

# **PORTUGUESE REPUBLIC**

*NATIONAL MARKET SURVEILLANCE PROGRAMME*

*2018*

*PORTUGAL*

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## INTRODUCTION

Market surveillance must guarantee satisfactory protection for consumers, public health, the environment and other aspects of protection of the public interest, and fair competition between economic operators.

Market surveillance activities are carried out by the public authorities and the measures taken by those authorities are intended to ensure that the products placed on the market or made available on the market comply with the specific EU harmonisation legislation.

Market surveillance activity thus takes a twofold approach:

– a **proactive** approach, based on plans drawn up at central level and duly coordinated at regional level, whereby surveillance activities are planned and implemented in line with pre-determined criteria, regional specificities, structural and economic situations and imperatives for interinstitutional cooperation;

— a **reactive** approach, based on complaints, in one-off situations detected in the field and also based on collaboration requests from other bodies and notifications issued through the RAPEX system or through exchanges of associated information on failure to comply with EU harmonisation legislation.

The operational methodology is described in various market surveillance procedures, covering visual inspection, documentary inspection and e-commerce.

The market surveillance authorities must take suitable measures with economic operators whose products do not comply with the requirements of the EU harmonisation legislation.

Adoption of these measures involves prohibition, restriction on making available, withdrawal or recall of a product pursuant to Article 20 of Regulation (EC) No 765/2008 of 9 July 2008 or pursuant to the applicable EU harmonisation legislation intended to harmonise the conditions for placing products on the market referred to in Article 21 of that same Regulation.

Pursuant to Regulation (EC) No 765/2008 of 9 July 2008, each Member State must develop, implement and monitor its national market surveillance programme, drawn up with contributions from all of the national market surveillance authorities.

The 2018 programme was drawn up in accordance with Article 18(5) of Regulation (EC) No 765/2008 of 9 July 2008, using the form proposed by the Commission.

## **1. GENERAL MARKET SURVEILLANCE ORGANISATION AND INFRASTRUCTURE**

With the publication of Decree-Law No 23/2011 of 11 February 2011, ensuring fulfilment of the requirements derived from Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products, responsibility for market surveillance, provided for in Article 18 of that Regulation, passed to eight authorities, two of which were the Autonomous Region of the Azores and the Autonomous Region of Madeira.

The names of the said authorities are:

- ASAE — Food and Economic Safety Authority;
- INFARMED — National Authority of Medicines and Health Products;
- ANACOM — National Communications Authority;
- IMT — INSTITUTE FOR MOBILITY AND TRANSPORT (IMT), I.P.;
- DGRM — Directorate-General for Natural Resources, Maritime Safety and Services;
- DNPSP — National Directorate of the Public Security Police;
- IRAE Azores — Regional Inspectorate for Economic Activities in the Azores;
- ARAE Madeira — Regional Inspectorate for Economic Activities in Madeira.

Under national law, monitoring external borders is the responsibility of the Autoridade Tributária e Aduaneira – AT (Tax and Customs Authority), which is not considered a market surveillance authority.

Decree-Law No 23/2011 of 11 February 2011 is intended to ensure that all products placed on the market or made available on the market comply with the legal requirements so as to not pose a risk to the health and safety of consumers or users.

In order to achieve the aims sought, this Decree-Law provides for the organisation of market surveillance at national level and lays down provisions relating to the responsibilities assigned to the market surveillance authorities and to the customs authority in relation to both the application of Articles 27 to 29 of the Regulation and the mechanisms for cooperation with 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 must adopt measures to prohibit, restrict the availability of, withdraw or recall the said product throughout the supply chain.

The responsibilities assigned to each of the market surveillance authorities and their respective contact details can be found in Annexes II and III to this report, as can a description of the areas assigned to each one and the shared responsibilities, within the national legislative framework, for the transposition of EU harmonisation legislation.

### **1.1. Identification and responsibilities of national market surveillance authorities**

The market surveillance authorities are described below:

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

Address of central services: Rua Rodrigo da Fonseca, n.º 73; 1269-274 Lisbon

Telephone: +351 21 798 36 00

Fax: +351 21 798 37 72  
Email: uno\_msa@asae.pt  
Website: www.asae.pt

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 service directly administered by the State within the framework of the Ministry of Economic Affairs and it has administrative autonomy. It carries out surveillance and prevention tasks 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 — in addition to its central services in Lisbon — a number of decentralised units that carry out market surveillance inspections. These are referred to as the Regional Units (UR) for the North (URN) the Centre (URC) and the South (URS) and are based in Porto, Coimbra and Lisbon respectively.

Each of the Regional Units also has Operational Units located at the following points:

- a) Regional Unit for the North: Porto, Barcelos and Mirandela;
- b) Regional Unit for the Centre: Coimbra, Castelo Branco and Tondela;
- c) Regional Unit for the South: Lisboa, Santarém, Évora and Faro.

The central offices are organised into the following departments and 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 Regulation on cosmetic products, the Directives on explosives for civil uses, medical devices and cableway installations designed to carry persons. As such, it is a member of a number of different Administrative Cooperation groups (ADCO groups), the “Note to the expert group on the internal market for products — IMP MSGroup” and of the “Note to the expert group on the internal market for products — IMP MSGroup — Subgroup ICSMS”. In addition, it serves as a coordinating authority and national contact point within the general support information system (ICSMS system) and, as a competent authority and surveillance authority within the scope of Regulation (EC) No 764/2008 of 9 July 2008, it participates in a range of cooperation actions coordinated by PROSAFE (Product Safety Forum of Europe).

As part of its cooperation activities it has participated in a number of projects such as: “BACCUS: comBAting food Crime by strengthening law enforcement Cooperation”, coordinated by the Carabinieri Health Protection Unit (NAS) and the implementation of the Coordinated European Programmes proposed by the European Commission (DG Sanco); in the operational actions ongoing over the 2014-2017 cycle, for the “Counterfeit Goods” priority, for OPSON operations — joint operational actions with a view to combating food fraud at international level, “IN OUR SITES” — joint international action focusing on e-commerce, and ARQUIMEDES — multidisciplinary joint operational action including, at international level, the nine priorities of the EMPACT project,

It represents Portugal within EUROPOL's EMPACT platform (European Multidisciplinary Platform against Criminal Threats), at the level of the “Counterfeit Goods” Priority — acronym of the EMPACT project “Counterfeit goods with impact on human health and safety”.

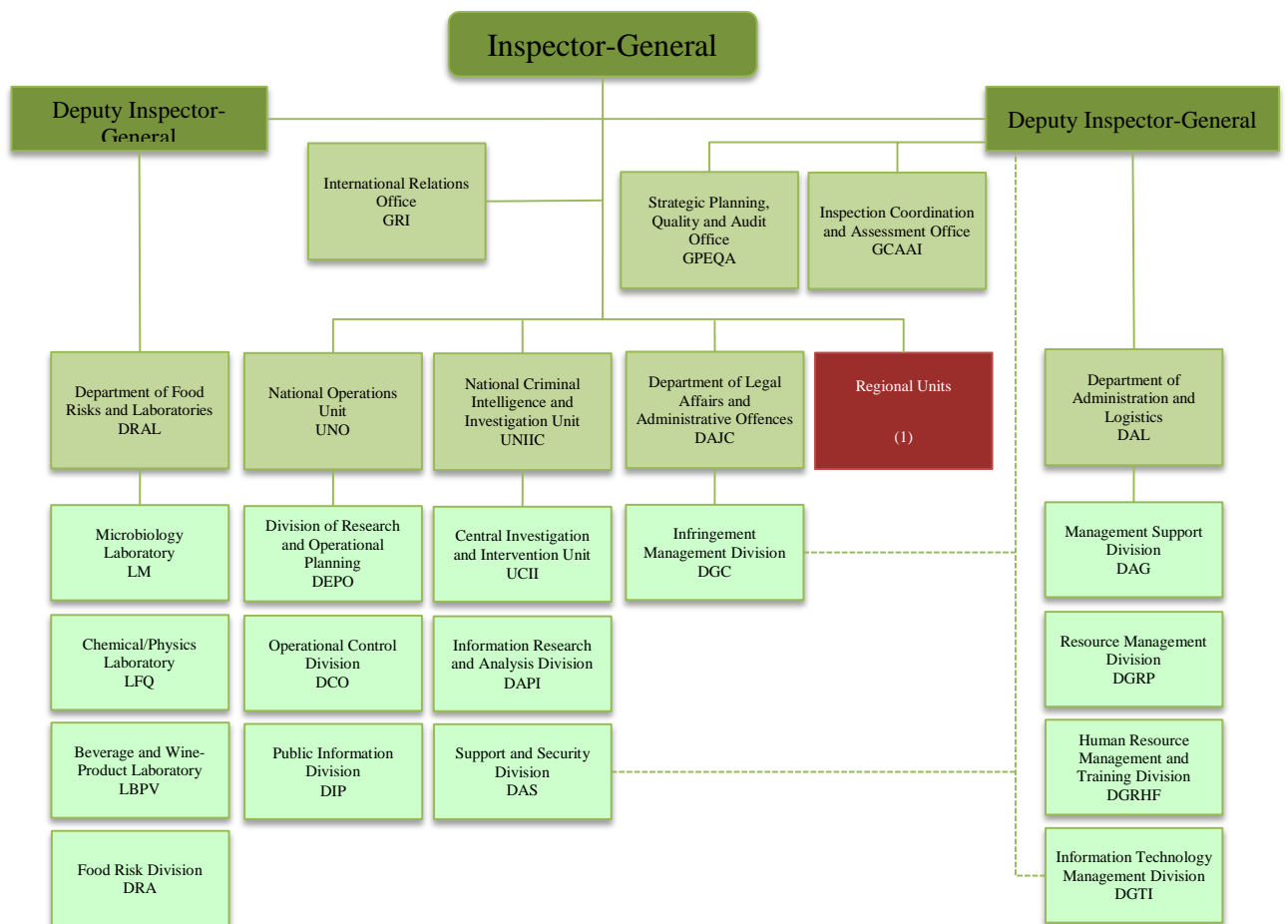
It currently holds the presidency of the *Fórum das Inspeções de Segurança Alimentar e Atividades Económicas*, FISAAE (Food Safety and Economic Activity Inspectorate Forum) organised by the countries of the CPLP (Community of Portuguese Language Countries).

