Algemene Rekenkamer

Products sold on the European market: unravelling the system of CE marking

2017

Products sold on the European market: unravelling the system of CE marking

The original report – *Producten op de Europese markt: CE-markering ontrafeld* – was adopted on 21 December 2016 and submitted to the House of Representatives on 19 January 2017.

Table of contents

Conclusions and recommendations

Every month, dozens of products are either removed or recalled from the European Union (EU) market, because they pose serious risk to the health and safety of consumers and professional users.[1] Interestingly, many of the products withdrawn or recalled from the market bear a CE marking:

CE

CE stands for *Conformité Européenne*, which means 'in compliance with EU law'. By affixing a CE marking on a product, the manufacturer declares that it complies with all the prevailing EU requirements in relation to aspects such as safety, health and the environment.

The system of CE markings is part of a broader package of EU measures designed to pave the way for a single European market. Community legislation specifies the products that are required to display a CE marking, and also the requirements that products need to fulfil in order to qualify for CE marking. Products displaying a CE marking are deemed to be in conformity with EU requirements and may therefore be sold throughout the European Economic Area (EEA), and also in Switzerland and Turkey.[2] In other words, a CE marking acts as a passport to the internal market.

Our audit was intended to find out why it is that there are products on the European market that do not comply with the relevant EU requirements and what the authorities are doing in order to prevent this from happening.

What did we find?

The system of CE marking is a complex European system. There is a massive body of Community legislation. One of the characteristic features of the system is that the EU has only laid down certain 'essential requirements' with which products need to comply. The details of these requirements are set out in harmonised EU standards drawn up by stakeholders themselves. Small and medium-sized businesses, government bodies and consumer organisations are underrepresented in this standardisation process.

The basic principle underlying the CE system is that economic operators, i.e. manufacturers, importers and distributors, must ensure that the products they sell on the European market comply with EU health and safety requirements, among others, and that they have

been properly assessed and tested. Under the CE marking legislation, public-sector actors are responsible for ensuring that economic operators fulfil these obligations. For example, the EU member states are required to organise market surveillance and accreditation in their own territories.

Accountability to the Dutch parliament is fragmented

In the Netherlands alone, a large number of public-sector actors are involved in policy-making in relation to, and the practical implementation of, the CE system: six ministers,[3] five national inspectorates[4] and a number of 'autonomous administrative authorities' (government agencies). These actors all have a role to play in the CE system and each of them reports individually to parliament on the way in which they have discharged their responsibility. In many cases, these reports cover a broader range of topics than the system of CE marking alone. As a result, parliament is unable to form a general picture of how well the system as a whole is operating and of areas in which improvements could be made, both by the Netherlands and by the EU.

Weaknesses in the regulation of the CE system

The fact that products bearing a CE marking are sold on the European market despite failing to comply with EU requirements is the result of certain weaknesses in the regulation of CE marking. In general terms, there is an inherent tension in the way in which the system is designed: the economic interests of the economic operators (such as their desire to increase their market share and maximise their profits) are not automatically compatible with the need to safeguard public interests, as is the intended purpose of the system of CE marking. In addition to this intrinsic inconsistency, we also uncovered a number of specific problems in the 'conformity assessment procedure' followed by manufacturers, which may explain why products are sold on the European market that do not comply with EU requirements. We found, for example, that the complexity of the regulations may lead to confusion, that not all innovative products are compatible with harmonised EU standards, and that it is not always easy to guarantee the conformity of products produced as part of a series.

One single market, multiple national surveillance authorities

There is a single European market, but every member state decides for itself how its system of market surveillance should operate. As a result, market surveillance in some member states is stricter than in others. Similarly, the market surveillance authorities in the various member states are not equally active in their use of European databases such as the *Rapid Alert System for Dangerous Non-Food Products* (RAPEX) and the *Information and Communication System on Market Surveillance* (ICSMS). These discrepancies have an impact

on the system as a whole: the European market is a chain and the strength of market surveillance is as strong as the weakest link.

The situation in the Netherlands is that five national inspectorates are responsible for overseeing compliance with the regulations on CE marking. Only a very small proportion of their budgets and staff capacity is available for monitoring compliance with the CE regulations.

Data and information systems are underused
Like the market surveillance authorities in other European countries, the Dutch inspectorates face a number of challenges: the trade in products is both dynamic and international, and a huge number of products reach the market every week. Despite our conviction that this situation requires a detailed, well-founded risk assessment, market surveillance authorities find it difficult to assess the precise size of the market and the number of players they are required to supervise. We also found that the exchange of data and inspection findings among market surveillance authorities, both in the same country and internationally, was not up to standard.

No role for end-users in the CE system
The legislation on CE marking does not make provision for end-users such as consumers and professional users to play a certain role, nor does it impose any obligations on end-users. End-users must be assured that the products they buy in shops or use for their work do indeed satisfy EU requirements in relation to safety and sustainability, for example. This need not be a problem if the system is watertight. However, as we have already pointed out, the system is not fully watertight.

Recommendations

Recommendations for the minister responsible for market surveillance in the Netherlands
The situation in the Netherlands is that the Minister of Economic Affairs, the Minister of Infrastructure and the Environment, the Minister of Health, Welfare and Sport, the Minister of Social Affairs and Employment, the Minister of Finance and the Minister for Housing and the Central Government Sector are required to monitor compliance with the CE regulations. We found certain weaknesses in the system of market surveillance. For this reason, we recommend that the above ministers:

- make better use of the information generated by national and international databases;
- seek to harmonise the practical implementation of market surveillance by continuing to take part in international activities undertaken by market surveillance authorities (such as joint audits) and provide other countries with examples of good practice;

- invest in people and resources with a view to organising market surveillance in such a way as to make better and smarter use of the available data. This should help to make better risk assessments and to improve cooperation among the member states;
- explore the opportunities for involving end-users in market surveillance, both as users and as suppliers of data, for example through social media.

Recommendations for the Minister of Economic Affairs

The Minister of Economic Affairs is responsible for coordinating the CE system in the Netherlands. We recommend that, acting in this capacity, the Minister of Economic Affairs reports to parliament in a systematic manner, by presenting a four-yearly report explaining how the Netherlands has discharged its responsibilities in relation to the CE system and how this has helped to prevent products from being sold that do not comply with the relevant requirements. This report could be combined with the four-yearly review of Dutch market surveillance that the Minister of Economic Affairs sends to the European Commission on behalf of the Netherlands as an EU member state.

We believe that the Minister of Economic Affairs should examine whether small and medium-sized businesses, consumer organisations and government bodies (such as the national inspectorates) play a proper role in the standardisation process and how any impediments can be removed.

The CE system is a European system run by the European Commission's *DG Growth*, for which the Commissioner for Internal Market and Services is responsible. Regarding the weaknesses we found in the way in which the system of CE marking is organised at a European level, we urge the Minister of Economic Affairs, acting in consultation with parliament, to adopt a standpoint, formulate a number of concrete action points and to present these to the European Commission. Among the points on which we believe action is required are the need to step up the active use that market surveillance authorities in the member states make of databases such as RAPEX and ICSMS, and the need to foster targeted cooperation and the exchange of inspection findings among market surveillance authorities in the member states.

Finally, we urge the Minister of Economic Affairs to examine, in conjunction with the European Commission, the opportunities for strengthening the information status of end-users in the European market, for example by improving the information on the provenance and traceability of products. The European Commission's *DG Justice and Consumers*, which includes *consumer empowerment* in its remit, could play a role in this process.

Ministers' response

The Minister of Economic Affairs responded to our report on 15 December 2016, acting also on behalf of the Ministry of Infrastructure and the Environment, the State Secretary for Infrastructure and the Environment, the Minister of Social Affairs and Employment, the Minister of Health, Welfare and Sport, and the Minister for Housing and the Central Government Sector. An abridged version of his response is provided below. This chapter concludes with our afterword.

Response of the ministers and the state secretary responsible for market surveillance in the Netherlands

According to the ministers and the state secretary, our recommendations underpin existing policy. In accordance with our recommendation, the five national inspectorates[5] are planning to continue their involvement in international activities. This means, for example, taking part in joint *audits* and alliances of European market surveillance authorities.

The ministers and the state secretary endorsed our recommendation that there is a need to make more use of information systems and the available data. They said that they were planning to ask the inspectorates to join forces to investigate ways and means of achieving this. They pointed out at the same time that certain information systems are not managed by the Netherlands, which makes it difficult for Dutch organisations to make any adjustments themselves.

The ministers and the state secretary agreed that there was a need to involve end-users in the work of the national inspectorates. The inspectorates currently all have different policies in this respect, and tend to distinguish between consumers on the one hand and professional end-users on the other. The 'market regulation alliance', as it is known (an alliance of national inspectorates involved in market surveillance), will be assessing whether there are any other ways of involving end-users in market surveillance.

Response of the Minister of Economic Affairs as the minister responsible for coordinating the CE system

The Minister of Economic Affairs shared our conclusion that reporting to the House of Representatives about the operation of the CE system is open to improvement. He promised to inform parliament more systematically about the operation of the CE system, in addition to the information provided on the operation of the system in individual industries. The minister said he would combine this information with the four-yearly report to the European Commission.

The minister underlined the importance of ensuring that all stakeholders were closely involved in the drafting of standards. He said that this was the prime responsibility of NEN, the Dutch Standardisation Institute. The minister referred to a recent plan announced by the European Commission for improving the European system of standardisation. The Dutch government and NEN have both signed up to the plan, one of the aims of which is to secure the closer involvement of all national stakeholders. The minister promised to monitor the implementation of the plan through his membership of a European steering committee. The minister said that he was also planning to ask NEN how it was intending to put the various initiatives contained in the plan into practice.

The minister concluded by promising to send the European Commission a letter setting out the Dutch standpoint on how to reduce the number of non-compliant products on the market. He said that the letter would take account of the court's recommendations about the use of data systems and the need to strengthen the role played by end-users. The House of Representatives would be receiving a copy of this letter.

Court of Audit's afterword

We are grateful to the ministers and state secretary for the constructive manner in which they responded to our report. The main ways of further strengthening the market surveillance of products are by making greater use of information systems, European systems in particular, and by encouraging the market surveillance authorities to share information and use the available data for risk assessment purposes. The response does not, however, provide much information on the specific measures the inspectorates are planning to take to improve information systems and the use of data resources, nor on the timelines for the adoption of these measures.

We believe that end-users should be more closely involved in the work of the market surveillance authorities. This should also help to improve their performance. We are gratified to see that the ministers endorsed the importance of this. We are assuming that the alliance of market surveillance authorities will come up with a concrete plan for making greater use of the 'eyes and ears' of end-users in the surveillance of markets and also that parliament will be duly informed about this. In our view, publishing inspection findings and improving the traceability of products are both part of this process.

The Minister of Economic Affairs agrees with our conclusion that it is absolutely vital for all stakeholders to be closely involved in standardisation procedures. At the same time, we wish to point out that it is by no means commonplace for small and medium-sized

enterprises and stakeholder organisations to play a role in the formulation of standards. While acknowledging that this is the prime responsibility of NEN, we believe that the minister should actively foster this engagement. The EU Regulation on European Standardisation states that member states should encourage government bodies, including market surveillance authorities, to take part in national standardisation procedures. This is also something that the minister could encourage more actively.

We welcome the Minister of Economic Affairs' proposal to write to the European Commission about our report. We assume that the letter will also discuss the weaknesses in the CE system that we identified in our report and which need to be analysed and resolved at a European level.

1 About this audit

1.1 Background and aims

Everyone in Europe handles or encounters products bearing a CE marking CE more or less on a daily basis – at home, in a shop or at work. CE markings are found for example on electrical appliances such as washing machines and smartphones, on toys, on packets of sticking plaster, on supermarket scales, on roadside petrol pumps, on ladders used by window-cleaners and on bread-slicers used by bakers.

Every year in the European Union (EU), dozens of products bearing a CE marking are taken off the market and/or recalled on the grounds that they pose a serious risk to the health and safety of consumers and professional users.[6]

One of the most infamous examples of the recent past has involved breast implants known as PIP (Poly Implant Prothèse) implants. These were found to have been filled with an industrial-grade silicone gel that formed a public health risk. A large number of telephone chargers and toys have also been removed from the market during the past few years on the grounds of constituting a risk to health and/or safety. Remarkably, many of the products withdrawn from the market or recalled carried a CE marking. This is striking in that, by affixing a CE marking on a product, the manufacturer affirms that the product in question complies with the relevant EU requirements on safety, health and environmental protection.

These various incidents (among other reasons) prompted us to ask how it is possible that these products, which clearly do not comply with EU requirements, are nonetheless traded on the European market bearing a CE marking, and what the government is doing to prevent and remedy this problem.

The system of CE markings is part of a broader package of EU measures designed to pave the way for a single European market. The CE system is not just a European system. It is also a mixed public-private system in which both private-sector parties (such as manufacturers) and public-sector parties (such as market surveillance authorities) have their own responsibilities and need to interact with each other.

We were interested in finding out whether anyone keeps track of all the various actors involved in this process, and also how this interaction takes place. Our interest was aroused by our observation that the vast majority of the questions raised about the system in the European Parliament and the Dutch House of Representatives were prompted by incidents

and that the questioners did not generally appear to be interested in the operation of the system as a whole.[7] We hope that this audit will give the Dutch House of Representatives a picture of the workings of the CE system and the design principles underlying it. Our aim is to focus on the opportunities available to the Dutch parliament for performing its role as a watchdog in this respect and thus helping to safeguard public interests such as safety, health and environmental protection.

1.2 What is CE marking?

The letters CE stand for *Conformité Européenne*, which means 'in compliance with EU law'. By affixing the CE marking on a product, the manufacturer declares that it complies with all the prevailing EU statutory requirements in relation to aspects such as safety, health and the environment.

EU legislation specifies the products that need to bear a CE marking, and also the requirements that products need to fulfil in order to qualify for CE marking. Products with a CE marking may be sold freely throughout the European Economic Area (EEA), and also in Switzerland and Turkey.[8] These countries are shown in Figure 1.

Products with a CE marking may be freely sold in 33 countries

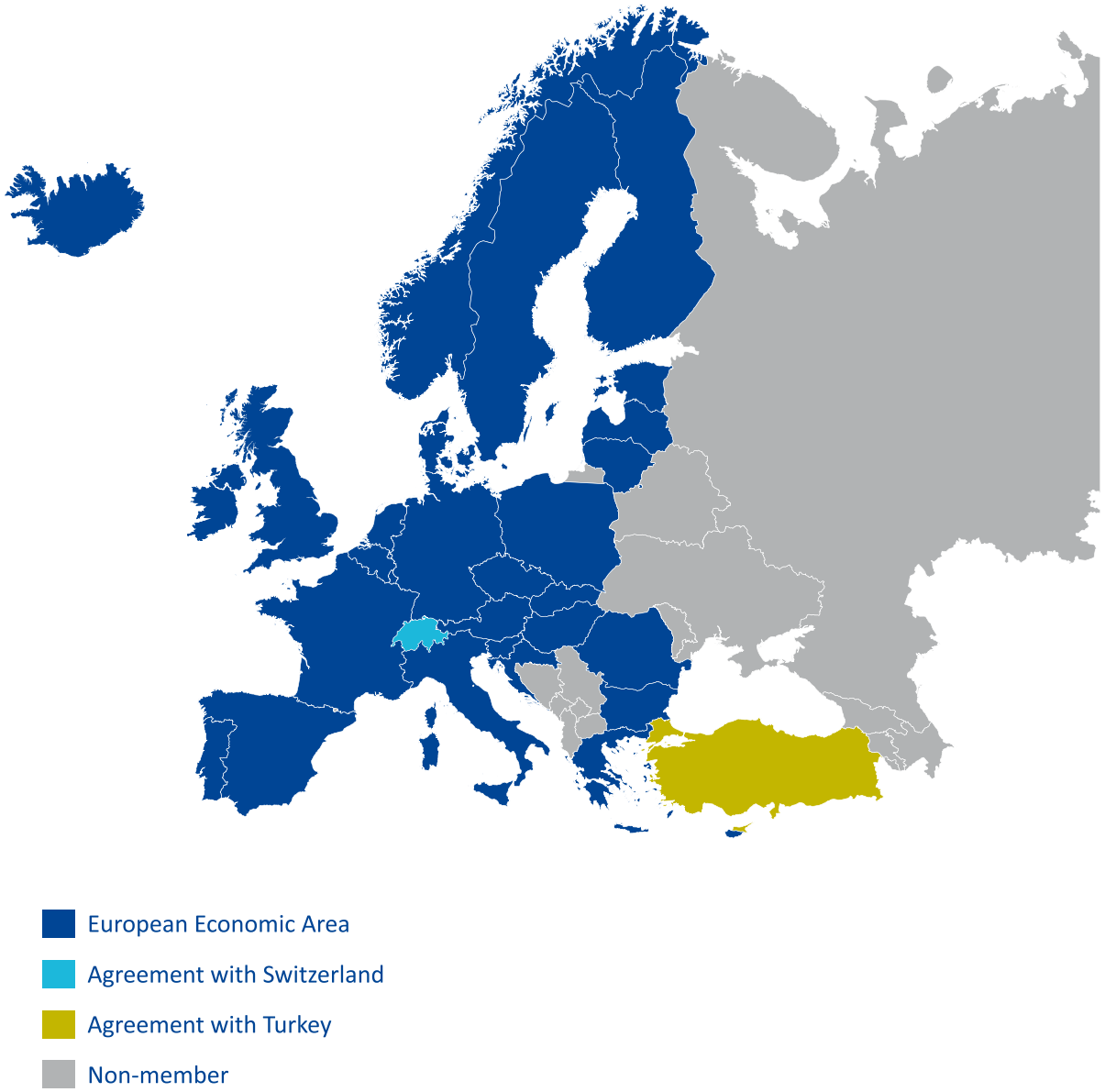


Figure 1 Map showing the 33 countries in which products with a CE marking may be freely sold

Products subject to a statutory requirement to display a CE marking may not be traded on the European market if they do not carry such a marking. This applies even if they nonetheless comply with the relevant European requirements. Similarly, a CE marking may not be placed on a product that is not subject to a statutory requirement to display such a marking.

