

# National Market Surveillance Plan

2020

SWEDEN

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## **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-approval of products 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 Regulations (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 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 more effective and more visible.

### **1. The market surveillance authorities and their areas of responsibility**

In Regulations (2014:1039), the Government has specially indicated 17 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 appendix 1 and 2.

## **2. Coordination and cooperation between 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 17 market surveillance authorities according to appendix 2, as well as the Swedish Customs Services and the National Board of Trade Sweden.

According to the Swedish Regulations 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 draw up 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, but one working group reporting to the Market Surveillance Council, the forum for customs related issues "Customs forum" 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 Regulations (2004:469), implements the EU Directive on General Product Safety (2001/95/EC). The Swedish Consumer Agency is also the contact point for Safety Gate (Rapex) (see section 4) and has coordinating responsibility towards other market surveillance authorities that

belong to the Safety Gate network, in accordance with Regulations (1993:1322) and Regulations (2014:1039).

Swedac is the national administrator of ICSMS (see section 5) in accordance with Regulations (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 Regulations (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 National Board of Trade Sweden, and Swedish Customs. The Council has also appointed a permanent working group for cooperation, called “Customs Forum” 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 have previously participated in the European Commission’s expert working group on product safety and compliance checks for imported goods (EWG), which was a joint group for customs and market surveillance authorities. Unfortunately, this group was abolished in 2016 and the questions are now partly dealt with by PARCS (*Prohibitions and Restrictions Customs Controls Strategy*), a group of representatives from customs authorities in the EU, working with the coordination of protection of health, cultural heritage, the environment. Starting from March 2019, joint meetings are held between the market surveillance authorities within the frame of *Internal Market for Products-Market Surveillance Group* (IMP-MSG) and custom authorities (PARCS).

### **4. Safety Gate (Rapex)**

Safety Gate (Rapex) is the EU Commission’s alert system for products with serious risks. The Swedish Consumer Agency is the national contact point for Safety Gate. Sweden has since 2004 participated in the EU Safety Gate network. Twelve market surveillance authorities actively participate in the national network together with the National Board of Trade Sweden and Swedish Customs for information. As from 2014, national Safety Gate network meetings are arranged in connection with national ICSMS network meetings.

Every week, the Swedish Consumer Agency sends out a newsletter with links to the EU Commission’s compilation of dangerous products: the Safety Gate (Rapex) Weekly Report. Its recipients are market surveillance authorities, consumer organisations and economic operators on the Swedish market. The Safety Gate Weekly Report is also

made available on the website of the Market Surveillance Council, [www.marknadskontroll.se](http://www.marknadskontroll.se).

The market surveillance authorities are responsible for notifying dangerous products they discover as well as investigating whether the Safety Gate notified products are available on the Swedish market. In cases where corrective measures are taken in Sweden, the authorities send their reactions in Safety Gate. The Swedish Consumer Agency participate as a national contact point in the European network meetings organized by the European Commission in Brussel.

## **5. ICSMS**

ICSMS is the EU Commission's information and communication system for market surveillance, based on a product database. All market surveillance in the EU are expected to use ICSMS in their daily work by putting in information on products they check and keeping themselves informed of products other member states check. 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 has been limited but has increased in recent years.

Swedac is the national administrator of 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 Safety Gate network meetings.

The internal part of ICSMS is available to the authorities in the Market Surveillance Council, i.e. the 17 market surveillance authorities, the National Board of Trade Sweden and Swedish Customs. Continuous feedback from activity as regards reported products is provided at the Market Surveillance Council's meetings. Several training sessions are held every year for the Swedish users.

## **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 Safety Gate 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, based on market analysis, 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 non-compliance very often depends on a lack of knowledge of applicable legislation among economic operators, the Swedish authorities attach great importance to information, education and dialogue with economic operators.

With few exceptions, the Swedish market surveillance authorities lack their own laboratories, and procure accredited testing services on the 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. This was subject of national review in the form of a special investigation in 2017 (SOU 2017:69) but did not result in any legislative measures. Since EU 2019/1020 was adopted in 2019, a new investigation has been appointed, which is expected to report on its assignment in August 2020.

## **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 National Board of Trade Sweden 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. Since the fall of 2019, The Swedish Civil Contingencies Agency holds the presidency of the ADCO group for the directive of pyrotechnic articles (PA).

Swedac's commission also includes, for example, serving as the Swedish representative in 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 and the National Board of Trade Sweden participate in the UN Economic Commission for Europe, in the working party for regulatory cooperation and standardisation policies (*UNECE WP.6*) as well as the working group for market surveillance (*UNECE MARS*).

