

# **Review and Assessment of Market Surveillance and External Border Controls from 2010 to 2013.**

**(Article 18(6) of Regulation (EC) No 765/2008)**

**Member State: The Netherlands.**

## **Part 1. General overview.**

### **Section A. Review**

#### *Organisation and operation.*

Market surveillance of products is divided between six national surveillance authorities, each with its own sector of responsibility: the Social Affairs and Employment Inspectorate (*Inspectie Sociale Zaken en Werkgelegenheid – I-SZW*), the Human Environment and Transport Inspectorate (*Inspectie Leefomgeving en Transport – ILT*), Verispect B.V., the Netherlands Radiocommunications Agency (*Agentschap Telecom – AT*), the Health Care Inspectorate (*Inspectie Gezondheidszorg – IGZ*) and the Netherlands Food and Consumer Product Safety Authority (*Nederlandse Voedsel en Waren Autoriteit – NVWA*). These six market surveillance authorities and the EC product legislation (sectors) that they monitor are described in detail in the sectoral part. The surveillance authorities are the political responsibility of four ministries: Economic Affairs (*Economische Zaken*), Social Affairs and Employment (*Sociale Zaken en Werkgelegenheid*), Infrastructure and the Environment (*Infrastructuur en Milieu*) and Health, Welfare and Sport (*Volksgesondheid, Welzijn en Sport*). The Ministry of Economic Affairs coordinates and monitors the implementation of Regulation (EC) No 765/2008.

The surveillance authorities performed both documentary checks and product examinations. The application of these two forms of surveillance was determined by the degree of risk and product complexity, and by the investigation costs as a result of this complexity. Proactive inspections were predominantly risk-oriented: which product groups present the most risks, due to their hazardous properties, in terms of harm to public interests protected by the legislation (safety, environment, sustainability, energy consumption, telecommunications, health and fair practices in trade), but also which product groups often demonstrate deviations with regard to these aspects (compliance risk) and at which businesses. Reactive inspections were based on complaints from businesses and consumers, RAPEX notifications or alerts from other stakeholders.

For the product examinations, the surveillance authorities used their own laboratories as much as possible and accredited private parties. The surveillance authorities tended to focus their surveillance on the start of the chain: manufacturer and EU importers. They also took account of the specific compliance behaviour of the companies in question: companies with a good record for compliance received fewer inspections than those with a poor one.

The surveillance authorities are all connected up to ICSMS with one national administrator and RAPEX. They all participate in their relevant ADCOs or comparable platforms for market

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surveillance within a particular sector. In these ADCOs, sectoral cooperation is planned and entered into with surveillance authorities from other Member States on the basis of a risk-oriented approach.

According to estimates, market surveillance involves a total of 175 FTEs and a total national budget of EUR 20 million. The headcount has increased in a number of domains in recent years as a consequence of Regulation (EC) No 765/2008.

Cooperation with customs authorities has received extra attention. During external border controls, cooperation with customs authorities and the division of responsibilities take various forms, according to the nature of the products, the economic operators and the commercial volumes. For example, the customs authorities inform the market surveillance authority of consumer products that are (yet) to be imported that match risk profiles (product groups) provided in advance by the market surveillance authority.

The market surveillance authority checks the products when they are imported (i.e. before they are released for free circulation). This is an efficient solution for the situation in the Netherlands, given the large volume of consumer goods imported into the EU every day through the port of Rotterdam. The market surveillance and customs authorities coordinate their activities four to five times a year in a national forum set up for this purpose in 2008, called the Alliance Working Group on Product Market Surveillance and External Border Controls (*Alliantiewerkgroep Markttoezicht en Buitengrenscontrole Producten*), referred to hereinafter as the Alliance Working Group, which is chaired by the Netherlands Food and Consumer Product Safety Authority (NVWA). Amongst other things, this is where the positions of the market surveillance authorities and the customs authorities on imports into the EU (IMP market surveillance, ADCO horizontal issues) are decided.

A number of horizontal issues as referred to in the Multi-Annual Action Plan for Market Surveillance of Products (*Meerjaren Actieplan Markttoezicht Producten – MAMP*) are also discussed here. These are issues that are common to all the domains of the market surveillance authorities and require as standardised an approach as possible.

### **Section B. Assessment**

Cooperation within the Alliance Working Group has brought the supervisory authorities significantly greater insight into each other's domains and into the operations and strategies employed there. There are many similarities here but also differences resulting from the specific characteristics of the domains. Aspects such as the size and diversity of the product groups within the domain, the public interests that are protected by the legislation, the volume and types of risks, the number of

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relevant economic operators, their compliance behaviour, the typical trade flows and, of course, the available capacity of the surveillance authority in question all play a role.

The Alliance Working Group has ensured that surveillance authorities are able to interact with each other more easily. This has led to verbal exchange and the sharing of useful information, including best practices. Another consequence of this cooperation is that attention to the task areas of market surveillance and external border controls for products has increased within the surveillance authorities involved which are often entrusted with several surveillance duties and fields. This has also caused a number of surveillance authorities to begin modernising the market surveillance strategies and operations that they have been employing to date.

Greater knowledge of each other's domains and operations has also made it clear that there are limits to cooperation when it comes to concrete market surveillance. Joint market surveillance can enhance the efficiency of the surveillance; a particular product is subjected to a one-stop investigation of the risks it poses to various public interests. That said, the number of product groups that lend themselves to such cooperation is limited. A risk-based surveillance operation with resulting establishment of priority reveals that the vast majority of products are only of interest to one surveillance authority.

For the other surveillance authorities, based on their own risk assessment, these product groups are less relevant or totally irrelevant. One reason for the latter may be that the product groups present very little risk to the public interest that these other surveillance authorities have to protect.

Where risk-based surveillance by several surveillance authorities does produce a common product group, joint market surveillance is hindered in practice by the different statutory powers, but also by internally managed operations and protocols within the agencies concerned. This was made clear in the joint surveillance project conducted in 2013 by three surveillance authorities on LED and energy-saving light bulbs. This project will be repeated in 2014 in a revised format that reflects the experience gained.

Despite these limitations and impediments, there are also examples of successful cooperation between surveillance authorities, including the joint surveillance of the REACH and CLP Regulations by three surveillance authorities. It is also worth mentioning in this context the cooperation that takes place with regard to the surveillance of products at the nexus between cosmetics and medical devices.

In the General Part of the 2013-2014 Annual Market Surveillance Plan (*Jaarplan Markttoezicht 2013-2014*) seven horizontal issues are mentioned by the five surveillance authorities. These topics

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affect the performance of all the surveillance authorities, but to varying degrees. Adequate tackling of these topics was therefore deemed very important for ensuring proper implementation of Regulation (EC) No 765/2008. The following developments are reported with regard to these points for attention.

#### *1. Risk assessment for non-compliant products*

The broad risk assessment model (RATF) developed at the European Commission's request for the application of Regulation (EC) No 765/2008 has been discussed in detail and demonstrated in the Alliance Working Group. All the inspectorates recognise the importance of risk assessment that is as standardised as possible. However, following a number of workshops the conclusion has been reached that the RATF model does not lend itself to standardised application. In particular, the model leads to confusion when it comes to determining the level of the risks where public interests other than health or safety are concerned. It has also prompted the question whether it is actually possible to develop a model that can be applied fully and at every stage for all domains and whether this is a prerequisite for proper implementation of the provisions of Regulation (EC) No 765/2008. An option might be to develop a corresponding risk assessment model for each public interest or group of interests.

#### *2. Cooperation with third countries*

The NVWA maintains close relations with the Chinese market surveillance authority in order to achieve a closed surveillance chain as regards the safety of consumer products manufactured in China and exported to the EU. The aim is to create a seamless link between the export controls by the Chinese Government on these products and the import controls performed by the NVWA at the Dutch external border (Rotterdam). This NVWA initiative has led to a Joint Action with ten other Member States, paving the way for it to become a European approach. This is a process of continuous improvement. The ILT has its own specific (fireworks) working relationship with the Chinese Government when it comes to market surveillance.

To date, ILT is the only surveillance authority to have established ties (MOU) with the Chinese Government in relation to fireworks. However, a number of surveillance authorities have started using the web tool Trade Route Asia (TRA), which is intended to inform EU importers doing business with China so that imported consumer products comply with European legislation.

The Chinese Government recently revised its export control system, shifting responsibility for the safety and conformity of export products away from the government onto the business (producer). In the case of medical devices, almost the opposite trend is evident; here the

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Chinese Government is keen to play a more prominent role regarding export products by collaborating with the surveillance authority for this domain, the IGZ.

#### *3. ICSMS*

Considerable efforts have been made to connect all the surveillance authorities to the ICSMS system. Numerous information events and workshops have been held for this purpose. As a result of these efforts, ICSMS is now operational for all domains falling under Regulation (EC) No 765/2008; all the surveillance authorities have been connected up to the system. The key to the success of ICSMS will be its ease of use and relevance to all domains. The surveillance authorities have indicated that necessary adjustments still need to be made to the system to achieve this.

#### *4. Cooperation with the business community and other stakeholders*

At the sectoral level, surveillance authorities have regular contact with the industry and national umbrella organisations over issues relating to legislation, compliance and surveillance. Agreements are also made with such organisations regarding the fulfilment and interpretation of statutory obligations, and an important sounding board role is found in this for the surveillance authority.

These consultations are seen as very useful by both parties. They contribute to a good relationship between (bona fide) business owners and the surveillance authority, a relationship in which the parties are made aware of what they can and may expect from each other. This relationship contributes to compliance.

What is still missing at present is a cross-sector national consultation forum to address the implementation of Regulation (EC) No 765/2008 and the MAMP. This should involve the five surveillance authorities, acting jointly, and the business community represented by umbrella organisations from trade and industry. The intention is to establish this cross-sector consultation forum during the second half of 2014. More horizontal issues, developments, plans and other topics relating to European and national market surveillance and external border controls on products will be discussed in this forum.

#### *5. E-commerce*

Surveillance of the booming internet trade is a top priority for every surveillance authority. In recent years, e-commerce surveillance projects have been carried out in various domains. The necessary experience gained, the operations and the insights have all been shared. Here, too, there seems to be a sense that the approach will differ for each domain – in some respects – so that maximum efficiency can be achieved within that specific domain. This will

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be dictated by the nature and scope of the domain, and the capacity of the relevant surveillance authority.