What does a CE marking not mean?

A CE marking shows that a product meets EU safety, health and environmental requirements. This does not necessarily mean that a product bearing a CE marking is also of high quality or that it has a long economic life.

A CE marking differs in certain respects from quality marks, which are used to confirm that the product in question meet requirements in relation to quality or durability, for example. The requirements pertaining to these quality marks are generally stricter than the statutory requirements, whereas CE markings are used to show that the product in question satisfies the statutory requirements.[9] As a further point, many non-food products are required by law to display a CE marking, whereas most quality are of a voluntary nature. For example, not all items of wooden garden furniture bear a quality mark or label showing that they are made of wood obtained from sustainable sources, but all teddy bears must carry a CE marking.

1.2.1 CE marking serves a dual purpose

CE marking serves a dual purpose: it is intended both to promote the free movement of goods on the European market and to afford a high level of protection in respect of public interests such as safety and health.

Promoting the free movement of goods

One of the cornerstones of the European Union is the development of a single market in which there is free movement of goods, services, capital and people. To this end, the EU has adopted and refined a vast array of rules and measures over the past few decades.

The system of CE marking is one of these measures. It is designed to remove trade barriers by harmonising the requirements for products on the European market. This is because one of the biggest barriers to the formation of a single, common market for products was the fact that the various EU member states all had their own product and safety requirements. Thus, bicycle helmets made in Spain could not be sold on the German market as they did not comply with German safety requirements. This problem was solved by harmonising product requirements throughout Europe, and by introducing a system of CE marking as part of this.

In theory, because product requirements are now laid down by the EU, trade can no longer be hampered by requirements and regulations drawn up by individual member states. This is conducive to free trade throughout the European market. Products with a CE marking are deemed to be in conformity with EU requirements and may therefore be sold in every member state. In other words, a CE marking acts as a passport to the internal market.

A high level of protection of public interests

Although the CE system was initially intended to promote free trade, the current CE legislation is also designed to safeguard public interests such as health and product safety. Regulation (EC) No 765/2008 of 9 July 2008 states: "It is necessary to ensure that products benefiting from the free movement of goods within the Community fulfil requirements providing a high level of protection of public interests such as health and safety in general, health and safety at the workplace, protection of consumers, protection of the environment and security [...]".

1.2.2 CE rules on 27 product groups

EU legislation specifies those products that must bear a CE marking. At the time we performed this audit, 23 EU Directives and one Regulation were in force, stating the types of products that are required to carry a CE marking. In addition to these, a further three product categories are covered by CE legislation, but do not carry a CE marking. This is the case, for example, with railway rolling stock.

Examples of product groups that fall under CE legislation are toys, machinery, radio equipment, medical devices and lifts.[10] Certain products, including a large number of electrical appliances, are covered by more than one Directive or Regulation.

Legislation on CE marking is 'work in progress'

The rules on the CE system are not static, but are constantly changing. New Regulations came into force in May 2016 on cableway installations, personal protective equipment and appliances burning gaseous fuels (Regulation (EU) 2016/424 of 9 March 2016; Regulation (EU) 2016/425 of 9 March 2016; Regulation (EU) 2016/426 of 9 March 2016). Following a two-year transitional period, these regulations will apply directly in all member states with effect from 21 April 2018. Two new Regulations on medical devices are expected to enter into force early in 2017. These will replace the current CE Directives on medical devices, active implantable medical devices and in-vitro diagnostic medical devices (European Commission, 2012b; 2012c). New rules are also being prepared for product groups not currently covered by the legislation on CE marking, such as fertiliser products (European Commission, 2016c).

The various product groups are shown in Figure 2.

Figure 2 List of product groups subject to CE marking

1.3 Audit scope and method

Audit question

This audit seeks to answer the following question:

How is it possible that products that do not comply with EU rules on CE marking are nonetheless sold on the European market, and what is the government doing in order to prevent and remedy this situation?

Operation of the CE system in the Netherlands

The CE system is a European system. The EU adopted the CE marking system as part of a raft of measures designed to pave the way for the creation of a single European market. The operation of the system is subject to the democratic control of the European Parliament and the member states. As an EU member state, the Netherlands has its own responsibilities. These include organising market surveillance and accreditation. We focused on the role played by the Netherlands in the CE system.

As we do not have a mandate in other member states, we are unable to examine how the system is organised both at a European level and in other EU member states. We therefore hope that the supreme audit institutions in other EU member states will undertake similar audits in order to obtain a broader picture of the operation of the CE system in Europe.

We were also unable to perform any audit activities at the EU itself. We did, however, examine a number of EU studies, as well as the member-state declaration submitted by the Netherlands to the EU.

Audit method

The main sources used in order to gain an insight into the CE system were document analyses, interviews and a number of sessions with experts from both the public and the private sector. See Appendix 3 for further information.

In order to find out which databases are used, we performed a *data inventory*. We also conducted in-depth interviews with data experts from the inspectorates, and analysed the data from RAPEX, the European rapid alert system for dangerous non-food products.

One of the things we did in order to ascertain how the system operates was to examine a number of incidents. Our principal source of information, however, came from two 'product journeys': we followed two products through the entire production and supply chain. We examined the role played by the Dutch government. We interviewed

companies, market surveillance authorities and customs. Further we audited databases held by market surveillance authorities and customs. The product journeys are shown in Appendices 1 and 2.

A full description of the audit methods used is given in Appendix 3.

2 Organisation of the CE system

The CE system is a European system in which both public-sector and private-sector actors have certain legal obligations. The basic principle underlying the CE system is that economic operators, i.e. manufacturers, importers and distributors, must ensure that the products they sell on the European market comply with the relevant EU requirements. Under the CE regulations, public-sector actors are responsible for ensuring that economic operators fulfil these obligations. For example, the EU member states are required to organise market surveillance and accreditation in their own territories.

The information provided to parliament about the CE system and the way in which it operates is fragmented. Each actor reports individually to parliament on the way in which it has discharged its responsibility. In many cases, these reports cover a wider range of topics than the system of CE marking alone. As a result, parliament is unable to form a general picture of how the system as a whole is operating, or of the areas in which improvements could be made, both by the Netherlands and by the EU.

This chapter describes the organisation of the CE system in general terms.[11] What are the rules and regulations governing the system and what roles are played by the various parties involved? The chapter concludes with a discussion of the consequences of this system in terms of the opportunities available to the Dutch parliament for performing its role as a watchdog in this particular area.

2.1 European legislation on CE marking

The body of EU legislation on CE marking is both massive and complex. The general rules are set out in Regulation (EC) No. 765/2008 of 9 July 2008 and the rules for affixing the CE marking on a product are set out in Decision No 768/2008/EC of 9 July 2008.[12]

Specific Directives and Regulations have been adopted for 27 different product groups. These specify, for each product group (and among other matters):

- the products that fall within the scope of the Directive or Regulation;
- the requirements that the products need to satisfy;
- the responsibilities and obligations of the parties concerned;
- the conformity assessment procedures that need to be followed;
- the requirements and conditions that need to be met in order for a CE marking to be placed on a product (where applicable).

There is a large and complex body of EU legislation on CE marking

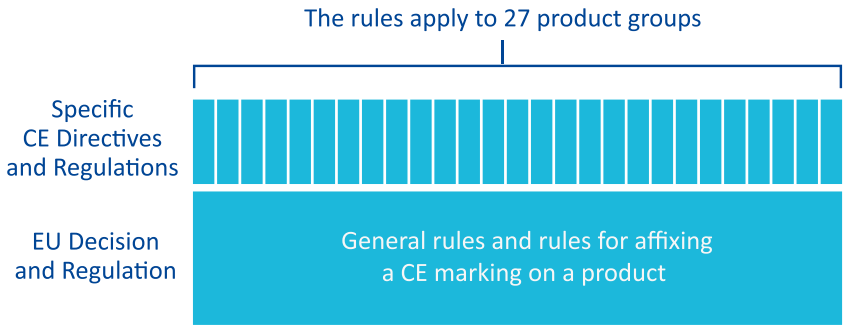


Figure 3 The rules on CE marking.

2.1.1 Essential requirements in Directives and Regulations

One of the characteristic features of the CE system is that it only contains certain 'essential requirements' with which products need to comply. These are formulated in general terms and specify the results that need to be obtained or the risks that need to be mitigated, for example in relation to product safety, health and environmental protection.

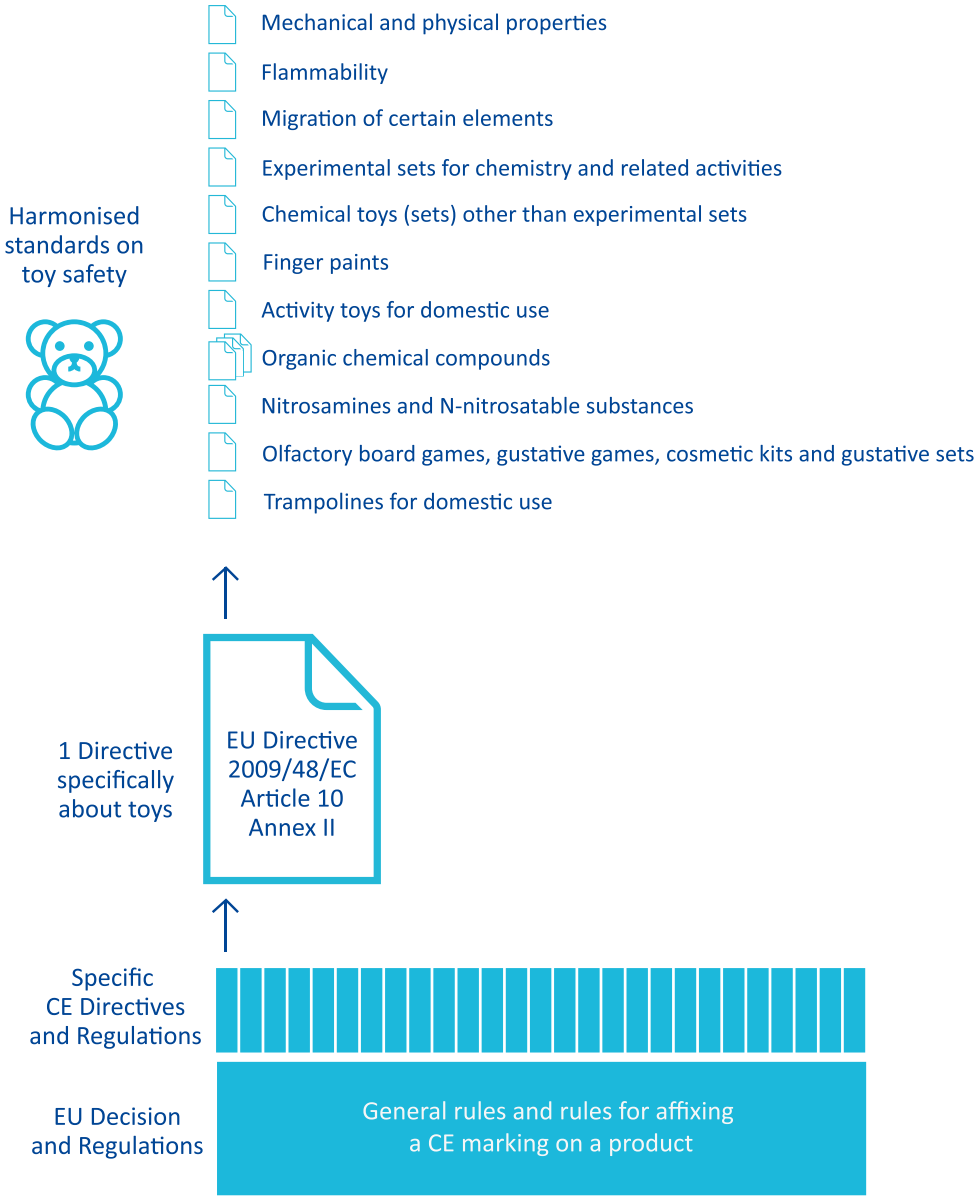
Example of essential requirements: Toy Safety Directive 2009/48/EC of 18 June 2009

1. Physical and mechanical properties […]
2. Accessible edges, protrusions, cords, cables and fastenings on toys must be designed and manufactured in such a way that the risks of physical injury from contact with them are reduced as far as possible.
3. Toys must be designed and manufactured in such a way as not to present any risk or only the minimum risk inherent to their use which could be caused by the movement of their parts.
4. a) Toys and their parts must not present a risk of strangulation. […]

2.1.2 From essential requirements to technical standards

The technical details of the essential requirements are not set out in European law.[13] Rather, they are laid down in the form of what are known as 'harmonised standards'.

Harmonised standards spell out the essential requirements, as in the case of toy safety



Source: Dutch Toy Safety Guidelines, NEN Standard (2016)

Figure 4 Rules and standards on toy safety.

The harmonised standards are voluntary: although manufacturers are free to use the standards in order to show that a given product complies with the essential requirements under the relevant CE legislation, they are equally free to do so in another way (European Commission, 2016b). There is an advantage to be gained from making use of the

standards, however: products which meet the harmonised standards are presumed to be in conformity with the applicable essential requirements.[14]

At the time of writing (2016), there were over 3,500 harmonised standards in operation for the 23 CE Directives and the single CE Regulation.

2.1.3 Development of harmonised standards

Unlike the essential requirements in the CE regulations, the harmonised standards are not drafted by the European Commission. Instead, they are developed by both public-sector and private-sector stakeholders such as manufacturers, importers, retailers and consultants. The drafting process is overseen by domestic and European standardisation institutes.[15]

Standardisation organisations

There are three European standardisation bodies: the European Committee for Standardisation (CEN), the European Committee for Electro-technical Standardisation (CENELEC), and the European Telecommunications Standards Institute (ETSI). Alongside these European organisations, each member state has one or more national standardisation bodies, whose job involves coordinating and facilitating the member state's contributions to European standardisation procedures. There are two designated national standardisation bodies in the Netherlands, NEN (the Dutch Standardisation Institute) and NEC (the Dutch Electro-technical Committee).

The European Commission leaves the details to the involved parties (through their membership of standardisation organisations)

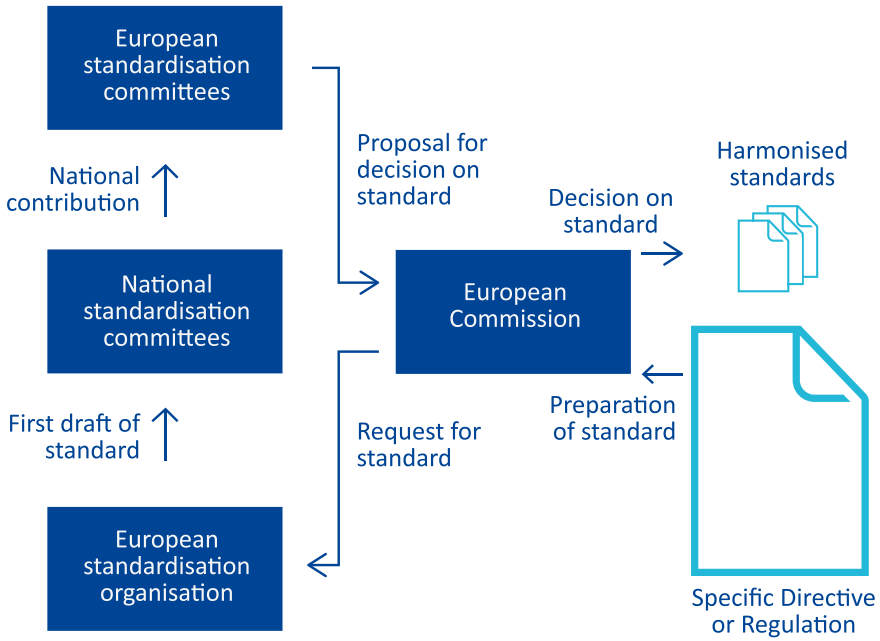


Figure 5 The procedure for creating harmonised standards.

The European Commission may request one of the European standardisation bodies to develop a harmonised European standard for a particular CE Directive or Regulation. A technical committee first draws up a draft text. This is discussed by national standardisation committees in each of the EU member states. The members of these committees include national stakeholders such as manufacturers and consultants.

The representatives of the various national standardisation committees then meet in a European standardisation committee, where they together decide on the draft European standard, based on their respective national positions. A draft standard passes back and forth a number of times during the various stages of the preparation process, i.e. from request to final version.

We found that the process of preparing a harmonised standard is a dynamic process lasting a number of years and is also of a highly technical, specialist nature.

Moreover, not all standards developed under the European standardisation process ultimately acquire the status of a harmonised standard. In the end, it is the European Commission

that decides whether a standard complies with the original request and satisfies the essential requirements to a sufficient degree.

Representativeness in the standardisation process

The success of standardisation hinges on the willingness of private-sector parties to invest time and money in the development of standards. Under EU legislation, the appropriate representation and effective participation of all stakeholders – including small and medium-sized businesses and consumer organisations – is a vital aspect of the standardisation process, particularly where the public interest is at stake.[16]

However, a review by the European Commission in 2015 showed that, generally speaking, small and medium-sized businesses are not particularly well represented in the European standardisation process. For many such firms, the benefits of contributing to the process are outweighed by the costs, in the form for example of contributions to standardisation committees, and travel expenses and staff costs relating to the representatives (European Commission, 2015a). Large companies, on the other hand, tend to be overrepresented in the standardisation procedure (European Commission, 2015a). As they are often members of national standardisation committees in more than one member state, big companies tend to have a greater say in the decision-making process.