Swedac and the National Board of Trade Sweden 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, often assisted by the Swedish Consumer Agency. Cooperation with other member states and third countries within different sectors are covered by the sector-specific market surveillance plans.

## **8. Evaluation and reporting**

There is no general method for evaluation of market surveillance in Sweden, but Sweden participated in the task force that the EU Commission established for this purpose at EU level. 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 twice (in 2014 for 2010-2013 and in 2017 for 2014-2016) 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 activities are grouped according to the tasks assigned to the Market Surveillance Council in the Ordinance (2014:1039) on Market Surveillance.

### **9.1 Exchange of experiences**

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

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

**The Market Surveillance Council shall arrange the "Market Surveillance Day 2020".**

It is also important that other than Council representatives, who also work with market surveillance at the authorities, have the opportunity to meet and exchange experiences. The Council therefore arranged a special seminar for the first time in 2016 for only market surveillance authorities. This was felt to be very rewarding and the Council has therefore decided to hold such seminars every two years.

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

Close and regular dialogue between public authorities and business, consumer and trade union organisations is an important part of the authorities' market surveillance. The Market Surveillance Council has therefore established links with representatives from the Association of Swedish Engineering Industries, the Swedish Trade Federation, Business Sweden, Swedish Consumers' Association and Swedish Trade Union Confederation. There may also be a need for contacts with more trade associations and larger companies to learn of their needs, views and experiences.

**The Market Surveillance Council shall arrange two meetings of the Customs Forum.**

Many non-compliant products come from third countries. From a market surveillance perspective, the most effective approach is if it is possible to stop such products immediately at the external borders of the EU, i.e. before they are placed on the internal market. In order to increase the effectiveness of both border and market surveillance, it is important that the cooperation between the customs and market surveillance authorities works well. The Market Surveillance Council's "Customs Forum" is the main platform where these issues are dealt with. Representatives from all the authorities in the Market Surveillance Council should participate in this forum.

**The Market Surveillance Council shall carry out an evaluation of its function.**

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, forms the basis for this evaluation.

## 9.2 Cooperation and efficiency

### **The Market Surveillance Council shall**

- **continue to work for market surveillance responsibility to be included in the instructions to the authorities.**
- **continue to work for objectives for market surveillance to be included in the Swedish Ordinance on Market Surveillance.**

The evaluation of Swedish market surveillance during the periods 2010-2013 and 2014-2016, in accordance with Art. 18.6 of EU Regulation 765/2008, showed some weaknesses in both implementation and reporting. Amongst other things, it can be concluded that in many areas market surveillance is non-existent or very limited, and that in most sectors, very few resources are allocated to market surveillance activities at the various authorities. This may be partly due to a lack of clarity in the Government's objectives for market surveillance and that in many cases the responsibility of the authorities is not clearly formulated. In the vast majority of the Government's instructions to the authorities, the market surveillance task is not included. There is also no overall objective for market surveillance in the Swedish Regulations (2014:1039) on Market Surveillance or within the different sectors. The fact that powers and sanction mechanisms vary between sectors and authorities hampers cooperation between authorities. These factors have consequences for the ability of the authorities to conduct effective market surveillance.

### **The Market Surveillance Council shall assist the Government in the development of supplementary provisions relating to the new Goods Package.**

Free movement of goods on the internal market is one of the fundamental principles of the EU. European cooperation in market surveillance issues is a prerequisite for being able to ensure fair competition and a high level of protection of consumers. On 28 October 2015, the EU Commission presented a new Single Market Strategy (COM (2015) 550 final), in which several initiatives related to market surveillance are included. In 2016-2017, a review was carried out of EU Regulation 764/2008 on mutual recognition and market surveillance provisions in EU Regulation 765/2008 on accreditation and market surveillance. A new "Goods Package" was adopted during 2019. The Market Surveillance Council shall contribute to the implementation of the EU's Internal Market Strategy in the issues linked to market surveillance.

### **The Market Surveillance Council shall inform about issues of horizontal interest from the respective sector working groups and networks.**

Most public authorities participate in working groups (ADCO-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 in these sector-specific networks, and these should be brought to the attention of the entire Market Surveillance Council. Each authority should therefore, among other things, send agendas and minutes from such meetings to the secretariat or publish them in the joint web forum that council members have access to. The Secretariat, in consultation with each individual authority, can identify issues that should be addressed at regular meetings of the Market Control Council or in some other way.

**The Market Surveillance Council shall ensure that all authorities consider carrying out at least one joint cooperation activity with the Customs within the framework of their sector plans.**

Experience from practical cooperation between customs and market surveillance authorities may lead to a revision of the national model for cooperation between the market surveillance authorities and the Swedish Customs. This requires an increase in practical cooperation.