There are a number of basic principles common to all domains, such as the fact that proactive surveillance will be limited to enterprises based in the Netherlands. Proactive surveillance on products offered by internet businesses in other Member States or third countries will not, in principle, be expedient for efficiency reasons and thus will not (or cannot) be considered a priority. It is evident that consumers must take their share of the responsibility, especially when it comes to products from third countries. They must not simply trust that any non-compliant products that they order in China will be stopped in external border controls. They will therefore need to be provided with the necessary information on the risks of such purchases.

Fulfilment houses demand special attention. These are facilities in the Netherlands (or other Member States) where internet businesses based in third countries keep a stock of goods that they offer on the internet. This enables them to deliver the products to the consumer quickly. These warehousing facilities regard themselves not as economic operators as referred to in Regulation (EC) No 765/2008 but merely as logistics service providers.

A number of measures have now been taken against these companies within the framework of proactive surveillance. It is unclear whether Regulation (EC) No 765/2008 offers sufficient legal grounds to conduct external border controls on products ordered by a consumer in a third country for personal use. After all, these products are not placed on the market within the EU.

#### *6. Harmonisation of intervention policy*

The Netherlands government intends for all its surveillance authorities to perform their duties in as clear and uniform a way as possible. This also applies to product market surveillance authorities when they take measures against non-compliant products in their sector. What powers does each surveillance authority have? What measures can it take and which measure is appropriate for which infringement? There ought to be a certain level of consistency here for each domain. There is also an obvious European dimension to this; if certain Member States operate a significantly softer regime for interventions, this may lead to a distortion of competition. The surveillance authorities are currently busy putting their intervention policies side by side and comparing them. It should also be noted that a distinction must be made between the package of measures that the surveillance authority has at its disposal (written warning, fines, business closure and imprisonment) and which measure it applies to which type of infringement.

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The latter notably depends on the severity of the infringement and on the behaviour of the business owner (intent, repeat offence). So, the determination of the severity of the infringement – which involves more than just the degree of risk caused by the infringement – will be a particular focus of the discussion.

#### *7. Risk-based market surveillance*

The work of the six market surveillance authorities involved is founded on risk-based surveillance. They focus on the product groups and risks (product and compliance behaviour) that can have the largest impact in terms of subverting and undermining (harming) the public interests protected by European product legislation if the statutory requirements are not met. As already stated, their risk-based approach means that the surveillance authorities do not readily come up with a product group or risk that is perceived by more than one surveillance authority to be a priority. The product groups, the public interests protected by the legislation and the managed risks, and the compliance behaviour in the various domains generally differ too greatly for this to happen. Collaboration can mainly be found in the exchange of information concerning companies' compliance behaviour and other attributes, and regarding the results of product inspections and certain best practices.

#### *Summary*

Prior to 2010 the majority of inspection agencies involved in the Netherlands conducted market surveillance on the basis of the obligation to implement European product directives. The inspection agencies believe that market surveillance of products in the 2010-2013 period changed for the better in the wake of mandatory execution of Regulation (EC) No 765/2008. Surveillance methods were shared and improved, and cooperation between the agencies was strengthened, both within the Netherlands and across borders, with the result that product groups that carry the highest risk of harm to public interests safeguarded by the directives were tackled.

## **Part 2. Sectoral overview.**

### **Dutch Food and Consumer Product Safety Authority (NVWA)**

#### *Section A. Review of the surveillance activities.*

The NVWA is charged with surveillance of the safety of consumer products.

To this end, the NVWA monitors compliance with the following Directives and Regulations:

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- Regulation (EC) No 1223/2009 (Cosmetics)
- Directive 2009/48/EC (Toys)
- Directive 89/686/EEC (Personal protective equipment for consumers)
- Directive 75/324/EEC (Aerosol dispensers)
- Directive 2006/42/EC (Machinery intended for consumers)
- Directive 2009/142/EC (Appliances burning gaseous fuels)
- Directive 2006/95/EC (Low-voltage directive)
- Regulation (EC) No 1907/2006 (REACH)
- Regulation (EC) No 1272/2008 (CLP)
- Regulation (EC) No 648/2004 (Detergents)
- Directive 2004/42/EC (Paints)
- Directive 2009/125/EC (Energy labelling)
- Directive 2001/95/EC (General product safety)
- Regulation (EC) No 528/2012 (Biocidal products)
- Regulation (EC) No 1007/2011 (Textile names)

For this purpose, the agency has a workforce of 110 FTEs in total: 45 inspectors, 45 laboratory workers and 20 development and strategy employees. The NVWA has its own laboratories assisting with market surveillance in the areas of physics, mechanical engineering, electrical engineering, microbiology and chemistry. The Minister for Health, Welfare and Sport (VWS), the NVWA's client in the field of product safety, provides an annual budget of around EUR 11 million. The NVWA aligns its surveillance with the policy objective of the VWS Minister: protecting the consumer against products that may cause serious injury or some other serious harm to health by being unsafe.

In recent years, proactive surveillance has gone from being product-oriented to more business-oriented. This is to do with efficiency. The target group for proactive surveillance is a core group of around 3 000 enterprises that are together responsible for 85 % of relevant products put on the market (high-risk products that regularly demonstrate deviations) and regularly reveal failings in terms of compliance. Many of these businesses are EU importers with large commercial volumes involving a huge range of different types of high-risk products. This specific business group needs to ensure compliance for all these product groups.

Business-oriented surveillance focuses on encouraging compliance at these companies. This is done by checking as many types of products as possible at the same company (Business-Oriented Product Surveillance, BOPS). Not only does this make the actual sampling process more efficient (one visit, several product groups sampled), it also produces a better picture of the company's compliance behaviour as a whole.



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Another form of business-oriented surveillance that has grown massively is System Surveillance (SS). This involves using audits to check a company's quality system, if it has one and if this system is focused on assuring compliance with product safety legislation. Companies with a demonstrably well-functioning system are subjected to less surveillance.

This demonstrability is substantiated by taking product samples as a reality check. System surveillance yields good results at companies that want to and are able to invest in compliance and which also trade in many different types of product groups. A good system ensures that all these products comply with the legislation. Not all companies are willing or able to realise a system of this nature.

Surveillance at such companies involves the aforementioned BOPS approach.

The capacity saved by this business-oriented surveillance (SS and BOPS) is concentrated on notorious offenders identified. These are inspected several times a year.

The companies that are the focus of the surveillance are divided according to their compliance behaviour into green, orange and red and receive the corresponding level of surveillance.

Less product-oriented surveillance means less sampling and fewer laboratory tests, and more audits and monitoring. As an instrument, product-oriented surveillance has its own merits alongside business-oriented surveillance. It is a very clever tool for gaining an impression of a particular product or product group: how safe is it?

A decision has been taken to concentrate more on external border controls rather than market surveillance. Cooperation with the customs authorities and the number of checks have been intensified, and this will continue. These import controls, as they are called, are predominantly product-oriented, though they do also give increasing insight into the compliance behaviour of relevant companies. Proactive surveillance takes up approximately 60 % of the agency's capacity. The remaining 40 % is dedicated to reactive surveillance (RAPEX notifications and consumer complaints, etc.) and involvement in Prosafe and other European and international ventures, such as with the Chinese authorities, with a view to improving the surveillance chain (coordinating export and import controls).

Over the coming years, special attention will be paid to improving data mining. The objective here will be to optimise understanding of the trade flows and volumes of the relevant product groups, and the compliance behaviour of the players involved and the profiles of these players. A greater focus will also be placed on cooperating with the authorities of exporting third countries, such as South Korea.

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The sectoral part below deals exclusively with surveillance of compliance with EU legislation for the safety of consumer products. Consequently, surveillance of compliance with national product safety legislation is not addressed. In the Netherlands this concerns legislation governing tattooing dyes, cot beds and boxes, packaging and consumer articles, chipboard, ladders and stairs, and the safety of fairground and playground equipment.

#### *Section B. Assessment*

##### *REACH Regulation (EC) No 1907/2006 and CLP Regulation (EC) No 1272/2008.*

REACH and CLP checks are carried out in conjunction with the I-SZW and ILT. The inspections focus on the obligation to keep records, the mandatory communication of information concerning substances and mixtures in the chain by means of Safety Data Sheets (SDSs), and the accuracy of the SDSs themselves. Checks usually take place on the manufacturers' premises. In that case, the classification, labelling and packaging of substances and mixtures, as prescribed by the CLP regulation, are also inspected there at the same time. The compliance percentage for SDS accuracy is below 50 % and improvements are slow. CLP compliance fluctuates around 75 %.

In addition to these inspections, checks are also performed with regard to the prohibitive provisions in Annex XVII of REACH and the suppliers' duty to inform customers of the presence of SVHCs (substances of very high concern) in everyday objects. Compliance with the prohibitive provisions is very high at around 90 %. The surveillance authority checked, among other things, for AZO dyes and phthalates in various product groups, including textiles and toys. Compliance with the duty to inform regarding the presence of SVHCs had been very low but it has climbed in recent years to around 50 %.

##### *Textiles. Regulation (EC) No 1007/2011 and fire safety of textiles within the framework of the GPSD.*

Surveillance of compliance with Regulation (EC) No 1007/2011 (composition and labelling of textile products) is reactive. No complaints have been received regarding this in recent years.

In 2010, an investigation was conducted into the fire safety of 'Oranje' articles (football promotion). The compliance percentage was very low, which is not uncommon with these types of promotional articles. Contacts were established with the industry to provide the companies in question with better information about the regulations and risks.

##### *Cosmetics. Regulation (EC) No 1223/2009.*

Structural checks were performed to examine compliance with GMP, and the completeness and accuracy of technical files. In terms of GMP compliance, a marked improvement was noted. As

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regards the creation of files, this improvement is also evident but it is expected that the entry into force of Regulation (EC) No 1223/2009 in July 2013 will lead to reduced compliance in 2014 due to more stringent requirements for file contents. Project-based investigations were conducted into the concentrations of certain substances in cosmetics, including NDELA in mascara and eyeliners. Numerous deviations were found. The presence of nano-ingredients was examined within the framework of Pemsac.

Checks into the microbiological safety of cosmetics revealed such a good picture of compliance that the decision was taken not to perform any more projects here for the time being. Nail polish removers were also tested for the presence of benzene. No notable deviations were found here. Tooth-whitening products do not give any cause for concern as regards deviations.