The impression we obtained from our audit is that the private sector is the main driver of the standardisation process in the Netherlands. Although European law stresses that government bodies such as market surveillance authorities should also be involved in these procedures, the Dutch government is usually only an informal member of Dutch standardisation committees. This is partly a result of spending cuts and the highly technical nature of the procedure. This means that the Dutch government is less directly engaged in the process than it might be.[17]

2.2 The actors in the CE system

Apart from stating the requirements with which products need to comply, EU legislation on CE marking also specifies the parties that have certain obligations and responsibilities in the CE system.

The following figure shows the various parties involved in the CE system.

Parties involved in the CE system in the Netherlands

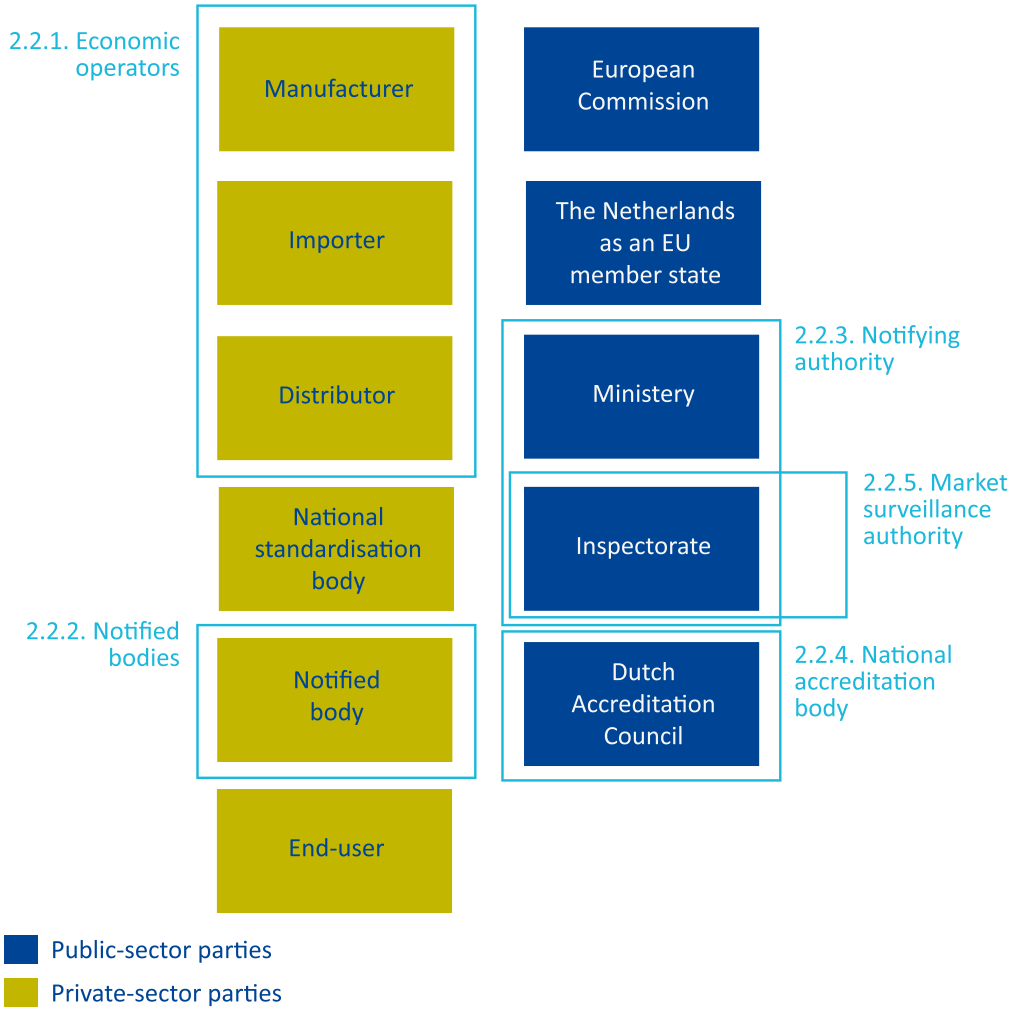


Figure 6 Private-sector and public-sector parties involved in the CE marking system.

2.2.1 Economic operators

Under the legislation on CE marking, the economic operators, i.e. manufacturers,[18] importers and distributors, are required to fulfil certain obligations. The basic principle underlying the system of CE marking is that manufacturers must ensure that the products

they sell on the European market comply with EU requirements and that they have been properly assessed and tested.[19] By affixing a CE marking on a product, the manufacturer declares that it complies with all the prevailing EU legislation on aspects such as safety, reliability, health and the environment.

It makes no difference whether the manufacturer is based in or outside the EU: as soon as a manufacturer brings a product onto the European market, it is required to comply with all EU legislation, including the regulations on CE marking.

EU legislation on CE marking also imposes certain obligations on other economic operators, such as importers and distributors. For example, before a product is sold on the market, the importer must ensure that the manufacturer has performed a proper conformity assessment, that the product displays a CE marking, and that the appropriate technical product documentation is present.

2.2.2 Notified bodies

There are a large number of products in relation to which the manufacturer is entitled to judge for itself whether they are in conformity with the relevant EU requirements. In the case of particular, often relatively high-risk products (such as lifts and certain medical devices), EU legislation states that the manufacturer must engage a third party to carry out one or more aspects of the assessment procedure. This conformity assessment body carries out an independent review in order to establish whether the product, the product design and/or the production process are in conformity with the relevant Community legislation.

The EU member states are obliged to notify the European Commission of the existence of these conformity assessment bodies in their territory (known therefore as 'notified bodies'). The Dutch government has registered 49 bodies in the *New Approach Notified and Designated Organisations Information System* (NANDO), the European registration system for conformity assessment bodies (European Commission, undated).

2.2.3 Notifying authority

Every EU member state is obliged to designate a government authority or public body that is responsible for assessing conformity assessment bodies and making the appropriate notifications to the European Commission. The practice in the Netherlands is for the ministries to act as notifying authorities. In some cases, a ministry delegates this responsibility, for example to the inspectorate responsible for enforcing the relevant EU Directive.

2.2.4 National accreditation body

Before a conformity assessment body can be registered with the European Commission, the member state in question first needs to assess whether the body is technically competent, is fit to carry out the assessment procedures prescribed under the legislation on CE marking, is sufficiently independent, and meets high ethical standards. Under Community legislation, member states are free to adopt either a system of accreditation or another, equivalent method of assessment. Although not compulsory, accreditation is the preferred way to assess the technical competence of conformity assessment bodies. This is why each member state is required to designate a single national accreditation body that is capable of carrying out accreditations.[20] The relevant body in the Netherlands is an autonomous administrative authority called the Dutch Accreditation Council.

2.2.5 Market surveillance authorities: supervising products sold on the market

Under EU legislation on CE marking member states are required to organise market surveillance. The way in which member states organise market surveillance is subject to certain requirements: member states must adopt procedures for market surveillance, draw up market surveillance programmes, and evaluate and assess the work of market surveillance authorities. They are required to designate market surveillance authorities and entrust them with the necessary powers, resources and knowledge.[21] The market surveillance authorities in the Netherlands consist of a number of national inspectorates, including the Food and Consumer Product Safety Authority and the Human Environment and Transport Inspectorate (see chapter 4).

2.3 The effects of the CE system on democratic control

As we have already explained, the system of CE marking is set out in EU legislation, and economic operators who place products on the European market are responsible for ensuring that these products comply with the relevant legislation. This has certain consequences for the legislative and monitoring and controlling duties of the member states' parliaments, including the Dutch parliament.

EU legislation on CE marking is adopted in accordance with what is known as the 'ordinary legislative procedure'.[22] Basically, this means that the European Commission submits a proposal, which both the Council of Ministers and the European Parliament are entitled to either approve or amend.

Dutch parliamentary influence over the EU legislative process

The EU Ministers of Economic Affairs meet four or five times a year in the Competitiveness Council. The Council has a legislative and budgetary responsibility in partnership with the European Parliament. The Council is required to approve a legislative proposal submitted by the European Commission. National governments can exert influence through their representatives in the Council.

In the Netherlands, the Dutch House of Representatives' standing committee on economic affairs may discuss the meetings of the Competitiveness Council with the Minister of Economic Affairs if it wishes to do so. The standing committee is also entitled to ask the Minister of Economic Affairs to place a particular item on the Competitiveness Council's agenda. In 2016, for example, the House of Representatives asked the Minister to make a reservation under which the Dutch parliament would be able to subject plans for selling fertiliser products bearing a CE marking to parliamentary scrutiny (House of Representatives, 2016).

The Minister of Economic Affairs sends the standing committee on economic affairs a report on the meetings of the Competitiveness Council. Depending on its content, the committee may wish to ask the Minister a number of written questions and/or to discuss the matter further in the form of a general parliamentary consultation.

The CE system is a European system run by the European Commission's *DG Growth*, whose work in relation to the system of CE marking involves constantly developing, monitoring and adjusting the EU's harmonisation legislation on products. To this end, the DG makes use of the market surveillance reviews submitted by the member states and also facilitates the creation of databases for market surveillance authorities to use. The Commissioner in charge of DG Growth is the Commissioner for Internal Market and Services, who is responsible (among other things) for the policy on CE marking and is required to inform the European Parliament on the state of affairs in this respect.

The EU member states, including the Netherlands, have certain statutory obligations in relation to the CE marking process. The Netherlands is required to enforce Community legislation on CE marking. This means first of all that EU Directives must be transposed into national law and that, in certain cases, Dutch law must be adjusted in order to enable EU legislation on CE marking to be implemented in the Netherlands. Secondly, under the terms of EU legislation, the Netherlands is required to organise market surveillance and accreditation. These are the areas on which the Dutch parliament is able to exert influence over the implementation of the CE system within the Dutch borders.

A large number of public-sector actors are involved in policy-making in the Netherlands in relation to, and the practical implementation of, the CE system: six ministers, five national inspectorates and a number of 'autonomous administrative authorities' (government

agencies). These actors all have a role to play in the CE system and each of them reports individually to parliament on the way in which they have discharged their responsibility. In many cases, these reports cover a broader range of topics than the system of CE marking alone. As a result, parliament is unable to form a general picture of how well the system as a whole is operating and of areas in which improvements could be made, both by the Netherlands and by the EU.

3 Producing for the market

The operation of the CE system is built largely on trust in the economic operators. They are the ones who must ensure that products they sell on the European market meet the relevant EU requirements. In practice, however, the market surveillance authorities often come across products that fall a long way short of complying with the relevant EU requirements. One of the possible reasons why certain products fail to comply with the relevant EU requirements is the presence of certain weaknesses in the CE system. The commercial interests of the economic operators are not necessarily compatible with the public interests that the CE system is intended to serve. We also uncovered a number of problems in the conformity assessment procedure.

3.1 Conformity of products on the European market

The basic principle underlying the CE system is that economic operators, notably manufacturers, must ensure that the products they sell on the European market comply with EU health and safety requirements, that they have been properly assessed *and* that they carry a CE marking. In practice, however, not all economic operators actually comply with their obligations. They sell products on the European market that do not comply with Community legislation. These may be:

- products on which the manufacturer has affixed a CE marking even though they do not comply with the relevant EU requirements;
- products on which the manufacturer has not affixed a CE marking even though it should have done;
- products on which the manufacturer has affixed a CE marking even though they are not subject to the regulations on CE marking.

The European Commission claims that it is impossible to say what proportion of the products sold on the European market are non-compliant (European Commission 2015b). The problem is that there are a large number of products in circulation whose non-compliant status is never actually established.

What is clear is that, on average, over 1,600 products were withdrawn from the European market and/or recalled from end-users every year between 2005 and 2015, after market surveillance authorities found that these products did not comply with EU legislation and posed a serious risk to consumer health or safety.[23] Half of these cases involved products that were subject to the regulations on CE marking.

Only a small proportion of total RAPEX notifications come from the Netherlands

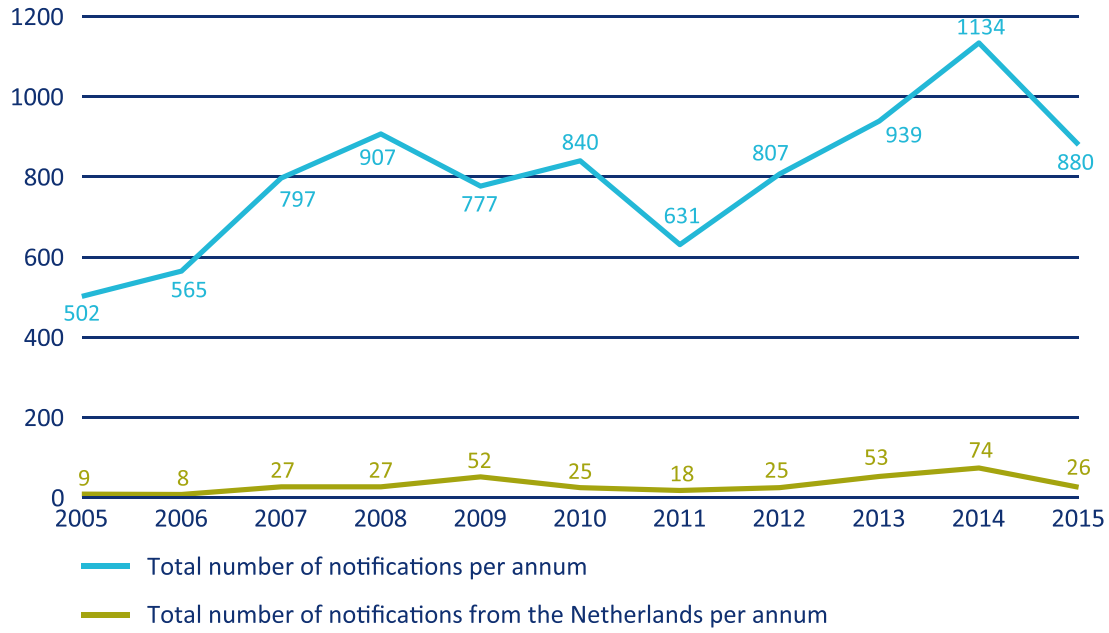


Figure 7 Number of RAPEX notifications of products bearing a CE marking, per annum, 2005-2015.

It is worth pointing out that not all products that do not comply with EU legislation pose a serious risk to consumer health and safety, as is the case with products that are registered in the RAPEX database. In some cases, only minor problems are involved and in others, the products do not meet certain administrative requirements.

In other words, the fact that a product is non-compliant does not automatically imply that it will affect the health or safety of end-users. It may, however, make the single European market less of a *level playing field*. Economic operators who sell products on the European market without complying with the CE regulations may derive an unfair competitive advantage over economic operators who meet the rules on CE marking.

According to the European Commission, inspection findings show that, between 2010 and 2013, over 30% of the inspected toys, 55% of the inspected construction products and 40% of the inspected items of personal protective equipment were found either not to comply or not to comply fully with EU requirements (European Commission, 2015b).[24] As far as

the EU Directive 'establishing a framework for ecodesign requirements for energy-related products' is concerned, it is estimated that between 10% and 20% of the products sold on the market do not comply, either fully or partly, with the relevant EU requirements (Centre for Strategy & Evaluation Services, 2012). The estimated figure in relation to gas cookers is between 5% and 10% (RPA Risk & Policy Analysts Ltd., 2012).

3.2 Tension between commercial and public interests

The fact that market surveillance authorities regularly withdraw non-compliant products from the market suggests there is good reason to suspect that economic operators do not always satisfy, or are not always able to satisfy, their obligations under the CE regulations.

In more general terms, there is an inherent tension in the way the CE system is designed: the commercial interests of the economic operators (such as their desire to increase their market share and maximise their profits) are not automatically compatible with the need to safeguard public interests, as is the purpose of the CE system.

Not all economic operators are prepared to guarantee their willingness to safeguard the public interests that the CE system is intended to protect, particularly if there are no powerful incentives for complying with the CE regulations and the costs are relatively high. For competitive reasons, these economic operators will tend either to abdicate their responsibilities under the CE system or to discharge them only to a limited degree: in other words, they either ignore the CE rules or comply with them only loosely (European Commission, 2015b). One of the most infamous examples of the recent past involved a French company called PIP, which sold breast implants bearing a CE marking. These were found to have been filled with an industrial-grade silicone gel instead of an approved medicinal silicone gel. The industrial-grade gel was not suited for use in the human body and posed a heightened risk of tearing and leakage. When this came to light, the company's PIP and M-Implants were recalled and taken off the market.

Particularly in high-volume markets, the current system makes it relatively easy for manufacturers and traders who are not interested in playing by the rules to sell their products on the European market. For example, there is a ready trade in containers for operators who are willing to take a risk. They buy cheap containers – contents and all – for a low price, in China for example, and then sell them on to other parties as quickly as they can, without bothering to undertake a proper assessment as to whether or not they comply with Community legislation. Many of these are fairly small firms that simply close down their business (together with any associated web shop) as soon as anything goes wrong. Some of them continue in operation, but under a different name. On the same lines,

Toy Industries of Europe (TIE), the association of European toy manufacturers, has noted that the majority of the toy manufacturers registered in the RAPEX database in 2015 were not TIE members and indeed were not even known to the association's members (TIE, 2016).

For many of these traders, 'market discipline', i.e. the risk of losing customers or suffering reputational damage, represents no more than a limited incentive for complying with the regulations on CE marking. A system of retrospective enforcement is both necessary and indispensable for this reason. We will be discussing this in more detail in chapter 4.

3.3 Weaknesses in the practice of conformity assessment

The CE system is regulated in such a way that economic operators have plenty of opportunity to allow commercial interests to prevail over public interests. We encountered a number of specific weaknesses in the conformity assessment procedure during our audit. These may explain why products are sold on the market that do not comply with EU legislation.

