

***NATIONAL MARKET SURVEILLANCE
PROGRAMME***

2016

Denmark

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1. GENERAL MARKET SURVEILLANCE ORGANISATION AND INFRASTRUCTURE

1.1. Identification and responsibilities of the national market surveillance authorities

In Denmark, market surveillance of products is split between a number of authorities each having professional expertise within an area. For example, the Danish Environmental Protection Agency verifies that products on the Danish market comply with chemicals legislation, while the Danish Safety Technology Authority carries out physical/mechanical market surveillance of electrical products, toys, fireworks, etc. This *decentralised* distribution of responsibilities ensures a high level of professional expertise at the authorities, and implies that market surveillance is organised and implemented differently in different areas. At the same time the Market Surveillance Committee, which will be described in more detail in point 1.2., ensures that there is coordination and cooperation between the market surveillance authorities.

Under the auspices of the Market Surveillance Committee, a strategic objective has also been developed for market surveillance in Denmark.

The overall strategic objective for market surveillance in Denmark is effective in promoting the free movement of safe and healthy products, in order to minimise risks to users, businesses and the environment, while ensuring a level playing field for businesses and the least possible administrative burden.

For an overview of the competent market surveillance authorities and their respective portfolios, please refer to the list of authorities listed on the Commission website¹ with one addition, the Danish Veterinary and Food Administration, which carries out market surveillance of food contact materials, cf. Regulation (EC) No 1935/2004.

For more detailed information on the role of each authority, see Section 2 of this programme on market surveillance in specific sectors.

1.2. Coordination and cooperation mechanisms between national market surveillance authorities

The Danish Market Surveillance Committee

The Danish Government has formulated an action plan for a more open and safe internal market. On this basis a *Market Surveillance Committee* has been set up, comprising the Danish market surveillance authorities under the auspices of the then Ministry of Economic and Business Affairs (now the Ministry of Business and Growth). In addition, in accordance with Article 18(1) of Regulation (EC) No 768/2008, the Committee must comply with the requirement to establish appropriate communication and coordination mechanisms between the national market surveillance authorities.

The Committee must ensure uniform and effective market surveillance in the form of increased dialogue and dissemination of best practices. Market surveillance must be organised so as to achieve the highest levels of compliance while minimising the

¹http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/index_en.htm

administrative burden as far as possible, thereby promoting free movement of safe products on the internal market. The Committee focuses on non-organic products in Denmark and products governed by both harmonised and non-harmonised rules.

Figure 1 shows the Market Surveillance Committee’s permanent members and the Committee’s objectives and tasks.

Figure 1: Overview of the Market Surveillance Committee



The tasks of the Market Surveillance Committee fall within three areas for action:

1) Planning and priorities

The tasks of the Market Surveillance Committee for planning and priorities are as follows:

- setting an overall market surveillance objective;
- drafting a concept for annual market surveillance programmes;
- the ongoing evaluation and impact assessment of the authorities’ market surveillance operations;
- investigating the options for a joint database and joint guidelines, e.g. for risk assessments.

The authorities contribute to the common national objective and draw up annual market surveillance programmes in their respective areas. The latter appear in Section 2 of this programme. The actual planning and prioritisation are to be determined by the individual authorities.

2) Coordination and cooperation

As market surveillance is divided between various competent authorities, it is essential to continuously coordinate the measures taken and cooperation in areas where this is useful. The main tasks of the Market Surveillance Committee for coordination and cooperation are as follows:

- promoting targeted and effective market surveillance (e.g. via joint information campaigns);
- exchanging experiences on enforcement procedures, sanctions and guidelines for good practice in relation to market surveillance;
- organising joint training programmes and skills development;
- organising cooperation between the market surveillance authorities and between these authorities and SKAT [Danish Customs and Tax Administration], with the focus on potential synergies;
- identifying the options for implementing harmonised checks on comparable areas;
- conducting analysis projects to increase the level of knowledge among administrations.