*Toys. Directive 2009/48/EC.*

In 2012 and 2013, 135 manufacturers and importers of toys were inspected, though it should be noted that some of these companies were trading in many different product groups. Much emphasis was placed on the contents of technical files. Many of the technical files were found to be still missing or incomplete.

From 2011 to 2014, 630 toy samples were examined in terms of their physical and mechanical safety. The focus is on toys for children under 3 years old and especially on combating the risk of choking.

In addition, various groups of toys (wooden and plastic toys, balloons, finger paints, fancy dress costumes, playhouses/tents and cuddly toys) were examined in terms of their chemical safety. Depending on the type of material, they were tested for plasticisers, heavy metals, AZO dyes, preservatives and nitrosamines. Fire safety was also inspected. To this end, tests were conducted to verify compliance with the requirements of Annex XVII to the REACH regulation and those of the GPSD. A general compliance level of 90 % was found. An inspection of the microbiological safety of cuddly toys did not reveal any deviations.

*Electrical products. Directive 2006/95/EC.*

Many of the checks on electrical products are carried out as part of system surveillance at companies and within the samples taken for reality checks. In terms of compliance there is no evident cause for concern here. With reactive surveillance following complaints and notifications, the number of deviations is higher. Many activities have been and are undertaken and coordinated within the LVD ADCO.

Product groups addressed are: 12V/230V transformers, Christmas lights, child-appealing light fixtures, household appliances with a look that appeals to children, extension cables, swimming

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pool pumps, sunbeds, adaptors and solar panels. LED lamps and other LED products have been receiving structural attention for some time now.

*Energy-labelling products. Directive 2009/125/EC.*

With the exception of cars and tyres (ILT), the NVWA is responsible for monitoring compliance with this directive. There are evident shortcomings here. These relate both to the presence and visibility of the label and to the accuracy of the label with regard to the characteristics of the product on which it has been affixed. The files are often not in order either. New product groups subjected to this legislation present a picture of compliance that is poorer again. However, compliance has been improving substantially in recent years.

Improvements in cooperation within the ADCO are essential, specifically for this legislation.

*Appliances burning gaseous fuels. Directive 2009/142/EC.*

At least one type of gas appliance was examined each year. These included terrace heaters, camping heaters and compact gas cookers. The necessary deviations were found. With this group of gas cookers it was found that the harmonised standard is unsatisfactory and that notified bodies wrongly solely examine whether the appliance meets this standard instead of assessing whether essential requirements are met. Documentary checks were performed at manufacturers of central heating boilers. No major deviations were found.

*Biocidal products. Regulation (EC) No 2012/528.*

Since 2012, surveillance of biocidal products has largely been conducted as part of system surveillance and business-oriented product surveillance. There have been no separate projects for this since then. A check performed in 2010 revealed a high percentage of biocidal products not permitted in the Netherlands. These products came mainly from Member States where they were allowed to enter the market without authorisation. With the entry into force of the Biocidal Products Regulation in September 2013 this picture is expected to improve as our neighbouring Member States will also be subject to authorisation requirements for biocidal products.

*Machinery (for consumer use). Directive 2006/42/EC.*

Since 2009, machinery surveillance has been shifted away from market surveillance and more towards external border controls for efficiency reasons. It had become clear that the number of deviations found with the latter controls was significantly higher than with normal market surveillance.

Recent years have seen a continuous reduction in the quantity and severity of the deviations. Since 2012, market surveillance has been included in system surveillance and business-oriented product

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surveillance. Both market surveillance and import controls were directed exclusively at the lower end of the market in 2012 and 2013.

*Personal protective equipment (for consumer use). Directive 89/686/EEC.*

Proactive surveillance of personal protective equipment has been suspended since 2009 on the basis of a risk analysis prompted by budgetary constraints. Up to 2009 there were regular projects for specific groups of equipment which involved raising compliance to an acceptable level. Reactive surveillance does, however, take place on the basis of consumer complaints, RAPEX notifications and safeguard measures by other Member States. Based on the findings from this reactive surveillance, there is as yet no reason to include this product group in proactive surveillance again if no extra resources are made available for this purpose.

*Imports. (External border controls).*

A very high percentage of consumer goods that are placed on the market in the EU come from third countries. In all, 25 % of this flow of goods enters the EU through the port of Rotterdam. It is therefore essential to collaborate well with the customs authorities to ensure that external border controls are efficient. During these external border controls, product groups such as lighting, toys, machinery, lighters and lasers are checked, and any deviant batches are detained. This is done using risk profiles supplied by the NVWA to the customs authorities for product groups that require checking.

Supplementary to this risk-based product selection, an ever-improving impression emerges of the compliance behaviour of the enterprises that bring in these product groups. This also makes it possible to make checks more and more focused because the profiles of both the product groups and the businesses involved can be ever more precise.

### **Netherlands Radiocommunications Agency (AT)**

*Section A. Review of the market surveillance activities.*

The Netherlands Radiocommunications Agency (AT) monitors the compliance of equipment subject to the R&TTE and EMC directives.

These directives have been implemented in the Telecommunications Act (*Telecommunicatiewet*).

AT applies a governance philosophy here that is partly based on the principles of the government policy as set out in the Framework Vision of Surveillance (*Kaderstellende visie op Toezicht*).

According to this governance philosophy, surveillance that is intelligence-led and risk-oriented is prioritised, with attention to the social relevance of the equipment. This also involves an element of risk acceptance; it is not impossible that a particular product that has not been prioritised in the

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surveillance will prove to be a non-conforming product. For this reason, AT also conducts reactive surveillance on the basis of fault notifications and complaints. AT collaborates nationally and internationally, liaises with its stakeholders and aims to make its surveillance activities more effective, with the least possible burden on businesses that comply with the regulations.

The workforce for market surveillance was extended by 1 FTE in 2011. This means that the budget available for market surveillance is around EUR 1.6 million in nominal terms. This amount is partly determined each year by the intended external tests and information activities, so it fluctuates year on year. A total of around 10 FTEs are involved in market surveillance, with available inspectors accounting for roughly 6 FTEs.

From 2010 to 2014, the Netherlands Radiocommunications Agency improved its market surveillance methods and operation. This is evident from the more detailed annual plans for 2013 using the template from the European Commission. The Netherlands Radiocommunications Agency is therefore leading the way in terms of providing specific details of activities to be performed. Feedback on the Dutch results was also set in motion via the R&TTE ADCO and EMC ADCO.

AT is actively engaged at European level. In 2010, AT handed over the chairmanship of the R&TTE ADCO to Switzerland. AT has created an impact assessment procedure that is used to determine the subject of European ADCO (EMC and R&TTE) market surveillance campaigns. AT has taken part in all European surveillance campaigns connected with the R&TTE and EMC ADCOs. The final reports of these campaigns can be found on the European Commission's website<sup>12</sup> and have been discussed with the industry via the EMC Working Party and via TCAM<sup>3</sup> (the committees belonging to the directive that involve stakeholders). The same applies to a bilateral campaign between the Netherlands and Germany with tablet PCs. AT has also contributed to the reflective role of surveillance by informing the aforementioned bodies that harmonised standards are not adequate, for example. The R&TTE ADCO provides the European Commission and TCAM with its annual statistics<sup>1</sup> for market surveillance, which include AT's key figures.

AT was the jammer coordinator in the R&TTE ADCO for a number of years. The Netherlands is at the forefront of efforts in the European Union to combat jammers. In 2013, 206 jammers were seized. This is thanks to adequate collaboration with and training of the customs authorities and police. The Netherlands has been asked to explain and promote its operation to the other countries in 2015.

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<sup>1</sup> [http://ec.europa.eu/enterprise/sectors/rtte/documents/state-of-play/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/rtte/documents/state-of-play/index_en.htm)

<sup>2</sup> [http://ec.europa.eu/enterprise/sectors/electrical/documents/emc/guidance/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/electrical/documents/emc/guidance/index_en.htm)

<sup>3</sup> Telecommunications Conformity Assessment and Market Surveillance Committee

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AT has worked on compliance assistance. The information on equipment on AT's website has been improved, and the surveillance operation and results have been shared with market players in at least three dialogue sessions per year.

AT reported annually on equipment market surveillance during the 2010-2013 period in its 'State of the Ether' (*Staat van de Ether*) annual report. These annual reports were published at <http://www.agentschaptelecom.nl/algemeen/frequentiemanagement/staat-van-de-ether>.

The State of the Ether addresses not just spectrum implementation and monitoring, but also the market surveillance carried out on equipment and reflects on this. It is evident from this that inspections and actions were performed, for equipment, on LED lamps, energy-saving light bulbs (PL lamps), EMFs of all kinds of transmitters, jammers, all sorts of unlicensed devices (incl. 2.4 GHz, 5 GHz), black markets, internet surveillance, tablet PCs, the SAR of laptops, WLANs (WiFi), GSM repeaters, GPS repeaters and DECT telephones. The number of inspections conducted annually is around 300.

#### *Section B. Assessment.*

The market surveillance is rated as adequate. During the 2010-2013 period, the market surveillance activities at AT improved all the time. Information-led and risk-oriented surveillance has been integrated into the operation. In addition, AT is held publicly to account for the work performed. However, more information needs to be collected to make improvements. For example, AT is keen to focus more on the start of the logistical chain (manufacturers and EU importers), but good information on trade flows is lacking. The dynamism of trade flows seems considerable. Internet surveillance could also be improved and deployed better in market surveillance. AT is worried about private imports of non-conforming equipment for personal use by consumers. Finally, the execution of the new regulatory framework for both the EMC directive and the revised radio equipment directive will require the necessary capacity in 2015 and 2016.

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### **Social Affairs and Employment Inspectorate (I-SZW)**

#### *Section A. Review of the surveillance activities*

Organisation of I-SZW market surveillance

#### *Risk-driven enforcement*

The I-SZW monitors compliance with 6 product directives according to Regulation (EC) No 765/2008.

These are machinery (Directive 2006/42/EC), personal protective equipment (Directive 89/686/EEC), lifts (Directive 1995/16/EC), pressure equipment (Directive 97/23/EC), simple pressure vessels (Directive 2009/105/EC) and explosion-safe equipment (Directive 2014/34/EU).

Proactive and reactive market surveillance was introduced by the I-SZW on 1 January 2012.

Prior to 2012, this surveillance task had been the responsibility of the Labour Inspectorate (*Arbeidsinspectie*), which became part of the I-SZW on 1 January 2012.