The tasks of the ASAE include the following:

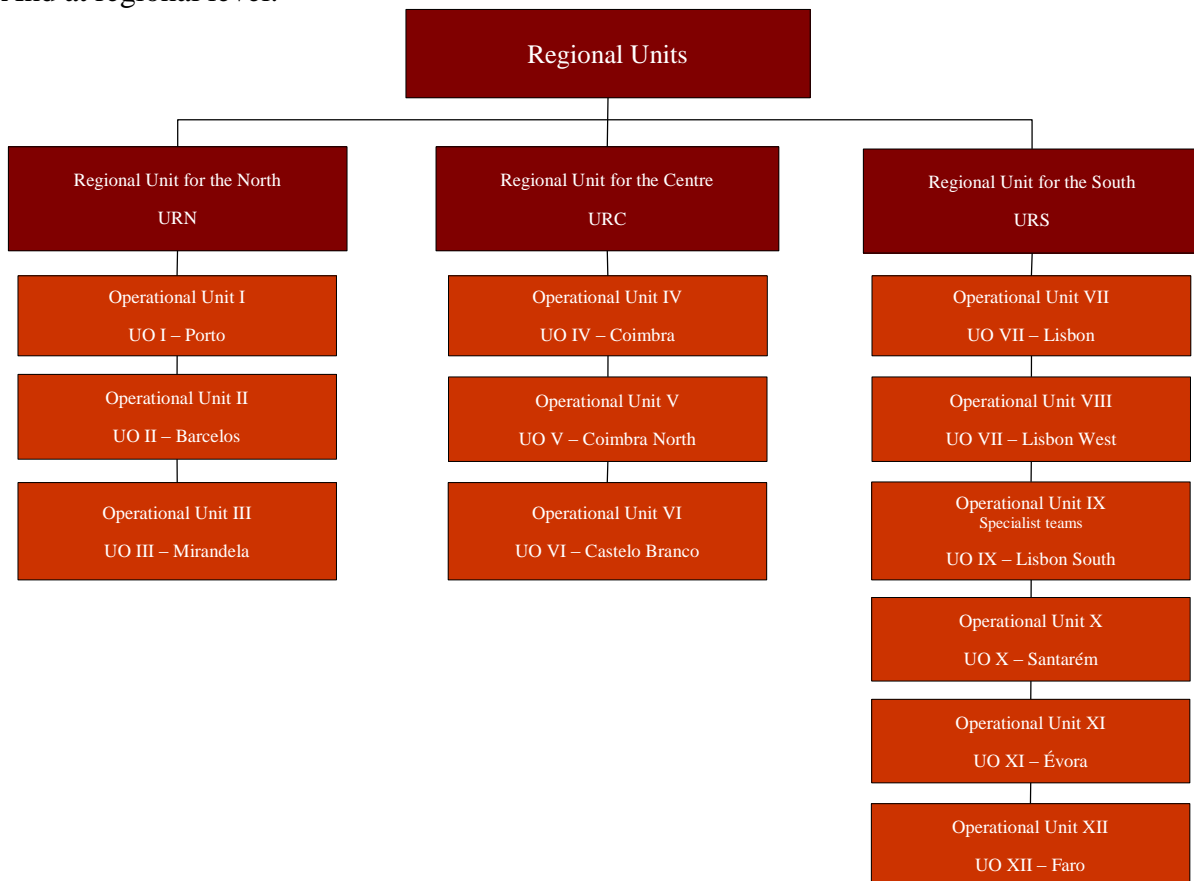
- a) surveillance of economic activities;
- b) developing, implementing and regularly disseminating the market surveillance programme, in accordance with Regulation (EC) No 765/2008 of the European Parliament and the Council of 9 July 2008, in addition to taking restrictive prohibition measures, restricting products from 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 cooperating 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 areas for which it is responsible.

At national level, ASAE's structure can be summarised as follows:





And at regional level:



**B) NATIONAL AUTHORITY OF MEDICINES AND HEALTH PRODUCTS, I.P. (INFARMED)**

Address: Parque de Saúde; Avenida do Brasil, n.º 53; 1749-004 Lisbon

Telephone: +351 21 798 71 00

Fax: +351 21 798 73 16

Website: [www.infarmed.pt](http://www.infarmed.pt)

INFARMED, 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 2012, INFARMED's mission 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.

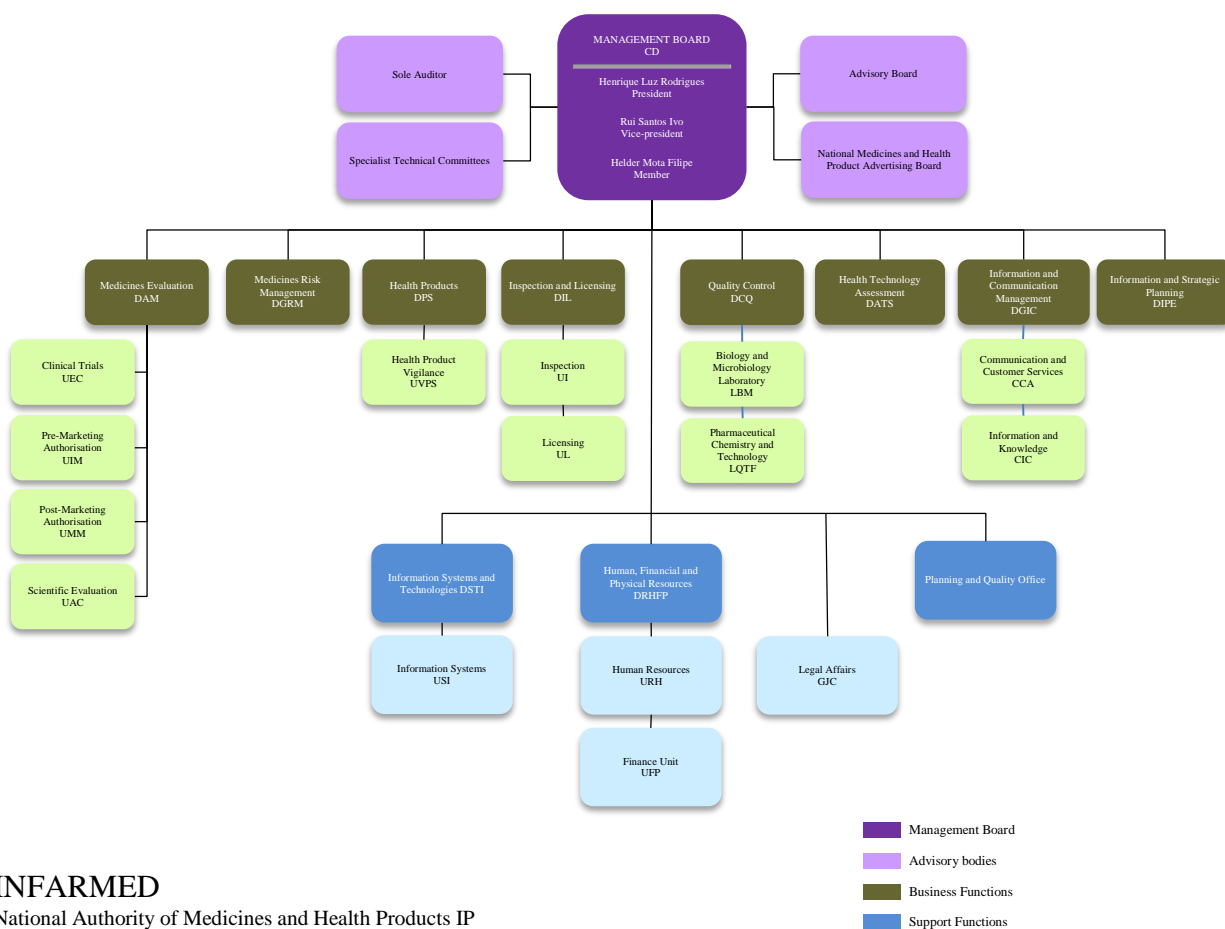
This mission is accomplished through the implementation of powers in the fields of policy definition and execution, regulations, compliance, assessment, authorisation, post-marketing surveillance, investigation monitoring and enforcement, production, distribution and marketing, consumption and use of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

In addition to the above, INFARMED's other powers 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. As regards cooperation, initiatives have been put in place with Portuguese-speaking countries (Cape Verde, Brazil and Angola), Macau and third countries, specifically with countries in the Maghreb and Latin America.

INFARMED's structure is summarised in the figure below:

## ORGANISATIONAL STRUCTURE OF INFARMED, I.P.



### INFARMED

National Authority of Medicines and Health Products IP

### C) NATIONAL COMMUNICATIONS AUTHORITY (ANACOM)

Address: Avenida José Malhoa No. 12 1099-0017 Lisbon

Telephone: +351 21 721 26 11

Fax: +351 21 721 20 89

Website: [www.anacom.pt](http://www.anacom.pt)

ANACOM has as its mission the regulation of the communications sector — including electronic and postal communications — and, without prejudice to its nature as an independent administrative body, the provision of assistance to the Government in these areas.

It serves as a central supervisory body, with responsibilities and powers in all areas governed by Decree-Law No 7/2004 of 7 January regulating certain legal aspects of information society services, in particular electronic commerce, and transposing Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000, except in matters where special law assigns sectoral competence to other authorities.