3) *International cooperation*

Consistent market surveillance throughout the internal market is a precondition for a harmonised level of protection for Danish consumers, irrespective of the goods' country of origin, and ensures a level playing field for Danish companies.

The main tasks of the Market Surveillance Committee for international cooperation include the following:

- exchanging experience on best practices with market surveillance authorities from other EU countries;
- reinforcing coordination of Denmark's input into horizontal EU initiatives on market surveillance;
- participating in the respective competent authorities' ADCO [Administrative Cooperation on Market Surveillance] groups;
- disseminating experiences and best practices from EU projects among all Danish market surveillance authorities;
- reinforcing coordination of Denmark's participation in pan-European information campaigns and visit programmes;
- coordinating Danish interests in relation to the Commission's multiannual action plan for market surveillance in the EU.

Bilateral cooperation between the Danish market surveillance authorities

In addition to the Market Surveillance Committee, the market surveillance authorities may enter into bilateral cooperation regarding specific actions, for example when there is an overlap in relation to portfolios or when coordinated action is deemed to achieve synergies. This will be described in more detail in the following section and in the sector-specific contributions in Section 2 of the programme.

1.3. Cooperation between national market surveillance and customs authorities

The market surveillance authorities cooperate with SKAT in various contexts.

Market surveillance is carried out on products from countries outside the EU to the same degree as checks on products already on the market, since a significant proportion of the particularly high-risk products within many sectors originate in countries outside the EU.

SKAT is in a perfect position to check shipments of goods imported from countries outside the EU and, where necessary, to withhold illicit goods. In this context SKAT requires input from the market surveillance authorities in order, for example, to draw up risk profiles for relevant products, producers or importers. Cooperation with SKAT is laid down in greater detail in cooperative agreements entered into bilaterally between SKAT and the individual market surveillance authorities². In addition, SKAT is a permanent member of the Market Surveillance Committee, which ensures a continuous dialogue between SKAT and the other market surveillance authorities.

1.4. **Rapid information exchange system - RAPEX**

The RAPEX network is established at national level through the Danish Safety Technology Authority as the RAPEX contact point. The RAPEX Contact Point organises and steers the work of the national RAPEX network. The network comprises:

- the RAPEX Contact Point - the Danish Safety Technology Authority;
- market surveillance authorities responsible for monitoring the safety of consumer and professional products. These authorities are as follows: the Danish Working Environment Authority [*Arbejdstilsynet*], the Danish Environmental Protection Agency [*Miljøstyrelsen*], the Danish Transport Authority [*Trafikstyrelsen*], the Danish Maritime Authority [*Søfartsstyrelsen*], the Danish Energy Agency [*Energistyrelsen*], the Danish Business Authority [*Erhvervsstyrelsen*], the Danish Veterinary and Food Administration [*Fødevarestyrelsen*], the Danish Health and Medicines Authority [*Sundhedsstyrelsen*], and the Danish Ministry of Justice.
- Authorities responsible for checks on external borders - Customs authorities.

The Danish Safety Technology Authority [*Sikkerhedsstyrelsen*] is responsible for validating Danish reports in the system before they are forwarded to the Commission.

The Authority works together with the other market surveillance authorities responsible for the various sectors that can give input into the RAPEX system. Each authority has appointed their own RAPEX contact point and there is also a contact person available outside normal working hours in the event of urgent notices.

The Danish Safety Technology Authority keeps the respective market surveillance authorities informed as to the incoming notifications concerning their sector.

The RAPEX Contact Point administers all user access in Denmark. It keeps the other market surveillance authorities informed of relevant meetings at the Commission and of any updates concerning the system. The Contact Point has held seminars on the RAPEX system and the RAPEX risk assessment tool at national level, in cooperation with the Commission. The Contact Point draws up various guidelines for the system on an ongoing basis and runs training courses for the national RAPEX network, as necessary.

² See Commission Guidelines for customs authorities and for cooperation between customs authorities and market surveillance authorities.