During the reporting period (2010 to 2013), the I-SZW gradually improved the execution of the market surveillance programme. Programmatic working (the system for managing projects and programmes is authoritative) and risk-driven surveillance (product groups are selected on the basis of tactical risk analyses) are starting points in the checks by the I-SZW.

Enforcement of the provisions of the Commodities Act (*Warenwet*) is part of the Enforcement Policy (*Handhavingsbeleid*) of the I-SZW. The Commodities Act Enforcement Instruments (*Handhavingsinstrumentarium Warenwet*) are used for market surveillance.

In 2011, a first attempt was made at developing the 2011-2015 market surveillance strategy. Risk profiles for enforcement and compliance were created using a proven analysis method, the Table of 11 (*Tafel van 11*), which examines reasons for compliance.

To standardise surveillance for product safety, a weighting method was developed for handling reactive market surveillance issues on the basis of notifications, complaints and alerts.

#### *Focus on target groups*

The I-SZW has worked on the basis of risk and environment analyses. Surveillance and detection are used where the most intractable problems lie and where the impact is greatest. Manufacturers and assemblers of machinery, traders in second-hand machinery in the EU, and manufacturers and



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importers of personal protective equipment have therefore been important target groups for the inspectorate.

#### *Qualified inspectors*

To ensure that checks remain legitimate and effective, the I-SZW invests in the professionalism of its inspectors. In all, 18 inspectors have received the Market Surveillance Inspector Qualification (*Kwalificatie Markttoezicht Inspecteur*) for the machinery product directive.

Each year, cases experienced by the market surveillance inspectors were discussed. This was done during peer review meetings and workshops.

The I-SZW Centre of Expertise (*Expertisecentrum*) facilitates and provides knowledge and guidance to the inspectors by drawing up inspection pointers for (re)active projects and giving legal advice on interpreting (re)active inspection projects and controls.

The Investigation & Analysis (*Onderzoek & Analyse*) section performs exploratory investigations and chain analyses to produce risk analyses for product groups and target groups.

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### *Capacity*

A team of 8 inspectors performed market surveillance during this period.

This group was facilitated by the I-SZW Centre of Expertise (2.5 FTEs). The project management consisted of a project leader and project secretary (1.5 FTEs).

The personnel costs were roughly EUR 600 000.

The investigation costs amounted to roughly EUR 375 000.

employees	2010	2011	2012	2013
inspectors	3	4	8	8
specialists	2	2	2.5	2.5
project management	0.5	0.5	1.0	1.5

Table: market surveillance capacity of the I-SZW

### *Information*

The I-SZW ensures that economic operators have access to the latest product safety information via the website [www.inspectieszw.nl](http://www.inspectieszw.nl).

### *International cooperation and exchange*

#### ADCO working groups

During the 2010-2013 period, the I-SZW took part in various ADCOs: Machinery, Personal Protective Equipment, ATEX, Pressure Equipment and Lifts.

The I-SZW's contribution to these ADCOs is specifically addressed below.

**Machinery:** The I-SZW attended meetings and gave presentations on the practice of market surveillance and the problems with certain types of machinery. It also took part in working groups: agricultural machinery, market surveillance working methods and the joint project NOMAD (investigation into the noise intensity of machinery within the machinery directive).

NOMAD examined the quality of the information on noise in the user manual. As a follow-up, the I-SZW took part in a seminar held by the European Commission with stakeholders and information material was prepared for manufacturers.

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Personal Protective Equipment (PPE): During the period from 1 January 2010 to 1 January 2013, the I-SZW acted as chair together with Denmark. The I-SZW also took part in the working group on market surveillance working methods for Personal Protective Equipment.

ATEX: in 2010, the I-SZW was involved in a joint action project organised by the ADCO working group ATEX. The assignment was to select ATEX products and perform documentary and marking checks. In 2012, an EU inspection list was drawn up, ranking the infringements.

Investigation by the I-SZW revealed that the products are regularly missing a Dutch user manual. This led to the identification of administrative infringements.

Pressure Equipment: The I-SZW attended the meetings of the pressure equipment ADCO.

Lifts: The I-SZW gave four presentations. It also contributed to the definition of the distinction between cableways and lifts.

In 2012, the Ministry of Social Affairs and Employment began fulfilling comitology agreements (elaboration of the product directives and regulations on product safety, known as the primary regulations) for the five product directives. Knowledge and insights from the comitology consultation are presented to the Standing Committee of the European Union.

*Information management within the European Economic Area (EEA).*

### **RAPEX**

During the reporting period, the I-SZW issued 4 RAPEX notifications. Three of these related to electric side curtain ventilation systems. A fourth notification related to a bending machine from Taiwan.

The I-SZW received five RAPEX notifications via the NVWA.

### **ICSMS**

The I-SZW began preparing for the implementation of the ICSMS system. The authorised inspectors and employees use the system to perform checks and surveillance tasks.

### **External border controls**

To begin external border controls, talks were held with the customs authorities and other state surveillance authorities. Preparations are underway for internal decisions on the execution of inspection projects, work agreements with the customs authorities and the drafting of risk profiles.

### **Joint actions**

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During the period under review, the I-SZW participated in the joint action ATEX. Further plans are being prepared for the coming review period.

#### *Section B. Assessment.*

##### *Reactive projects and activities*

The inspectorate investigates product complaints or notifications of accidents with products. Inspectors examine whether the machine has been made unsafe by modifications or the machine has been used incorrectly.

During the 2010–2013 period, almost 100 notifications were processed. These were mainly reports of possible non-conforming machines and, in some cases, non-conforming personal protective equipment (PPE).

##### *Active projects and activities*

These relate to inspections with regard to the machinery product directive (scissor lifts, servicing lifts, side curtain ventilation systems and cloth cleaners) and auctions as a trade instrument.

##### *Scissor lifts*

In 2012, the I-SZW launched the inspection project as a consequence of a fatal accident with a scissor lift and pipe-rail trolley defects. International investigations also revealed that a number of scissor lifts do not meet the safety requirements.

A total of 45 inspections were performed at manufacturers, importers and suppliers that sell scissor lifts on the Dutch market. The results of the inspections were discussed with the industry and announced to the users of scissor lifts via articles in trade journals.

The I-SZW concluded that the scissor lifts of large manufacturers comply with the machinery directive. The same applies to small platforms. Only once had there been an administrative infringement.

##### *Servicing lifts*

Servicing lifts made by various manufacturers were found not to meet statutory requirements, so unsafe servicing lifts were sold on the market. The I-SZW therefore initiated an inspection project. The inspections revealed that importers and traders were not fully aware of the product regulations. In all, 31 importers and distributors of servicing lifts were investigated.

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In 55 % of cases enforcement actions were taken. Warnings were issued for missing conformity declarations and/or the absence of Dutch user instructions. The approach at the manufacturers means that non-conforming servicing lifts are traded.

#### Side curtain ventilation systems

Two fatal accidents prompted the inspectorate to investigate manufacturers and importers. In all, 17 manufacturers were inspected, resulting in 16 enforcement actions.

Discussions were then held with the industry about implementing modifications. Owing to the absence of a standard, the Netherlands Standardisation Institute (*Nederlands Normalisatie Instituut* – NEN) drew up a Netherlands Technical Agreement (*Nederlands Technische Afspraak* – NTA). This NTA 8344 was published in 2012. A proposal for the development of a European standard was also submitted to the European Committee for Standardization (CEN). This proposal was approved, and the committee began developing the standard.

Since the actions taken by the inspectorate, the side curtain ventilation systems placed on the market have been compliant.

#### Cloth cleaners

There were three accidents involving cloth cleaners in 2012. The manufacturer was ordered to cease trading and to modify the product. This manufacturer then informed customers of the danger and risk associated with the cloth cleaners. After that, the manufacturer brought the hazards to the attention of the users. The manufacturer went bankrupt shortly after.

#### *Auctions*

Machines are traded by manufacturers, distributors and importers. Auctions are also a channel for trading machinery.

The I-SZW conducted a detailed investigation into the auctioning of machines. The focus was on identifying machines (origin and destination) that are placed on the European market for the first time via auctions.

The inspectorate also explored whether the use of auctions poses an additional risk in respect of bringing unsafe machines to the European market. Were it to transpire that non-conforming machines are entering the European market via auctions, the intention was to notify the European Member States and the European Commission with a view to launching a joint action project.

In all, 17 business addresses were investigated.

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In only one case was the machine not compliant with the machinery directive. Large auction houses operate in accordance with the directives.

#### *Summary*

The I-SZW performed its surveillance task reactively mainly in response to alerts from the Netherlands and abroad. The focus was placed on the following target groups: machine modifiers, personal protective equipment manufacturers and machinery assemblers.

The I-SZW states that the majority of products comply with the statutory requirements and harmonised standards. Specific groups of economic operators were found to be insufficiently aware of the legal and regulatory requirements. Warnings were issued and the instrument of administrative fines was used.

Efforts were made in collaboration with industries and market players to communicate information and exchange knowledge with the help of information events, digital media and trade magazines. Dutch input was achieved through participation in the ADCO working groups.

Checks were performed in 2012 and 2013. The number of inspections in 2013 was roughly 30 % higher than in 2012.

### **Human Environment and Transport Inspectorate (ILT)**

#### *Section A. Review of the surveillance activities*

The Home Environment and Transport Inspectorate (ILT) monitors compliance with the following Directives and Regulations:

Regulation (EC) No 1907/2006 (REACH)

Regulation (EC) No 1272/2008 (CLP)

Regulation (EC) No 1102/2008 (Mercury)

Regulation (EC) No 689/2008, repealed and replaced by Regulation (EC) No 649/2012 (Prior informed consent)

Regulation (EC) No 850/2004 (Persistent organic pollutants, POPs)

Directive 87/217/EEC (Asbestos)

Directive 2011/65/EU (Restriction of the use of hazardous substances in electrical and electronic equipment, ROHS II)

Commission Decision 2002/359/EC (Drinking water)

Directive 93/15/EEC (Explosives for civil use)

Directive 2007/23/EC, repealed and replaced by Directive 2013/29/EC (Pyrotechnic articles)

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Regulation (EC) No 1005/2009 (Substances that deplete the ozone layer)

Regulation (EC) No 842/2006 (Fluorinated greenhouse gases)

Directive 98/70/EC (Quality of petrol and diesel fuels)

Directive 1999/32/EC (Sulphur content of liquid fuels)

Directive 2004/42/EC (Volatile organic compounds)

Regulation (EC) No 528/2012 (Biocidal products)

Regulation (EC) No 1451/2007 (Biocidal products)

Directive 89/106/EEC, repealed and replaced by Regulation (EC) No 2011/305 (Construction products)

Directive 2005/32/EC, repealed and replaced by Directive 2009/125/EC (Ecodesign)

Directive 2004/12/EC (Packaging and packaging waste)

Directive 2003/37/EC (Type-approval of trailers, etc.)