Under its Statutes – published in Decree-Law No 39/2015 of 16 March 2015 – and for the accomplishment of its mission, ANACOM’s responsibilities include the following:

- As national regulatory authority (NRA);

- b) to promote competition in the provision of networks and services;
- c) to guarantee access to networks, infrastructure, resources and services;
- d) to guarantee freedom in the offer and provision of networks and services;

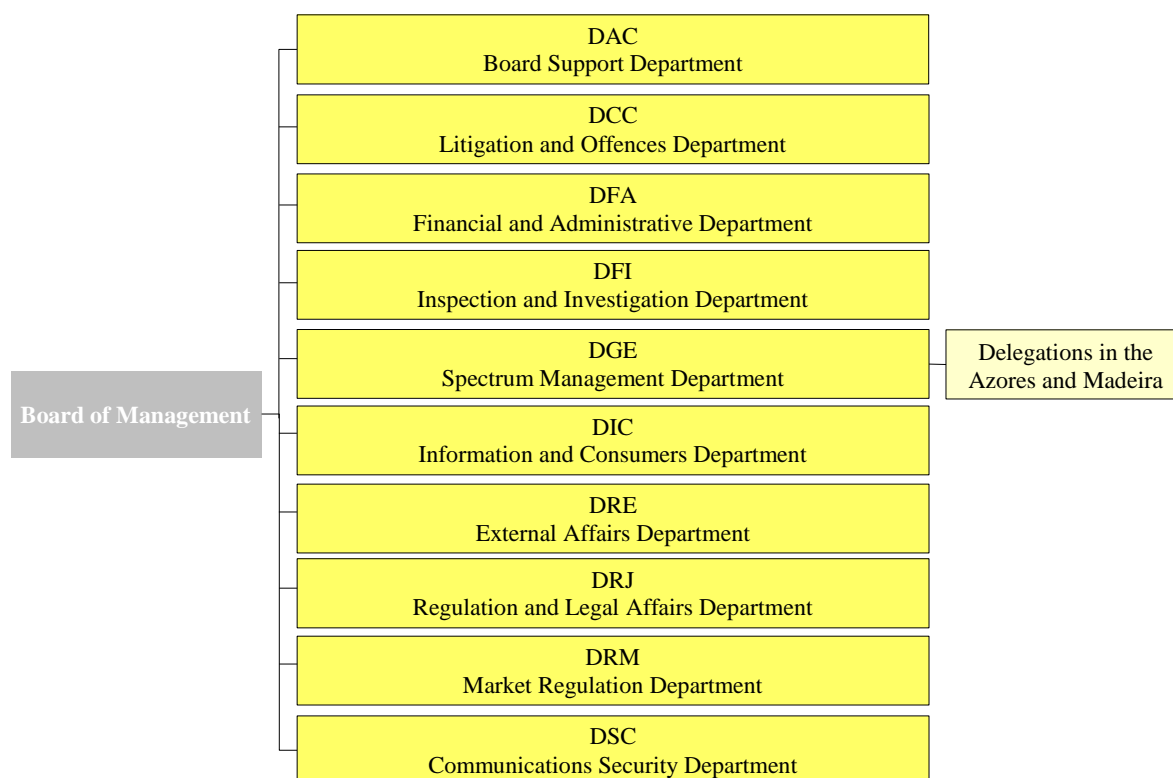
to contribute to the development of the EU internal market of electronic communications networks and services and postal services;

to protect the rights and interests of consumers and other end users;

to take an active role in the activities and decisions of regulator bodies, including the Body of European Regulators for Electronic Communications (BEREC) and the European Regulators Group for Postal Services (ERGP).

ANACOM has a laboratory accredited by the national accreditation body, or IPAC (Portuguese Accreditation Institute): that laboratory, the Testing and Calibration Laboratory (LEC), undertakes technological research and development and carries out tests and calibrations with the rigour required to guarantee the effective and efficient use of the radioelectric spectrum.

Succinctly, ANACOM’s structure is as follows:



**D) NATIONAL DIRECTORATE OF THE PUBLIC SECURITY POLICE (DNPSP)**

Address: Rua Artilharia 1, no 21 1269-003 Lisbon

Telephone: +351 21 811 10 00

Fax: +351 21 387 47 72

Email: depaex@psp.pt

Website: [www.psp.pt](http://www.psp.pt)

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 the product sectors relating to pyrotechnics and explosives for civilian use.

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.

Furthermore, external cooperation mainly takes place with the services of the Tax and Customs Authority (AT) 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.

The DAE is also represented in various working parties coordinated by the Commission in the area 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.

**E) DIRECTORATE-GENERAL FOR NATURAL RESOURCES, SECURITY AND MARITIME SERVICES (DGRM)**

Address: Avenida Brasília; 1449-030 Lisbon

Telephone: +351 21 303 57 00

Fax: +351 21 303 57 02

Email: [dgrm@dgrm.mam.gov.pt](mailto:dgrm@dgrm.mam.gov.pt)

Website: [www.dgrm.mm.gov.pt](http://www.dgrm.mm.gov.pt)

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.

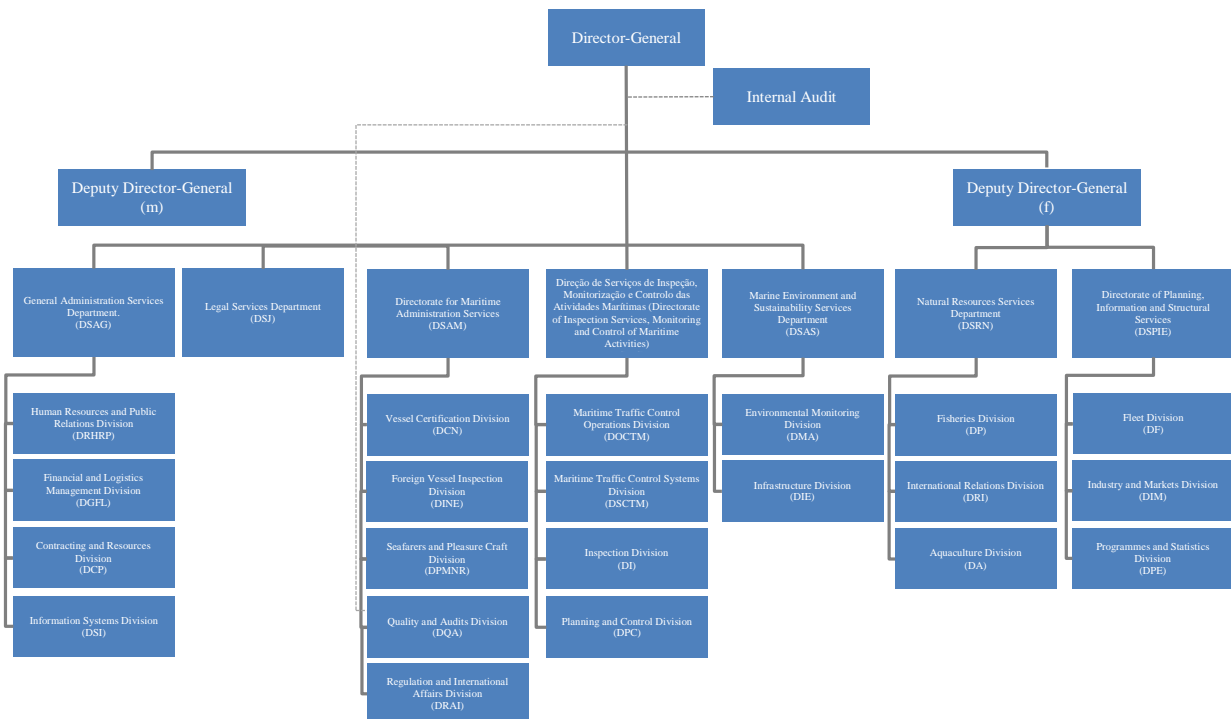
The DGRM, part of the Ministry of Agriculture and of the Sea (MAM) is a central service directly administered by the State and with administrative autonomy, tasked with implementing policies geared towards the preservation and discovery of natural marine resources, the implementation of policies in the area of fishing, aquaculture, processing and related activities, implementation of maritime safety and services, including the maritime-ports sector, and guaranteeing the regulation, inspection, coordination and monitoring of the activities carried out under these policies.

It is led by a director-general assisted by two deputy directors-general, and is structured in the following units, each of which is headed by a services director:

- a) Maritime Administration Services Department;
- b) Natural Resources Services Department;

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

Succinctly, DGRM's structure is as follows:



## F) INSTITUTE FOR MOBILITY AND TRANSPORT (IMT)

Address: Avenida das Forças Armadas, n.º 40; 1649-022 Lisbon

Telephone: +351 21 794 90 00

Fax: +351 21 794 37 77

Website: [www.imtt.pt](http://www.imtt.pt)

The IMT is a public institute integrated under the indirect administration of the State, with administrative and financial autonomy and its own assets.

It is a central body, with jurisdiction over the entire national territory. Its headquarters are in Lisbon and its decentralised services are the Regional Directorates for Mobility and Transport for the Northern Region, the Centre, Lisboa e Vale do Tejo, the Alentejo and the Algarve.

The IMT exercises the powers of the Ministry of the Interior, the Ministry of Planning and Infrastructures, and the Ministry of the Environment and of the Sea under the supervision and guidance of the Ministry of Planning and Infrastructures.

The IMT, I.P. took over the powers of:

- a) the Institute for Road Infrastructures;
- b) the Ports and Maritime Transport Institute;
- c) the Emergency Road Transport Planning Commission.

It has also incorporated the powers of the SIEV — Electronic Vehicle Identification System, S.A — as regards the operation and management of the electronic vehicle identification system.