It has provided guidance at national level for the RAPEX network on the obligation to report notifications in the system on:

- how to follow up on incoming notifications;
- the obligation to send feedback within the system.

Denmark has in recent years been very effective, by comparison with other EU countries, in providing follow-up and feedback to the RAPEX system on the notifications received. At the annual European RAPEX Contact Point meeting in 2013 this effectiveness resulted in the Danish RAPEX Contact Point informing the other Member States about the Danish practice for following up notifications received and providing feedback.

1.5. ICSMS information system

The ICSMS (Information and Communication System for Market Surveillance) was introduced to the Danish market surveillance authorities via a 'Train the Trainer' course in September 2012.

The Danish Safety Technology Authority is the ICSMS National Contact Point in Denmark.

It provides support for the other market surveillance authorities in Denmark and contacts the ICSMS team at the Commission, where necessary. It is also responsible for setting up authorities and carrying out translations in the system. The Danish Safety Technology Authority also provides training on the system where necessary.

In Denmark, the Working Environment Authority and the Environmental Protection Agency also use the system. The Transport Authority and the Energy Agency have also been introduced to the system.

The individual authority itself assesses how the system is administered, and what is needed. Each individual authority appoints an authority administrator who maintains contact with the Danish Safety Technology Authority on all matters relating to the ICSMS. This administrator is also responsible for recruiting staff and creating and maintaining the list of the Directives that the authority administers. The authorities are responsible for adding their own products to the system.

1.6. General description of market surveillance activities and relevant procedures

Reactive and proactive market surveillance

The market surveillance authorities organise both reactive and proactive market surveillance initiatives, depending on the needs identified within the individual areas for action.

Reactive market surveillance

Reactive market surveillance is initiated on the basis of information on specific incidents. The information may come, for example, from citizens, enterprises or the media, and it is for the competent authority to assess the extent to which this information is critical and whether it intends to investigate the case further. If the authority chooses to investigate the case, this will usually involve a risk assessment. When an authority assesses reactive market surveillance, it may be appropriate to openly undertake a risk-based division of

the incoming cases into critical and non-critical cases. This can ensure rapid processing of critical cases that may, for example, involve fatalities or serious accidents.

Reactive market surveillance may typically be initiated in response to:

1. accidents;
2. reports from authorities' inspection staff;
3. reports from inspection bodies;
4. reports from competing enterprises;
5. follow-up to complaints from users or the press;
6. notifications from the authorities in another country via RAPEX (EU Rapid Alert System for non-food dangerous products) or the ICSMS, CIRCA (Communication & Information Resource Centre Administrator) or similar systems.

Proactive market surveillance

Proactive market surveillance is short- and long-term market surveillance planned by the authorities. It may be based on the systematic collection of data, including statistics, with the aim of undertaking risk-based prioritisation of market surveillance operations, or of establishing a strategy to ensure that the product area is monitored. A proactive operation may start with the identification of risks in particular product groups or general problems relating to enterprises' understanding of legislation, and may involve giving general guidance on the correct and safe use of products. A major part of the proactive approach in Denmark involves authorities providing information on laws and rules e.g. via campaigns.

In practice, proactive market surveillance may involve:

1. targeted information campaigns;
2. on-the-spot checks;
3. sample checks on enterprises' own checks or specific products;
4. cooperation with producers, importers, distributors and stakeholder organisations;
5. cooperation with the customs authorities (SKAT);
6. screening to gain knowledge.

Basic principles for market surveillance

When organising their work, the authorities must ensure that their market surveillance, whether reactive or proactive, is based on the following fundamental principles:

Proportionality

Organisation of surveillance, checks and enforcement must, in general, comply with the proportionality principle. This means that surveillance etc. must be justified and must not be more intrusive than what is necessary in order to achieve the objective.

Open and transparent cooperation with enterprises

As enterprises are responsible for complying with legislation, it is for the authorities to strive for open and transparent cooperation with the relevant enterprises. Should the authorities encounter illegal practices, they are duty-bound to intervene. However, the least intrusive approach may sometimes involve an enterprise voluntarily changing an illegal practice merely because it has heard about the inspection operation.