We will now discuss these specific weaknesses in the CE system. We first describe the various stages of the process that a manufacturer is required to complete under the CE legislation before a product (for which a CE marking is compulsory) may be sold.

The conformity assessment procedure

Before a manufacturer can place a CE marking on a product, it first has to establish, in both the design and the production stage, that the product in question satisfies the relevant EU regulations. This is known as a 'conformity assessment'. The conformity assessment procedure consists of the following five stages:

- identify the applicable CE Directive(s)/Regulation and harmonised standards;
- identify whether an independent conformity assessment is required from a notified body;
- test the product to check its conformity;
- draw up the required technical documentation;
- draw up an 'EU Declaration of Conformity' and place the CE marking on the product.

These stages are shown in the following figure.

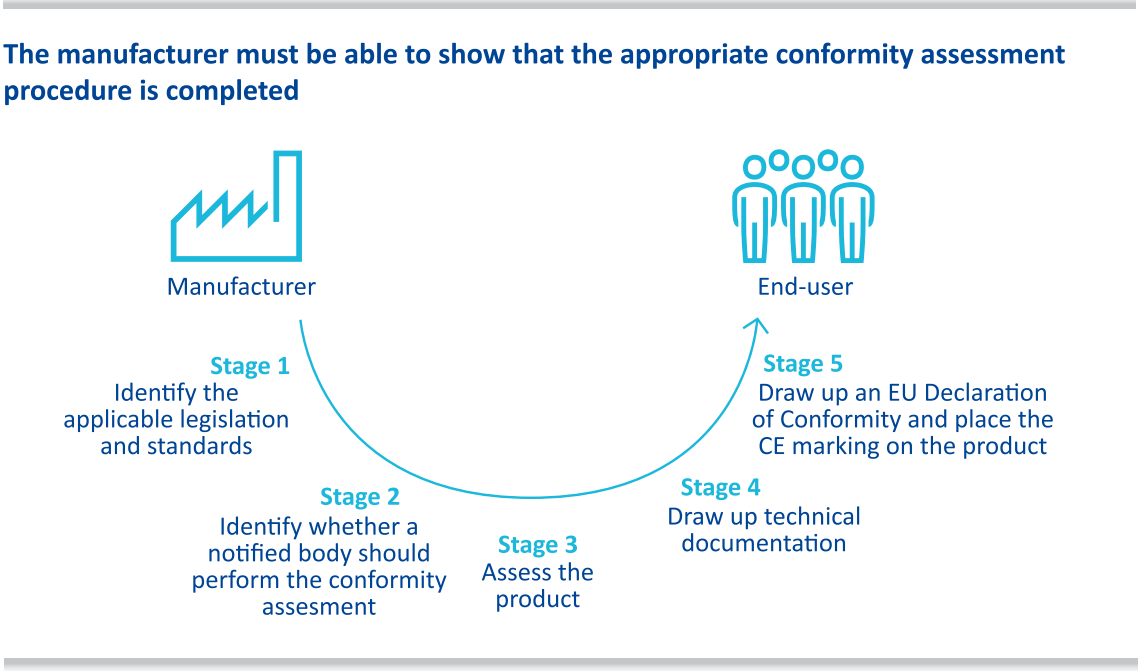


Figure 8 Stages of the conformity assessment process that manufacturers are required to follow.

3.3.1 Stage 1: Identify the applicable legislation and standards

In the first stage in the conformity assessment process, the manufacturer is required to identify the specific CE Directives or Regulation to which the product is subject. Having done this, it must then establish which harmonised standards apply to the product. Some products are covered by more than one Directive or Regulation.

Limited knowledge of complex body of legislation

The body of EU legislation on CE marking is both substantial and complex. Small firms and start-ups in particular tend not to be familiar with the contents of this legislation (European Commission, 2015b). Moreover, they face an added problem in that the costs of using harmonised standards may form a barrier to actually applying them. There is therefore a risk that the product they manufacture might not comply with the essential requirements set out in the relevant CE Directive or Regulation.

Relatively high cost of complying with CE legislation

The *Evaluation of the internal market Legislation for Industrial Products* shows that it takes time – and hence money – to find out what the legislation entails and subsequently to implement it. On average, the cost of compliance represents between 15% and 20% of companies' aggregate HRM expenditure. In other words, businesses that comply with the rules pay more to do so. This has an adverse impact on their competitiveness compared with firms that either ignore the rules or are simply unaware of their existence (European Commission, 2014).

Innovative products are not necessarily covered by existing standards

Although the process of standardisation is dynamic, and standards are subject to continuous refinement, we found that new and innovative products and designs are not necessarily covered by existing legislation and standards.

Product journey of a portable gas cooker: see Appendix 2

We tracked the journey of a portable gas cooker, an innovative product. The manufacturer had designed a new type of camping gas cooker in which the gas cylinder is positioned next to the gas ring instead of underneath it.

The market surveillance authority tested the product following a series of accidents that had caused serious injuries. The product was found strictly speaking to be in compliance with the harmonised European standard for liquefied gas appliances (NEN, 2006) and hence with the essential requirements set out in the EU Gas Appliances Directive. In practice, however, large pans were used on the cooker, causing the gas cylinder to overheat. The harmonised European standard for liquefied gas appliances did not make any allowance for the cooker being used in this way.

3.3.2 Stage 2: Identify whether a notified body should perform the conformity assessment

The CE legislation specifies, for each product group and for each risk category within each product group, how a manufacturer must show that a product complies with EU requirements.

There are a large number of products for which manufacturers are entitled to perform the conformity assessment themselves. However, in the case of high-risk products such as lifts, gas appliances or certain medical devices, the manufacturer is required to engage a 'notified body'. The notified body performs an independent assessment of whether the product, the product design and/or the production process complies with the relevant EU legislation.

The manufacturer decides, on the basis of the regulations, whether to assess the product itself or to ask a notified body to do so

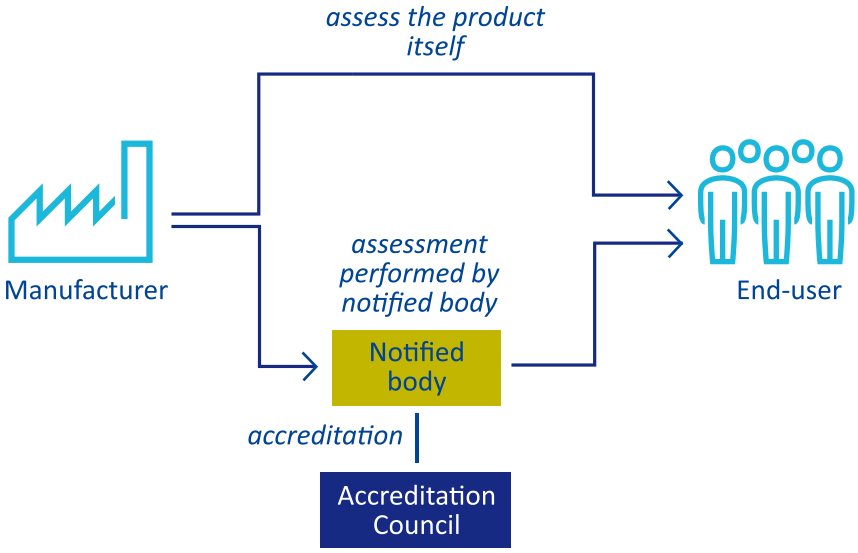


Figure 9 Manufacturer decides who will perform the conformity assessment.

Manufacturers are free to choose a notified body, but there are big disparities between these notified bodies them in terms of quality

The notified bodies are private-law legal entities operating in a competitive, open market in which they are free to offer their services throughout the EU, subject to the limitations of their remit. In other words, a manufacturer based in Hungary is free to engage a notified body based in Belgium. Not only notified bodies, but also manufacturers and market surveillance authorities pointed out during our audit that, in practice, there are wide quality discrepancies between the notified bodies. Some notified bodies are keen to stand out from their competitors as offering a high-quality service, whereas others compete more on price.

Shortcomings in the performance of notified bodies

We identified a number of shortcomings in the performance of notified bodies within the EU. The European Commission is concerned about the disparities in the quality of notified bodies. The same applies to their independence from manufacturers (Van der Voort, 2013; 2016). It was for this reason that the European Commission tightened up the requirements for notified bodies assessing the conformity of medical devices. This recently led to a reduction in the number of notified bodies involved in the assessment of high-risk medical devices.

The database of notified bodies is corrupted

All notified bodies in Europe are listed in an electronic database called NANDO (New Approach Notified and Designated Organisations). Manufacturers can use the NANDO website to see which notified bodies they can use for conformity assessments. The European Commission found that the information held on over 800 of the total of more than 1,700 notified bodies in the NANDO database was either out of date, unclear or incomplete (European Commission, 2015c). Although the European Commission cleaned up the database during the course of the audit, it remains inaccurate: one and the same legal entity still has more than one identification number, for example. This is not as it should be (European Commission, 2016b, p. 86).

Product journey of a portable gas cooker: see Appendix 2

If a product has been assessed by a notified body, a four-figure code is placed next to the CE marking. This code is supposed to correspond with the name of the notified body. We found that the gas cooker in question had not been assessed by the notified body whose name corresponded with the code displayed on the product. The notified body said that it had approved a design similar to that of the product in question.

3.3.3 Stage 3: Assess the product

Once it has been decided whether the product needs to be assessed by a notified body , testing can begin. The operation of the CE system is largely a matter of trust in the economic operators. They are the ones who are assumed to assess a product in accordance with the appropriate procedure.

It is hard to assess the conformity of products bought in other countries

Many manufacturers buy raw materials or components in other countries, or outsource certain production activities. Even if this is the case, the manufacturer is still responsible for guaranteeing the conformity of the product that it sells on the European market. The manufacturer is required to ascertain the properties of the raw materials or components it uses. It must assess whether the product complies with the relevant requirements, even if it is being produced as part of a series. For example, the Toy Safety Directive states that "Manufacturers shall ensure that procedures are in place for series production to remain in conformity."[25]

In practice, it may be hard for manufacturers to know whether certain raw materials or components are compliant, particularly if they have been imported from non-EU countries.

Product journey of a toy: see Appendix 1

The manufacturer imported one of the components of the toy from China. When the manufacturer first launched the product on the market, it decided that it was in conformity with all relevant EU legislation. Once the product had been placed on the market and a number of batches were found to comply with EU requirements, the manufacturer gradually phased out the checks of incoming components. When the supplier suddenly started using a different raw material for the particular component, the manufacturer failed to take note of this. It was not until the Food and Consumer Product Safety Authority tested the product that it was found no longer to be in compliance with the relevant requirements. The test showed that the product's phthalate (i.e. plasticiser) content was much too high.

Cost of testing may be high

In many cases, toys are subjected not just to physical tests of their mechanical properties, but also to chemical tests. The object of the latter is to ascertain whether any harmful raw materials were used in its production. Manufacturers gave us to understand that expensive equipment is often needed to perform these tests and that, as a consequence, they are often outsourced to external laboratories. The cost of testing may be high as a result. For example, every colour included in the toy must be subjected to separate checks for the presence of heavy metals. The high level of cost also prompts manufacturers to make risk assessments in which they compare the cost with the risk of accidents occurring or the market surveillance authority ordering an inspection.

3.3.4 Stage 4: Draw up technical documentation

Once the product has been assessed (either by a notified body or by the manufacturer itself), the manufacturer or importer is required to draw up a set of technical documentation showing that the product complies with all relevant EU requirements.

Lack of transparency about the production process

The main problem here is that manufacturers are not keen to disclose the technical documentation and the details of their production process, principally for competitive reasons. There is no reason to assume that, in a system run largely by the private sector, players will readily espouse key public-sector values such as transparency. In many cases, it is not in a company's commercial interests to provide greater openness, for example by publishing test results or by making product trails easier to follow. Indeed, importers often decide to sell products under their own name so as to keep competitors in the dark about their provenance.

Product journey of a toy: see Appendix 1

The toy was shipped to the Netherlands from China as a number of separate components, which the importer then assembled in the Netherlands. By doing so, the importer became the product's manufacturer. In certain cases, the same importer/manufacturer produces the toy, or certain parts of the toy, itself, provided the cost price is competitive.

3.3.5 Stage 5: Draw up an EU Declaration of Conformity and place the CE marking on the product

The manufacturer or importer then issues an 'EU Declaration of Conformity' stating that the product meets the relevant requirements. Once this has been done, the manufacturer can affix a CE marking on the product signifying that it complies with all the relevant statutory regulations.

Product journey of a toy: see Appendix 1

In November 2015, we bought a product carrying the same European Article Number (EAN) code as that listed in the RAPEX database in a Dutch shop. When we made enquiries about it, however, we discovered that it was a new version of the product and that its plasticiser content was under the maximum limit. Because the manufacturer still had a lot of old packaging materials left, it had decided to sell the new versions of the product in the old packaging. Consumer were thus unable to see from the packaging that the product was in fact 'safe'.

China Export logo looks like a CE marking

Another important point that has featured prominently in the media is the China Export logo placed on Chinese products, which looks very much like a CE marking. This can be a source of confusion for both consumers and market surveillance authorities. Our understanding is that, because the EU regulations on the CE system apply only in the EU, it is not a criminal offence in China to place a CE mark on a product that does not meet the requirements set out in the relevant EU legislation.

It is almost impossible to tell the difference between a CE mark and a China Export logo

Conformité Européenne

China Export

Figure 10 CE logo compared with China Export logo.

4 Market surveillance

The need to check compliance with the regulations on CE marking poses a number of challenges for the market surveillance authorities (Scientific Council for Government Policy, 2013). First of all, they have to deal with economic operators who are obliged to guarantee that their products comply with EU requirements, even though it may not be in their commercial interests to do so. Although the organisation of market surveillance is subject to EU regulations, the individual EU member states are themselves responsible for the practical aspects of market surveillance in relation to non-food consumer products bearing a CE marking. Each member state has its own specific market surveillance practices, which can lead to discrepancies in terms of enforcement and also to inequality before the law.

Another problem is that market surveillance authorities find it difficult to estimate the size of the market and the number of players involved. Many products are sold on large markets, by an unknown number of suppliers and as part of an international trade. While market surveillance authorities have to make a detailed, well-founded risk assessment precisely for this reason, it is difficult to do so without a good picture of the market as a whole. This problem could be solved by taking a different approach to market surveillance and making better use of the available data.

4.1 EU requirements for the organisation of market surveillance

Market surveillance is the tool that is used in order to prevent – or in any event minimise – the risk of non-compliance. Under EU legislation, the way in which member states organise this market surveillance is subject to certain requirements: member states must adopt procedures for market surveillance, draw up market surveillance plans, and evaluate and assess the work of market surveillance authorities. They are required to designate market surveillance authorities and entrust them with the necessary powers, resources and knowledge.

The aim of market surveillance in Europe

Under EU legislation, market surveillance is designed to achieve the following aim: to guarantee that products fulfil the applicable requirements by providing a high level of protection of public interests such as health and safety in general, health and safety in the workplace, protection of consumers, protection of the environment and security, while ensuring that the free movement of products is not restricted to any extent greater than that which is allowed under EU harmonisation legislation or any other relevant EU rule. Market surveillance entitles citizens to an equivalent level of protection throughout the single market, regardless of the origin of the product. Further, market surveillance is important for the interest of economic operators, because it helps to eliminate unfair competition (European Commission, 2016b).

4.1.1 Member states required to organise market surveillance themselves

One single European market, multiple national surveillance authorities

There is no single pan-European market surveillance authority for products. The operation of the single market is overseen by a number of national surveillance and enforcement systems. According to the European Commission's *DG Growth*, over 500 market surveillance authorities are active in the EU member states in the field of non-food products (European Commission, 2016d). The member states are expected to plan and implement their market surveillance systems themselves. While they are required to take due account of the provisions of Community legislation on the organisation of market surveillance authorities, they are free to decide on the practical details for themselves. For example, although the member states are required to designate market surveillance authorities and entrust them with the necessary powers, resources and knowledge,[26] it is up to each member state to decide what is actually entailed by 'the necessary resources'.

A *DG Growth* review of market surveillance of the CE marking system revealed big differences among member states in the deployment of inspectors. The number of inspectors deployed by Malta, Ireland and Romania, for example, is less than the equivalent of 50 FTEs. Denmark, Sweden, Finland and the Netherlands deploy between 50 and 100 FTEs. However, there are a number of big positive exceptions, including Italy (which employs 1,116 FTEs) and Poland (2,477 FTEs). It is also striking to note that statistics are not available for all countries: there are no figures on the number of FTEs deployed in 11 countries, including Germany, the UK, France and Greece (European Commission, 2016a).

We regard this diversity in market surveillance as one of the weaknesses of the CE system. The European Commission even states that "a major reason for the considerable number of non-compliant products on the market is that market surveillance does not operate effectively within the EU" (European Commission, 2013b).[27] Although we did not examine the effectiveness of market surveillance, it is clear that market surveillance in Europe is a chain, which is as strong as its weakest link. If market surveillance in a given country is not well organised, the risk of offenders being caught will be relatively slim and it will be easier to sell products that do not comply with the requirements.

Varied levels of cooperation with customs

Another example of differences in the practical implementation of market surveillance is the level of cooperation between market surveillance authorities and customs authorities. Huge numbers of products enter the single market every day by passing through the EEA's external borders. Given that it is up to each individual member state to decide whether its customs authorities should work in close collaboration with the market surveillance

authorities, the products entering the EEA are not subjected to the same conformity checks in each member state.

4.1.2 Cooperation and information-sharing among market surveillance authorities in different countries

Since market surveillance authorities work on a national basis, cooperation between market surveillance authorities and information-sharing among market surveillance authorities in the various member states is of vital importance. One of the main reasons for this is the fact that many products are sold in a number of countries.