The IMT's mission is as follows:

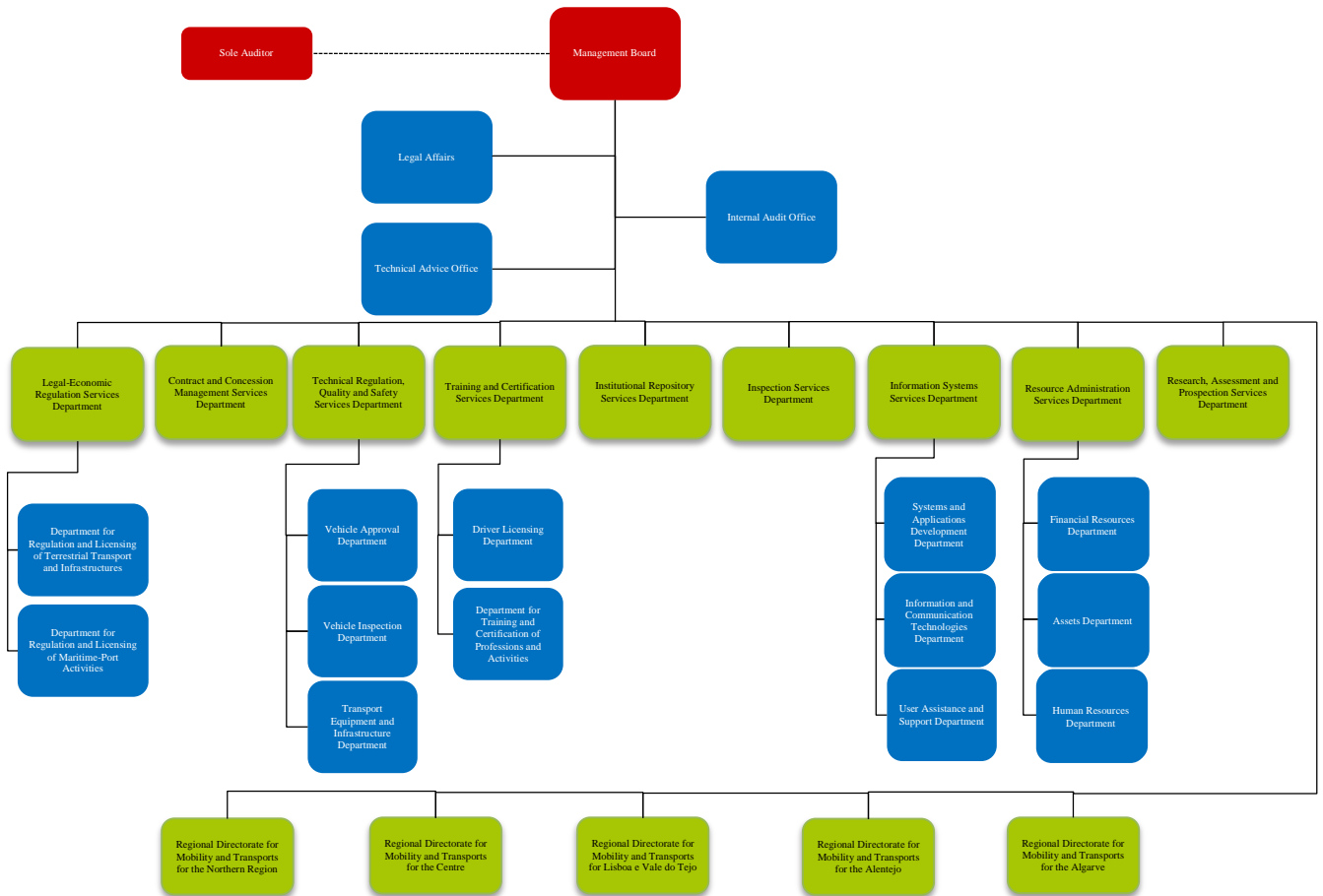
- a) To carry out technical regulation, licensing, coordination, inspection and planning tasks in the sector of road and river transport and in relation to the corresponding infrastructure, and on the economic side of the commercial ports and maritime transport sector;
- b) to manage concession contracts awarded by the State in the cited sectors or in other sectors, particularly in relation to air transport and airport infrastructures, with a view to satisfying the need for mobility of persons and goods.

The powers of the IMT, I.P. are determined by Decree-Law No 236/2012 of 31 October 2012, amended and republished by Decree-Law No 77/2014 of 14 May 2014 as amended by Decree-Law No 83/2015 of 21 May 2015.

Cooperation with counterpart bodies in other European Union countries has been ensured through attendance at the meetings of the “ADCO Group”.

IMT's structure can be summarised as follows:

# IMT — Mobility and Land Transport Institute





## **AUTONOMOUS REGIONS**

### **G) REGIONAL AUTHORITY FOR ECONOMIC ACTIVITIES — MADEIRA (ARAE MADEIRA)**

Address: Rua Direita, n.º 27; 9050-450 Funchal

Telephone: +351 29 121 50 40

Fax: +351 29 121 50 60

Email: [arae@madeira.gov.pt](mailto:arae@madeira.gov.pt)

Website: [www.madeira.gov.pt/arae/](http://www.madeira.gov.pt/arae/)

ARAE Madeira 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.

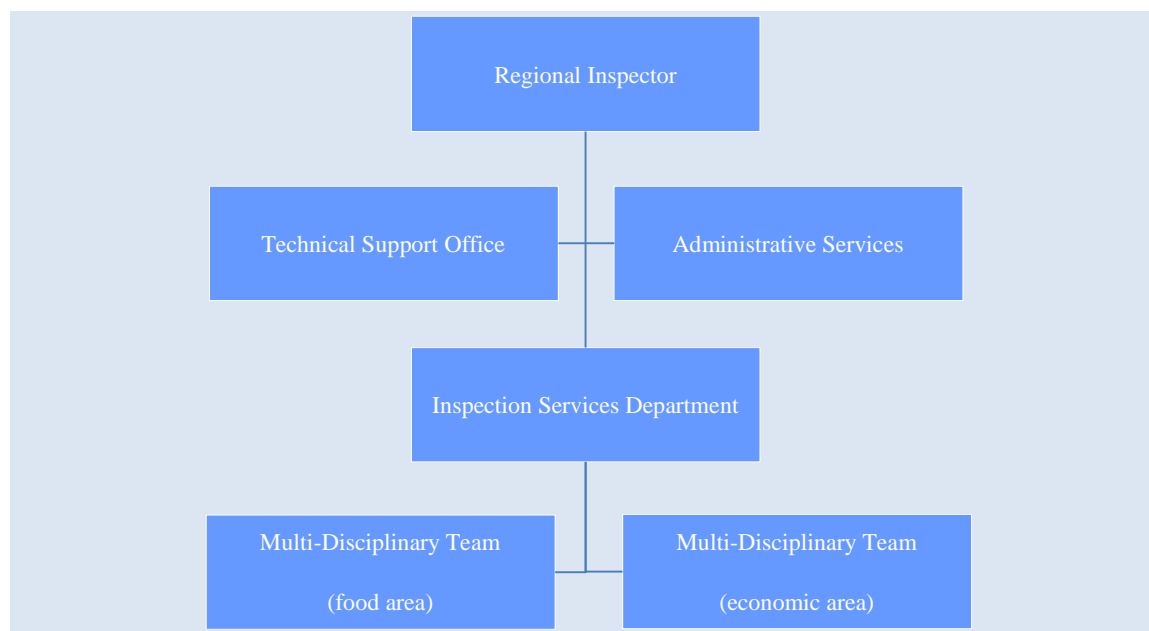
It is an inspection service directly administered by the Autonomous Region of Madeira as referred to in Article 6(1)(f) and Article 16 of Regional Regulatory Decree No 4/2015/M of 18 June 2015 adopting the organisational chart of the Regional Secretariat for the Economy, Tourism and Culture.

For the purposes of paragraph (1), the ARAE is a regional authority with responsibilities in the area of food safety and economic surveillance and exercises its activity throughout the Autonomous Region of Madeira.

The ARAE is the regional body responsible for the management and notification of risks along the food chain.

In the performance of its tasks, the ARAE is part of the criminal police.

The following is the structure of ARAE Madeira:



## H) REGIONAL INSPECTORATE FOR ECONOMIC ACTIVITIES IN THE AZORES (IRAE AZORES)

Address: Rua Margarida de Chaves, n.º 103, 1.º; 9500-088 Ponta Delgada

Telephone: +351 29 630 22 70

Fax: +351 29 628 43 95

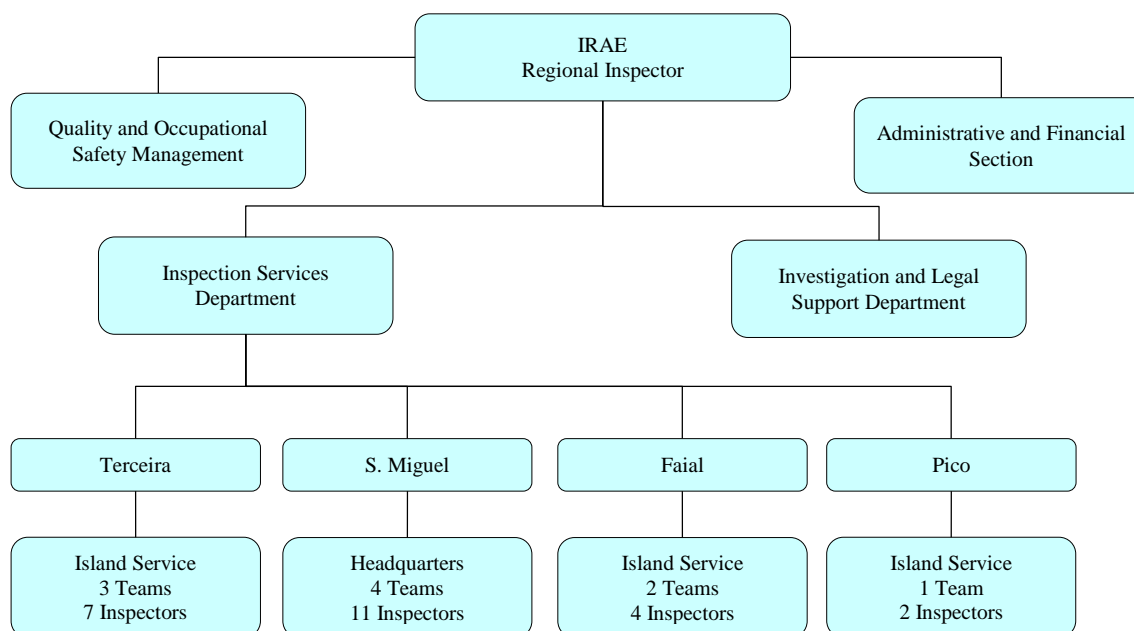
Email: irae@azores.gov.pt

Website: www.azores.gov.pt

IRAE Azores is tasked with enforcing all of the legislation governing the pursuit of economic activities in the food and non-food sectors, and it exercises its activities throughout the territory of the Autonomous Region of the Azores.

Its headquarters are in Ponta Delgada on the island of S Miguel, and it has delegations on the islands of Terceira, Faial and Pico.

### Regional Inspectorate for Economic Activities



## I) TAX AND CUSTOMS AUTHORITY (AT)

Address: Rua da Alfândega, n.º 5, r/c; 1149-006 Lisbon

Telephone: +351 21 811 10 00

Fax: +351 21 811 39 00

Website: www.e-financas.gov.pt

The AT is tasked with administering the taxes, duties and other charges within its field of competence, and with controlling the external border of the European Union and the national customs territory for tax, economic and social protection purposes in accordance with the policies defined by the Government and by EU law.

It is led by a Director-General assisted by 12 Deputy Directors-General, who hold first- and second-level senior management positions respectively.

