

National Market Surveillance Plan

2016

SWEDEN

Contents

Introduction.....	3
1 The market surveillance authorities and their areas of responsibility	3
2 Coordination and cooperation among national market surveillance authorities.....	4
3 Cooperation between market surveillance and customs authorities	5
4 RAPEX	5
5 ICSMS	6
6 General principles for market surveillance	6
7 Cooperation with other member states and countries outside the EU	7
8 Evaluation and reporting.....	7
9 Planned activities	8
9.1 Exchange of experiences	8
9.2 Support.....	9
9.3 Information	12
Appendix 1 The market surveillance authorities and their areas of responsibility.....	14
Appendix 2 The market surveillance authorities and their ministerial affiliation	15
Appendix 3 Organization Chart.....	16

Introduction

Market surveillance shall establish satisfactory protection of consumers, employees, public health, the environment and other aspects of protection in the public interest, as well as fair competition between businesses.

Market surveillance means activities carried out and measures taken by public authorities to ensure that products on the market comply with applicable legislation. The authority shall take action against economic actors whose products do not meet the requirements imposed. Measures that may come into question are, for example, prohibition of sales, withdrawal of products from the market, or recall of products from end users.

Market surveillance is carried out in the form of informational activities, planned inspections at manufacturers, importers or distributors or reactions to reported accidents, complaints from the public or warnings from public authorities in other countries. Market surveillance does not cover pre-market inspection or inspection of products in use.

Each member state in the EU shall draw up, carry out, and follow up on market surveillance plans. In Sweden, the Market Surveillance Council has been given the task of drawing up a national market surveillance plan through the Regulation (2014:1039) on market surveillance of goods and other related surveillance activities. This national plan is supplemented by sector-specific market surveillance plans that are drawn up by every central market surveillance authority. This year's national plan is based on the Commission's template for a national market surveillance program according to Article 18.5 of Regulation (EC) No. 765/2008 and focuses on joint activities by public authorities to make the Swedish market surveillance and the Market Surveillance Council more effective and also more visible.

1 The market surveillance authorities and their areas of responsibility

In Regulation (2014:1039), the Government has specially indicated 16 public authorities as responsible for market surveillance. In addition, the 290 municipalities have market surveillance responsibilities. The government authorities are in most cases also the regulatory authorities for the products or product characteristics for which they have market surveillance responsibility. These authorities, and their areas of responsibility and ministerial affiliation, are listed in the appendix.

2 Coordination and cooperation among national market surveillance authorities

Swedac, the Swedish Board for Accreditation and Conformity Assessment, has overall responsibility for coordinating the Swedish market surveillance. This responsibility includes serving as chairman and maintaining the secretariat for the Market Surveillance Council, a body consisting of the 16 market surveillance authorities above, as well as the Swedish Customs Services and the Swedish National Board of Trade.

According to the Swedish Regulation on Market Surveillance, the tasks of the Market Surveillance Council are to:

- act as a national coordinating body for issues relating to market surveillance;
- promote cooperation and efficiency;
- organise a continuous exchange of experiences;
- be responsible for disseminating information on market surveillance;
- facilitate contacts between the general public and the business sector and the market surveillance authorities;
- promote cooperation with market surveillance authorities in other EU member states; and
- annually prepare and implement a national action plan for market surveillance.

The work consists to a great extent of information exchange, legislative work, interpretation and method development.

The Market Surveillance Council has adopted its own rules of procedure. These govern the tasks of the chairman and the secretariat, the process for appointing members and alternates, working methods and decision-making. According to the rules of procedure, the Council shall (for example) hold ordinary meetings at least four times per year and decisions shall be made by a simple majority. Apart from ordinary meetings, the Council's work include continuous contacts and activities, sometimes via working groups that investigate and propose guidelines for and solutions to common questions and problems. The majority of the working groups are of a temporary character. One working group reporting to the Market Surveillance Council, however, the "Forum for Customs-Related Issues" is permanent.

Representatives from the Government Offices' coordinating ministries on market surveillance issues, the Ministry for Foreign Affairs and the Ministry of Finance, participate in ordinary meetings of the Market Surveillance Council. Representatives from business, consumer and employee organisations participate in every other ordinary meeting.