Directive 2002/24/EC (Type-approval of two or three-wheel motor vehicles)

Directive 2007/46/EC (Approval of motor vehicles and trailers and components thereof)

Directive 94/25/EC, as amended by Directive 2003/44/EC (Recreational craft)

Directive 2006/66/EC (Batteries and accumulators)

Directive 2000/53/EC (End-of-life vehicles)

Since 1 January 2012, surveillance of compliance with these Directives and Regulations has been the responsibility of the ILT. Prior to 2012, the surveillance task lay with the Housing, Spatial Planning and the Environment Inspectorate (*VROM-Inspectie*) and the Transport, Public Works and Water Management Inspectorate (*Inspectie Verkeer en Waterstaat – IVW*). The number of issues monitored by the ILT is very varied. The corresponding surveillance is carried out with a workforce of more than 65 FTEs.

The ILT enforces compliance with laws and regulations in three ways:

#### *Service provision*

The provision of services to the parties that are subject to surveillance involves the supply of information and advice on legislation and regulations by the inspectorate. The inspectorate also makes it easier for these parties to meet their obligations by, among other things, digitising request and information requirements, simplifying forms and providing a good system for handling complaints. The processing of notifications concerning such things as fireworks and drinking water is also among the services provided by the inspectorate.

#### *Surveillance*

The inspectorate conducts surveillance according to the principle of 'trust, unless ...'. The basis for this is a compliance and risk selection system that the inspectorate will develop further over the next few years. The tools at its disposal are object inspections, administrative checks, digital

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inspections and audits. Where 'permanent improvement' is a requirement, the inspectorate also monitors that aspect.

When choosing its interventions, the inspectorate uses the intervention ladder. The steps represent interventions with increasing impact on the party that is subject to surveillance. Within statutory powers and according to general principles of sound administration, the inspector chooses the intervention that he expects to have the greatest impact.

In the event of proper compliance, the party is subjected to less surveillance and enforcement agreements can be concluded. This also satisfies the political desire to pursue horizontal surveillance more. In the case of good compliance by companies with management systems, the inspectorate may also limit itself to the following:

- system surveillance (audits);
- reality checks (object and administrative checks, audits).

#### *Detection*

Detection is aimed at systematically investigating criminal offences under the guidance of the Public Prosecution Service (*Openbaar Ministerie* – OM). The objective of the detection task is to provide evidence of criminal offences as required to put a stop to these criminal activities, to enable the OM to pursue any prosecution, to deprive the party concerned of the economic profit from these activities or to claim back such profit. Detection activities are carried out at the inspectorate by general investigative officers working for the Information and Investigation Service (*Inlichtingen- en Opsporingsdienst*) and by special investigative officers (*buitengewone opsporingsambtenaren* – BOAs) working in the domains.

#### *Inspection procedure*

The inspections performed by the ILT are based on national regulations that incorporate EU Directives and Regulations. Any mention below of a particular Directive or Regulation therefore refers to its transposition into national regulations.

With regard to REACH, etc., the ILT's role is to monitor the entire chain of substances and chemical products through to the end user. The end user is monitored by the I-SZW. The ILT focuses on the professional products chain, while the NVA focuses on the consumer products chain. Where there is overlap between the two chains, consultation takes place. The ILT conducts surveillance using integrated checks on compliance with REACH rules at companies and by processing alerts.

The task of monitoring the prevention and reduction of (environmental) damage as a consequence of asbestos is the responsibility of different bodies. At municipal level, the Regional Implementation Offices (*Regionale Uitvoeringsdiensten* – RUDs) monitor the removal of asbestos from buildings,



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while the ILT does the same for objects. The I-SZW monitors the certification system created for identifying and removing asbestos. The I-SZW also monitors the working conditions for asbestos removal. In recent years, the ILT has made an effort to improve cooperation between surveillance authorities within the asbestos chain. The ILT is relying increasingly on proactive enforcement through risk-driven inspections. It also performs industry-specific investigations into possible asbestos-containing objects. This topic aside, the ILT's surveillance was mainly reactive on the basis of notifications.

In the case of waste electrical and electronic equipment and packaging, the ILT's surveillance is aimed at producers and importers. The surveillance is both object-oriented and business-oriented, whereby checks are made as to the extent to which the target group at system level ensures that the products that are placed on the Dutch market comply with product regulations.

Increasing numbers of integrated checks are also performed. These involve checking a party that is subject to surveillance in relation to ROHS (Directive 2011/65/EU), Ecodesign (Directive 2009/125/EC) and Packaging (Directive 2004/12/EC). With these administrative checks, a random sample of products is taken for which the requisite documents (conformity declaration, test report, etc.) are checked, and object checks are also conducted for verification. With object checks, indicative measurements are taken using measuring equipment to check for the presence of heavy metals in electrical and electronic equipment or in packaging. If the indicative measurement indicates non-compliance, the sample is measured representatively by an accredited laboratory. An object check can also involve measuring the energy consumption of electronic and electrical equipment.

There has been a shift away from risk-oriented surveillance towards surveillance that is (partly) aimed at producing a representative picture of compliance. Up to the end of 2012, surveillance had been geared towards the highest potential for infringements. From 2013 onwards, the ILT focused on producing a representative picture of compliance for the entire target group. This means a different selection criterion for the sample that is checked.

Notifications are also processed. Possible notifications are reports that an importer/manufacturer has not made a disclosure. Other notifications may be reports from a company that a product is not compliant or from another Member State that a product is not compliant but the manufacturer or importer is based in the Netherlands. All notifications are processed.

The regulations with regard to newly marketed batteries and accumulators and cars in the directives are limited. They mainly concern rules for the presence of heavy metals in batteries and vehicles. The ILT only conducts reactive surveillance based on notifications and alerts. However, there has been none of these in recent years.

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As regards biocidal products, the ILT's checks during the 2008-2013 period prioritised the trade in and use of unauthorised products. Checks were also conducted into whether authorised products are used for the application for which they were authorised. In this respect, the ILT focuses on products for professional use and the NVWA on products for use by consumers; the ILT and NVWA also alert one another to possible infringements in the other inspectorate's territory.

At pest control businesses, the ILT also checked for compliance with the instructions for use and the presence of a certificate of professional competence.

Surveillance on the basis of Regulation (EC) No 1005/2009 and Regulation (EC) No 842/2006 (substances that deplete the ozone layer and fluorinated greenhouse gases) is carried out both by the municipalities (RUDs) and by the ILT. The ILT monitors installers, mobile installations and larger stationary installations. The municipalities/RUDs monitor smaller installations, partly within the context of enforcement of regulations under the Environmental Permits (General Provisions) Act (*Wet Algemene Bepalingen Omgevingsrecht – WABO*). The customs authorities monitor imports and exports on behalf of the ILT.

Surveillance of the specifications for fuels (Directive 98/70/EC) is carried out according to the prescribed directives. Surveillance of compliance with the sulphur directive (Directive 1999/32/EC) is mainly done on the basis of received letters of protest pursuant to MARPOL Annex VI. Surveillance of volatile organic compounds (Directive 2004/42/EC) has mainly been based in recent years on notifications and targeted actions with the sale of residual batches of paints and varnishes. With the latter two subjects there is no collaboration with other agencies outside the ILT, nationally or internationally.

#### *National cooperation*

For the purposes of enforcing REACH and CLP, the ILT collaborates with the NVWA, the I-SZW, the customs authorities and the State Supervision of Mines (*Staatstoezicht op de Mijnen – SodM*). For enforcement of the POP regulation, the ILT works with the NVWA. In addition, to enforce the PIC and mercury regulations, the ILT cooperates with the customs authorities. Since 2009, the ILT has drawn up annual reports on the enforcement of REACH and CLP together with its enforcement partners (in English, too).

The target group of producers/importers of electrical and electronic equipment is partly known. It includes members of collective implementing organisations, such as Wecycle and the Technological Equipment Recycling Foundation (*Stichting Recycling Technologische Apparatuur – RTA*). These implementing organisations work on behalf of member producers and importers to collect and

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recycle waste electrical and electronic equipment. The ILT also uses import data from the customs authorities to analyse its target group. Finally, there is an unknown, dynamic group of free riders.

To enhance opportunities for cooperation in the field of market surveillance, LED lamps were monitored as a joint action with the NVWA and the Netherlands Radiocommunications Agency (AT) (2013-2014). The results will be available in September 2014.

For enforcement of the biocidal products rules, the ILT works with the NVWA and the water boards. In 2013, a report was drawn up on enforcement during the 2008-2012 period, and work is ongoing on a report covering 2013.

For the purposes of enforcing compliance in relation to explosives for civil use, the ILT collaborates with the police, the customs authorities, the DCMR environmental protection agency for Rijnmond and the State Supervision of Mines (SodM).

To enforce compliance relating to fireworks, the ILT cooperates with the customs authorities, Regional Implementation Offices and the police. Work agreements have been entered into with the customs authorities with regard to cooperation. For instance, the customs authorities will report all incoming batches of fireworks to the ILT. This will make it possible to check these batches at an early stage.

#### *European cooperation*

For planning with regard to REACH, etc., use is made of the information on records in the REACH Information Portal for Enforcement (RIPE) of the European Chemicals Agency (ECHA), and this system is consulted for business checks.

In relation to REACH, etc. and biocidal products, enforcement information is exchanged with other Member States, but this does not involve ICSMS for the time being because it does not yet meet the requirements for the kind of information that has to be exchanged (level of confidentiality). For construction products and recreational craft, the ILT still makes little use of ICSMS because it is still waiting, in a number of areas, for specific input fields related to the various Directives/Regulations. These new input fields are currently being developed by the EC.

The ILT is a member of an ADCO for various matters: Ecodesign, ROHS, fireworks, CE marking on construction products and CE marking on recreational craft.