**The Market Surveillance Council shall increase its use of ICSMS.**

According to EU Regulation 765/2008 on accreditation and market surveillance, all market surveillance authorities are obliged to enter information about products in ICSMS (*Information and Communication System for Market Surveillance*). This does not currently take place to a sufficient extent. In order for the system to be used as intended, it is imperative that the authorities use it in their daily activities.

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

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 participate in joint Safety Gate (Rapex) and ICSMS network meetings.**

The market surveillance authorities shall also use the Safety Gate system to inform other Member States and the EU Commission of dangerous products. The Swedish Consumer Agency, which is the national contact point for Safety Gate, shall arrange network meetings for use of the system. These network meetings shall take place in conjunction with network meetings for ICSMS.

**The Market Surveillance Council shall**

- **conduct one or more market surveillance projects that focus on the surveillance of products sold online**
- **draw up guidance and routines for the market surveillance of products sold on-line.**

The increasing e-commerce involves a range of challenges, both legal and practical, for market surveillance authorities. The Market Surveillance Council has therefore begun a more comprehensive work on reviewing difficulties and drawing up best practices for such surveillance.

**The Market Surveillance Council shall conduct joint market surveillance actions to a greater extent.**

There are many areas where the market surveillance authorities are responsible for different aspects of the same product, or where the authorities see the need to check the same company. In these cases, there is a great need for coordination, both in order to use limited authority resources as efficiently as possible and to avoid several authorities checking the same company on different occasions. It may range from joint information efforts to joint documentation checks, checks on retail premises and

testing. Coordinated actions already take place today, but there is a need to expand the cooperation. The sector-specific market surveillance plans should provide a starting point for identifying and implementing possible cooperation.

**The Market Surveillance Council shall analyse new developments, to increase the understanding on how different markets and behaviours work.**

In an increasingly changeable and digital world, new trends appear and previous common trade behaviour changes. New practice to conduct business and new methods for import and export emerge, which could affect the future market surveillance. In order to keep up with the rapid development and to prevent negative impacts on the product safety, the Market Surveillance Council shall analyse new developments, to increase the understanding on how different markets and behaviours work. This will be addressed at a forthcoming meeting at the Market Surveillance Council, when the business and consumer organizations are present.

### **9.3 Information**

**Market Surveillance Council shall**

- **participate in the “Start a Business” exhibition arranged by the NyföretagarCentrum**
- **carry out information events between the major seminars**

There have been requests to arrange training courses and seminars similar to “Your Product, Your Responsibility” in locations other than Stockholm. The regional chambers of commerce, NyföretagarCentrum and Almi have important roles to play for informing especially small businesses and start-ups throughout the country. Contact was made with all these actors in 2016, resulting in a number of concrete collaborations with the Chamber of Commerce and Industry of Southern Sweden and the Enterprise Agency. In 2019, some of the authorities in the Council attended the “Start a Business” exhibition aimed at small businesses, new businesses and potential new companies. The Market Surveillance Council will coordinate a common participation for the Market Surveillance Council at the exhibition “Start a Business” in 2020. It is also of importance that the Market Surveillance Council develops a concept where e.g. three or four authorities together carries out information events locally or regionally. In 2016 and 2018 the full-day seminar “Market Surveillance Day” was organised for the Market Surveillance Authorities who are working with these types of questions. A working group has been appointed to work on the planning and implementation of the upcoming seminar 2020.

**The Market Surveillance shall**

- **inform about decisions on restrictive measures as well as warnings on [marknadskontroll.se](http://marknadskontroll.se).**
- **produce a common calendar for seminars, workshops and lectures for publication on the website.**
- **contribute with news and blog posts, as well as make sure that information on sector legislation in force is up-to-date.**

Today, information is primarily sought out on the Web. It is therefore important to ensure that useful and topical information is available on the Market

Surveillance Council's joint website, [www.marknadskontroll.se](http://www.marknadskontroll.se), and especially to attract visitors. A working group has been appointed to work on the development of the website.

**The Market Surveillance Council shall inform Swedish platforms on current safety requirements and other product requirements, and discuss the possibility of a national pledge (the Pledge).**

In 2018, four online platforms targeting the European Market signed a pledge of product safety (the Pledge) in which they undertook a number of voluntary measures to quickly remove dangerous products sold by third-party vendors on their website. However, the actors behind the Pledge is not focusing on the Swedish market specifically and, since there are other actors on the Swedish market, the Market Surveillance Council can inform them about safety and other product requirements and the possibility to make a national pledge.