The Swedish Consumer Agency has general responsibility for the Product Safety Act (2004:451), which together with the Product Safety Regulation (2004:469) implements the EU Directive on General Product Safety (2001/95/EC). The Swedish Consumer Agency is also the contact point for RAPEX and has coordinating responsibility towards other market surveillance authorities that belong to the RAPEX network, in accordance with Regulation (1993:1322) and Regulation (2014:1039).

Swedac is the national administrator of ICSMS in accordance with Regulation (2014:1039), which supplements EU Regulation 765/2008 on accreditation and market surveillance.

The Swedish National Board of Trade is the contact point in accordance with Regulation (2014:1039), which supplements EU Regulation 764/2008 on mutual recognition, and national coordinator of IMI (information system for the internal market).

3 Cooperation between market surveillance and customs authorities

The Market Surveillance Council consists of representatives of market surveillance authorities, the Swedish National Board of Trade, and Swedish Customs. The Council has also appointed a permanent working group for cooperation, called “Forum for Customs-Related Issues” where both practical and theoretical issues are discussed. The Forum convenes twice a year and is open to all authorities in the Council. The Forum has also developed a model for cooperation based on articles 27–29 of EU Regulation 765/2008 and a template for planned control operations. Swedish Customs and Swedac participate in the European Commission’s expert working group on product safety and compliance checks for imported goods (EWG), which is a joint group for customs and market surveillance authorities.

4 RAPEX

RAPEX is the EU Commission’s alert system for products with serious risks. The Swedish Consumer Agency is the national contact point for RAPEX. Ten market surveillance authorities actively participate in the national network, as do the Swedish National Board of Trade and Swedish Customs. As from 2014, national RAPEX network meetings are arranged in connection with national ICSMS network meetings.

The Swedish Consumer Agency sends out a newsletter regularly (every week), with links to the EU Commission’s compilation of dangerous products: the RAPEX Weekly Report. Its recipients are market surveillance authorities, consumer organisations and economic operators on the Swedish market. The RAPEX Weekly Report is also made available on the website of the Market Surveillance Council.

The market surveillance authorities are responsible for investigating if the RAPEX-notified products are available on the Swedish market. In those cases where corrective measures are taken in Sweden, the authorities send their reactions to RAPEX.

The Swedish Consumer Agency, as national contact point, participates in European network meetings held by the EU Commission in Brussels.

5 ICSMS

ICSMS is the EU Commission's information and communication system for market surveillance, based on a product database. Sweden is one of the original founders of the system, which has been available to the Swedish market surveillance authorities since 2000. The activity in the system, however, has been limited during the time the system has been voluntary. A number of training courses have been conducted nationally over the years for ICSMS users.

Swedac is the national administrator for ICSMS and contact point in relation to the EU Commission. Swedac also takes part in the Commission's IMP-ICSMS (*Internal Market for Products – Information and Communication System for Market Surveillance*) expert working group. As from 2014, national ICSMS network meetings are arranged in connection with national RAPEX network meetings.

The internal portal of ICSMS is available to the authorities in the Market Surveillance Council, i.e. the 16 market surveillance authorities, the Swedish National Board of Trade and Swedish Customs. Continuous feedback from activity as regards reported products is provided at the Market Surveillance Council's meetings.

6 General principles for market surveillance

The Swedish market surveillance authorities normally base their supervision on risk assessment, i.e. they target their efforts mainly towards the product/product properties/economic operators that may be suspected of not meeting applicable requirements and where the consequences of non-compliance are particularly serious. Such information can originate from previous inspections, complaints, accident reports, information from RAPEX and ICSMS etc.

According to the Market Surveillance Council's guidelines for drawing up and following up of sector plans, these shall contain an overall accounting of how the risk assessment has been performed.

Authorities shall also report on the approximate distribution, in percentage figures, between proactive and reactive inspections (inspections on own initiative and inspections based on notifications or complaints) for their respective sectors, on how complaints or notifications are handled and on principles for when documentary checks, physical checks, testing etc. shall be carried out.

As insufficient compliance very often depends on ignorance of applicable legislation among economic operators, the Swedish authorities attach great importance to information, education and dialogue.