For Ecodesign (Directive 2005/32/EC), the number of regulations is still on the increase. The ILT prioritises the execution of agreements made in the Ecodesign ADCO; the ILT chaired the Ecodesign ADCO until September 2014. A major focus of this ADCO is the promotion of closer

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cooperation between countries and the realisation of more efficiency in market surveillance by stimulating the exchange of information/data.

The current inspection programme, including the associated measurement programme, partly stems from the now ongoing European cooperation project, Ecopliant. This project involves 10 European countries working together. The principal objective of the project is to develop directives for the execution of market surveillance according to Ecodesign regulations. These directives concern all elements of surveillance, such as product selection, the performance of document inspections, the taking of measurements and the adoption of enforcement measures, making use of information received from surveillance authorities abroad.

For ROHS (Directive 2011/65/EU), priority is given to the agreements forged internationally in the ROHS ADCO. This means specific attention to cheap electronics.

With regard to fireworks, the ILT collaborates internationally with other countries within the EU. There is a platform (ADCO) where cooperation relating to market surveillance is coordinated and improved further. In addition, a Memorandum of Understanding (MOU) has been drawn up and signed between the Netherlands and China, leading to the launch of cooperation projects with China, too.

For surveillance of the CE marking on construction products, the ILT has taken part in the Construction Products Regulation ADCO since 2010. The Netherlands chaired these ADCO consultations in 2013 and 2014.

For surveillance of the CE marking on recreational craft, the ILT has taken part in the Recreational Crafts Directive ADCO since June 2013.

The ILT has also participated in the horizontal consultation forum for ADCO Chairs. This is a new forum organised by DG Enterprise and Industry, Unit C1. It took place in March, and the next forum is scheduled for October 2014.

International cooperation in the area of explosives for civil use currently occurs ad hoc on a case-oriented basis. However, efforts are being made to examine whether a platform (ADCO) can be set up where the cooperation between European Member States with regard to market surveillance can be coordinated and improved further.

For type-approvals of vehicles and components, 2015 will be all about further developing surveillance by establishing contacts at European level with European enforcers and European type-approval bodies. At the moment, there are no active ADCOs in this area. The inspectors are familiar with RAPEX and ICSMS, but they are not yet actively used.

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As regards asbestos and chemicals in drinking water, there has been virtually no European cooperation here.

### *Section B. Assessment*

*Regulation (EC) No 1907/2006 (REACH)*

*Regulation (EC) No 1272/2008 (CLP)*

*Regulation (EC) No 1102/2008 (Mercury)*

*Regulation (EC) No 689/2008, repealed and replaced by Regulation (EC) No 649/2012 (Prior informed consent)*

*Regulation (EC) No 850/2004 (Persistent organic pollutants, POPs)*

During the 2010-2013 period, the ILT performed checks on compliance with the obligation to keep records, the duty to inform and the bans or restrictions on use for substances posing the highest risk. Compliance with the obligation to keep records was checked at producers, importers and sole representatives. Compliance here increased during the 2010-2013 period and is now roughly 90 %. In terms of the duty to inform, most companies do have safety data sheets (SDSs), but these are often outdated or do not meet the requirements. Compliance here for the entire chain from producers/importers to end users was less than 50 %.

The ILT also checked bans and restrictions on use for the following substances and products: PFOS in fire-fighting foams, PAHs in car tyres, BDEs in plastic waste, creosote-treated wood, and nonylphenol and nonylphenol ethoxylates in mixtures. In addition, the customs authorities check for cadmium and mercury in imported products on behalf of the ILT. The ILT also deals with alerts concerning substances that are banned or subject to restrictions on use; various alerts concerning asbestos in products were processed. Compliance with the bans and restrictions on use is extremely varied and depends on the substances, previous enforcement actions and any change in the rules.

The customs authorities also check compliance with the PIC regulation on behalf of the ILT. Compliance is higher than 90 %.

*Directive 87/217/EEC (Asbestos)*

For the time being, product surveillance is performed mainly on the basis of notifications and complaints. While the use of asbestos continues not to be subject to globally uniform regulations, there remains the possibility that new products containing asbestos will be placed on the market.

*Directive 2011/65/EU (Restriction of the use of hazardous substances in electrical and electronic equipment)*

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While examining cheap toys at importers (object inspections), it was found that the majority of the companies had electrical or electronic equipment with an overly high content of hazardous substances (2010).

Examinations of large household appliances at importers (object inspections) revealed no non-compliance with the standards for heavy metals (2011).

From 2013 onwards, ROHS inspections were carried out as part of combination checks. Administrative checks were performed at importers of tertiary lighting and external power supplies. For verification purposes, a random sample of products were subjected to object inspections (ROHS, energy consumption). The corresponding compliance figures have yet to be analysed.

In addition to administrative checks, targeted ROHS checks (object checks) were carried out on containers with electronic products in 2013 and 2014 as a collaboration between the ILT and the customs authorities. As agreed in the ROHS ADCO, specific attention here was paid to cheap electronics. It transpired that over 60 % of the objects sampled were compliant, while almost 40 % did not satisfy the regulations.

#### *Commission Decision 2002/359/EC (Drinking water)*

Companies that produce materials and chemicals that come into contact with drinking water must have these materials and chemicals tested for possible detrimental consequences for public health and then certified. Companies that supply drinking water and independent water abstraction facilities (small-scale drinking water abstraction) must only use materials and chemicals that have been tested/certified.

The ILT monitors the use of (certified) materials and chemicals by the 10 Dutch water companies and approximately 250 independent water abstraction facilities. This is part of the integrated surveillance of water companies and independent water abstraction facilities. Water companies demonstrate good compliance with the legislation and regulations. An investigation in 2010 revealed that 96 % of the chemicals used by water companies for the production of drinking water were certified. In the case of independent water abstraction facilities, actions taken are reactive.

#### *Directive 93/15/EEC (Explosives for civil use)*

During the 2010-2013 period, the ILT performed checks on compliance with the Act on Explosives for Civil Use (*Wet Explosieven Civiël Gebruik*). The checks focused particularly on transfer licences, the recognition obligation and the obligation to keep records. Checks into tracking and tracing are being prepared. Enforcement action has been intensified since 2012, with approximately 150 parties subject to surveillance being investigated annually. During the 2012-2013 period, these

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checks were performed mainly at professional users of explosives. These checks revealed that the willingness of professional users of explosives to comply is high but that deficiencies were identified regularly due to unfamiliarity with the regulations. At the end of 2013, it was established that the targeted checks had improved compliance among this target group considerably (>70 %).

The checks at non-professional users of explosives, particularly users of gunpowder, such as reloaders, re-enactment associations and shooting clubs, reveal a less positive picture. Compliance is too low due to unfamiliarity with the regulations, but especially due to overlap with regulations relating to weapons and munitions. This overlap creates a lot of confusion among this group of recreational users, so compliance leaves much to be desired (<40 %). Owing to these checks-based findings, initiatives were undertaken, in collaboration with the police, to forge work agreements concerning enforcement for these specific target groups. These agreements will be finalised in 2014. In addition, work agreements will be entered into with the police concerning enforcement for a limited number of airport-related companies that have to deal with overlap with aviation regulations.

#### *Directive 2007/23/EC, repealed and replaced by Directive 2013/29/EC (Pyrotechnic articles)*

During the 2010-2013 period, the ILT performed checks on compliance with the Fireworks Decree (*Vuurwerkbesluit*). For market surveillance purposes, roughly 150 samples of fireworks were examined each year. This check mainly took place at fireworks importers. Compliance here during the 2010-2013 period averaged around 60 %.

Of the articles rejected (40 %) more than half were withdrawn from the market by the ILT. In respect of the other articles where deviations had been established, the importer was notified by means of a warning.

In addition, action was and will be taken vis-à-vis transport companies in connection with fireworks in postal packages. One of the reasons for this action was to intercept actual fireworks in postal packages. The outcome was modest in view of the large quantity of postal packages. The other (main) reason for the action was to encourage transport companies to organise their systems in such a way as to prevent future supply of fireworks in postal packages.

#### *Regulation (EC) No 1005/2009 (Substances that deplete the ozone layer)*

#### *Regulation (EC) No 842/2006 (Fluorinated greenhouse gases)*

Surveillance is focused on the trade in and production of ozone-depleting substances and fluorinated greenhouse gases and on preventing emissions of these substances.

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The ILT cooperates with the customs authorities with regard to the trade in ozone-depleting substances. The customs authorities check the import and export of these substances. If they suspect non-compliance, the ILT takes action. The ILT also reacts to other alerts, such as from the European Commission, and banned products offered on the internet.

In addition, the ILT conducts administrative surveillance at larger traders of ozone-depleting substances and fluorinated greenhouse gases. Compliance with the regulations is relatively high. Alongside these periodic inspections, the ILT also enforces compliance on the basis of alerts and complaints.

#### *Directive 98/70/EC (Fuel specifications)*

The ILT takes the prescribed number of samples of summer and winter fuels at sales outlets for petrol and diesel. Compliance is high.

#### *Directive 1999/32/EC (Sulphur content of fuels)*

Surveillance is reactive on the basis of received letters of protest. These allow the masters of the vessels, on the basis of MARPOL Annex VI, to raise an objection to the quality of the oil supplied. The number of letters of protest received is rising. In many of the cases it transpired that there had not been any infringement of the standard.

#### *Directive 2004/42/EC (Volatile organic compounds)*

Reactive surveillance is performed on the basis of notifications and alerts. Random checks for infringements are also carried out on offers of paints, varnishes or lacquers. These principally relate to one-off batches. In 2013, the regulations had been infringed in half of the cases.

#### *Regulation (EC) No 528/2012 (Biocidal products)*

#### *Regulation (EC) No 1451/2007 (Biocidal products)*

During the 2010-2013 period, the ILT performed checks in relation to unauthorised biocidal products, instructions for use and competence requirements. Checks were performed at producers of and traders in biocidal products, at pest control businesses and their clients, and in various other industries where biocidal products are used, including the textile industry, façade cleaners and the water sports industry (biocidal products in antifouling coatings).

Even after five years of enforcement action, unauthorised biocidal products are still found regularly. This is partly because users themselves can order the biocidal products directly from companies abroad. Up until 2013, it was not a level playing field in Europe, and biocidal products that were not authorised in the Netherlands were sometimes permitted in neighbouring countries. From 2013 onwards, the European playing field has been levelled increasingly as a consequence of the entry into force of the Biocidal Products regulation and the transitional periods included therein. Every



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year, the ILT uses the necessary capacity to perform internet inspections. These detect not only unauthorised products but also incorrect advertising of authorised products. The checks have repeatedly revealed that traders and users still have a lot of ignorance regarding the rules for biocidal products. Producers are well aware of the rules, but there is often debate surrounding the definition of a biocidal product, such as whether a product is actually a biocidal product or just a detergent.

