributors and retailers.

The infringements detected related to the failure to communicate toxicology data and information on first aid, the failure to communicate toxicology data and information on first aid, the failure to provide information (anti venom information centre) and the failure to provide information to medical staff at the AVIC.

**Sector 39: Packaging waste management**

***39.A. Review of market-surveillance activities in the sector***

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

	<b>ASAE</b>	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)	32	0	0	66
3.1	Number of reactive inspections	0	0	0	0
3.2	Number of self-initiated inspections	32	0	0	66
3.3	Number of inspections prompted by the customs				
4	Number of inspections based on:				
4.1	Tests performed in laboratories	0	0	0	0
4.2	Physical checks of products	32	0	0	66
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	8	0	0	3
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	0	0	0	0
5.4	Application of sanctions/penalties	7	0	0	3
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

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

[ASAE] Documentary and visual inspection procedures have been drawn up.

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

[ASAE] The infringements detected related to placement on the market without a packaging and waste management system and the failure to comply with the duty to ensure waste management.

**Sector 40: All product sectors**

***40.A. Review of market-surveillance activities in the sector***

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

	<b>IRAE Madeira</b>	2010	2011	2012	2013
1.	Number of product-related accidents / user complaints	2	6	2	3
2.	Number of substantiated complaints by industry concerning unfair competition	2	0	0	1
3.	Number of inspections (total number)	12	16	22	16
3.1	Number of reactive inspections	8	11	19	12
3.2	Number of self-initiated inspections	4	5	3	4
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				
4.2	Physical checks of products	2	5	3	3
5	Number of inspections resulting in:				
5.1	Finding of non-compliance	0	1	2	1
5.2	Corrective actions taken by economic operators ('voluntary measures')	0	1	2	1
5.3	Restrictive measures taken by market	0	0	0	1

	surveillance authorities				
5.4	Application of sanctions/penalties	N	Y	N	Y
6	Number of inspections where other Member States were invited to collaborate	n.a.	n.a.	n.a.	n.a.

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

	<b>IRAE Madeira</b>	2010	2011	2012	2013
7.1	Budget available to market-surveillance authorities in nominal terms (€)	n.a.	n.a.	n.a.	n.a.
7.2	Budget available to market-surveillance authorities in relative terms (% of total national budget)	n.a.	n.a.	n.a.	n.a.
8	Staff available to market-surveillance authorities (full-time equivalent units)	18	18	17	16
9	Number of inspectors available to market-surveillance authorities (full-time equivalent units)	18	18	17	16

## Annex 1: Reference list of sectors

Product sectors	Relevant legislation	Included in this report? (Y/N)
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	Y
2. Cosmetics	Regulation (EC) No 1223/2009	Y
3. Toys	Directive 88/378/EEC and Directive 2009/48/EC	Y
4. Personal protective equipment	Directive 89/686/EEC	Y
5. Construction products	Regulation (EC) No 305/2011	Y
6. Aerosol dispensers	Directive 75/324/EEC	Y
7. Simple pressure vessels and pressure equipment	Directives 2009/105/EC and 97/23/EC	Y
8. Transportable pressure equipment	Directive 2010/35/EC	N
9. Machinery	Directive 2006/42/EC	Y
10. Lifts	Directive 95/16/EC	N
11. Cableways	Directive 2000/9/EC	N
12. Noise emissions for outdoor equipment	Directive 2000/14/EC	Y
13. Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	Directive 1994/9/EC	N <sup>16</sup>
14. Pyrotechnics	Directive 2007/23/EC	Y (jointly with sector 15)
15. Explosives for civil uses	Directive 93/15/EEC	Y (idem sector 14)
16. Appliances burning gaseous fuels	Directive 2009/142/CE	Y
17. Measuring instruments, Non-automatic weighing instruments and Pre-packaged products	Directives 2004/22/EC, 2009/23/EC and 2007/45/EC	Y
18. Radio and telecom equipment under EMC	Directive 2004/108/EC	Y
19. Radio and telecom equipment under RTTE	Directive 1999/5/EC	Y
20. Electrical appliances and equipment under LVD (Low Voltage Directive)	Directive 2006/95/EC	Y

<sup>16</sup> No products were found on the market and as such, no inspections were conducted.