With few exceptions, the Swedish market surveillance authorities lack their own laboratories, and procure accredited testing services on the private market.

The authorities have a number of different possibilities of sanctions at their disposal, from administrative measures such as deciding on prohibition of sales, corrections, withdrawals, recalls, payments of penalties and sanction fees to penal measures such as fines and – in serious cases – even imprisonment. Today the authorities' powers and possibilities for sanction vary for different reasons, which will very likely be the object of a national review in the form of a special governmental inquiry.

7 Cooperation with other member states and countries outside the EU

Sweden attaches great importance to international cooperation for the purpose of developing market surveillance.

Swedac, the Swedish Consumer Agency, the Swedish National Board of Trade and Swedish Customs are the authorities that participate in non-sector-specific networks and working groups at the EU and global level in the sphere of market surveillance, and work to promote cooperation among the national authorities and their counterparts in other member states within various sectors.

Swedac's commission also includes, for example, serving as the Swedish representative on the European Commission's expert working groups for market surveillance issues, such as IMP-MSG (*Internal Market for Products-Market Surveillance Group*) and IMP-ICSMS (*Internal Market for Products-Information and Communication System for Market Surveillance*). Swedac participates alongside the Swedish Customs Agency in the European Commission's working group on cooperation between customs and market surveillance authorities (*EWG*) and alongside the Swedish Consumer Agency in the Prosafe (*Product Safety Enforcement Forum of Europe*) general assembly. Swedac and the Swedish National Board of Trade participate in the UN Economic Commission for Europe (UNECE), in the working party for regulatory cooperation and standardisation policies (*WP.6*) as well as the working group for market surveillance (*MARS*).

Swedac and the Swedish National Board of Trade also organise and participate in programmes/courses on market surveillance for third countries, including within the framework of international development.

The Ministry of Finance (the consumer unit) is Sweden's representative in the GPSD Committee and in OECD's working party on consumer product safety and is market surveillance and product safety work, often assisted by the Swedish Consumer Agency.

Cooperation with other member states and third countries within different sectors are discussed in the sector-specific market surveillance plans.

8 Evaluation and reporting

There is no general method for evaluation of market surveillance in Sweden. Evaluation of Swedish market surveillance primarily occurs through the follow-up of

the market surveillance plans within various sectors. Government authorities shall, for example, account for the results of activities that were carried out and that were not carried out. The follow-ups, according to the Market Surveillance Council's own guidelines, shall be finished by the end of March each year and submitted to Swedac. After that, they are published on the web site of the Market Surveillance Council. In addition, market surveillance projects can be part of a special government assignment or of a joint EU action. In such cases, the evaluation and reporting takes place as part of these activities.

According to EU Regulation 765/2008, the member states shall regularly—at least every fourth year—review and assess market surveillance. This has occurred once (in 2014) and in accordance with the Commission's guidelines. Similar processes exist for individual sector specific pieces of legislation.

The Swedish Customs also provides statistics on measures taken at the border in accordance with the guidelines developed at EU level.

9 Planned activities

The following activities are primarily grouped according to the duties given to the Market Surveillance Council in the Regulation (2014:1039) on market surveillance.

9.1 Exchange of experiences

One prerequisite for effective market surveillance is that public authorities are given opportunities to meet and exchange experiences. The basis of the Market Surveillance Council's work is the ordinary meetings. At such Council meetings, information of general interest is communicated, such as legislative work at national and EU level. Various issues of interpretation and implementation are also discussed.

- **The Market Surveillance Council shall arrange five ordinary meetings**

Close and regular dialogue between public authorities and business, consumer and employee organisations is an important part of the authorities' market surveillance. The Market Surveillance Council has therefore established permanent contact persons from The Association of Swedish Engineering Industries, The Swedish Trade Federation, Business Sweden, The Swedish Consumers' Association and The Swedish Trade Union Confederation.

- **The Market Surveillance Council shall invite representatives from business, consumer and employee organisations to two of the Council's ordinary meetings**

From a market surveillance perspective, the most effective way is to stop products that do not comply with the requirements of the legislation already at the external borders of the EU, i.e. before they are placed on the market. In order to increase the effectiveness of the market surveillance, it is important to develop the cooperation between the customs and the market surveillance authorities, so that in the longer

term it becomes a natural part of the national market surveillance work. The Market Surveillance Council's forum for customs-related issues is, from this perspective, an important constituent in the development of effective market surveillance in Sweden.