Prioritisation of market surveillance

This concerns the overall allocation of resources to various operations and product areas. In accordance with the strategic objective for market surveillance in Denmark, cf. Section 1.1, prioritisation of the operation must ensure the free movement of safe and healthy products. Protecting users from hazardous or risky products is thus the starting point for prioritisation. However, free movement and free competition are also significant parameters, and it may therefore be appropriate to use them as a basis for prioritisation. For example, non-compliance in some areas (e.g. on the part of importers) can have a major economic impact on competing national producers, and this may justify a prioritised approach.

In practice, prioritisation of market surveillance is chiefly decentralised and is based on the division of duties, as reflected in the organisation of the various authorities. Prioritisation will be determined by specific assessments from one product area to another. As there are considerable differences in the availability of data from the various authorities, the basis for undertaking prioritisation also varies. The following data may be included when prioritising:

- a. incident and injury statistics (accidents and ailments);
- b. notifications from RAPEX, CIRCA, ICSMS and similar systems;
- c. correct use of the CE mark;
- d. new rules;
- e. interfaces with other authorities;
- f. market analyses (information on new product trends);
- g. enquiries from users or enterprises;
- h. information gained from national and international cooperation;
- i. experiences from previous operations;
- j. the volume of a given product group.

Taking these data into consideration should help to build a more accurate picture of which potential operations would have the greatest impact. For example, interfaces with other authorities are used in prioritisation to avoid the authorities duplicating checks, or to institute cooperation on checks. How these data are used depends on the situation and on the authority's sphere of responsibility, and the extent to which an authority needs to formalise the prioritisation mechanisms may therefore also vary³. In order to promote uniformity in the prioritisation of market surveillance operations in Denmark, the Market Surveillance Committee is working on identifying the potential for common principles for data collection and processing.

Impact measurement

In order to be able to prioritise resources allocated to market surveillance effectively, authorities should provide for continuous monitoring and impact assessments of their surveillance operations, to demonstrate the probable impact of the individual operations. Impact assessments involve an assessment of the behaviour underlying rising and falling compliance with rules, together with an assessment of the background to fluctuations in various product-related injury statistics. Impact assessments may be based on an 'impact chain', in which the impact is linked to activities and output. Impact assessments in the individual authority areas may also be linked to the overall assessment of market surveillance activities, as required under Regulation (EC) No 765/2008.

³ It may also be relevant to address the issue that the use of databases is subject to the requirements of confidentiality as regards sensitive product information.

Principles of risk assessment

Risk assessment is the process used to determine the risk that specific products with hazardous properties pose to humans, animals, property and the environment⁴. It is performed once the overall prioritisation for the operation is complete. Risk assessment is based on a combination of evaluating the severity of the harm and the probability of harm occurring⁵.

It is important for all authorities to apply the same approach to risk assessment and for there to be transparency surrounding its application⁶. Uniform application of risk assessments by the authorities may help to improve compliance and reduce administrative burdens. Under the aegis of the Market Surveillance Committee, guidelines have been produced on risk assessments in order to ensure uniformity of practices among the authorities. Moreover, the development of a common method of undertaking risk assessments prioritised at European level is part of the Commission's multiannual action plan for market surveillance.

Enforcement

Enforcement encompasses the means that the authorities have at their disposal for getting enterprises to comply with legislation, including guidance, injunctions, bans and other types of legal action.

Enforcement may vary in some areas between the various authorities in Denmark. It is therefore also important for authorities to coordinate their activities with a view to ensuring the appropriate use of inspection visits and existing means of enforcement.

The enforcement of professional regulations in Denmark should essentially be targeted and effective, and authorities need to choose the means that has the greatest impact in terms of the behaviour of enterprises now and in the future. In this connection it is important to involve users on an ongoing basis in order to be able to adapt market surveillance initiatives. It is also possible to use alternative enforcement mechanisms to make the enforcement more effective. For example, this may be achieved by 'nudging', or promoting appropriate behaviour within enterprises, including ensuring better compliance, bringing with it more effective use of resources and reducing administrative and economic costs for both enterprises and authorities.