International cooperation among market surveillance authorities

We noted a number of examples of cooperation. For example, the European Commission funds *'joint surveillance and enforcement actions'* with the aim of promoting closer international collaboration among market surveillance authorities. The emphasis in these *joint actions* generally lies on product testing, risk assessments, market monitoring, the exchange of information and the sharing of *best practices*. All the Dutch inspectorates responsible for supervising the market in products bearing CE markings (see section 4.2) take part in these *joint actions*.

Then there are the Administrative Cooperation Groups (AdCos). These are groups of market surveillance authorities created for a specific Directive or Regulation. The aim is to share information and work together on practical matters concerning the enforcement of Community legislation. All the Dutch inspectorates are members of one or more AdCos.

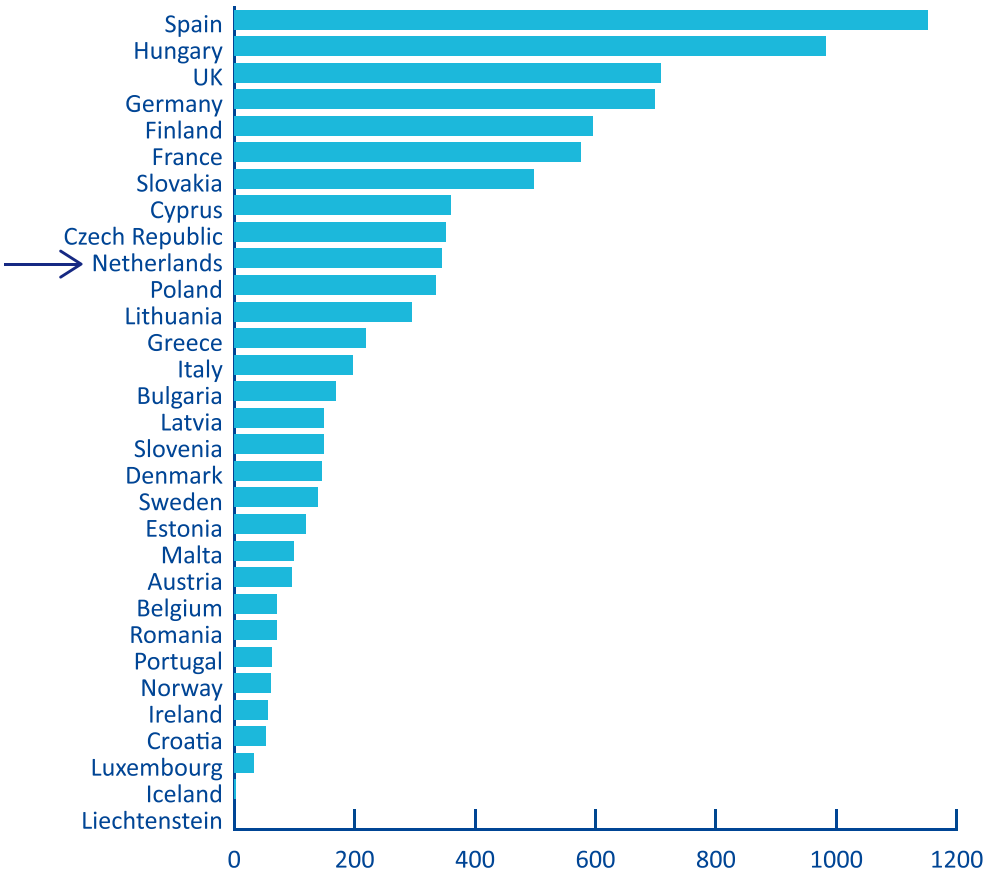
Adco: Radio and Telecommunications Terminal Equipment

The Dutch Radiocommunications Agency facilitated a meeting of the *Radio and Telecommunications Terminal Equipment* AdCo in The Hague in February 2016. Auditors from the Court of Audit were invited to attend as observers. Virtually all the EU member states were represented at the meeting, during which information was shared, practical experiences were discussed and practical arrangements were made for joint inspections of radio-controlled toys.

Information-sharing: analysis of RAPEX data

We found that not all countries and market surveillance authorities are equally active members of *joint actions* and *AdCos*. The same applies to notifications of non-compliant products: some countries are active notifiers, other countries are not. There are huge discrepancies in the numbers of notifications from one country to another. As Figure 11 shows, Spain, Hungary and the UK were responsible for the largest number of notifications in the period between 2005 and 2015. The Netherlands ranks tenth in terms of the number of notifications of unsafe products bearing a CE marking.

Spain, Hungary and the UK are responsible for the largest number of notifications of unsafe products with a CE marking in 2005-2015*



** See Appendix 3 for details of the method used.*

Figure 11 Number of RAPEX notifications of products with a CE marking, by country, 2005-2015.

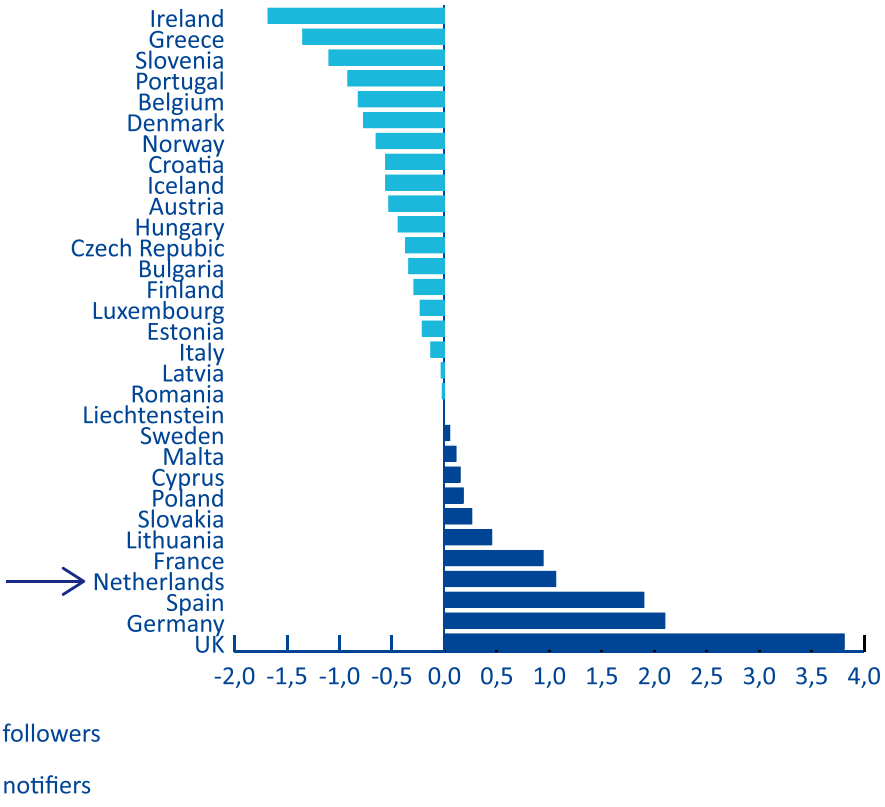
Market surveillance authorities in the various countries are expected to inform each other about non-compliant products, so that they can also be taken off the market in other countries. A European data exchange system known as RAPEX is available for this purpose. Countries can register product notifications in the RAPEX database. Other countries may then act on a notification made by one of the other countries. After analysing the data in the RAPEX database, we concluded that some countries are much more active notifiers than others. We also found that some countries are much more liable to act on notifications than others.

In our analysis, we labelled those countries that made a larger number of notifications than the number of notifications made by other countries that they themselves acted on as 'net

notifiers'. Countries that are more likely to act on notifications than to make notifications themselves we labelled as 'net followers'. Of the 8,779 notifications of products bearing a CE marking made in 2005–2015, 1,769 were acted on by one or more countries.[28] Our analysis showed that Ireland, Greece, Slovenia, Portugal and Belgium are the main net followers, whereas the UK, Germany, Spain, the Netherlands and France are the main net notifiers. The Netherlands ranks fourth in terms of the number of country notifications that are acted on (see Figure 12).

The following figure shows the net notifiers (with a positive score) and the net followers (with a negative score). Liechtenstein has never either made or acted on a notification, which is why it is listed with a score of 0 (see Appendix 3).

The Netherlands ranks fourth on the list of countries whose notifications are acted on*



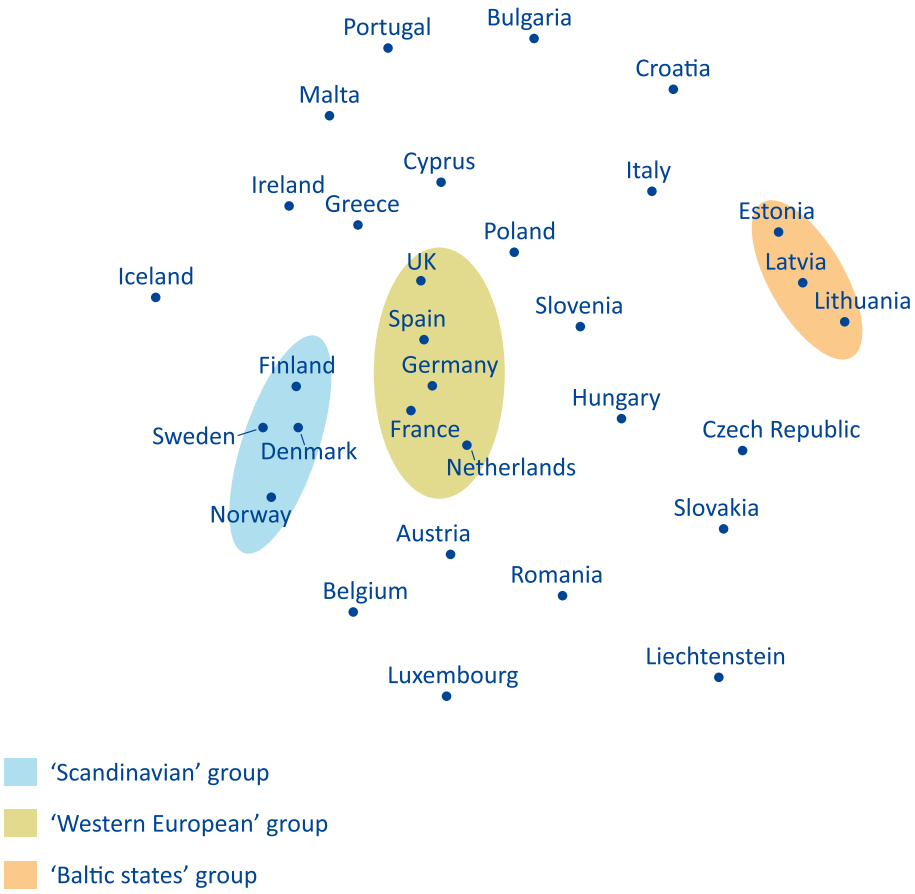
**See Appendix 3 for details for the method used. The countries listed above are members of the EEA, which is why Switzerland and Turkey are not included.*

Figure 12 List of net notifiers and net followers in RAPEX (1,769 notifications were acted on).

In order to make a more detailed analysis of the interrelationship between the European countries, we used a data visualisation method known as a 'multidimensional scaling'. This

involves approximating data with distances, thus producing a 'data map' showing the pattern of product notifications that were acted on. Those countries that are closer to each other on the map are more likely to act on each other's notifications than countries that are positioned more remotely from each other (see Appendix 3). This is shown in the following figure.

The greater the distance between countries, the smaller the number of product notifications that were acted on (data map*)



See Appendix 3 for details for the method used. The countries listed above are members of the EEA, which is why Switzerland and Turkey are not included.

Figure 13 Results of a multidimensional scale analysis of RAPEX data (see Appendix 3)

It is interesting to see that certain countries that are located in close geographic proximity to each other are also close to each other on the data map. For example, there are three groups of countries in the above figure that are close to each other both in geographic terms and on the map, i.e. the Baltic states (Estonia, Latvia and Lithuania), the Scandinavian countries (Finland, Norway, Sweden and Denmark) and the Western European countries (the UK, Spain, Germany, France and the Netherlands).

Although the data do not explain the differences between the net notifiers and the net followers, we believe that it is very much worth trying to find an explanation. In other words, why is it that some member states register more (or fewer, as the case may be) products in RAPEX than other member states? And why is it that notifications made by certain countries are more likely to be acted on than those made by other countries? Questions along these lines could help trigger a debate on cooperation among European market surveillance authorities.

4.2 Market surveillance in practice in the Netherlands

Just like every other member state, the Netherlands has its own specific way of implementing market surveillance in practice. This section discusses exactly how market surveillance operates in the Netherlands and which measures the Dutch government therefore regards as being 'necessary' in order to guarantee the effective operation of the surveillance system.

4.2.1 Five ministries and five inspectorates involved in market surveillance in the Netherlands

Under EU legislation, member states are required to designate market surveillance authorities and entrust them with the necessary powers, resources and knowledge. Within the Dutch government apparatus, five ministries are responsible from a policy viewpoint for implementing the CE regulations:

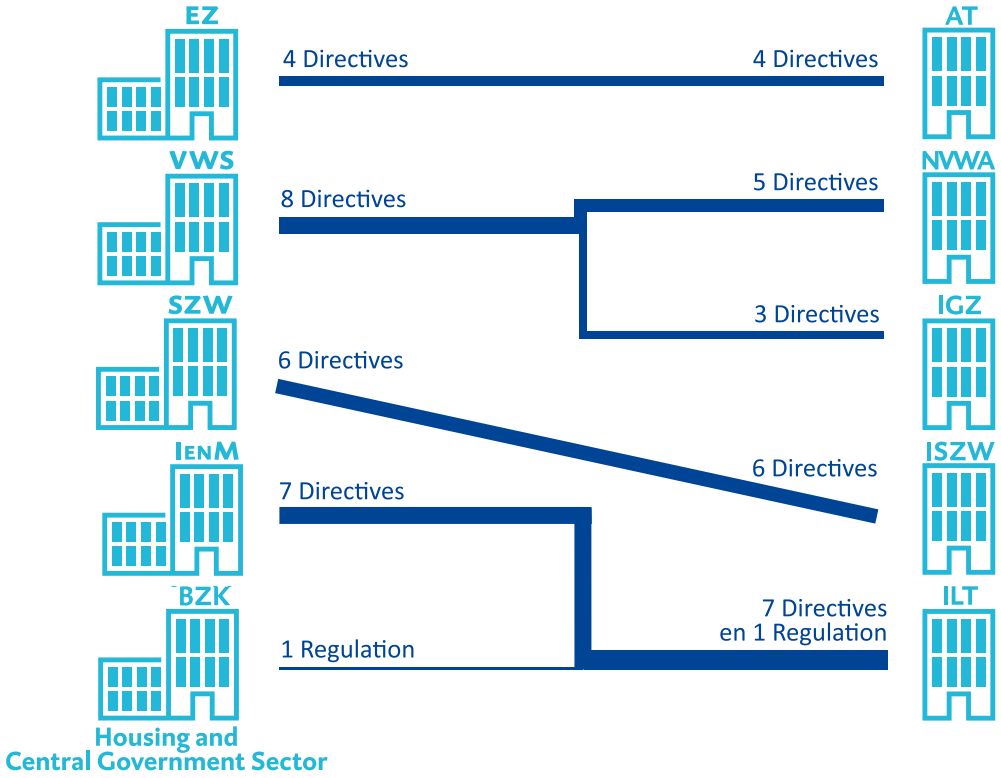
- the Ministry of Economic Affairs;
- the Ministry of Infrastructure and the Environment;
- the Ministry of Social Affairs and Employment;
- the Ministry of Health, Welfare and Sport;
- the Ministry of the Interior and Kingdom Relations.[29]

The ministries have delegated responsibility for supervising the operation of the market, and hence also for enforcing the rules on CE marking, to the following inspectorates:

- the Food and Consumer Product Safety Authority (which is accountable to the Ministry of Economic Affairs, in Dutch NVWA);
- the Radiocommunications Agency[30] (which is accountable to the Ministry of Economic Affairs, Dutch AT);
- the Healthcare Inspectorate (which is accountable to the Ministry of Health, Welfare and Sport in Dutch IGZ);
- the Social Affairs and Employment Inspectorate (which is accountable to the Ministry of Social Affairs and Employment, in Dutch ISZW);

- the Human Environment and Transport Inspectorate (which is accountable to the Ministry of Infrastructure and the Environment, in Dutch ILT).

Responsibility for supervising the implementation of the CE Directives* is distributed over five ministers



** The body of legislation consists of 23 Directives and 1 Regulation.*

Figure 14 Distribution of responsibility for supervising the CE system.

A number of ministries have asked inspectorates from other ministries to undertake market surveillance on their behalf. We believe that it is important in these cases that the ministers concerned should make arrangements about the division of responsibilities and the exercise of powers ensuing from their roles.[31]

In certain instances, the market surveillance authorities also work together with the customs authorities,[32] who are responsible for border controls. The nature of this collaboration is set out in the form of covenants and/or bilateral arrangements and involves information-sharing. In other words, the market surveillance authorities supply customs with risk profiles that the latter can act on, ranging from identifying high-risk cargoes to intercepting specific cargoes.

4.2.2 Capacity for market surveillance

Most inspectorates perform their market surveillance duties in addition to other monitoring activities for which they are responsible under other legislation. Thus, the Social Affairs and Employment Inspectorate also supervises the use of lifts, the Human Environment and Transport Inspectorate is responsible for the safety of road, water and air transport, and the Food and Consumer Product Safety Authority also monitors food safety. The capacity available specifically for supervising the market in products bearing a CE marking is relatively limited.