- **The Market Surveillance Council shall arrange two meetings of the Forum for customs-related Issues**

In recent years, annual evaluations have been carried out of the Market Surveillance Council's tasks, working practices, composition, etc., which have provided good input for continuous improvement to achieve the overall goals. A questionnaire sent to all public authorities participating in the Market Surveillance Council, representatives of business, consumer and employee organisations and the Government Offices has formed the basis for this evaluation. These annual evaluations should therefore continue.

- **The Market Surveillance Council shall carry out an evaluation of its function, tasks, working practices, composition, etc.**

9.2 Support

The review of the Swedish market surveillance performed between 2010 and 2013 in accordance with article 18.6 in EU Regulation 765/2008 showed a number of weaknesses in both performance and reporting. In several sectors there were no, or very few, activities reported and within the majority of sectors the resources attributed to market surveillance within the authorities were very limited.

The reasons for this could be that the Government's objectives for market surveillance and that the authorities' tasks are not clearly expressed. The market surveillance responsibility is missing in the majority of the Government's instructions to the authorities. There is no overall objective for market surveillance in the Swedish regulations on market surveillance (2014:1039) or within sector legislation. That the powers vary between sectors and authorities makes cooperation more difficult. These factors have implications on the conditions for an effective surveillance.

- **The Market Surveillance Council shall continue to work for that the market surveillance responsibility is included in the Government's instructions to authorities.**
- **The Market Surveillance Council shall continue to work for that objectives for market surveillance are included in the Swedish regulations on market surveillance.**
- **The Market Surveillance Council shall monitor the follow-up of the request for an official inquiry to review the powers of market surveillance authorities that the Council submitted in February 2014.**

The existing statistics and information on dangerous or non-compliant products is fragmented and difficult to draw conclusions from. There are no qualitative and quantitative studies on the importance of market surveillance for the society, e.g. for

the protection of consumers, employees and the environment, or for job opportunities, competition and growth. The absence of such basis for decision-making contributes to the fact that market surveillance is not given the attention needed.

- **The authorities of the Market Surveillance Council shall, within the work on their sector market surveillance plans, further develop their methods for market analysis, data collection, follow-up and reporting in accordance with the Council guidelines.**
- **The Market Surveillance Council shall work for that studies on the importance of market surveillance for the society are performed.**

The free movement of goods on the internal market is one of the fundamental principles of the EU. In order to safeguard fair competition and good user protection, European cooperation on market surveillance issues is a prerequisite. In October 2015, the European Commission presented a new strategy for the internal market (COM(2015)550 final), in which several initiatives in relation to market surveillance are foreseen. Among these can be mentioned activities to increase the knowledge of the principle of mutual recognition and a revision of Regulation 764/2008 and initiatives to strengthen product compliance by intensifying compliance checks and promoting closer cross-border cooperation. It is possible that several of these initiatives will be included in a new multiannual action plan for market surveillance in the EU (the present (COM(2013) 76 final) expires in December 2015).

- **The Market Surveillance Council shall contribute to the implementation of the market surveillance initiatives of the Internal Market Strategy**

Most public authorities participate in working groups or similar at the EU level where issues relating to interpretation and implementation of various legal product acts are discussed. Issues of horizontal interest are often raised, and these should become known to the entire Market Surveillance Council. Each authority shall therefore undertake to send agendas and reports from such meetings to the secretariat which, in consultation with the authority concerned, identifies issues that should be taken up for discussion at the Market Surveillance Council's ordinary meetings or in another manner.

- **The Market Surveillance Council shall inform about issues of horizontal interest from the respective working groups**

The Market Surveillance Council's Forum for Customs Related Issues has identified a need to review the national model for cooperation which should, among other things, be extended to comprise additional customs procedures, where the market surveillance authorities might be involved in. Today, the model takes its starting point only from the customs procedure "release for free circulation" in EU Regulation 765/2008 on accreditation and market surveillance. The Market Surveillance Council has the ambition to appoint a working group to further develop the model.