Pest control businesses tend to use only authorised products, but there has also been an increase in the number of sole traders that focus on one type of pest control and use unauthorised products as well, such as for combating spiders. It is a similar situation with the competence requirements: the majority of pest control businesses satisfy them, but new sole trader start-ups do not always do so. Compliance with the instructions for use by pest control businesses is often still inadequate, but it transpired in 2014 that the rules are often unenforceable. Efforts are now being made to improve them. Pest control clients do not always have a good knowledge of the rules. During the 2010-2013 period, the ILT carried out checks and communication actions at waste processing companies, food storage companies and municipal authorities.

*Directive 89/106/EEC, repealed and replaced by Regulation (EC) No 2011/305 (Construction products)*

The regulation entered into force in its entirety on 1 July 2013 and is certainly new legislation for distributors and importers. For manufacturers, there are changes, such as the drafting of a declaration of performance and production of a technical file. The regulation also imposes clearer rules that the CE marking on the product must satisfy.

The ILT currently inspects the following types of market players: manufacturers, distributors and importers (construction products from outside the EU to the Netherlands). These market players are checked to see whether they comply with the obligations under the regulation. The emphasis in the checks is on administrative obligations. At manufacturers, the ILT also establishes whether the product has the features claimed by the manufacturer.

The product range that is checked is very broad. Having begun in 2013 with defined product groups, the ILT has now moved to a broad approach in which all construction product groups may be subject to its inspections. The interventions involve issuing a warning in the event of minor infringements. Where infringements are serious, administrative enforcement measures are applied, such as an order for periodic penalty payments.

The Netherlands is active at European level with regard to CE marking on construction products. The ILT is currently chairing the European ADCO consultation forum (biennial forum of EU surveillance authorities). The ILT is developing an ever closer working relationship with the other

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European surveillance authorities and since last year has been participating in thematic inspections at European level.

Market players are evidently making a greater effort to meet their obligations under the regulation. Market players are also being asked more often about the CE marking on products. Questions are also put to the ILT's Reporting and Information Centre (*Meld- en Informatie Centrum* – MIC). The MIC regularly receives queries regarding CE marking, and alerts concerning wrongdoings in the market and enforcement requests.

The number of distributors, manufacturers and importers of construction products is estimated at 12 000. Compliance currently stands at 20 %.

*Directive 2005/32/EC, repealed and replaced by Directive 2009/125/EC (Ecodesign)*

Surveillance of Ecodesign was initially concentrated on the regulations for standby mode and off mode, household refrigerating appliances and lighting.

With the surveillance of standby mode and off mode, the focus was on screening IT (computers, laptops, speakers and hardware), external power supplies and televisions. Approximately 85 % of the products screened satisfied the requirements for energy consumption in standby mode or off mode (2010-2012).

For the surveillance of household refrigerating appliances, the declaration of conformity and technical documentation were requested. In some 80 % of cases, the documentation supplied was incomplete or not in order (2010-2012).

Lighting surveillance involved assessing various brands of energy-saving lamps to see whether all the mandatory information was on the packaging and the obligatory documentation was in order. Given the approach (packaging already on the market was assessed), no conclusion can be drawn concerning compliance. There may have been old stocks assessed that did not have to satisfy the requirements. Here, too, it turned out that information often could not be supplied or was incomplete (2010-2012).

Partly due to the aforementioned agreements at European level, surveillance is now focused on tertiary lighting (autumn 2014) and external power supplies (2013 and 2014). With external power supplies, the focus is on manufacturers and importers of consumer electronics and office equipment. This surveillance was performed as part of a combination check.

In 2013, the permitted energy consumption for external power supplies was found to have been

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exceeded in 11 % of the cases. The picture for 2014 is not yet clear but compliance with regard to energy consumption appears to be higher. In general, the completeness and accuracy of the documentation to be supplied (including test reports) is still inadequate and therefore a focus of the checks.

#### *Directive 2004/12/EC (Packaging and packaging waste)*

For packaging (Directive 2004/12/EC), the ILT focuses on the 3 600 producers/importers that place more than 50 tonnes of packaging on the market each year, including glass, wood, metal, paper and plastic (jointly responsible for 70 % of the packaging material on the Dutch market).

Before a product is placed on the market in packaging, the producer or importer must look into whether the product's packaging satisfies 'essential requirements' (hereinafter ER). The packaging must not be too heavy or too large; it must be easy to recycle if it is disposed of and (partly) made from recycle. In addition, the packaging must not contain any hazardous or harmful substances (heavy metals).

The focus of the surveillance was initially on the use of heavy metals in packaging. At producers/importers/distributors, various types of packaging were tested for the presence of heavy metals. The ILT particularly looked at sales packaging and outer packaging made of plastic. In approximately 90 % of the packaging no evidence was found that the standard had been exceeded (2010).

The surveillance was broadened to include weight reduction for packaging materials, packaging recyclability and maximisation of recycled raw materials in new packaging.

Object inspections were performed at a number of companies. A quarter of the businesses demonstrated sufficiently that one or several selected types of packaging satisfied the essential requirements. The use of recycle in new packaging still receives little explicit attention from companies. The same applies to the recyclability of packaging.

The packaging was screened for the presence of heavy metals. In the majority of the screened packaging (90 %) no evidence was found that the standard had been exceeded (2011).

In a number of companies, administrative checks were conducted in combination with product measurements. For each company, a random sample of packaging was tested, for verification purposes, to verify compliance with the essential requirements (object inspection). A number of types of packaging were measured for heavy metals. These checks revealed non-compliance in a few per cent of cases on average (2013-2014).

#### *Directive 2003/37/EC (Type-approval of trailers, etc.)*

#### *Directive 2002/24/EC (Type-approval of two or three-wheel motor vehicles)*

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*Directive 2007/46/EC (Approval of motor vehicles and trailers and components thereof)*

At the end of 2012, the ILT was appointed as the surveillance authority and the designated officials were charged with monitoring compliance with Articles 34 and 35 of the Road Traffic Act (*Wegenverkeerswet*).

These concern the sales bans that stem directly from European Framework Directives 2002/24/EC, 2003/37/EC and 2007/46/EC and that were implemented in Articles 4.1 and 4.2 of the Vehicle Regulations (*Regeling Voertuigen*). The European Directives are currently being replaced by European regulations in which market surveillance will be afforded increasing importance. The first year was principally about exploring the new surveillance arena and forging contacts with relevant players: most notably gaining familiarity with the legislation and regulations, and clarifying the scope of the products that require type-approval and the process of verifying the type-approval numbers encountered. In 2014, in response to an adopted motion, a field investigation was conducted into the legal and practical possibility of more intensive inspection of the sale of mopeds that do not satisfy the type-approval requirements.

The focus until now has been on lights, trailers, exhausts and tyres, but other products are also inspected. The ILT now has a number of large market players in its sights and is addressing these at system/process level.

Many legal gaps were found in relation to scope and powers. These bottlenecks were identified and discussed with policy-makers and are now being remedied by revising Dutch legislation and regulations. The task of verifying the type-approvals found with type-approval bodies all over Europe is likely to be very labour-intensive. There is no European database containing all type-approvals issued. The ILT has recently been given access to the type-approvals issued by the Netherlands, but selective verification might lead to a distortion of the market and is therefore undesirable. At present, the ILT is gaining experience requesting type-approvals from importers. It is doing this in collaboration with the customs authorities.

*Directive 94/25/EC, as amended by Directive 2003/44/EC (Recreational craft)*

The ILT monitors CE markings on recreational craft. The directive has been implemented in the Recreational Craft Act (*Wet Pleziervaartuigen*). Surveillance is focused on technical requirements that the vessels must satisfy and on administrative requirements. The ILT is a member of the ADCO.

During the 2009-2013 period, the ILT visited manufacturers and importers of recreational craft. It visited some 50 companies in 2009. The number of businesses visited for the purpose of checking compliance with the Recreational Craft Act rose steadily to around 125 in 2013, with approximately

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200 vessels assessed in 2013. Every year, there are roughly 10 RAPEX notifications prompting the inspectorate to take action.

Compliance with the Recreational Craft Act up to 2013 was mediocre. The number of vessels that satisfied the requirements was no greater than 30-35 % over the 2009-2013 period.

In the Netherlands, there are roughly 2,500 to 3,500 companies that are permanently or occasionally involved in the trade in or manufacture of recreational craft.

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### **Verispect B.V.**

#### *Section A. Review of the surveillance activities.*

Surveillance relates to Directive 2004/22/EC on measuring instruments (MID) and Directive 2009/23/EC on non-automatic weighing instruments (NAWI).

#### General

In the Netherlands, legal metrology is confined to those areas of measuring instrument usage for which there is the expectation of significant risk that the free market mechanism offers inadequate protection for individual parties involved in commercial transactions.

The concept for this legislation is as follows:

- only implement in those areas in which legislation is absolutely necessary;
- keep the costs of the administrative burden as low as possible;
- harmonise existing rules as much as possible;
- realise regulations at a high level of abstraction;
- ensure a strict separation of tasks between the certification bodies and the market surveillance authority.

Where possible and/or desirable, and where a sufficient level of professional competence and a sufficient degree of organisation exist, self-regulation is accepted and encouraged under strict conditions.

This conceptual framework was implemented in national legislation concerning metrology, which contains separate chapters relating to the following:

- the transactions to which statutory requirements apply;
- the assessment of conformity;
- the placing on the market and use of measuring instruments;
- the performance of surveillance and checks (statutory control);
- the penalties in the event of an infringement of the law.

With regard to the conformity assessment, the available European directives were implemented, namely Directive 2004/22/EC on measuring instruments (MID) and Directive 2009/23/EC on non-automatic weighing instruments (NAWI). Certain instruments are subject to the MID but their use in commercial transactions is not regulated by Dutch legislation; in such cases, enforcement is still applicable if these measuring instruments are marked in accordance with the MID.

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There are also certain measuring instruments that are not subject to the European directives but are covered by supplementary national regulations in corresponding legally regulated areas of application. The national legislation also contains the requirements for enforcement with regard to the EU regulation for market surveillance. The certification of measuring instruments, subsequent to and on the basis of the outcome of the execution of the conformity assessment, is the primary responsibility of the manufacturer. Some of this work is carried out by an authorised conformity assessment body made known to the EU and other Member States by a government authority.