Working with stakeholders

Cooperating with stakeholders is necessary in order to reduce the administrative burden on enterprises and carry out targeted checks. The involvement of relevant stakeholders,

⁴ This definition is based on the Prosafe publication: *'Best practice techniques in market surveillance'*. In the GPSD (General Product Safety Directive 2001/95/EC) and RAPEX guidelines, the definition merely covers the risk to humans, but here a broad definition is used to ensure the possibility of broad application.

⁵ Pursuant to the Offshore Safety Act (*offshoresikkerhedsloven*) (Act No 1424 of 21 December 2005 as subsequently amended), the following principle applies to risk assessments: Risks shall be reduced to a level that is 'as low as reasonably practicable' (ALARP). The ALARP principle is applied in view of the significant international dimension to the Danish offshore sector.

⁶ During a consultation undertaken by the European Commission in November 2010 in connection with the revision of the General Product Safety Directive, risk assessments were deemed to be an important topic. Risk assessments have also been the subject of discussions within the Market Surveillance Group (SOGS-MSG).

such as the Confederation of Danish Industry [*Dansk Industri*], the Confederation of Danish Enterprise [*Dansk Erhverv*], the Danish Energy Association [*Dansk Energi*], the Danish Construction Association [*Dansk Byggeri*], the Association of Danish internet trade [*Foreningen for Dansk Internet Handel*] and the ‘Tænk’ Consumer Council [*Forbrugerrådet Tænk*], is therefore an integral part of the Market Surveillance Committee’s work. External stakeholders thus participate in the meetings of the Market Surveillance Committee once a year.

Communication initiatives

Pursuant to Articles 12 and 17 of Regulation (EC) No 765/2008, market surveillance authorities have certain obligations to inform the public of their areas of competence and of hazardous products on the market. However, communication initiatives for enterprises and users may often be better carried out jointly by a number of authorities. These information initiatives can help to ensure effective use of resources and improve familiarity with legislation. They may take the form, among other things, of guidelines on rules, kick-off meetings for business start-ups, presentations, newsletters, dialogues with professional associations and advice from authorities. The Market Surveillance Committee regularly discusses ongoing communication initiatives to which the Committee’s members contribute ideas for establishing sound principles. In 2015 and 2016 a project on successful communication is being implemented under the aegis of the Market Surveillance Committee. The aim of the project is to identify and bring together good communication practices in order to achieve a high level of compliance through a common pool of ideas. Thus, the authorities have the possibility of subsequently drawing inspiration and tailoring their communication initiatives with a view to both improving the effectiveness of their market surveillance initiatives and gaining better access to their target group.

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

The participation of market surveillance authorities in international coordination and cooperation is therefore important in preventing the emergence of divergent market surveillance practices in different Member States and encouraging notification of hazardous products through joint information systems. This is a prerequisite to achieving a harmonised level of protection for Danish consumers, irrespective of whether they buy Danish or foreign-produced goods, or whether they buy goods in Denmark or in other EU Member States.

At the present time, the Danish market surveillance authorities are cooperating on various horizontal platforms that aim for greater coordination in connection with, for instance, market surveillance and product safety. The following are examples of such platforms for exchanging information: GRAS-RAPEX⁷, CIRCA, ICSMS, IMP-MSG⁸, RIF⁹, ADCO¹⁰, WELMEC¹¹, PROSAFE¹² and NPF¹³.

⁷ GRAS: General Rapid Alert System

⁸ Internal Market for Products – Market Surveillance Group

⁹ RIF: Risk Information Form

¹⁰ ADCO: Administrative Cooperation

¹¹ WELMEC: European Cooperation in Legal Metrology

¹² PROSAFE: Product Safety Forum of Europe

1.8. Evaluation of market surveillance actions and reporting

At national level, market surveillance activities are evaluated every four years in line with Article 18(6) of Regulation 765/2008. The evaluation of Danish market surveillance activities for the period 2010-13 is available at <https://erhvervsstyrelsen.dk/sites/default/files/media/evalueringmo.pdf>.