The five Dutch inspectorates had an aggregate budget of over €664 million in 2015. The inspectorates stated that they spent €25.9 million (3.9%) of this budget on market surveillance. A figure of €7.9 million (representing 1.2% of the aggregate budget) was earmarked specifically for supervising the implementation of the rules on CE marking.[33]

Only a fraction of the inspectorates' budget is available for market surveillance and supervising the CE system

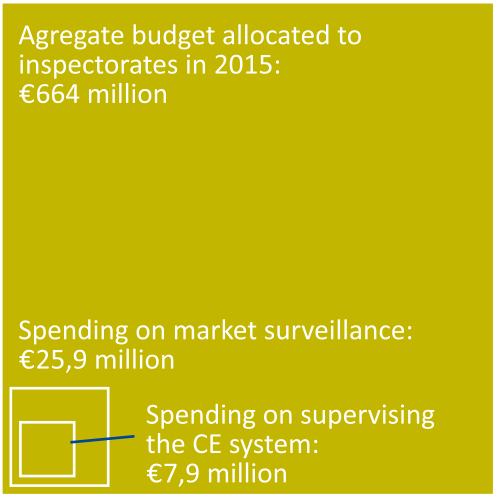


Figure 15 Funding allocated to the inspectorates.

The situation is the same in terms of FTEs: only a small proportion of the workforce employed by the inspectorates work on market surveillance: 242 FTEs (4.3% of the total). Of this figure, a much smaller number are specifically involved in monitoring the CE system: 65 FTEs (1.2% of the total). As we have already mentioned, the Dutch inspectorates have various other responsibilities in addition to the market surveillance of products. Thus, the Food and Consumer Product Safety Authority employed a total workforce of 2,438 FTEs in 2015 and the Social Affairs and Employment Inspectorate had a staff complement of 1,185 FTEs.

The Dutch inspectorates performed a total of 12,755 product checks or investigations in 2015. Of these, 3,722 involved products with a CE marking. We were not able to ascertain what percentage this represents of the total number of products on the Dutch market, partly because the Dutch inspectorates hold only a limited amount of data on this. The Food and Consumer Product Safety Authority did give us to understand that about six million containers with non-food products arrive in Dutch ports from China every year and that the Authority is only able to examine some 300 of these. On the basis of the risk profiles drawn up by the Authority, customs warn the Authority about high-risk cargoes. Whether the Authority then proceeds to examine the cargoes in question depends on the staff capacity that is available at that particular moment.

Only a fraction of the inspectorates' workforce is available for market surveillance and supervising the CE system

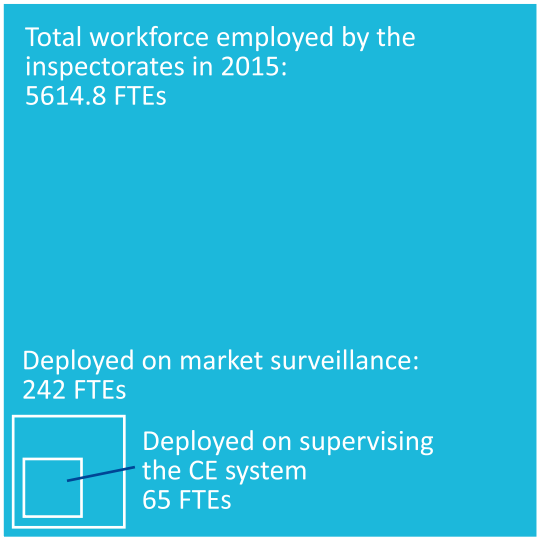


Figure 16 Staff capacity of the Dutch inspectorates.

4.2.3 Forming a picture of the size of the market

It is difficult for market surveillance authorities to build up a picture of the size of the market covered by the regulations on CE marking. Although firms operating on the market are required to register with the Chamber of Commerce, they are not required to specify exactly which products they sell. Moreover, the market is constantly changing, with more and more small businesses and pop-up stores joining the fray and consumers being able to go online to buy products from outside the EU. According to a rough estimate by the Food

and Consumer Product Safety Authority, there are approximately 250,000 'monitoring points' in the Netherlands (ranging from vast warehouses to tiny kiosks) holding products bearing a CE marking.

The Radiocommunications Agency, the Human Environment and Transport Inspectorate and the Social Affairs and Employment Inspectorate stated that the markets covered by certain Directives are huge and that it is either difficult or impossible to estimate the size of the overall market. This is because, although industry associations, the Chamber of Commerce and the central statistical office have access to data on economic operators, this data is not always readily compatible with the product groups listed in the CE regulations and not all of it is publicly accessible. Moreover, it is not always possible to access data held in international databases such as RAPEX, and the computer systems used by the inspectorates are not always able to process and analyse the data even if it is obtainable. For example, files and programs are often difficult – or even impossible – to unlock (see section 4.3).

4.2.4 Risk assessments

Precisely in those situations in which surveillance authorities are required to monitor a large market, making it impossible to inspect every operator every year, it is vitally important to base inspections on the outcome of risk assessments. However, a risk assessment cannot be performed without a clear picture of the market: in other words, which companies manufacture or import products? How many large and small businesses are there? What are high-risk products? Which businesses are previous offenders? As we have already made clear, this information is hard to come by.

Dutch market surveillance authorities do their best to perform risk-based inspections (Scientific Council for Government Policy, 2013). Their risk assessments are based largely on the views of inspectors (*'expert judgements'*) and warnings about unsafe products received from manufacturers, industry associations and other European market surveillance authorities. Based on an analysis of the risks, the market surveillance authorities then make certain choices and set certain priorities in their activities. They also sometimes take part in 'joint actions' initiated by European committees, which centre on a specific product group or topic.

However, in performing their risk assessments, the market surveillance authorities make very little use of information (data analysis) from European database such as ICSMS or RAPEX. Nor do they generally perform analyses of their own data to this end. We believe that there are opportunities here for improving the quality of risk assessments.

4.3 Insufficient use made of data

Not enough use is made of the opportunities presented by the available data and information systems for information-sharing and risk assessment purposes, both in the Netherlands and among the EU member states. This makes it more difficult for the European market surveillance authorities to work together. This aspect could be improved by stepping up the level of coordination in Europe and by investing in the inspectorates' information systems in the Netherlands.

4.3.1 The value of data for market surveillance authorities

The past decade has seen digital information become an integral part of inspectors' work. The inspectorates have all sorts of different information systems and databases in which they record complaints, reports of unsafe products, fines, the results of enforcement activities and test results. Thanks to these computerised systems, inspectors can share information with each other and work more efficiently than would otherwise have been the case.

ICSMS is a European information system that the various national inspectorates use for sharing information on product safety. It contains reports of unsafe products, inspection findings or the results of enforcement activities, and test results. There is also the RAPEX rapid alert system for dangerous non-food products, which contains notifications from national market surveillance authorities of unsafe products (description of product, manufacturer's name, safety risk) and a description of the measures taken in response. RAPEX is a public database.

What are RAPEX and ICSMS?

The EU member states are obliged to use the RAPEX rapid alert system. Market surveillance authorities in the EU use RAPEX to alert inspectorates and consumers in other EU countries if they come across unsafe products that pose a high health or safety risk. On average, 1,600 notifications are made every year. About half of these concern products with a CE marking.

ICSMS is designed to enable countries to exchange and store information on inspection findings. The member states are not obliged to use ICSMS, which is therefore used by the market surveillance authorities on a voluntary basis alongside their own databases.

Market surveillance authorities in Europe face a number of challenges: the trade in products is both dynamic and international, and a huge number of products reach the market every day. We believe that this situation requires closer cooperation between market surveillance authorities in the member states and more accurate risk assessments. The use of data and the exchange of data among market surveillance authorities could help to bring this about.

4.3.2 Data-based risk assessment

Data can be used to boost the accuracy of risk assessments. At present, however, the inspectorates are not accustomed to using data for this purpose. The problem is not that they do not have the right data available to them. Rather, there are a number of practical causes:

- the Dutch inspectorates are obliged to use a large number of different internal and European databases alongside one another. These systems are difficult to connect;
- ICSMS has only limited analytical and report-generating features;
- the inspectorates use different working methods;
- the data in ICSMS, RAPEX and the inspectorates' own databases covers more than just products bearing a CE marking.

Databases are difficult to connect

The market surveillance of products with a CE marking is just a small part of the inspectorates' work. They have designed their own databases, many of which are not capable of performing a data analysis and which also cannot easily be linked up with EU databases. The latter problem means that data needs to be recorded twice, thus reducing the attraction of the ICSMS database, for example. To date, the Radiocommunications Agency is the only Dutch inspectorate to make exclusive use of EU databases for its market surveillance activities.

Limited analytical and report-generating features in ICSMS

Apart from not being able to link up with other databases, the ICSMS database is also not capable of performing analyses and generating reports, which means that inspectorates cannot export data from ICSMS for use in their own analyses and risk assessments. As a result, market surveillance authorities tend not to make full use of EU databases such as ICSMS, which are thus used alongside existing internal databases. This explains why one and the same product may be tested in a number of member states. Such a situation could be avoided if inspection findings were shared through ICSMS.

Inspectorates use different working methods

A third obstacle to the use of ICSMS is the differences that may exist between member states in the way in which they conduct their inspections and report their findings in ICSMS and RAPEX. There is a big difference between a check to ensure that all mandatory documentation is complete and an in-depth laboratory examination of a product. This difference is not always clear from the data, even though it is something the inspectorates need to know in order to perform their inspections. It is also difficult to analyse the data in ICSMS as the member states are free to record data in ICSMS in whatever manner and language they wish.

Lack of information on CE marking

Finally, neither ICSMS nor RAPEX makes a specific record of whether or not a given product complies with the regulations on CE marking: both databases contain information on more product groups than those covered by the CE regulations. This makes it difficult to analysis the data on CE product groups and to produce lists and reports specifically in connection with CE marking. In order to do so, the relevant file needs to be exported and cleaned up to make it fit for an inspectorate's own CE analyses. At the same time, the databases do not contain data on *all* the product groups covered by the CE regulations. Information on certain product groups needs to be obtained from other sources (see Table 1).

Product groups included in ICSMS and RAPEX	Product groups not included in ICSMS and RAPEX
Equipment and protective systems intended for use in potentially explosive atmospheres	Active implantable medical devices
Construction products	Explosives for civil use
Pressure equipment	Noise emission in the environment
Simple pressure vessels	Cableway installations designed to carry persons
Eco-design of energy-related products	Medical devices
Electromagnetic compatibility	In vitro diagnostic medical devices
Hot-water boilers	Recreational craft
Restriction of hazardous substances in electrical and electronic equipment	Equipment for ocean-going vessels
Low voltage	
Lifts and safety components for lifts	
Machinery	
Measuring instruments	
Non-automatic weighing instruments	
Personal protective equipment	
Pyrotechnics	
Radio equipment	
Safety of toys	
Transportable pressure equipment	
Railway rolling stock and high-speed trains	

Table 1 Product groups included and not included in ICSMS and RAPEX.

It is precisely this type of practical problem that makes it hard to perform checks in ICSMS or RAPEX, even if the databases themselves are easy to access. This is illustrated by the product journey of a toy, where we saw that two inspectorates tested the same product, each without knowing that the other had done so (see box).

Product journey of a toy: see Appendix 1

Two notifications were made in relation to the toy, one at the end of July 2015 and the other in mid-August 2015. Without being aware of the duplication, both a Dutch inspectorate and a German inspectorate tested the same toy. Although both tests produced the same result, i.e. the product was found to be unsafe, they led to unnecessary extra work that could have been avoided if information had been shared in good time or if a check had been carried out in the ICSMS database.

4.3.3 Integrating databases

Various improvements have now been made to both EU databases, i.e. both ICSMS and RAPEX. As we see it, the options for further improvements are as follows:

- RAPEX and ICSMS should be linked up and an analytical and reporting tool developed for ICSMS;
- RAPEX should be made available for consultation by consumers in a more user-friendly way.

We believe that *DG Growth* has a role to play in passing on data to the inspectorates in the member states (for example on the size of the market) and, more specifically, in improving cooperation with *Eurostat*, for example.

In the Netherlands, the Inspection Council recognises the value of data use and the need to improve the inspectorates' databases (Inspection Council, 2016). While integrating databases to pave the way for data-based risk assessments is the key to the solution, it is also a problem in itself. The following obstacles need to be overcome:

- great deal of data is held by private-sector parties (for example, market information flows and data originating from businesses and notified bodies) and/or is available only on a commercial basis (as is the case with the Chamber of Commerce);
- people and resources are needed in order to tackle the problems with data at the inspectorates.

5 The role played by end-users

Community legislation on CE marking does not make provision for end-users such as consumers and professional users to play a role, nor does it impose any obligations on end-users. End-users must be assured that the products they buy in shops or use for their work comply with EU requirements in relation to safety and sustainability, for example. This need not be a problem if the system is watertight. However, as we have already pointed out, the system is not fully watertight. We believe that there is scope for improving the information on the significance of CE marking. At the same time, the inspectorates could make greater use of the 'eyes and ears' of end-users, for example through social media, as part of a drive to make the supervisory system better and smarter.

5.1 The formal status of end-users in the CE system

Community legislation on the system of CE marking does not define the term 'end-users'. Nor does it accord them any rights, responsibilities or obligations (European Commission, 2016b).[34] This applies even where no economic operators are active on the European market, for example, if consumers buy products directly, by acquiring them online from a supplier from outside the EU.

This is a clear reflection of the fact that the CE system was created primarily to foster the efficiency of the single market and only in the second instance to cater for public interests such as safety and environmental protection. The basic principle is that the same product rules apply to all economic operators, thus creating a *level playing field*. It is for this reason that, from an institutional viewpoint, the CE system falls within the remit of the European Commission's *DG Growth*.

In the current system, end-users are represented by various public-sector actors and do not themselves play any role. We see the same line of thinking in the consumer policy adopted by the Ministry of Economic Affairs: 'The government uses supervisory authorities to protect consumers by inspecting businesses so as to ensure that they comply with rules and regulations' (Ministry of Economic Affairs, 2012).

The European Association for the Coordination of Consumer Representation in Standardisation (ANEC) is critical about CE marking, claiming that consumers have only a very limited degree of influence over the system (ANEC, 2012).

5.2 Information supplied *to* end-users

Many of the products displaying a CE marking that economic operators bring into circulation on the European market ultimately find their way into the hands of end-users. The latter comprise both consumers and professional users such as construction companies and hospitals. They are the ones who eventually use or work with the product in question. In the current system, they must be assured that the products they buy on the European market satisfy EU requirements in relation to safety and health, for example.

5.2.1 Opportunities for improving consumer information

In the context of the single market, the EU has adopted a consumer policy the core objectives of which include giving consumers a greater say and efficiently protecting consumer safety and consumers' economic interests (European Parliament, 2016a). The European Commission's *DG Justice and Consumers* is responsible for implementing this policy.

In order for consumers to have a greater say, the European Commission maintains that they must have access to clear, reliable and comparable information, and the tools to understand it (European Commission, 2012a). We believe that the Minister of Economic Affairs, acting in his capacity as a member of the Competitiveness Council, should urge *DG Growth* and *DG Justice and Consumers* to perform a joint review of the policy on CE marking with a view to bringing the role played by end-users more closely into line with the EU policy of giving consumers a greater say.

Raising consumer awareness of CE marking

In the light of the above, we believe that the first step would be to improve the information supplied to end-users on the system of CE marking and its significance.[35] We are thinking particularly of information on the CE mark itself: what does it mean and what value does it have for consumers? There is a great deal of confusion, particularly among consumers, about the significance of CE marking.

In 2011, the European Commission published the findings of a wide-ranging survey of European consumers (European Commission, 2011). Although the majority (66%) of consumers claimed to be familiar with CE marking, only 25% of respondents were able to say exactly what it meant. Most respondents (33%) thought that CE markings were placed on products to signify that they originated from the EU.

ANEC has also pointed out (2013) that the presence of a CE marking on a product conveys little or no consumer information. More than that, ANEC claims, the mark is actually

misleading in that consumers believe that it is a mark of approval indicating that the product in question is of good quality.

Information on CE marking

The EU has in fact informed consumers about the system of CE marking in various ways during the past few years. In 2012, for example, the EU posted a video clip on the internet featuring a robot singing a song about CE marking (https://www.youtube.com/watch?v=IyE45yzFlJc). This may be seen as information provided by the EU to consumers as end-users.

Better information on inspection findings and product provenance

There are also opportunities for improving the information on the inspection findings of market surveillance authorities and on the provenance of products. If consumers are better informed about the provenance of products and about inspection findings (where relevant), those consumers who wish to do so will be in a better position to make informed choices about the products they wish to buy on the single European market.

Market surveillance authorities

More specifically, market surveillance authorities could be encouraged to distribute user-friendly, on-line information on product recalls prompted by RAPEX alerts. At present, only a fraction of the massive amount of data is publicly available to end-users. Only the NANDO and RAPEX databases are accessible to members of the public. There is scope for improving the information value of data that is freely available, in RAPEX for example. For example, no user-friendly list of European product recalls is published.

Market surveillance authorities could be more active in publishing their inspection findings in the form of open data. A policy of transparency about the inspections undertaken and their findings would help to make clear what each individual surveillance authority has and has not done, and what actions have been taken by market surveillance authorities in response to inspection findings and complaints. Although the Dutch inspectorates are generally unwilling to publish information on their inspections, the Food and Consumer Product Safety Authority started a trial at the end of 2015 with the publication of product inspection findings. It has now published reports on its inspections of finger paints and USB chargers, for example (Netherlands Food and Consumer Product Safety Authority, 2015; 2016).

Economic operators

In line with the process that has taken place in the food industry, manufacturers could provide more information on the origin of products and on the production process. Product provenance and traceability are also both key issues in the debate on corporate

social responsibility, an area in which both the general public and the government are taking more and more interest.[36]

Example of accessible production information for end-users

In terms of information value, manufacturers in the non-food industry could take a lead from schemes such as the Tagologic Tag (TTag). The TTag is an advanced code that gives access to information on a product and the production chain. Apart from direct product information, it also includes information on the businesses involved, marketing information and data on customer loyalty. This helps to improve product traceability and consumer awareness of the provenance of products.