Among other responsibilities, the AT carries out tax audits and ensures the application of regulations to which goods introduced in the territory of the European Union are subject. It also carries out controls relating to the entry, exit and movement of goods in the national territory, preventing and combating tax and customs avoidance and evasion, and illicit trafficking. It provides control of the external border of the European Union and licensing of external trade of products covered by special legislation. It also administers regimes that have restrictive effects on external trade.

## **1.2. Coordination and cooperation mechanisms between national market surveillance authorities**

Pursuant to Article 11 of Decree-Law No 23/2011 of 11 February 2011, ensuring fulfilment of the requirements derived from Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products, the Directorate-General for Economic Activities (DGAE) of the Ministry of the Economy is responsible for monitoring the implementation of that legislation, and for the following in particular:

- a) The collection of data and information on the application of the rules of the Regulation from the relevant market surveillance and border control authorities;
- b) Processing and compilation of the data and information relevant for assessing the breadth of scope of application of Chapter III of the Regulation, pursuant to Article 40 of the Regulation;
- c) Communicating the above information to the European Commission.

As the ASAE is the market surveillance authority with responsibility for surveillance in the most areas, it acts as national coordination body for issues related to market surveillance, and is also responsible for the following among other things:

- a) Preparing and drawing up the national market surveillance programme at regular intervals;
- b) Promoting cooperation and efficiency;
- c) Promoting cooperation with the market surveillance authorities of the other EU Member States;
- d) Taking responsibility for dissemination of market surveillance information;
- e) Representing Portugal, as national body, in matters related to market surveillance in meetings of the “Note to the expert group on the internal market for products — IMP MSGroup” and of the “Note to the expert group on the internal market for products — IMP MSGroup — Subgroup ICSMS”.

Although the **Consumer Directorate-General (DGC)** is not a market surveillance authority, it is responsible as national contact point for the RAPEX System – the European system for the rapid exchange of information on non-food products that pose a serious risk to consumers and users – for managing the RAPEX network in Portugal and is thus a member of the Emergency Committee within the the General Product Safety Directive Network.

The DGC's contact details are shown below:

Address: Praça Duque de Saldanha n.º 31 – 1.º, 2.º, 3.º and 5.º; 1069-013 Lisbon

Telephone: +351 21 356 46 00

Email: [dgc@dg.consumidor.pt](mailto:dgc@dg.consumidor.pt)

Website: [www.consumidor.gov.pt/ms/1/default.aspx?id=5004](http://www.consumidor.gov.pt/ms/1/default.aspx?id=5004)

Within the meaning of Article 17 of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008, the **Inspectorate General for Agriculture, Sea, Environment and Spatial Planning** (IGAMAOT) is not considered a market surveillance authority but does have surveillance powers under the EU harmonising legislation, namely Regulation (EC) No 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 649/2012 in relation to environmental matters.

Address: Rua de O Século, No 51 1200-433 Lisbon

Telephone: +351 21 321 55 00

Email: [igamaot@igamaot.gov.pt](mailto:igamaot@igamaot.gov.pt)

Website: [www.igamaot.gov.pt](http://www.igamaot.gov.pt)

### **1.3. Cooperation between national market surveillance authorities and customs**

There is excellent cooperation between the various market surveillance authorities – including the Autonomous Regions of the Azores and Madeira – 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 2008.

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 market surveillance authority which, by law, is competent to engage in surveillance activities related to the type of product involved, so that that market surveillance authority can state its views and intervene 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 same Regulation.

As the process in question needs to be completed rapidly to comply with the three-day time limit set in accordance with EU harmonisation legislation, requests from the customs authority may be made in two ways: by fax or email.

The AT participates in various European Commission expert groups on product safety and conformity checks on imported products, particularly those within DG TAXUD.

### **1.4. Rapid information exchange system – RAPEX**

RAPEX, the European Rapid Information Exchange system, is the Commission's alert system for products presenting a serious risk, and its national contact point is the Consumer Directorate-General (DGC).

All of the national market surveillance authorities, plus the AT, participate actively in the national network.

In 2018 the ASAE will promote meetings between all of the market surveillance authorities and the customs authority.

This working group will meet at least once every six months and will discuss uniformity of criteria and procedures in relation to RAPEX and its connection to the ICSMS system.

As regards reactive surveillance undertaken following RAPEX notifications under Article 12 involving Portuguese economic operators, the procedure adopted by the ASAE is as follows:

- a) When the market surveillance authority becomes aware of the notification and the grounds for it, via the national contact point it sends a letter to each of the economic operators involved calling on them to refrain from marketing the product, failing which they will be committing a breach of the legislation.
- b) At the same time an inspection is organised with a view to confirming on the premises indicated in the notification whether or not the products are being made available. This entire procedure takes place within five days of the notification being sent. Normally, the product should no longer be available on the market.
- c) If the economic operator is found to have not followed the order given by the market surveillance authority it will be found guilty of an infringement and the products are immediately seized.

Concerning these inspections carried out in the wake of RAPEX notifications containing information on Portuguese economic operators, the reaction forms for the corresponding notifications are completed and sent to the national RAPEX contact point so that the information with the details obtained can be provided to the Commission.

The DGC sends validated RAPEX notifications every day and regularly sends reports with the compilation made by the European Commission of the products that constitute a serious risks to the market surveillance authorities so they can investigate whether the products in question are present on the Portuguese market.

### **1.5. ICSMS information system**

The ICSMS is a general system for filing and exchanging information electronically, containing details of non-compliant products covered by EU harmonisation legislation.

In Portugal, the ASAE performs the role of national administrator, coordinating authority and National Contact Point in the framework of the general information support system (ICSMS system).

For this reason, the ASAE takes part in meetings of the “Note to the expert group on the internal market for products — IMP MSGroup — Subgroup ICSMS”, promoted by the European Commission. The members of that group are experts from all of the market surveillance authorities in the circulation of products in the Internal Market and are national contact points for this purpose.

Taking account of the amendments made to the ICSMS system, for 2018 the ASAE will propose creation of a working group made up of all of the market supervision authorities and by the customs authority which will meet at least twice a year and simultaneously promote training activities for all surveillance authority users with access to the ICSMS system.

Internally, the ASAE will continue the work started in 2015 with the creation of a Working Group directed by UNO/DEPO and made up of representatives of all of the Regional Units to

discuss, among other issues, operational procedures related to the application of the ICSMS system.

This group will meet once a quarter.

#### **1.6. General description of market surveillance activities and relevant procedures**

As stated, market surveillance activity has two key components: a proactive element and a reactive element. The operational methodology is described in various market surveillance procedures, covering visual inspection, documentary inspection and, since 2015, e-commerce.

In terms of proactive operational activity by the ASAE, the plan is as follows. For each inspection to take place, a numbered document known as an Operations Order (OP) is drawn up, describing the scope and aim of the inspection and the type of products targeted. The Operations Order also includes the procedures involved, with one table listing the types of infringement and another 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 except in case of emergency.

The visual and document inspections comprise various steps. The first stage is verification of the product purchase 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 information has been acquired, the traceability process begins, i.e. identifying the seller.

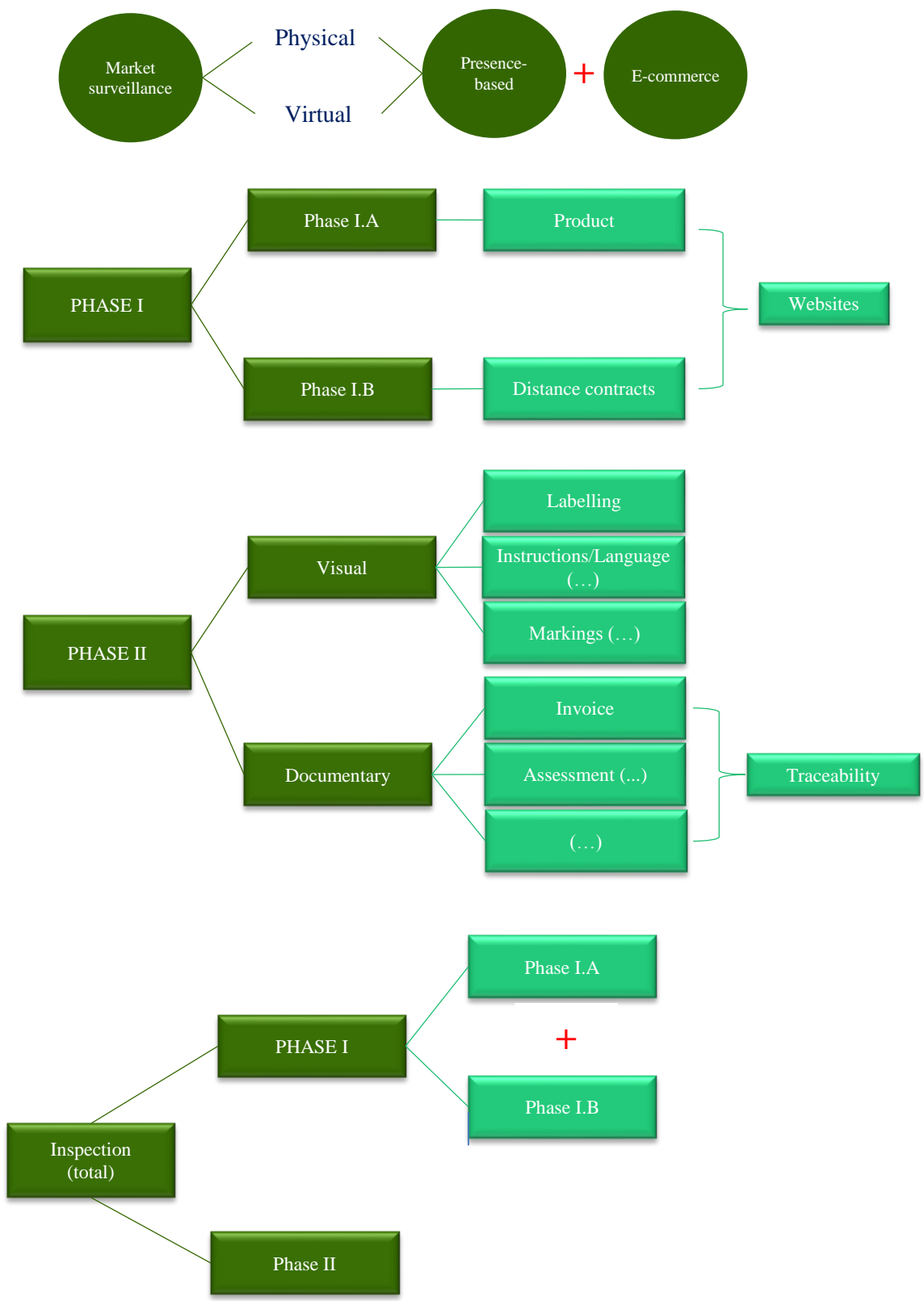
Following this, surveillance starts with visual inspection of the labelling of the product, warnings, instructions, Portuguese language and conformity markings, e.g. CE marking and Pi marking, amongst others.