In addition, the authorities are each working on an ongoing basis on evaluation and impact measurement, partly at strategic level, and partly in relation to concrete initiatives. Please refer to the individual paragraphs in Section 2 for more detailed information on this topic.

Finally, evaluation is an ongoing activity of the Market Surveillance Committee. The authorities' market surveillance operations are evaluated on an ongoing basis in preparation for the three annual meetings. Exchanging experience on methods for measuring impact is also one of the proposed subjects for the Market Surveillance Committee in 2016.

1.9. Horizontal activities planned for the relevant period

Future market surveillance activities include first and foremost the continuation of the Market Surveillance Committee, which is working to ensure overall coordination of national market surveillance. The Market Surveillance Committee has established a two-year work programme (2015-16) with selected focus areas providing a framework for its activities.

The plan in 2016 is to follow up on the Committee's project on successful communication prior to inspection visits, which will be completed by the end of 2015. In addition, the Committee is launching a project on risk-based supervision to examine the extent to which enterprises' management certification and the accompanying third-party inspection may be incorporated as a priority of inspection activities. The project is expected to be launched in December 2015 and completed by the summer of 2016. Another issue is online trading and its associated problems for the market surveillance authorities.

In addition, the Danish Safety Technology Authority holds an annual thematic day for inspectors on a selected topic.

Other activities include regular participation in the IMP-MSG and other relevant working groups, as well as ongoing participation in ADCO and other relevant fora.

¹³ NPF: Nordic Product Safety Forum

2. MARKET SURVEILLANCE IN SPECIFIC SECTORS

2.1. Medical devices – Directives 93/42/EEC, 98/79/EC and 90/385/EEC

2.1.1. Responsible authority and contact details

- The Danish Medicines Agency [*Lægemiddelstyrelsen*], Axel Heides Gade 1, DK-2300 Copenhagen S
Tel.: +45 4488 9595, dkma@dkma.dk, www.laegemiddelstyrelsen.dk
Medical Devices Section, Kristine Rasmussen, Head of Section
- 13 full-time equivalent units (FTE)

2.1.2. Market surveillance procedures and strategy

The relevant procedures in the sector concerned

- Follow-up to inspections of importers/distributors of medical devices
- Follow-up to inspections in the dentistry field
- Inspections of manufacturers based on market information
- Handling of occurrence reports
- Awareness campaigns

Specific cooperation agreements

- Cooperation with the National Institute of Radiation Protection [*Statens Institut for Strålebeskyttelse*] (SIS) on occurrence reports relating to radioactivity
- Cooperation with the Danish Patient Safety Authority [*Styrelsen for Patientsikkerhed*] on the overlap between adverse events and serious incidents involving medical devices
- Participation in EU cooperation in the field of medical devices; this also includes market surveillance
- Nordic cooperation in the field of medical devices

The overall strategy for market surveillance in the sector

- Forward-looking work taking a proactive and risk-based approach where, in order to target the approach, enterprises are selected for inspection on the basis of market data.
- Follow-up to information initiatives

2.1.3. Report from activities carried out under the previous planning period

- Follow-up to inspections of dental laboratories in the form of information material. This material has been developed with the involvement of relevant stakeholders in user groups, in order to achieve a suitable product.
- Follow-up to inspections of importers/distributors of medical devices. Targeted communication via electronic mail.
- Inspections of manufacturers, importers and distributors of in-vitro diagnostic medical devices. The general standard for compliance with statutory requirements was found to be sufficient.
- Information campaigns on reporting incidents with tools targeting municipalities.