A good example of accessible information on product safety is to be found on an Australian government website: www.productsafety.gov.au/. Consumers can use this website to report unsafe products and access information on product safety requirements and product recalls. Businesses can use it to find information on the legislation on product safety and to report product recalls. The website also contains information on all the market surveillance authorities and their duties.

5.3 Information supplied *by* end-users

We saw in the previous sections that it is difficult for end-users to obtain information on the significance of CE marking.

Equally, however, end-users are themselves also vital sources of information for market surveillance authorities. Although the idea of the CE system is that market surveillance should protect the general public, it is clear that, in the present situation, market surveillance authorities also face a number of challenges, such as the size of the market (see chapter 4). We believe that this situation requires a different – and smarter – form of market surveillance, in which market surveillance authorities are explicitly able to make use of information supplied by end-users.

Market surveillance authorities do not yet make use of the 'eyes and ears' of end-users

Market surveillance authorities currently do not make enough use of the 'eyes and ears' of end-users. Although market surveillance authorities already respond to alerts in the form of complaints, much more could be done to prompt consumers to report unsafe products. Moreover, if end-users are better informed (see above), they will be more alert and hence better able to contribute to market surveillance. Market surveillance authorities could also benefit from following and analysing social media and internet fora.

Example of consumer input

There are already plenty of examples of industries and countries in which consumers act as data suppliers by making notifications. The US, for example, has enacted legislation formally according consumers the status of an extra step in the market surveillance process, thus enabling them to help the market surveillance authorities. Consumers can go to a website (www.saferproducts.gov) to file valid complaints about product safety. The same website also contains a list[37] of all product recalls issued by manufacturers. In other words, consumers are both data suppliers and data users. Thanks to a policy of 'naming and shaming', the system encourages manufacturers and importers to raise their product safety standards. It contains a number of safeguards to prevent economic operators from suffering as a result of false accusations.

Appendices

Appendix 1

The product journey of a toy

Reconstruction product journey toys

The manufacturer placed the toy on the market. We reconstructed three 'journeys' the product made: which travel did they make and what was the reason that a product with a CE marking entered the market while it did not comply to the EU rules.

Product journey 1
first time on the market

Product journey 2
rejected product

Product journey 3
current product

Commissioned by the **supplier**. Chinese testing agencies tested the components, samples were sent to the manufacturer.

After the product had been approved, the testing in China stopped. The **supplier** shipped the components to the Netherlands.

The **importer** tested the components once again after they arrived in the Netherlands.

After receiving the components, the **importer** assembled the toys and affixed a CE marking on them.

By affixing a CE marking on the products the importer assumed responsibility from the **manufacturer**.

This toy was among a number of toys selected by the Dutch Food and Consumer Product Safety Authority as part of a major inspection. A laboratory test performed by the authority showed that the toy contained too many chemicals. The same test was performed simultaneously by the German market surveillance authority. The test findings were recorded in both the ICSMS and the RAPEX databases. The manufacturers asked the distributors to return all toys made as part of the production batch in question, as well as the previous batch and the following batch. The safety risk was not such that consumers needed to be informed. A total of 8,500 products were recalled in total, including 7,000 that were in circulation on the EU market.

The **distributor** distributed the toys to the shops. This only happened for the first and the current product.

The **shops** offered the toys for sale. This only happened for the first and the current product.

The product found its way to the **consumer**.

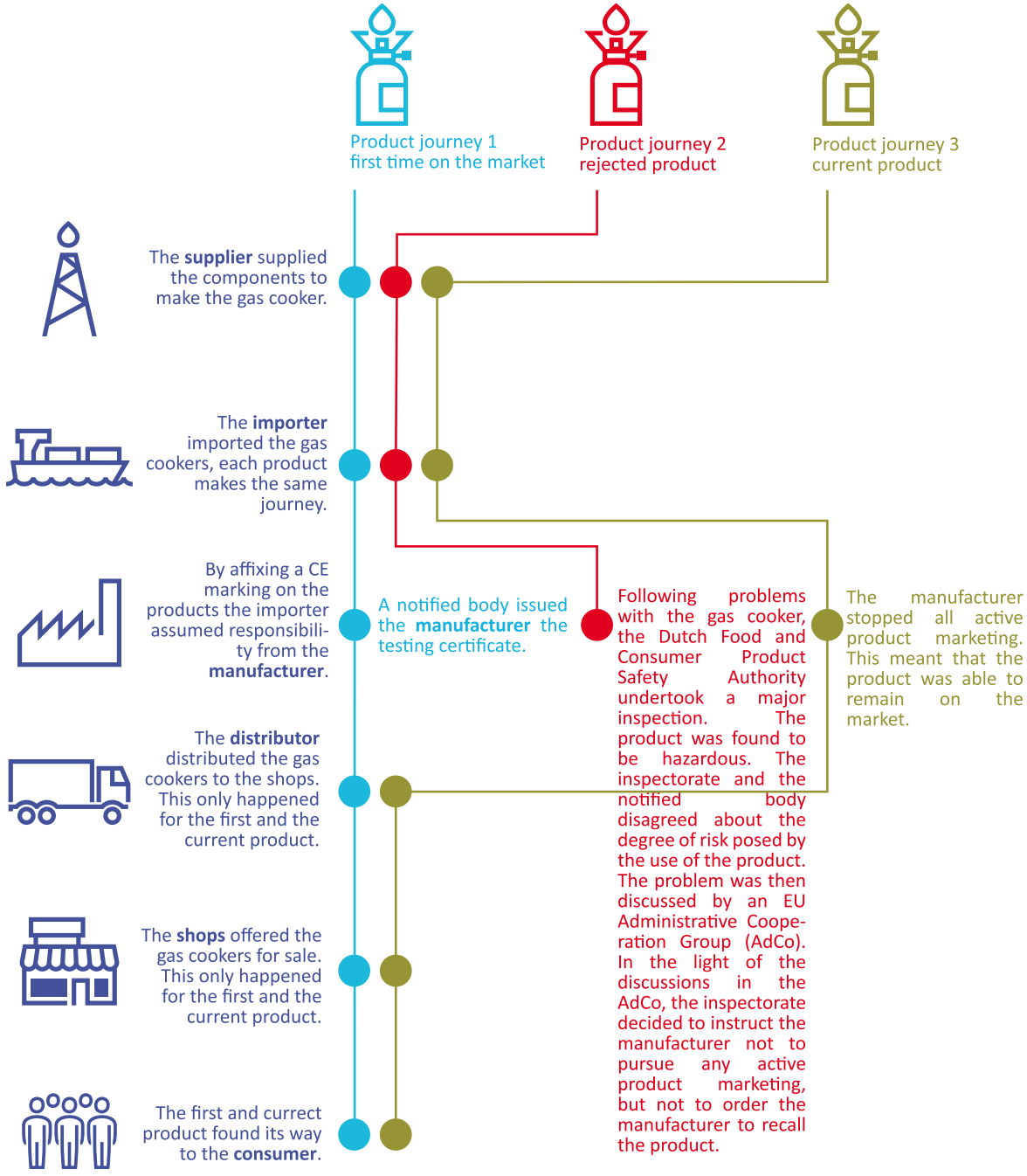
The toys were to be sold in the same packaging because the manufacturer still had a large stock of unused packaging. This meant that consumers could not know whether the toy was or was not the subject of a RAPEX notification.

Appendix 2

The product journey of a portable gas cooker

Reconstruction product journey gas cooker

The manufacturer placed an innovative gas cooker on the market. We reconstructed three 'journeys' the product made: which travel did they make and what was the reason that a product with a CE marking entered the market while it did not comply to the EU rules.



Appendix 3
Audit method

The *audit question* was as follows: How is it possible that products are sold on the European market that do not comply with EU legislation on CE marking, and what is the government doing to prevent and remedy this situation?
We sought to answer the following sub-questions:

- how does the CE system work?
- what role is played by public and private information systems in the CE system?
- what weaknesses are there in the CE system, such as may result in products being placed on the European market that carry a CE marking even though they do not comply with EU requirements or which do not carry a CE marking even though they are required to do so?
- what is the Dutch government doing to solve these problems, particularly in terms of market surveillance?

The audit team used a combination of qualitative and quantitative methods. In addition to undertaking document analyses and conducting in-depth interviews, they organised three meetings attended by experts with practical experience from both the public and the private sector. Two of the audit methods, and the expert meeting, are discussed in more detail below.

1. Product journeys

The product groups that are required to undergo conformity assessment are highly varied in nature. We collected information on two product groups in order to gain an impression of how the system of CE marking works in practice, and of any problems there might be in this connection. We selected a product from each of these product groups that did not comply with the relevant requirements and tried to find out why this was. The products in question were a toy and a portable gas cooker, both of which belong to product groups that rank among the top three in terms of the number of RAPEX notifications. We selected one specific toy and one specific gas cooker about which RAPEX notifications had been made. We conducted interviews about them, and obtained relevant documents at various points of the production and supply chain, starting with the manufacturer and ending with the consumer. In the case of medical devices, we looked at PIP breast implants in particular, making use of public information in this connection.

2. Statistical analysis of RAPEX data

The RAPEX database contains products classified as class 4 products. This is the most serious category of hazardous products on which action must be taken, for example by

withdrawing them from the market. If an EU member state believes that a given product is not safe, it is obliged to report the product in question to RAPEX. We performed a statistical analysis of the relative activeness of member states, in terms of the frequency with which they make RAPEX notifications and act on notifications made by other member states.

Data

The file we used for our statistical analysis was downloaded from the European Commission's website. It was not suitable for analysis in its original state, which is why we adapted it before starting the analysis. We made the following changes to the file:

- we cleaned up the country names;
- we made a selection of products notified during the period up to the end of 2015;
- we selected those product groups that are covered by the CE system.

We then selected two columns: the first listing the *notifying countries* and the second showing the countries in which the *products were found and in which measures were also taken*. The latter column may contain the names of more than one country.

Because the data set may be regarded as asymmetrical, we were able to use Gower's method of asymmetry analysis (Gower, 1977). This meant decomposing the data into a symmetrical and a skew-symmetrical component. The first step involved converting the two columns into a table, in which the rows represented the notifying countries and the columns represented the countries acting on notifications.

R script

The table was compiled with the aid of the R programming language for data analysis. This R script analyses the data and compiles the table by raising the value for each pair of countries in the table by '1'. The values in the table were initialised at zero. For example, if Hungary was the first line in the data file for Slovenia, the value in the table corresponding with the row for Slovenia and the column for Hungary was raised by one. A row containing Sweden, Greece and Finland resulted in two adjustments, i.e. a rise in the value of the row for Sweden and the column for Greece, and again in the value of the row for Sweden and the column for Finland. A total of 31 European countries were represented in the data file.

Asymmetry

The result was a table consisting of 31 rows and 31 columns, both of which referred to the EU countries. Asymmetry was one of the main characteristics of this table. This was because the number of notifications made by Sweden that are acted upon by the

Netherlands is not necessarily the same as the number of Dutch notifications that are acted upon by Sweden. The model was designed explicitly to take account of this asymmetry.

We then analysed this table to detect any notification errors. We found that, in the file containing 31 countries, 24 notifications were made by 10 countries, which is an impossibility. These figures were excluded from the analysis. The total number of notifications acted upon by other countries was 1,769.

Symmetry and skew symmetry
Any asymmetrical matrix can be broken down into a symmetrical and a skew-symmetrical component. This decomposition is additive, i.e. the two components can be combined to form the original data. We were then able to study the interrelationship between the countries with the aid of two grids each depicting a different aspect of the notification process. The symmetrical component is the mean for a pair of countries and the skew-symmetrical component is the deviation from this mean. A symmetrical table is symmetrical relative to the diagonal, i.e. the values below and above the diagonal are the same. The symmetrical component describes the interrelationship between the countries. Where countries assess the same risks in the same way, they will be more likely to act on each other's notifications. This method of asymmetry analysis was first introduced by Gower in 1977 (1977; 2014).

Cluster analysis
We used cluster analysis to show the interrelationship between countries. This involved combining countries that act on each other's notifications in a single cluster. Notifications made by countries in the same cluster are more likely to be acted on by countries in the same cluster. Countries in different clusters are less likely to act on each other's notifications.

Multidimensional scaling
A multidimensional scaling is another suitable method of analysing data of this type. In our case, it involved producing a map in which the distance between countries corresponds with the number of notifications made by one country that another country has acted on. Countries positioned close to each other are more likely to act on each other's notifications, whereas countries positioned a long way from each other are less likely to act on each other's notifications. This analysis was performed with the aid of the *smacof package* (CRAN, 2017).

3. Expert meetings and other meetings

We organised three expert meetings: the first was held on 14 January 2016, the second on 4 February 2016 and the third on 23 August 2016. These meetings were attended by representatives of the ministries concerned (i.e. the Ministry Economic Affairs, the Ministry of Infrastructure and the Environment, and the Ministry of Health, Welfare and Sport), customs, the inspectorates (i.e. the Food and Consumer Product Safety Authority, the Human Environment and Transport Inspectorate, the Social Affairs and Employment Inspectorate and the Radiocommunications Agency), private-sector actors (i.e. manufacturers, importers, distributors, notified bodies and the Dutch Standardisation Institute), the Accreditation Council and the Dutch Consumers' Association.

The first two expert meetings were organised in conjunction with an external partner. The topic of the first of these meetings was 'responsibilities', while the second centred on 'IT and data'. The expert meeting held in August was convened to discuss our audit findings.

We attended an international conference that was held in Amsterdam on 23 February 2016 under the heading of '*Enforcement in a Europe without borders*'. The conference was also attended by all the Dutch Inspectors-General and the heads of the EEA inspectorates, and by representatives of the *Organization for Economic Cooperation and Development* (OECD) and the European Commission. We contributed to a workshop on 'good market surveillance'.

We also attended meetings of two international committees: a meeting of one of the Administrative Cooperation Groups (AdCos) of market surveillance authorities, and a working meeting of the European Committee for Standardisation (CEN).

Appendix 4
Glossary

Accreditation
A formal statement issued by a national accreditation body to the effect that a conformity assessment body satisfies the requirements laid down in harmonised standards, as well as (where applicable) any supplementary requirements such as those set out in the relevant sectoral regulations, with the effect that it is authorised to perform a specific conformity assessment activity. Accreditation in the Netherlands is the responsibility of the Accreditation Council.

Authorised representative
A natural person or legal entity situated in an EU country that a manufacturer has authorised in writing to perform certain specific duties on the latter's behalf.

CE marking
A marking affixed on a product by a manufacturer to indicate that the product complies with all the relevant requirements of EU harmonisation legislation on CE marking. The letters CE stand for '*Conformité Européenne*'. A CE marking is not a quality mark or a quality guarantee.

Conformity assessment
A procedure designed to show whether or not a particular product, process, service, system, person or body complies with the relevant requirements (also referred to as 'certification').

Conformity assessment body
See under 'notified body'.

Data
Data falls into two categories;
- quantitative data, i.e. data originating from RAPEX, ICSMS, NANDO and informants,
- and qualitative data, i.e. data obtained from files, interviews, brainstorming sessions and product journey analyses.

Distributor
A natural person or legal entity in the supply chain who is not the manufacturer or the importer and who offers a product for sale.

Economic operator
The manufacturer, the manufacturer's authorised representative, the importer or the distributor.

EEA
The European Economic Area. The EEA was formed under an agreement between the 28 EU member states, Liechtenstein, Norway and Iceland. The EEA agreement is designed to promote the free movement of people, goods, services and capital between the member countries.

Harmonised standard
A standard which, pursuant to a request made by the Committee under Article 6 of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations in relation to the services of the information society (1), has been adopted by one of the European Standardisation Bodies listed in Annex I to the Directive.

ICSMS
Information and Communication System on Market Surveillance. ICSMS is a European database for the purpose of market surveillance.

Importer
A natural person or legal entity situated in an EU country that places a product originating from a non-EU country on the EU market.

Manufacturer
A natural person or legal entity who makes a product, or arranges to have a product designed or made, and who sells it under its own name or brand name.

Market surveillance
The activities performed and the steps taken by government authorities to ensure that products comply with the provisions of relevant harmonisation legislation and that they do not pose a risk to health, safety or other aspects of the protection of the public interest.

Market surveillance authority
An authority in a member state that is responsible for supervising the market in the member state's territory.

NANDO
An electronic registration system designed and managed by the European Commission, which lists notified bodies (together with their identification numbers) in relation to each member state and/or Directive.

National accreditation body
The only body in a member state which the member state in question has authorised to award accreditations.

Notified body
A body that performs conformity assessments, including calibrating, testing, certifying and inspecting. Certain products must undergo a conformity assessment by a notified body before a CE marking may be affixed on them.

Notifying authority
The government body responsible for designating conformity assessment bodies and registering them with the European Commission.

Quality mark
A quality mark or certification mark is a logo that is affixed to a product or accorded to a service and which shows that the product or service in question meets a certain quality standard. A manufacturer or service-provider may associate a quality mark with its product or service only if it has been given permission to do so by the mark's owner. An example of a Dutch product quality mark is the EKO mark for organic food; an example of a Dutch service quality mark is the 'Erkende Verhuizers' ('Recognised Removal Firm') mark. There are no general rules for the creation of new quality marks
anyone who wishes to do so is entitled to launch a new quality mark.

RAPEX
An EU database designed to facilitate the exchange of information on consumer products, as referred to in article 2 (a) of EU Directive 2001/95/EC, such as pose a serious risk to consumer health or safety. The database contains information on non-food consumer products and products for professional use. The system is not CE-specific and therefore also contains products that are not covered by the system of CE marking.