Product sectors	Relevant legislation	Included in this report? (Y/N)
21. Electrical and electronic equipment under RoHS, WEEE and batteries	Directives 2011/65/EU, 2002/96/EC and 2006/66/EC	Y
22. Chemicals (detergents, paints, persistent organic pollutants)	Regulation (EC) No 648/2004 Directive 2004/42/EC Regulation (EC) No 850/2004	N
23. Ecodesign and Energy labelling	Directives 2009/125/EC and 2010/30/EU	N
24. Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	Directive 1992/42/EEC	N
25. Recreational craft	Directive 1994/25/EC	Y
26. Marine equipment	Directive 96/98/EC	Y
27. Motor vehicles and tyres	Directives 2002/24/EC and 2007/46/EC, and Regulation (EC) No 1222/2009 <sup>17</sup>	N
28. Non-road mobile machinery	Directive 97/68/EC	
29. Fertilisers	Regulation (EC) No 2003/2003	Y
30. Other consumer products under GPSD (General Product Safety Directive) (optional)	Directive 2001/95/EC	Y
31. Labelling of textile products	Directive 96/74/EC and Regulation (EU) 1007/2011	Y
32. Labelling of footwear	Directive 94/11/EC	Y
33. Biocidal products	Directive 98/8/EC Regulation (EU) 528/2012	Y
34. Food imitating products	Directive 87/357/EEC	Y
35. Misuse of the CE marking	Regulation (EC) 765/2008	Y
36. Plant protection products	Directive 2009/128/EC	Y
37. Energy efficiency labelling	Directive 2010/30/EU	Y
38. Dangerous Substances and Preparations	Directive 1999/45/EC Directive 2001/60/EC Directive 2001/58/EC Directive 2006/8/EC	Y
39. Packaging waste management	Directive 94/62/EC and its amendments	Y
40. All product sectors (IRAE Madeira)	Series of identical regulatory directives ASAE	Y

<sup>17</sup>

Despite being part of the Tyre Adco group, ASAE did not inspect this type of product, as the implementation rules for Regulation (EC) No 1222/2009 have not yet been published.

## Annex 2: List of the market-surveillance authorities, within the meaning given by Article 17 of Regulation (EC) No 765/2008 of 9 July

MARKET-SURVEILLANCE AUTHORITY	AREAS OF RESPONSIBILITY
<p><b>ASAE Authority for Food and Economic Safety</b></p> <p>Address: Rua Rodrigo da Fonseca, n.º 73 1269-274 Lisbon</p> <p>Telephone: + 351 21 798 36 00 Fax: + 351 21 798 37 72</p> <p>Website: <a href="http://www.asae.pt">www.asae.pt</a></p>	<ul style="list-style-type: none"> <li>▪ EC Fertiliser and fertilisers</li> <li>▪ Appliances burning gaseous fuels</li> <li>▪ Equipment Intended for use in Potentially Explosive Atmospheres</li> <li>▪ Pyrotechnics</li> <li>▪ Lifts</li> <li>▪ Batteries, primary cells and accumulators</li> <li>▪ Hot boilers</li> <li>▪ CLP/GHS</li> <li>▪ Fuels</li> <li>▪ Electromagnetic compatibility</li> <li>▪ Volatile organic compounds</li> <li>▪ Detergents</li> <li>▪ ECODESIGN</li> <li>▪ Aerosol dispensers</li> <li>▪ Packaging and packaging waste</li> <li>▪ Recreational craft<sup>18</sup></li> <li>▪ Noise emissions for outdoor machines</li> <li>▪ Equipment under LVD</li> <li>▪ Marine equipment<sup>19</sup></li> <li>▪ Personal protective equipment</li> <li>▪ Radio equipment and telecommunications terminal equipment (R&amp;TTE)</li> <li>▪ Pressure equipment</li> <li>▪ Simple pressure vessels</li> <li>▪ Transportable pressure equipment</li> <li>▪ Energy efficiency labelling</li> <li>▪ Energy labelling of tyres</li> <li>▪ Labelling of textile products</li> <li>▪ Food imitating products</li> <li>▪ Measuring instruments</li> <li>▪ Non-automatic weighing instruments</li> <li>▪ Restrictions on the marketing and use of certain dangerous substances and preparations</li> <li>▪ Limits on the sulphur content of marine fuels<sup>20</sup></li> <li>▪ Machinery</li> <li>▪ Misuse of the CE marking</li> <li>▪ Non-road engines</li> <li>▪ Pre-packaged products</li> <li>▪ Drug precursors (categories 1, 2 e 3)<sup>21</sup></li> <li>▪ Biocidal products</li> <li>▪ Construction products</li> <li>▪ REACH</li> </ul>