The next stage relates to documentary inspection — declaration of conformity and/or performance declaration (depending on the class of product), technical documentation and purchase documentation (invoices).

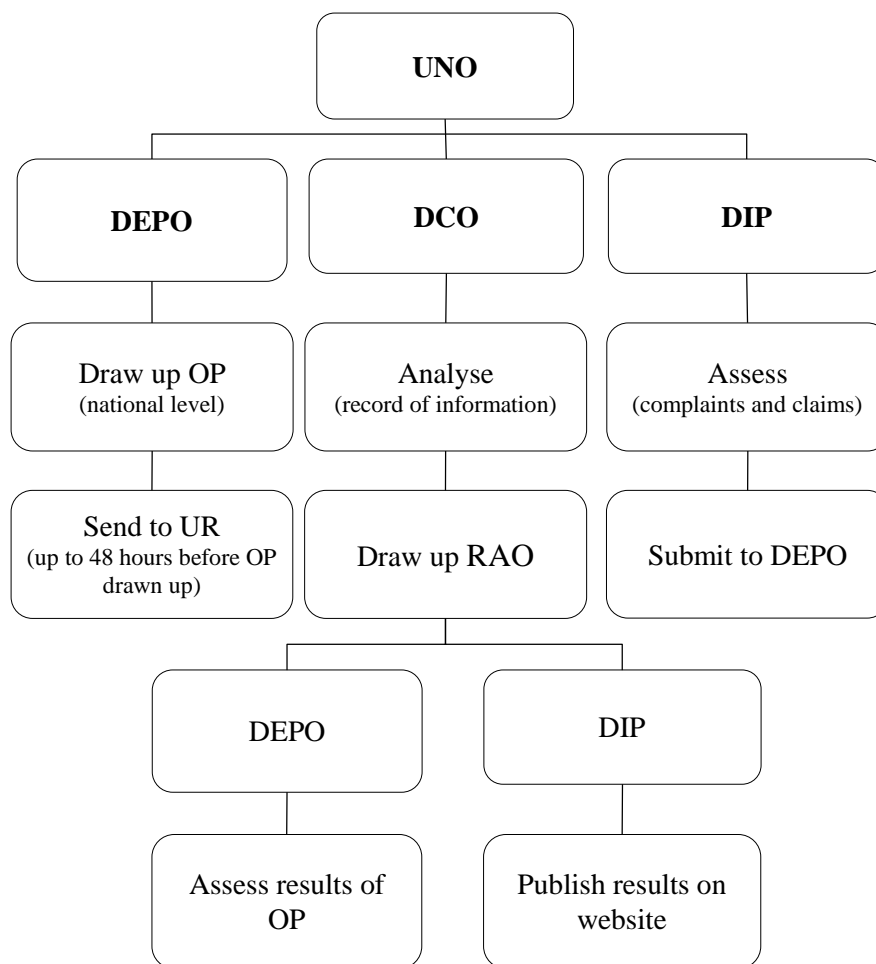
If the documents are not in the possession of the economic operators concerned, the ASAE notifies them in writing that they are required to provide the documents within a time limit of 5 days (as set out in the VAT — Value Added Tax — Code and the Code of Administrative Procedure, respectively), as appropriate.

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.

In sum, the current operational methodology adopted by the ASAE is in accordance with the following:



The model used for the assessment of market surveillance activities is the following:



**KEY:**

UNO — National Operations Unit  
 DEPO — Division of Research and Operational Planning  
 DCO — Operational Control Division  
 DIP — Public Information Division  
 OP — Operations Order  
 RAO — Operational Assessment Report

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

The ASAE attaches great importance to the cooperation provided for in Articles 24 to 26 of Regulation (EC) No 765/2008 of 9 July 2008.

Its inspection activities and priorities are complemented with its participation in the meetings and work of the ADCO groups, of which it is a member, and its participations in various Joint Market Surveillance Actions promoted by PROSAFE and supported by the European Commission.

In terms of the legislation in force, the ASAE performs the role of a coordinating authority and national contact point within the ICSMS system in accordance with Article 23 of Regulation (EC) No 765/2008 of 9 July 2008, as well as contributing directly and indirectly to the exchange of information, via the RAPEX system, on products placed on or made available on the market that present a serious risk.



The ASAE is also the competent and inspecting authority pursuant to Regulation (EC) No 764/2008 of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State.

Based on Articles 24 to 25 of Regulation (EC) No 765/2008 of 9 July 2008,

the ASAE participates in the following cooperation actions:

- Household electrical appliances 1;
- Toys 4 – Chemical Risks;
- Power tools 2 (circular saws);
- Energy Efficiency Compliant Products 2016 (EEPLIANT2 2016) (Call: H2020-EE-2016, Type of action: CSA, Project ID: 752591, Project EEPLIANT2, title Energy Efficiency Compliant Products 2);
- INTAS – INdustrial and tertiary product Testing and Application of Standards (Topic: EE-15-2015, Type of action: CSA, Proposal number: 695943, Proposal acronym: INTAS);
- ANTICSS – Oeko-Institut E.V. – Institut fuer Angewandte Oekologie (Topic: EE-16-2016-2017, Type of action: CSA, Proposal number: 785122, Proposal acronym: ANTICSS);
- REACH-EN-FORCE 6 (REF 6).

INFARMED participates in the following cooperation actions:

- “Joint Action on Market Surveillance”, JAMS, Market surveillance of medical devices WP4 “Manufacturer inspection” and in WP5 “Clinical Process and resources development”. These are aimed at helping to improve market surveillance between the Member States and promoting sharing of best practices, training, knowledge and resources to increase protection of public health in the medical devices sector.

It also took part in the cooperation action:

- “Joint Market Surveillance Actions on medical devices intended to be re-sterilised focusing on information in the Instruction for use and validation data necessary for the re-sterilisation by the user” (COEN JA2014)

This joint action, which lasted 18 months and concluded in 2017, was aimed at verifying whether the leaflets of medical devices intended for re-use by health professionals (such as surgical retractors, drills, clamps, scalpel handles, surgical scissors and saws, and probes), include instructions to ensure appropriate re-processing, observing compliance with the legal requirements.

### **1.8. Assessment of market surveillance actions and reporting**

In accordance with Regulation (EC) No 765/2008, the Member States must regularly review and assess the operation of market surveillance actions, at least every fourth year. Accordingly, the first implementation report was drawn up in 2014 and the second in 2017, with contributions from all of the market surveillance authorities, except DGRM and IMT which have not so far responded to the request.

The cited reports were drawn up on the basis of the model and guidelines proposed by the European Commission.

## **1.9. Horizontal activities planned for the relevant period**

Portugal participates in the meetings of various ADCO groups, which deal with matters that essentially relate to the assessment and analysis of issues and the production of documents related to the safety of products placed on or made available on the market. During the meetings, the participants present their work and publicise some of the activities undertaken by the authorities among other matters.

Currently the ASAE, on behalf of Portugal, holds the Presidency and the Vice-Presidency of the Fertiliser ADCO group (FERTI), working in close cooperation with the European Commission on the future of market surveillance in this area, inviting bodies to clarify some situations falling within grey areas.

In 2017, Portugal took part in the meeting of the ADCO Chairs as it held the Presidency of the FERTI ADCO group, cooperated on the European Union programme Exchange of enforcement officials in the areas of consumer safety between Portugal & Croatia, Portugal & Bulgaria and Portugal & Poland, where it presented its operating methodology – both theoretical and practical – and hosted the meetings of the PED ADCO group (April), FERTI ADCO group (June) and RCD ADCO group (November), where it acted as Chair.

For 2018, meetings of the ATEX ADCO group and the CPR ADCO group are scheduled to take place in Lisbon, and this should contribute to cooperation between the Member States and the Commission.

## **2. MARKET SURVEILLANCE IN SPECIFIC SECTORS**

### **2.1. Medical devices**

#### *2.1.1. Responsible authority and contact details*

#### **INFARMED — National Authority for Medicines and Health Products**

Address: Parque de Saúde de Lisboa Avenida do Brasil, 53  
1749-004 Lisbon

Telephone: +351 21 798 71 00

Fax: +351 21 798 7316

Website: [www.infarmed.pt](http://www.infarmed.pt)

### **2.2. Cosmetics**

#### *2.2.1. Responsible authority and contact details*

#### **INFARMED — National Authority for Medicines and Health Products**

Address: Parque de Saúde de Lisboa Avenida do Brasil, 53  
1749-004 Lisbon

Telephone: +351 21 798 71 00

Fax: +351 21 798 7316

Website: [www.infarmed.pt](http://www.infarmed.pt)

### **2.3. Toys**

#### *2.3.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon  
Telephone: + 351 21 798 36 00  
Fax: + 351 21 798 37 72  
Email: uno\_msa@asae.pt  
Website: www.asae.pt

## **2.4. Personal protective equipment**

### *2.4.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon  
Telephone: + 351 21 798 36 00  
Fax: + 351 21 798 37 72  
Email: uno\_msa@asae.pt  
Website: www.asae.pt

## **2.5. Construction products**

### *2.5.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon  
Telephone: + 351 21 798 36 00  
Fax: + 351 21 798 37 72  
Email: uno\_msa@asae.pt  
Website: www.asae.pt

## **2.6. Aerosol dispensers**

### *2.6.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon  
Telephone: + 351 21 798 36 00  
Fax: + 351 21 798 37 72  
Email: uno\_msa@asae.pt  
Website: www.asae.pt