- **The Market Surveillance Council shall review the model for cooperation between customs and market surveillance authorities.**

Both national and international cooperation requires well-functioning IT solutions. Since 2008, Swedac has been financing a web-based system that functions as the Market Surveillance Council's internal system for information exchange and document management. This system will be replaced by another and a transition shall be performed in the beginning of 2016.

- **The Market Surveillance Council shall ensure a smooth transition to the new system for information exchange**

According to EU Regulation 765/2008 on accreditation and market surveillance, all market surveillance authorities are obliged to enter information about products in ICSMS (*International Communication System for Market Surveillance*). Swedac, which is the national administrator of ICSMS, shall arrange training courses and all authorities shall ensure that they have the required knowledge in-house to use the system.

- **The Market Surveillance Council shall organise and take part in ICSMS training courses**

The market surveillance authorities shall also, via the RAPEX (*Rapid exchange of information*) system, inform other member states and the Commission of dangerous products. The Swedish Consumer Agency, the national contact point for RAPEX, shall arrange network meetings for use of the system. These network meetings shall take place in connection with network meetings for ICSMS.

- **The Market Surveillance Council shall participate in joint RAPEX and ICSMS network meetings**

For many years, the Market Surveillance Council has promoted an integration of RAPEX and ICSMS to avoid duplication of data input. Such a pilot project has now been initiated within the European Commission.

- **The Market Surveillance Council shall participate in the Commission pilot project of the integration of the RAPEX and ICSMS systems**

Even if the internal cooperation at the respective authorities functions properly, exchanging experiences across sectoral and authority boundaries is equally important. This takes, to a great extent, place within the Market Surveillance Council, where the participants often have good contacts. It is, however, also important that people other than the representatives of the Council who also work with market surveillance at the authorities are given opportunities to meet and exchange experiences.

- **The Market Surveillance Council shall arrange the "Market Surveillance Day 2016"**

The evaluation of the Swedish market surveillance conducted for 2010–2013 that was carried out in accordance with EU Regulation 765/2008 indicated weaknesses in some parts, which could be explained by insufficient knowledge in evaluation methodology. The Swedish Agency for Public Management should be able to contribute to the development of such a methodology. This authority is tasked by the Government to investigate, evaluate and monitor publicly funded activities and general issues about the functioning of public administration. This includes analysing activities and

authorities from an efficiency perspective, reporting on the effects of public actions, and providing a basis for review.

- **The Market Surveillance Council shall promote an evaluation of the Swedish market surveillance by the Swedish Agency for Public Management and shall assist the agency in this work**

9.3 Information

In order for the market surveillance authorities to have the best possible conditions for carrying out its tasks, it is important that the principals are well informed. The Market Surveillance Council has identified a need to arrange special meetings for concerned government officials to inform them about market surveillance and to discuss topical issues. In 2015 a seminar was arranged in the Government offices, hosted by the Ministry of Foreign Affairs. This seminar will be followed-up in 2016 with sector contacts with responsible ministries.

- **The Market Surveillance Council shall have meetings with government officials**

Good dialogue between public authorities and the business sector facilitates a common objective of safe products and fair competition. All market surveillance authorities should maintain continuous contacts with the sector organisations concerned. In addition, there is a need for input at a more overall level in terms of product legislation, the obligations of economic operators and the role of the authorities.

In September 2015, the Swedish Government presented a national strategy for export. This strategy concerns not only export but also import and trade issues in general. The overall objective is to create growth, employment and increased welfare. There are several initiatives in this strategy that the Market Surveillance Council could contribute to.

- **The Market Surveillance Council shall investigate how the Council could contribute to the implementation of the strategy for export.**

In 2013 and 2015, the Market Surveillance Council, together with the Swedish Trade Federation, Business Sweden and the Association of Swedish Engineering Industries, arranged a full-day seminar "Your Product, Your Responsibility" aimed at manufacturers, importers and distributors. The seminar was well-attended and appreciated. Therefore, the Market Surveillance Council has decided to hold these types of seminars regularly, at least every other year.