#### Surveillance and control

In the Netherlands, approximately 163,000 measuring instruments have been installed for use in the consumer sector and in industry for trading purposes. See the table below. This quantity has remained reasonably stable in recent years.

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Table 1: The number of measuring instruments installed at the start of the 2014 calendar year.

Category		Quantity
Weighing in retail	NAWI with weighing capacity up to 150 kg	64 600
Weighing / measuring in industry	Multi-dimensional measuring instruments	45
	NAWI with weighing capacity up to 1 000 kg	15 000
	Automatic weighing instruments	4 400
	Weighbridges	4 300
	NAWI with weighing capacity from 1 000 kg to 10 000 kg	4 800
Measuring liquids in retail	Petrol pumps	60 200
	LPG installations	3 300
Measuring liquids in industry	Large liquid meters	3 300
	Liquid level gauges	3 600

Surveillance of measuring instruments that are brought to market (market surveillance) and those already in use (surveillance in use) is performed by the appointed authority, Verispect B.V. (hereinafter Verispect) on behalf of the government. Verispect has held ISO 17020 accreditation for its surveillance activities since 1996.

The surveillance activity includes an inspection at companies that use measuring instruments for trading purposes. In principle, this inspection is unannounced. It focuses on compliance with metrological requirements and other formal aspects. The extent to which these checks are applied is partly dictated by the risk that results from use of a specific type of measuring instrument if this does not satisfy the statutory requirements. The checks include tests for compliance with the applicable requirements. Every year, a report is published on the instruments inspected and the deviations detected.

A major part of surveillance traditionally involves 'surveillance in use'. Measuring instruments in use are generally assessed against three criteria. The measuring instrument must:

- 1) be authorised for the application for which it is used;
- 2) not exhibit any measuring deviations that lie outside the legally permitted boundaries;
- 3) fulfil the other formalities.

Together, these form the yardstick for the level of compliance. A level of compliance has been defined for every category of measuring instruments. An average level of compliance of 95 % is targeted.



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In mid-2013, the surveillance authority began switching to more proactive market surveillance, making use of risk analysis and quality management tools, such as the *Deming Cycle*<sup>4</sup> (Plan-Do-Check-Act).

By picking up signals from the market, collecting complaints and carrying out screening projects, information is produced which is used to launch targeted market surveillance projects. If, during surveillance in use, certain brands/types of measuring instruments are found that may not be compliant or which are used in a manner that is not in accordance with the requirements, an action plan is drawn up to identify the nature of the possible deviation. This entails establishing whether the deviation is incidental or systematic. This may produce a need for additional tests that are more in-depth, such as a targeted investigation of temperature sensitivity or propensity to malfunction, and other conformity tests. The result of targeted market surveillance investigations is discussed with the manufacturers/suppliers, and the other EU Member States are informed.

With regard to utility meters, legal metrological control is carried out by the trade association. This is done on the basis of data obtained from statistical surveys. Verispect assesses the statistical procedure and reports to the Ministry on this approach and the results of the execution of this metrological control. If necessary, certain clusters of these measuring instruments are categorised as 'rejected' on the basis of the inventoried information and measures must be taken, such as replacing the instruments.

If Verispect receives complaints owing to investigation results and/or warnings from other EU Member States, action is taken.

There is no mandatory periodic re-inspection in the Netherlands, except in respect of the regime for taximeters. Re-inspection is only obligatory following a repair that may affect the metrological properties of the measuring instrument.

#### Cooperation with other market surveillance organisations

Verispect collaborates with other market surveillance organisations both at horizontal level within the Netherlands and with the corresponding authorities in other Member States responsible for market surveillance within the framework of the MID and NAWI directives.

Horizontal cooperation mainly takes place within the national Alliance Working Group, as described in Part 1 of this document.

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<sup>4</sup> *William Edwards Deming, who developed a creative tool for quality management and problem-solving.*

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International cooperation is achieved through WELMEC. WELMEC is a voluntary European venture for collaboration between the national organisations responsible for legal metrology within the EU and EFTA. The principal objective of WELMEC is to achieve a harmonised and consistent approach to legal metrology in Europe. There are 37 countries represented within WELMEC.

#### Informing the business community and other stakeholders

Verispect plays an active role in informing the business community of developments within 'surveillance in use' and 'market surveillance' by discussing them at meetings with stakeholders. Each of these platforms concerns one particular area of metrology: 'liquid', 'energy' and 'weighing'. For the participants of these platforms, a twice-yearly meeting is arranged jointly by the Federation of Technology Branches (*Federatie van Technologie Branches* – FHI) and Verispect.

#### Staffing level and available budget

The staffing level within surveillance of compliance with the Metrology Act (*Metrologiewet*) has remained stable in recent years. There has only been a shift from hours spent on 'surveillance in use' to hours spent on 'market surveillance'. In 2011, market surveillance accounted for just 1 % of the total number of available hours; this has since increased to 5 %. The market surveillance share has therefore risen from 0.3 FTEs to 1.5 FTEs, and a shift has also taken place in the level of education, from intermediate vocational (MBO) to higher vocational (HBO) or university (WO) standard. This shift is expected to continue over the coming years. The overall budget for monitoring compliance with the Metrology Act was cut by 8 % over the last four years and now stands at around EUR 2.5 million (excl. 21 % VAT), of which roughly EUR 0.2 million is for market surveillance.

#### *Section B. Assessment.*

Surveillance in the field of legal metrology has changed during the recent period from a more reactive approach to a proactive one, and it has become more risk-driven for both surveillance in use and market surveillance. As a consequence, product-oriented surveillance is gradually being replaced by a combination of product-oriented and business-oriented surveillance. The interaction between surveillance in use and market surveillance has been strengthened, as a result of which surveillance will also be targeted more at all stakeholders (economic operators) in the chain in which measuring instruments are traded and used, such as manufacturers, importers and/or dealers and the companies where the measuring instruments are applied. Steps have been taken to obtain even more specific information so that targeted surveillance actions can be initiated.

#### Surveillance and control

With 'surveillance in use', non-compliance with the rules has been found to be greatest for instruments that are used in industry. This means that the focus of the surveillance is now on

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companies with measuring instruments that pose a greater risk if they are inaccurate. To reduce the administrative burden on parties subject to surveillance, the 'self-declaration' method has been introduced. This enables the owner of a measuring instrument to declare personally that the measuring instrument has been repaired and now satisfies the statutory requirements again. The initial results are positive.

At the start of the 2010-2013 period, market surveillance was reactive and investigations were conducted following complaints, such as inadequate protection for the adjustment on baby scales, incorrect instrument information on scales for sale to the public, and a potentially misleading gas meter.

In 2012, work began on strengthening the link between 'surveillance in use' and 'market surveillance'. An investigation was conducted that involved analysing the results of 'surveillance in use' on measuring instruments that had been on the market for under two years. This investigation produced the necessary information on the extent to which measuring instruments are compliant, broken down into manufacturer, type and sector. As a consequence, targeted market surveillance projects were launched in 2013. The approach may be to contact the manufacturer directly because a systematic error has been established or to conduct a supplementary investigation at a supplier in relation to one or more types of measuring instruments made by the same manufacturer. If insufficient information is obtained, this may be a reason to carry out additional screening of the type in question. Channelling information from 'surveillance in use' to 'market surveillance', and vice versa, will strengthen the link still further over the years to come.

During the 2012-2013 period, eight non-automatic weighing instruments for sale to the public were examined. These instruments underwent not just 'surveillance in use' tests but also temperature and EMC tests, and a further conformity assessment. One of the objectives was to establish whether the purchase price of the instrument might give an indication of the need for market surveillance. However, this turned out not to be the case. The investigation did reveal that a number of instruments were not compliant, however. It also led to several follow-up investigations, some of which have now been completed. The deviations found related to information accompanying and/or on the instrument and/or the operation of the instrument. It was also found, in a number of cases, that the information in the EU type examination certificate and/or the technical documentation was inadequate, either because of shortcomings on the part of the designated body or due to manufacturer negligence.

The results of these investigations and follow-up investigations were used as material for the 'WELMEC WG 5 Market Surveillance' workshop in 2014. The workshop had a number of objectives: promoting harmonisation between market surveillance authorities within Europe, learning by doing, clarifying the role of the surveillance authority and demonstrating the need to exchange

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information. This workshop was organised by representatives of the Dutch and German market surveillance authorities involved in metrology.

In 2013, Verispect was granted access to the European Information and Communication System on Market Surveillance (ICSMS). The above investigations and the investigations conducted prior to 2013 were entered into ICSMS. Staff who deal with market surveillance were given training in how to use ICSMS. Verispect is now actively involved in improving ICSMS and promoting its use. In 2014, in collaboration with Austria and Belgium, the Netherlands developed a tool that can help establish the risk class in ICSMS for an instrument examined. Before ICSMS became available, the exchange of information took place at the annual WELMEC WG 5 meetings.

#### Cooperation

At horizontal level, cooperation takes place between national market surveillance authorities by means of information sharing and harmonising elements of market surveillance where possible; see Part I.

At international level, the market surveillance authorities of Denmark, Spain, Switzerland and the Netherlands have started to choose cross-border projects on the basis of risk analyses. In 2013, this resulted in two projects: the MID heat meters and kWh meters project (1) and the NAWI screening project (2). At the end of 2013, the European Commission presented an opportunity to tender for the receipt of financial support for the execution of both projects. The MID project has since been selected and is underway. This is the first cross-border project in metrology. The second cross-border project – the NAWI screening project – will be launched in 2015.

#### Informing the business community and stakeholders

Verispect has informed the business community about developments at national and international level twice a year via the energy, liquid and weighing platforms. It has also done likewise regarding surveillance, giving details of the plans and results. It also accounts for its work on the Verispect website.

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**Health Care Inspectorate (IGZ)**

The IGZ monitors compliance with the legislation relating to medical devices, including those for in-vitro diagnostics and active implantable medical devices (Directives 93/42/EEC, 98/79/EC and 90/385/EEC).

For the evaluation of the surveillance performed, please refer to the Market Surveillance Questionnaire initiated by DG SANCO in 2012 in the wake of the PIP affair. This questionnaire, which was completed by the IGZ in 2012, is appended.