## **2.7. Simple pressure vessels and pressure equipment**

### *2.7.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon  
Telephone: + 351 21 798 36 00  
Fax: + 351 21 798 37 72

Email: uno\_msa@asae.pt

Website: www.asae.pt

## **2.8. Transportable pressure equipment**

### *2.8.1. Responsible authority and contact details*

#### **IMT — Mobility and Land Transport Institute**

Address: Av. das Forças Armadas, 40  
1649-022 Lisbon

Telephone: +351 21 794 90 00

Fax: +351 21 797 37 77

Website: www.imtt.pt

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon

Telephone: + 351 21 798 36 00

Fax: + 351 21 798 37 72

Email: uno\_msa@asae.pt

Website: www.asae.pt

## **2.9. Machinery**

### *2.9.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon

Telephone: + 351 21 798 36 00

Fax: + 351 21 798 37 72

Email: uno\_msa@asae.pt

Website: www.asae.pt

## **2.10. Lifts**

### *2.10.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon

Telephone: + 351 21 798 36 00

Fax: + 351 21 798 37 72

Email: uno\_msa@asae.pt

Website: www.asae.pt

## **2.11. Cableways**

### *2.11.1. Responsible authority and contact details*

#### **IMT — Mobility and Land Transport Institute**

Address: Av. das Forças Armadas, 40  
1649-022 Lisbon

Telephone: +351 21 794 90 00  
Fax: +351 21 797 37 77  
Website: www.imtt.pt

## **2.12. Noise emissions for outdoor equipment**

### *2.12.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon

Telephone: + 351 21 798 36 00

Fax: + 351 21 798 37 72

Email: uno\_msa@asae.pt

Website: www.asae.pt

## **2.13. Equipment and protective systems intended for use in potentially explosive atmospheres**

### *2.13.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon

Telephone: + 351 21 798 36 00

Fax: + 351 21 798 37 72

Email: uno\_msa@asae.pt

Website: www.asae.pt

## **2.14. Pyrotechnics**

### *2.14.1. Responsible authority and contact details*

#### **DNPSP — National Directorate of the Public Security Police**

(Weapons and Explosives Department)

Address: Rua de Artilharia 1, n.º 21  
1269-003 Lisbon

Telephone: +351 21 811 10 00

Fax: +351 21 387 4772

Website: www.psp.pt

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon

Telephone: + 351 21 798 36 00

Fax: + 351 21 798 37 72

Email: uno\_msa@asae.pt

Website: www.asae.pt

## **2.15. Explosives for civil uses**

### *2.15.1. Responsible authority and contact details*

#### **DNPSP — National Directorate of the Public Security Police**

(Weapons and Explosives Department)

Address: Rua de Artilharia 1, n.º 21  
1269-003 Lisbon

Telephone: +351 21 811 10 00

Fax: +351 21 387 4772

Website: [www.psp.pt](http://www.psp.pt)

## **2.16. Gas appliances**

### *2.16.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon

Telephone: + 351 21 798 36 00

Fax: + 351 21 798 37 72

Email: [uno\\_msa@asae.pt](mailto:uno_msa@asae.pt)

Website: [www.asae.pt](http://www.asae.pt)

## **2.17. Measuring instruments, Non-automatic weighing instruments, Pre-packaged products and Units of measurement**

### *2.17.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon

Telephone: + 351 21 798 36 00

Fax: + 351 21 798 37 72

Email: [uno\\_msa@asae.pt](mailto:uno_msa@asae.pt)

Website: [www.asae.pt](http://www.asae.pt)

## **2.18. Electrical equipment under EMC**

### *2.18.1. Responsible authority and contact details*

#### For all equipment

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon

Telephone: + 351 21 798 36 00

Fax: + 351 21 798 37 72

Email: [uno\\_msa@asae.pt](mailto:uno_msa@asae.pt)

Website: [www.asae.pt](http://www.asae.pt)

#### Electronic communications equipment

#### **ANACOM — National Communications Authority**

Address: Avenida José Malhoa 12  
1099-017 Lisbon  
Telephone: +351 21 721 26 11 (05/07/09)  
Fax: +351 21 721 20 89  
Website: www.anacom.pt

## **2.19. Radio equipment (RED)**

### *2.19.1. Responsible authority and contact details*

#### **ANACOM — National Communications Authority**

Address: Avenida José Malhoa 12  
1099-017 Lisbon  
Telephone: +351 21 721 26 11 (05/07/09)  
Fax: +351 21 721 20 89  
Website: www.anacom.pt

## **2.20. Electrical appliances and equipment**

### *2.20.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon  
Telephone: + 351 21 798 36 00  
Fax: + 351 21 798 37 72  
Email: uno\_msa@asae.pt  
Website: www.asae.pt

## **2.21. Electrical and electronic equipment under RoHS and WEEE and batteries**

### *2.21.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon  
Telephone: + 351 21 798 36 00  
Fax: + 351 21 798 37 72  
Email: uno\_msa@asae.pt  
Website: www.asae.pt

#### Medical devices

#### **INFARMED — National Authority for Medicines and Health Products**

Address: Parque de Saúde de Lisboa Avenida do Brasil, 53  
1749-004 Lisbon  
Telephone: +351 21 798 71 00  
Fax: +351 21 798 7316  
Website: www.infarmed.pt

#### Electronic communications equipment

#### **ANACOM — National Communications Authority**

Address: Avenida José Malhoa 12

1099-017 Lisbon  
Telephone: +351 21 721 26 11 (05/07/09)  
Fax: +351 21 721 20 89  
Website: www.anacom.pt

## **2.22./A Chemical substances under REACH and Classification and Labelling Regulations**

### *2.22.1/A Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon  
Telephone: + 351 21 798 36 00  
Fax: + 351 21 798 37 72  
Email: uno\_msa@asae.pt  
Website: www.asae.pt

## **2.22./B Chemical substances under REACH and Classification and Labelling Regulations**

### *2.22.1/B Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon  
Telephone: + 351 21 798 36 00  
Fax: + 351 21 798 37 72  
Email: uno\_msa@asae.pt  
Website: www.asae.pt

## **2.23 Eco-design and Energy Labelling**

### *2.23.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon  
Telephone: + 351 21 798 36 00  
Fax: + 351 21 798 37 72  
Email: uno\_msa@asae.pt  
Website: www.asae.pt

## **2.24 Tyre labelling**

### *2.24.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon  
Telephone: + 351 21 798 36 00  
Fax: + 351 21 798 37 72



Email: uno\_msa@asae.pt

Website: www.asae.pt

## **2.25 Recreational craft**

### *2.25.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73

1269-274 Lisbon

Telephone: + 351 21 798 36 00

Fax: + 351 21 798 37 72

Email: uno\_msa@asae.pt

Website: www.asae.pt

#### **DGRM — Directorate-General of Natural Resources, Security and Maritime Services**

Address: Avenida Brasília; 1449-030 Lisbon

Telephone: +351 21 303 57 00

Fax: +351 21 303 57 02

Email: dgrm@dgrm.mam.gov.pt

Website: www.dgrm.mm.gov.pt

## **2.26 Marine equipment**

### *2.26.1. Responsible authority and contact details*

#### **DGRM — Directorate-General of Natural Resources, Security and Maritime Services**

Address: Avenida Brasília; 1449-030 Lisbon

Telephone: +351 21 303 57 00

Fax: +351 21 303 57 02

Email: dgrm@dgrm.mam.gov.pt

Website: www.dgrm.mm.gov.pt

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73

1269-274 Lisbon

Telephone: + 351 21 798 36 00

Fax: + 351 21 798 37 72

Email: uno\_msa@asae.pt

Website: www.asae.pt

## **2.27 Motor vehicles and tractors**

### *2.27.1. Responsible authority and contact details*

#### **IMT — Mobility and Land Transport Institute**

Address: Av. das Forças Armadas, 40

1649-022 Lisbon

Telephone: +351 21 794 90 00

Fax: +351 21 797 37 77

Website: www.imtt.pt

## **2.28 Non-road mobile machinery**

### *2.28.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon

Telephone: + 351 21 798 36 00

Fax: + 351 21 798 37 72

Email: uno\_msa@asae.pt

Website: www.asae.pt

## **2.29 Fertilisers**

### *2.29.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon

Telephone: + 351 21 798 36 00

Fax: + 351 21 798 37 72

Email: uno\_msa@asae.pt

Website: www.asae.pt

## **2.30 Other consumer products under GPSD**

### *2.30.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon

Telephone: + 351 21 798 36 00

Fax: + 351 21 798 37 72

Email: uno\_msa@asae.pt

Website: www.asae.pt

## **2.31 Biocides**

### *2.31.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon

Telephone: + 351 21 798 36 00

Fax: + 351 21 798 37 72

Email: uno\_msa@asae.pt

Website: www.asae.pt

## **2.32 Textile and Footwear labelling**

### *2.32.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon  
Telephone: + 351 21 798 36 00  
Fax: + 351 21 798 37 72  
Email: uno\_msa@asae.pt  
Website: www.asae.pt

### **2.33 Misuse of the CE marking**

#### *2.33.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon  
Telephone: + 351 21 798 36 00  
Fax: + 351 21 798 37 72  
Email: uno\_msa@asae.pt  
Website: www.asae.pt

### **2.34 Plant protection products**

#### *2.34.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon  
Telephone: + 351 21 798 36 00  
Fax: + 351 21 798 37 72  
Email: uno\_msa@asae.pt  
Website: www.asae.pt