- **The Market Surveillance Council shall prepare the "Your product, Your responsibility 2017" seminar**

There have been requests to arrange trainings and seminars like "Your Product, Your Responsibility" in other locations than Stockholm. The regional chambers of commerce, the Enterprise Agency and Almi have important roles to inform particularly start-ups and SMEs all over the country.

- **The Market Surveillance Council shall investigate the possibilities to cooperation with the regional chambers of commerce.**
- **The Market Surveillance Council shall investigate the possibilities to cooperation with the Enterprise Agency**
- **The Market Surveillance Council shall investigate the possibilities to cooperation with Almi**

The Market Surveillance Council's forum for customs-related issues has identified a need to inform importers of the different rules and procedures for import of products. Such complete information is today not available at one place and the Council has the ambition to establish a working group that will develop informational material.

- **The Market Surveillance Council shall produce up a brochure on import of products.**

Today, information is primarily sought out on the Web. It is therefore important to ensure that good, topical information is available on the Market Surveillance Council's joint website, www.marknadskontroll.se and especially to attract visitors to it. In 2014, guidelines for publishing information on the Council's web site were drawn up and several authorities, but not all, follow them today.

- **The Market Surveillance Council shall to a greater extent contribute with information to the web site.**
- **The Market Surveillance Council shall investigate the possibility for different media to subscribe, link or refer to news on the web site.**

Verksamt.se is a web site that gathers a lot of information to companies, especially start-ups. Information on product legislation, responsible regulatory and market surveillance authorities is, however, to a large extent missing.

- **The Market Surveillance Council shall investigate the possibilities of contributing to information on verksamt.se.**

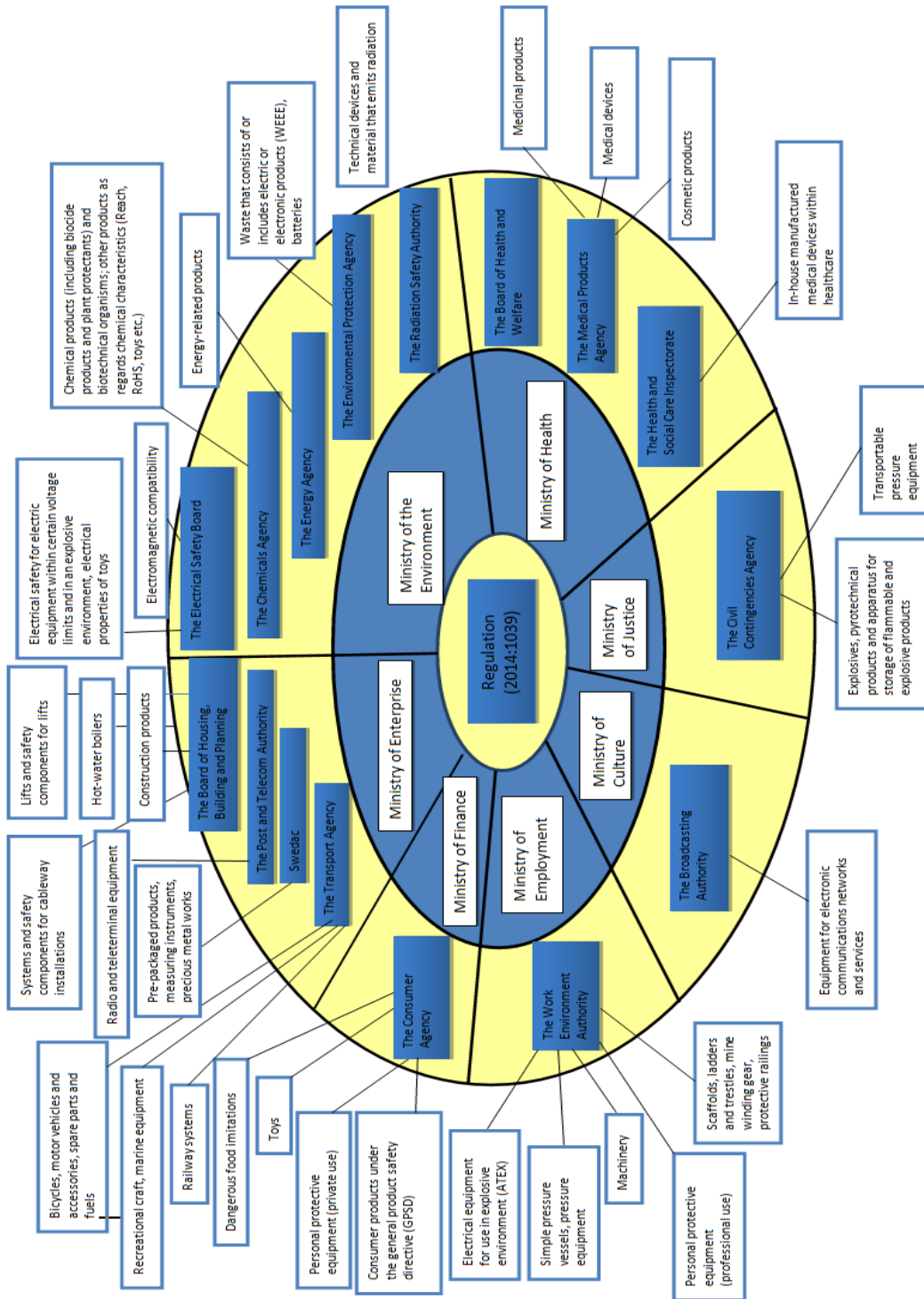
Appendix 1 The market surveillance authorities and their areas of responsibility