Appendix 5
Key to abbreviations

AdCo	Administrative Cooperation Group
ANEC	European Association for the Coordination of Consumer Representation in Standardisation
CE	Conformité Européenne
CEN	European Committee for Standardisation
CENELEC	European Committee for Electro-technical Standardisation
CPSC	Consumer Product Safety Commission
CRAN	Comprehensive R Archive Network
DG	Directorate-General
EAN	European Article Number
EEC	European Economic Community
EEA	European Economic Area
EC	European Community
ETSI	European Telecommunications Standards Institute
EU	European Union
FTE	Full-time equivalent
HRM	Human resource management
IT	Information technology
ICSMS	Information and Communication System on Market Surveillance
NANDO	New Approach Notified and Designated Organisations Information System
NEC	Dutch Electro-technical Committee
NEN	Dutch Standardisation Institute
OECD	Organization for Economic Cooperation and Development
PIP	Poly Implant Prothèse
RAPEX	Rapid Alert System for Dangerous Non-Food Products
TIE	Toy Industries of Europe
UK	United Kingdom
US	United States of America

Appendix 6
References

Publications are listed under their original title. Publications are available in the original language only unless stated otherwise.

ANEC (2012). *Position paper on CE marking: 'Caveat emptor – buyer beware'*. ANEC-SC-2012-G-026final. Brussels: Author.

ANEC (2013). *Leaflet on CE marking*. Brussels: Author.

Centre for Strategy & Evaluation Services (2012). *Evaluation of the Ecodesign Directive (2009/125/EC) - Final Report*. Kent: Author.

CRAN (undated). https://CRAN.R-project.org/package=smacof, consulted on 12 May 2016.

Dutch House of Representatives (2016). *Conceptbrief aan de minister en de staatssecretaris van Economische Zaken inzake het plaatsen van een parlementair behandelvoorbehoud bij de EU-Meststoffenverordening. ('Draft letter to the Minister of Economic Affairs and the State Secretary for Economic Affairs on making a parliamentary scrutiny reservation in respect of the EU Fertilisers Regulation.') House of Representatives, 2015-2016 session, annexe to 34467, no. 1.* The Hague: Sdu.

Dutch Standardisation Institute (undated). *www.nen.nl*, consulted on 1 April 2016.

Dutch Standardisation Institute (2006). *Norm NEN-EN 521:2006 en. Vloeibaargastoestellen – Draagbare toestellen werkend op de dampfase van vloeibaar flessengas. ('Standard NEN-EN 521:2006 en. Liquefied gas appliances: portable appliances operating on the vapour phase of liquefied cylinder gas.')* Delft: Author.

European Commission (undated). http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=country.notifiedbody&cou_id=528, consulted on 27 September 2016.

European Commission (2011). *Special Eurobarometer 342 'consumer empowerment'*. Brussels: Author.

European Commission (2012a). *Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions. A European Consumer Agenda - Boosting confidence and growth.* COM(2012) 225 (final). Brussels: Author.

European Commission (2012b). *Proposals for Regulations of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, and on in vitro diagnostic medical devices.* COM(2012) 541 (final). Brussels: Author.

European Commission (2012c). *Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009.* COM(2012) 542 (final). Brussels: Author.

European Commission (2013a). *Proposal for a Regulation of the European Parliament and of the Council on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EU) No 305/2011, Regulation (EC) No 764/2008 and Regulation (EC) No 765/2008 of the European Parliament and of the Council.* COM(2013) 75 (final). Brussels: Author.

European Commission (2013b). *Commission Staff Working Document. Executive summary of the Impact Assessment. Accompanying the document: Product Safety and Market Surveillance Package. A proposal for a Regulation of the European Parliament and the Council on consumer product safety and a proposal for a Regulation of the European Parliament and of the Council on market surveillance for products.* SWD(2013) 34 (final). Brussels: Author.

European Commission (2014). *Commission Staff Working Document. Part 1: Evaluation of the Internal Market Legislation for Industrial Products.*
Accompanying the document: the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee. A vision for the internal market for products. SWD(2014) 23 (final). Brussels: Author.

European Commission (2015a). *Independent Review of the European Standardisation System. Final Report.* Ref. Ares(2015)2179280. Brussels: Author.

European Commission (2015b). *Commission Staff Working Document: A Single Market Strategy for Europe - Analysis and Evidence. Accompanying the document: Upgrading the Single Market: more opportunities for people and business.* SWD(2015) 202 (final). Brussels: Author.

European Commission (2015c). *Note to the Expert Group on the Internal Market for Products (IMP). The functioning of NANDO with regard to providing accurate information, objection periods, notification procedures and notified bodies groups.* CERTIF 2015-01 REV2. Brussels: Author.

European Commission (2016a). *Summary of Member States' assessment and review of the functioning of market surveillance activities according to Article 18(6) of Regulation (EC) No. 765/2008.* Ref. Ares(2016)5928363. Brussels: Author.

European Commission (2016b). *Commission Notice. The 'Blue Guide' on the implementation of EU products rules 2016* (OJ 2016, C 272/01).

European Commission (2016c). *Proposal for a Regulation of the European Parliament and of the Council laying down rules on the making available on the market of CE marked fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009.* COM(2016) 157 final. Brussels: Author.

European Commission (2016d). *List of national market surveillance authorities by country.* Ref. Ares(2016)5631042. Brussels: Author.

European Parliament (2016a). *Eurofeiten 2016: Consumentenbeleid: beginselen en instrumenten. ('Eurofacts 2016: Consumer policy: principles and instruments.')* Brussels: Author.

European Parliament (2016b). *Eurofeiten 2016: Vrij verkeer van goederen. ('Eurofacts 2016: Free movement of goods.')* Brussels: Author.

Food and Consumer Product Safety Authority (2015). *Vingerverf 2015, Onderzoek chemische stoffen en beoordeling etiket. ('Finger paint 2015, Examination of chemical substances and assessment of label.')* Utrecht: Author.

Food and Consumer Product Safety Authority (2016), *USB-laders, Onderzoek elektrische veiligheid USB-laders 230 Volt. ('USB chargers: Examination of electrical safety of 230V USB chargers.')* Utrecht: Author.

Gower J.C. (1977). *The analysis of asymmetry and orthogonality. In: J.R. Barra et al. (eds.), Recent Developments in Statistics (p. 109–123).* Amsterdam: North-Holland.

Gower J.C. (2014). *Skew symmetry in retrospect. Advances in Data Analysis and Classification, 2014, p. 1-9.* doi: 10.1007/s11634-014-0181-7.

Inspection Council (2016). *Toekomst van het Toezicht, een verkenning van wat nodig is.* (*'The future of supervision: a review of needs.'*) The Hague: Author.

Ministry of Economic Affairs (2012). *Brief van de minister van Economische Zaken, Landbouw en Innovatie. Versterking van de positie van de consument.* ('Letter from the Minister of Economic Affairs, Agriculture and Innovation. Strengthening the status of consumers.') House of Representatives, 2011-2012 session, 27879, no. 41. The Hague: Sdu.

Ministry of the Interior and Kingdom Relations (2005). *Minder last, meer effect. Zes principes van goed toezicht. Kaderstellende Visie op Toezicht 2005.* ('Less work, more impact. Six principles of effective supervision. Supervisory strategy for 2005.') Annexe to House of Representatives, 2005-2006 session, 27 831, no. 15. The Hague: sdu.

RPA Risk & Policy Analysts Limited (2012). *Impact assessment study on the review of the Gas Appliances Directive (Directive 2009/142/EC).* Loddon: Author.

Scientific Council for Government Policy (2013). *Toezien op publieke belangen. Naar een verruimd perspectief op Rijkstoezicht.* ('Monitoring public interests. Towards a broader view of government supervision.') Amsterdam: Amsterdam University Press.

Social and Economic Council (undated). www.ser.nl/nl/themas/imvo.aspx, consulted on 22 September 2016.

TIE (2016). http://www.tietoy.org/news/article/effective-and-well-enforced-market, consulted on 27 September 2016.

Van der Voort (2013). *Naar een drie-eenheid van co-regulering over spanningen tussen drie toezichtsregimes.* ('Towards a trinity of co-regulation over tensions between three surveillance regimes.') Delft: Delft University of Technology.

Van der Voort (2016). *Transnational cooperation over public-private divide: The challenges of co-regulation*. In: M. van der Steen, M. en N. Chin-A-Fat (eds.), Cross-border cooperation between national inspectorates. Conference paper to be presented at the International Conference on Enforcement in a Europe without Borders, 23 February 2016, Amsterdam, The Netherlands (p. 58-67). The Hague: Bureau Inspectieraad.

Legislation

Arrangement adopted by the Prime Minister, the Minister of General Affairs, on 30 September 2015, no. 3151041, setting out instructions for the national inspectorates, *Government Gazette* 2015, 33574.

Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (89/686/EEC) (*OJ* 1989, L 399/18).

Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC) (*OJ* 1990, L 189/17).

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (*OJ* 1993, L 169/1).

Council Directive 96/98/EC of 20 December 1996 on marine equipment (*OJ* 1997, L 46/25).

Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (*OJ* 2008, L 218/82).

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (*OJ* 1998, L 331/1).

Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity (*OJ* 1999, L 91/10).

Directive 2000/9/EC of the European Parliament and of the Council of 20 March 2000 relating to cableway installations designed to carry persons (*OJ* 2000, L 106/21).

Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors (*OJ* 2000, L 162/1).

Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (*OJ* 2006, L 157/24).

Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community (*OJ* 2008, L 191/1).

Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (*OJ* 2009, L 170/1).

Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products (*OJ* 2009, L 285/10).

Directive 2009/142/EC of the European Parliament and of the Council of 30 November 2009 relating to appliances burning gaseous fuels (*OJ* 2009, L 330/10).

Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC (*OJ* 2010, L 165/1).

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (*OJ* 2011, L 174/88).

Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (*OJ* 2013, L 354/90).

Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (*OJ* 2014, L 96/1).

Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (*OJ* 2014, L 96/107).

Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (*OJ* 2014, L 96/149).

Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (*OJ* 2014, L 96/251).

Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (*OJ* 2014, L 96/309).

Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles (*OJ* 2013, L 178/27).

Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels (*OJ* 2014, L 96/45).

Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (*OJ* 2014, L 96/79).

Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (*OJ* 2014, L 96/357).

Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (*OJ* 2014, L 189/164).

General Guidelines for the Cooperation between CEN, Cenelec and ETSI and the European Commission and the European Free Trade Association (*OJ* 2003, C 91/04).

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 and repealing Regulation (EEC) No 339/93 (*OJ* 2008, L 218/30).

Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (*OJ* 2011, L 88/5).

Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (*OJ* 2012, L 316/12).

Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (*OJ* 2016, L 81/1).

Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (*OJ* 2016, L 81/51).

Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (*OJ* 2016, L 81/99).

Websites

European Commission: The CE-e Robot Song: Our toys are good to go! https://www.youtube.com/watch?v=IyE45yzFlJc).

NANDO: http://ec.europa.eu/growth/tools-databases/nando/, consulted on 27 September 2016.

RAPEX: http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/index_en.htm, consulted on 8 April 2016.

www.productsafety.gov.au/

www.saferproducts.gov

Appendix 7
End notes

1. See RAPEX, a European 'rapid alert system for dangerous non-food products': http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/index_en.htm.
2. The EEA consists of 31 countries, i.e. all 28 EU member states plus Liechtenstein, Norway and Iceland. Switzerland and Turkey also adhere to the rules on CE marking, in accordance with the terms of an Agreement on Mutual Recognition in the case of Switzerland and a Custom Union Agreement in the case of Turkey. See European Commission (2016b).
3. The Minister of Economic Affairs, the Minister of Infrastructure and the Environment, the Minister of Health, Welfare and Sport, the Minister of Social Affairs and Employment, the Minister of Finance and the Minister for Housing and the Central Government Sector.
4. The Food and Consumer Product Safety Authority, the Radiocommunications Agency, the Healthcare Inspectorate, the Human Environment and Transport Inspectorate and the Social Affairs and Employment Inspectorate.
5. The Radiocommunications Agency, the Social Affairs and Employment Inspectorate, the Healthcare Inspectorate, the Food and Consumer Product Safety Authority, and the Human Environment and Transport Inspectorate.
6. See RAPEX, a European 'rapid alert system for dangerous non-food products': http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/index_en.htm The RAPEX database does not however include all product categories for which CE marking is required. For example, a separate database known as EUDAMED has been set up specifically for medical devices, in vitro diagnostic medical devices and active implantable medical devices. This database (which is not public) was not included in the audit.
7. We use the term 'CE system' to refer to: a) the complex of rules for placing a CE marking on products sold on the European market, b) the actors involved in this. The system of CE markings is part of a broader package of EU measures designed to pave the way for a single European market.
8. The EEA consists of 31 countries, i.e. all 28 EU member states plus Liechtenstein, Norway and Iceland. Switzerland and Turkey also adhere to the rules on CE marking, in accordance with the terms of an Agreement on Mutual Recognition in the case of Switzerland and a Custom Union Agreement in the case of Turkey. In other words, products displaying a CE marking may be sold freely in a total 33 countries. See European Commission (2016b).

9. In the case of construction products for which CE marking is compulsory, private quality marks may not be used if they overlap with the harmonised rules.
10. Certain CE Directives make exceptions for products that are sold without any CE marking. These include customised medical devices, for example.
11. The European Commission has published a 'Blue Guide' with comprehensive information on the guidelines for product requirements and the workings of the CE system. See: European Commission (2016b). This chapter discusses the general nature of the CE system. There are a number of cases in which the standard model is not followed: Regulation (EU) No. 305/2011 of 9 March 2011 on the marketing of construction products is one of the main exceptions to the basic rule.
12. We based our audit on the existing legislation. We did not look into the way in which the relevant Regulation and Directives were prepared.
13. As was indeed the case until the 1980s. In practice, however, this meant that the European Commission was forced to reach detailed agreements on product properties with all the member states. This proved to be a time-consuming and relatively inflexible process.
14. Article R8 of Decision No. 768/2008/ EC.
15. The procedure for the development and adoption of harmonised standards is based on Regulation (EU) No. 1025/2012 and the General Guidelines for the Cooperation between CEN, Cenelec and ETSI and the European Commission and the European Free Trade Association (2003/C 91/04).
16. See Articles 5 and 7 of Regulation (EU) No 1025/2012 of 25 October 2012.
17. As claimed during the expert meeting held on 23 August 2016 (see Appendix 3).
18. This may also be a natural person or legal entity whom the manufacturer has authorised in writing to perform certain tasks on its behalf in connection with its statutory obligations, i.e. to act as its authorised representative.
19. Article 30 of Regulation (EC) No 765/2008; Annex 1, article R2 of Decision No 768/2008/EC.
20. Article 4 of Regulation (EC) No 765/2008.
21. Articles 17 and 18 of Regulation (EC) No 765/2008.
22. Before the Treaty of Lisbon came into force late in 2009, this procedure was referred to as the 'co-decision procedure'.
23. This is clear from the weekly reports published on the RAPEX website: http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/index_en.htm (consulted on 8 April 2016).

24. The products in question were selected on the basis of risk assessments. For this reasons, the figures are not necessarily representative of all products in the same product group.
25. Article 4 (4) of Directive 2009/48/EC.
26. Articles 17 and 18 of Regulation (EC) No 765/2008.
27. On 13 February 2013, the European Commission adopted a proposal for a new, stand-alone Regulation on market surveillance bringing together all market surveillance provisions from Regulation (EC) No. 765/2008, the General Product Safety Directive, and sectoral legislation. See European Commission, 2013a.
28. See description of method in Appendix 3.
29. In this case, responsibility has been delegated to the Minister for Housing and the Central Government Sector.
30. Verispect became part of the Radiocommunications Agency on 1 January 2016. Until the end of 2015, Verispect was an independent authority responsible for supervising two EU Directives, i.e. the Measuring Instruments Directive (2014/32/EU) and Directive 2014/31/EU on non-automatic weighing instruments.
31. See Ministerial Regulation of 30 September 2015, Government Gazette 2015, 33574.
32. The Dutch customs are responsible mainly for controlling the Dutch borders and for levying and collecting domestic and European duties.
33. The Healthcare Inspectorate budget does not distinguish between spending on market surveillance and spending on the supervision of the CE system.
34. Directive 2013/53/EU on recreational craft and personal watercraft does impose certain obligations on private importers. Dutch legislation, for example, also forbids professional users from using products that do not comply with the Directives on medical devices, i.e. Directive 90/385/EEC of 20 June 1990; Directive 98/79/EC of 27 October 1998; and Directive 93/42/EEC of 14 June 1993.
35. During the debate on new CE legislation, the European Parliament (2016b) also explicitly underlined the need to raise consumer awareness of CE marking.
36. See for example the work done by the Social and Economic Council on international corporate social responsibility (Social and Economic Council, undated).
37. It should be borne in mind that, in the US, a single market surveillance authority, i.e. the Consumer Product Safety Commission (CPSC), is responsible for supervising all consumer products.

Audit team

Ms D.M.E. (Diny) van Est (project manager)
Ms J. (Jane) van 't Hoff
Ms L.C.M. (Linda) Meijer-Wassenaar
Ms N.A.E. (Nicolien) Pinkse
Mr R. (Ronald) Plantinga
Mr M.H.A. (Marcus) Schaefers
Ms T. (Tanneke) Vandersmissen
Mr R. (Rutger) Vos
Ms E.M.M. (Noortje) van Willegen
Mr A.J.W. (Berrie) Zielman

Imformation

The Netherlands Court of Audit
Communications Department
P.O. Box 20015
2500 EA The Hague
The Netherlands
T: +31-70-342 44 00
E: voorlichting@rekenkamer.nl
I: www.rekenkamer.nl

Translation

Tony Parr

Cover

Layout: Corps Ontwerpers
Photograph: Martine Hendriksen/
The Netherlands Court of Audit

The Hague, February 2017