<sup>18</sup> Responsibility shared with DGRM

<sup>19</sup> Responsibility shared with DGRM

<sup>20</sup> Responsibility shared with DGRM

<sup>21</sup> Responsibility shared with INFARMED

	<ul style="list-style-type: none"> <li>▪ Waste from Electrical and Electronic Equipment</li> <li>▪ RoHS</li> <li>▪ Labelling of footwear</li> <li>▪ Safety of toys</li> <li>▪ General Product Safety</li> <li>▪ Substances which deplete the ozone layer</li> <li>▪ Units of measurement</li> <li>▪ Crystal glass and resonant glass</li> </ul> <p style="text-align: right;">(...)</p>
<p><b>INFARMED National Authority of Medicines and Health Products</b></p> <p>Address: Parque de Saúde de Lisboa Avenida do Brasil, 53 1749-004 Lisbon</p> <p>Telephone: +351 21 798 71 00 Fax: +351 21 798 7316</p> <p>Website: <a href="http://www.infarmed.pt">www.infarmed.pt</a></p>	<ul style="list-style-type: none"> <li>▪ Medical devices</li> <li>▪ Drug precursors (category 1)<sup>22</sup></li> <li>▪ Cosmetics</li> </ul>
<p><b>ICP National Communications Authority (ANACOM)</b></p> <p>Address: Avenida José Malhoa, n.º 12 1099-017 Lisbon</p> <p>Telephone: +351 21 721 26 11 (05/07/09) Fax: +351 21 721 20 89</p> <p>Website: <a href="http://www.anacom.pt">www.anacom.pt</a></p> <p><b>IMT Mobility and Land Transport Institute</b></p> <p>Address: Av. das Forças Armadas, 40 1649-022 LISBON</p> <p>Telephone: +351 21 794 90 00 Fax: +351 21 797 37 77</p> <p>Website: <a href="http://www.imtt.pt">www.imtt.pt</a></p>	<ul style="list-style-type: none"> <li>▪ Electromagnetic compatibility<sup>23</sup></li> <li>▪ Radio equipment and telecommunications terminal equipment (R&amp;TTE)</li> <li>▪ Transportable pressure equipment<sup>24</sup></li> <li>▪ Helmets</li> <li>▪ Inoperability of the rail system</li> <li>▪ Cableways installations designed to carry persons</li> <li>▪ Vehicles</li> </ul>
<p><b>DGRM Directorate-General of Natural Resources, Security and Maritime Services</b></p> <p>Address: Avenida Brasília 1449-030 LISBON</p> <p>Telephone: +351 21 303 57 00 Fax: +351 21 303 57 02 Website: <a href="http://www.dgrm.min-agricultura.pt">www.dgrm.min-agricultura.pt</a></p>	<ul style="list-style-type: none"> <li>▪ Recreational craft</li> <li>▪ Marine equipment</li> <li>▪ Limits on the sulphur content of marine fuels</li> </ul>

<sup>22</sup> Responsibility shared with ASAE

<sup>23</sup> Responsibility shared with ASAE

<sup>24</sup> Responsibility shared with ASAE



<p><b>DNPSP — National Directorate of the Public Security Police</b> (PSP Arms and Explosives Department)</p> <p>Address: Rua de Artilharia 1, n.º 21 1269-003 Lisbon</p> <p>Telephone: +351 21 811 10 00 Fax: +351 21 387 4772</p> <p>Website: <a href="http://www.psp.pt">www.psp.pt</a></p>	<ul style="list-style-type: none"> <li>▪ Pyrotechnics<sup>25</sup></li> <li>▪ Explosives for civil uses</li> <li>▪ System for the identification and traceability of explosives for civil uses</li> </ul>
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AUTONOMOUS REGIONS	
MARKET-SURVEILLANCE AUTHORITY	AREAS OF RESPONSIBILITY
<p><b>IRAE Azores The Regional Inspectorate For Economic Activities - Azores</b></p> <p>Address: Rua Margarida de Chaves, n.º 103, 1.º 9500-088 Ponta Delgada Azores</p> <p>Telephone: +351 29 630 22 70 Fax: +351 29 628 43 95</p> <p>Email: <a href="mailto:irae@azores.gov.pt">irae@azores.gov.pt</a></p>	<ul style="list-style-type: none"> <li>▪ The same competences as ASAE</li> </ul>
<p><b>IRAE Madeira The Regional Inspectorate For Economic Activities - Madeira</b></p> <p>Address: Rua Direita nº 27, 3º andar 9050-450 Funchal</p> <p>Telephone: +351 291 215 040 Fax: +351 291 215 060</p> <p>Email: <a href="mailto:srrh.rae@netmadeira.com">srrh.rae@netmadeira.com</a></p>	<ul style="list-style-type: none"> <li>▪ The same competences as ASAE</li> </ul>

EXTERNAL BORDER CONTROL	AREAS OF RESPONSIBILITY
<p><b>AT Portuguese Tax and Customs Authority</b></p> <p>Address: Rua da Alfândega, n.º 5, r/c 1149-006 Lisbon</p> <p>Telephone: +351 21 811 10 00 Fax: +351 21 881 39 00</p> <p>Website: <a href="http://www.e-financas.gov.pt">www.e-financas.gov.pt</a></p>	<ul style="list-style-type: none"> <li>▪ All products</li> </ul>

<sup>25</sup> Responsibility shared with ASAE