The Swedish Work Environment Authority	Equipment for use in explosive environments (ATEX), simple pressure vessels, pressure equipment, machinery, personal protective equipment for professional use, scaffolds, ladders and trestles, mine winding gear, protective railings
The Swedish National Board of Housing, Building, and Planning	Construction products, subsidiary systems and safety components for cableway installations designed to carry persons, lifts and safety components for lifts, certain hot-water boilers
The National Electrical Safety Board	Electrical equipment for use in explosive atmospheres (ATEX), electrical equipment within certain voltage limits and, as well as for the electrical properties of toys, electromagnetic compatibility
The Swedish Energy Agency	Energy-related products
The Health and Social Care Inspectorate	In-house manufactured medical devices within healthcare
The Swedish Chemicals Agency	Chemical products (including biocide products and plant protectants) and biotechnical organisms; other products (with certain exceptions) related to chemical characteristics (Reach, RoHS, toys etc.)
The Swedish Consumer Agency	Toys, personal protective equipment for private use, dangerous food imitations, consumer products and services under the General Product Safety Directive (2001/95/EC)
The Medical Products Agency	Cosmetic products, medicinal products, medical devices
The Swedish Environmental Protection Agency	Waste that consists of or includes electric or electronic products (WEEE), batteries
The Swedish Post and Telecom Authority	Radio and tele terminal equipment
The Swedish Broadcasting Authority	Equipment for electronic communications networks and services
The Swedish Civil Contingencies Agency	Explosives, pyrotechnical products, certain apparatus for storage of flammable and explosive goods, transportable pressure equipment
The Swedish National Board of Health and Welfare	
The Swedish Radiation Safety Authority	Technical devices and material that emits radiation
The Swedish Board for Accreditation and Conformity Assessment (Swedac)	Pre-packaged products, measuring instruments, precious metal work
The Swedish Transport Agency	Bicycles, motor vehicles and accessories, spare parts and fuels for these, recreational craft, marine equipment, railway systems

Appendix 2 The market surveillance authorities and their ministerial affiliation

Ministry	Agency
Ministry of Employment	The Swedish Work Environment Authority
Ministry of Finance	The Swedish Consumer Agency
Ministry of Justice	The Swedish Civil Contingencies Agency
Ministry of Culture	The Swedish Broadcasting Authority
Ministry of the Environment	The National Electrical Safety Board The Swedish Energy Agency The Swedish Chemicals Agency The Swedish Environmental Protection Agency The Swedish Radiation Safety Authority
Ministry of Enterprise, Energy, and Communications	The Swedish National Board of Housing, Building, and Planning The Swedish Post and Telecom Authority The Swedish Board for Accreditation and Conformity Assessment (Swedac) The Swedish Transport Agency
Ministry of Health and Social Affairs	The Medical Products Agency The Health and Social Care Inspectorate The Swedish National Board of Health and Welfare

Appendix 3 Organization Chart





Head office	Stockholm office
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