### **2.35 Packaging waste management**

#### *2.35.1. Responsible authority and contact details*

#### **ASAE — Food and Economic Safety Authority**

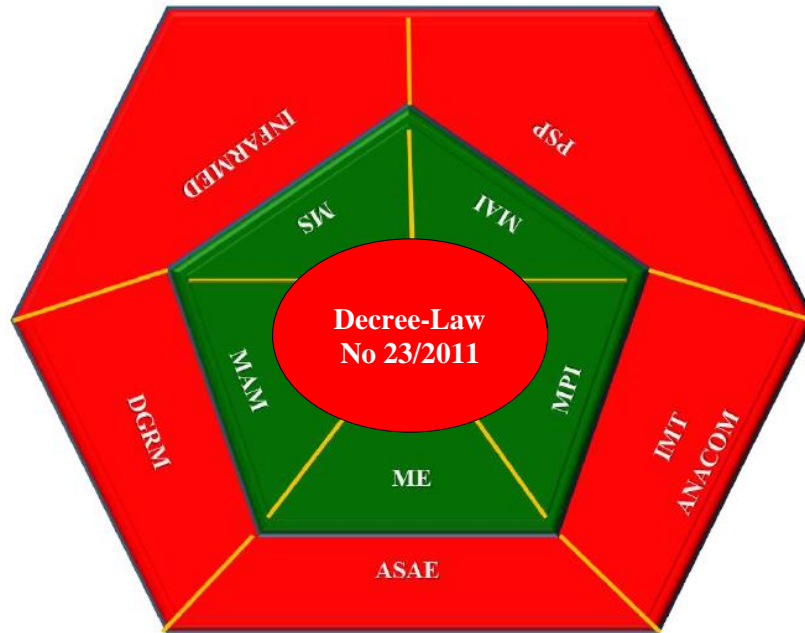
Address: Rua Rodrigo da Fonseca, n.º 73  
1269-274 Lisbon  
Telephone: + 351 21 798 36 00  
Fax: + 351 21 798 37 72  
Email: uno\_msa@asae.pt  
Website: www.asae.pt

**ANNEX I**  
**REFERENCE LIST OF PRODUCT SECTORS**

<b>Product sectors</b>	<b>Relevant legislation</b>
1. Medical devices (including <i>in vitro</i> diagnostic medical devices and active implantable medical devices)	Directives 93/42/EEC, 98/79/EC and 90/385/EEC
2. Cosmetics	Regulation (EC) No 1223/2009
3. Toys	Directive 2009/48/EC
4. Personal protective equipment	Directive 89/686/EEC
5. Construction products	Regulation (EC) No 305/2011
6. Aerosol dispensers	Directive 75/324/EEC
7. Simple pressure vessels and pressure equipment	Directives 2014/29/EU and 2014/68/EU
8. Transportable pressure equipment	Directive 2010/35/EU
9. Machinery	Directive 2006/42/EC
10. Lifts	Directive 2014/33/EU
11. Cableways	Directive 2000/9/EC
12. Noise emissions for outdoor equipment	Directive 2000/14/EC
13. Equipment and protective systems intended for use in potentially explosive atmospheres	Directive 2014/34/EU
14. Pyrotechnics	Directive 2013/29/EU
15. Explosives for civil uses	Directive 2014/28/EU
16. Gas appliances	Directive 2009/142/EC
17. Measuring instruments, Non-automatic weighing instruments, Pre-packaged products and Units of measurement	Directives 2014/32/EU and 2014/31/EU; Directives 2007/45/EC, 75/107/EEC, 76/211/EEC and Directive 80/181/EEC
18. Electrical equipment under EMC	Directive 2014/30/EU
19. Radio equipment (RED)	Directive 2014/53/EU
20. Electrical appliances and equipment under LVD	Directive 2014/35/EU
21. Electrical and electronic equipment under RoHS and WEEE and batteries	Directives 2011/65/EU, 2002/96/EC and 2006/66/EC
22./A Chemical substances under REACH and Classification and Labelling Regulations	Regulations (EC) Nos 1907/2006 and 1272/2008
22./B Other chemicals (detergents, paints, persistent organic pollutants, fluorinated greenhouse gases, substances that deplete the ozone layer, etc.)	Regulation (EC) No 648/2004, Directive 2004/42/EC, Regulation (EC) No 850/2004, Regulation (EC) No 842/2006 and Regulation (EU) No 517/2014, Regulation (EC) No 1005/2009
23. Eco-design and Energy Labelling	Directives 2009/125/EC and 2010/30/EU
24. Tyre labelling	Regulation (EC) N° 1222/2009
25. Recreational craft	Directive 2013/53/EU
26. Marine equipment	Directive 2014/90/EU
27. Motor vehicles and tractors	Regulation (EU) 168/2013; Directive 2007/46/EC; Regulation (EU) No 167/2013
28. Non-road mobile machinery	Directive 97/68/EC
29. Fertilisers	Regulation (EC) No 2003/2003

30. Other consumer products under GPSD (General Product Safety Directive)	Directive 2001/95/EC
31. Biocides	Regulation (EU) No 528/2012
32. Textile and Footwear labelling	Regulation (EC) No 1007/2011 and Directive 94/11/EC
33. Crystal glass	Directive 69/493/EEC
34. Misuse of the CE marking	Regulation (EC) No 765/2008
35. Plant protection products	Directive 2009/128/EC and Regulation (EC) No 1107/2009
36. Packaging waste management	Directive 94/64/EC and its amendments

## ANNEX II ORGANISATIONAL CHART



### KEY:

MAI – Ministry of Internal Affairs

MAM – Ministry of the Agriculture and the Sea

ME – Ministry of the Economy

MPI — Ministry of Planning and Infrastructure

MS – Ministry of Health

ANACOM — National Communications Authority

ASAE — Food and Economic Safety Authority

DGRM — Directorate-General for Maritime Resources

IMT — Mobility and Land Transport Institute

INFARMED — National Authority for Medicines and Health Products

PSP — Public Security Police

**ANNEX III**  
**THE MARKET SURVEILLANCE AUTHORITIES AND THEIR AREAS**  
**OF RESPONSIBILITY**

MARKET SURVEILLANCE AUTHORITY	AREAS OF RESPONSIBILITY
<p><b>ASAE — Food and Economic Safety Authority</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            Email: uno_msa@asae.pt            Website: www.asae.pt</p>	<ul style="list-style-type: none"> <li>▪ EC Fertilisers and fertilisers</li> <li>▪ Gas appliances</li> <li>▪ Equipment Intended for use in Potentially Explosive Atmospheres</li> <li>▪ Pyrotechnic articles</li> <li>▪ Lifts</li> <li>▪ Batteries, primary cells and accumulators</li> <li>▪ Hot-water boilers</li> <li>▪ CLP/GHS</li> <li>▪ Fuels</li> <li>▪ Electromagnetic compatibility<sup>1</sup></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>2</sup></li> <li>▪ Noise emissions for outdoor machines</li> <li>▪ Marine equipment<sup>3</sup></li> <li>▪ Personal protective equipment</li> <li>▪ Radio equipment and telecommunications terminal equipment (RED)<sup>4</sup></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 machines</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>5</sup></li> <li>▪ Machinery</li> <li>▪ Misuse of the CE marking</li> <li>▪ Electrical equipment</li> <li>▪ Non-road engines</li> </ul>

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<sup>1</sup> Responsibility shared with ANACOM (ANACOM is only responsible for electronic communications equipment)

<sup>2</sup> Responsibility shared with DGRM

<sup>3</sup> Responsibility shared with DGRM

<sup>4</sup> Responsibility shared with ANACOM

<sup>5</sup> Responsibility shared with DGRM

	<ul style="list-style-type: none"> <li>▪ Drug precursors (categories 1, 2 and 3)<sup>6</sup></li> <li>▪ Biocidal products</li> <li>▪ Construction products</li> <li>▪ REACH</li> <li>▪ E-waste</li> <li>▪ RoHS</li> <li>▪ Labelling of footwear</li> <li>▪ Labelling of tyres</li> <li>▪ Safety of toys</li> <li>▪ General product safety</li> <li>▪ Ozone-depleting substances</li> <li>▪ Textiles</li> <li>▪ Units of measurement</li> <li>▪ Crystal glass and resonant glass (...)</li> </ul>
<p><b>INFARMED — National Authority for 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>7</sup></li> <li>▪ Cosmetics</li> <li>▪ RoHS<sup>8</sup></li> </ul>
<p><b>ANACOM — National Communications Authority</b></p> <p>Address: Avenida José Malhoa 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>	<ul style="list-style-type: none"> <li>▪ Electromagnetic compatibility<sup>9</sup></li> <li>▪ Radio equipment and telecommunications terminal equipment (RED)</li> <li>▪ RoHS<sup>10</sup></li> </ul>
<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>▪ Transportable pressure equipment<sup>11</sup></li> <li>▪ Helmets</li> <li>▪ - Cableways installations designed to carry persons</li> <li>▪ Vehicles</li> <li>▪ Tyres</li> </ul>

<sup>6</sup> Responsibility shared with INFARMED

<sup>7</sup> Responsibility shared with ASAE

<sup>8</sup> Responsibility shared with ASAE (Medical devices)

<sup>9</sup> Responsibility shared with ASAE (Electronic communications equipment)

<sup>10</sup> Responsibility shared with ASAE (Electronic communications equipment)

<sup>11</sup> Responsibility shared with ASAE



<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</p> <p>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>
<p><b>DNPSP — National Directorate of the Public Security Police</b> (Weapons 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>▪ Pyrotechnic articles<sup>12</sup></li> <li>▪ Explosives for civil uses</li> <li>▪ Systems for the identification and traceability of explosives for civil uses</li> <li>▪ Checks on gun purchases and ownership</li> </ul>

<b>AUTONOMOUS REGIONS</b>	
<b>MARKET SURVEILLANCE AUTHORITY</b>	<b>AREAS OF RESPONSIBILITY</b>
<p><b>IRAE Azores — Regional Inspectorate for Economic Activities in the Azores</b></p> <p>Address: Rua Margarida de Chaves, n.º 103, 1.º; 9500-088 Ponta Delgada</p> <p>Telephone: +351 29 630 22 70 Fax: +351 29 628 43 95</p> <p>Website: <a href="http://www.azores.gov.pt">www.azores.gov.pt</a></p>	<ul style="list-style-type: none"> <li>▪ Same areas of responsibility as the ASAE</li> </ul>
<p><b>ARAE Madeira — Regional Inspectorate for Economic Activities in Madeira</b></p> <p>Address: Rua Direita, n.º 27; 9050-450 Funchal</p> <p>Telephone: +351 29 121 50 40 Fax: +351 29 121 50 60</p> <p>Website: <a href="http://www.madeira.gov.pt/arae/">www.madeira.gov.pt/arae/</a></p>	<ul style="list-style-type: none"> <li>▪ Same areas of responsibility as the ASAE</li> </ul>

<b>EXTERNAL BORDER CONTROL</b>	<b>AREAS OF RESPONSIBILITY</b>
<p><b>AT — 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>12</sup> Responsibility shared with ASAE