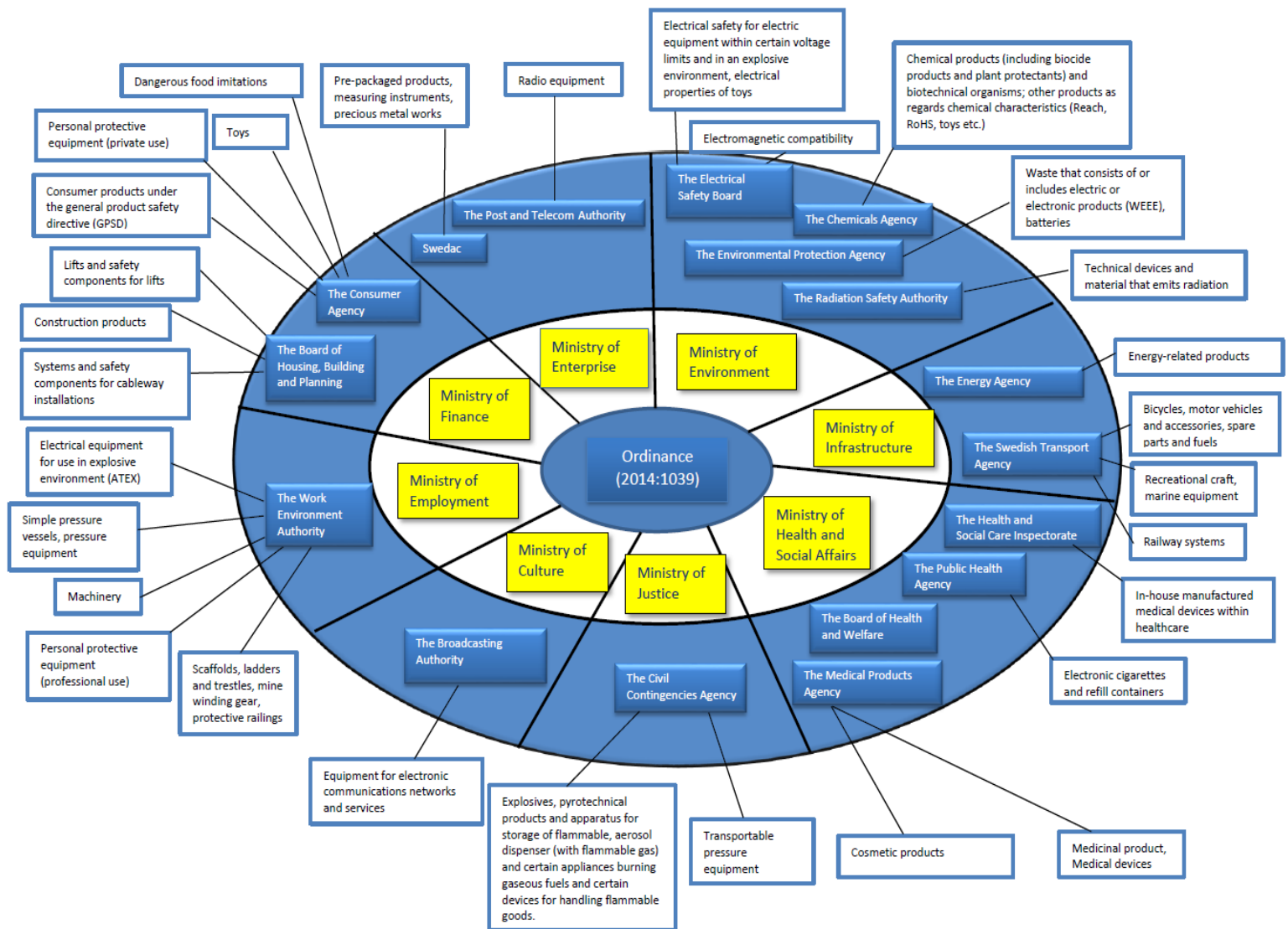
## Appendix 1 The market surveillance authorities and their areas of responsibility

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
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 Public Health Agency of Sweden	Electronic cigarettes and refill containers
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 equipment
The Swedish Broadcasting Authority	Equipment for electronic communications networks and services
The Swedish Civil Contingencies Agency	Explosive goods including pyrotechnic articles, transportable pressure equipment, aerosol dispensers (with flammable gas) and certain appliances burning gaseous fuels and certain devices for handling flammable goods.
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 Infrastructure	The Swedish Energy Agency The Swedish Transport 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 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)
Ministry of Health and Social Affairs	The Health and Social Care Inspectorate The Medical Products Agency The Public Health Agency The Swedish National Board of Health and Welfare

## Appendix 3 Organization Chart







<b>Head office</b>	<b>Stockholm office</b>
Österlånggatan 5	Gustavslundsvägen 151 E
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