2.2. Cosmetic products – Regulation (EC) No 1223/2009

2.2.1. Responsible authority and contact details

- The Danish Environmental Protection Agency • Strandgade 29 • 1401 Copenhagen K, Tel. +45 7254 0000 mst@mst.dk www.mst.dk, for the attention of Dorte Balle Hermansen, Chemical Inspection Service
- In 2016 the Danish Environmental Protection Agency has the following resources at its disposal for market surveillance in the field of cosmetics:
 - Information and guidance: 1.2 full-time equivalent units
 - Checks (monitoring and enforcement): 2.0 FTEs and a budget for analyses etc. of approx. DKK 400 000.

2.2.2. Market surveillance procedures and strategy

Market surveillance in this field is risk-based. The efforts undertaken in the form of information, guidance and checks are organised and carried out on the basis of risk assessments, based on knowledge from scientific works and news in the broader sense; the age and scope of the rules/consolidated guidance, the number of reports, including RAPEX alerts, and the number of infringements detected in checks.

The Environmental Protection Agency gives a high priority to information and guidance in the field of cosmetics. In connection with the entry into force of the Cosmetics Regulation in 2013 the Agency produced a great deal of information for producers and distributors that is now available on its website. This information was updated in a new format in 2015.

(see <http://mst.dk/virksomhed-myndighed/kemikalier/fokus-paa-saerlige-produkter/kosmetik/>).

Two to three dialogue meetings are held annually with the cosmetics industry. If necessary they are supplemented by information days on major issues. In addition, the Agency also holds two to five information briefings per year depending on the number of queries – these mostly target operators in the industry and may cover sun protection, labelling, or misleading marketing, etc.

Every other year, information campaigns are run and aimed at consumers, typically focusing on particular consumer groups, such as the parents of children under two years of age, or teenagers. One priority is to regularly update the section of the website that targets consumers, constantly featuring the latest recommendations. Facebook is also used to inform consumers/citizens.

The prioritisation of checks on cosmetic products varies, although cosmetics are generally given a high priority, both in terms of work with a relatively high number of reports and proactive checks, e.g. following up on major information campaigns.

The growing amount of e-commerce is a focal area for both reactive and proactive monitoring. At the beginning of 2015 a market survey was carried out, providing an insight into which consumers are buying cosmetics online, the types of product concerned and online commerce's share of the total market.

Three initiatives launched in 2015 are to be pursued in 2016, as set out below. Checks on cosmetic products marketed for children and young people are also to be carried out.

2.2.3. Report on activities carried out under the previous planning period

Information and guidance initiatives in 2015:

In 2015, the Chemicals Inspection Service regularly provided information to consumers via Facebook, press releases and web news stories. We provide information on Facebook regarding eco-labels, allergies and various specific types of products. News and press releases have, for example, covered recalls of nail files and warnings concerning a lip balm.

Inspection operations in 2015:

Four proactive measures were launched in 2015:

- Verification of GMP (Good Manufacturing Practice) among Danish cosmetics producers. This initiative is similar to a pilot project, since the GMP requirement is still relatively recent and experience with market surveillance in this field is still very limited. The initiative will continue in 2016.
- Identification of health claims of cosmetic products on the Danish market.
- Identification of the use of Danish labelling of cosmetic products on the Danish market. The initiative will continue in 2016.
- Checks on cosmetic and other chemical products for nails, in particular artificial nails. The initiative will continue in 2016.

In 2015, as in previous years, many reports of possibly illegal cosmetic products have been received and processed.

2.3. Toys – Directive 2009/48/EC

2.3.1. Responsible authority and contact details

Market surveillance is divided up between the Danish Safety Technology Authority and the Danish Environmental Protection Agency.

Danish Safety Technology Authority

- Sikkerhedsstyrelsen, Nørregade 63, 6700 Esbjerg, Tel.+45 33732000, sik@sik.dk, www.sik.dk
- Resources: 1 FTE and DKK 15 000 for tests on products.

The Danish Environmental Protection Agency (the Danish EPA is the competent authority for toys' chemical properties)

- Miljøstyrelsen, Strandgade 29, 1401 Copenhagen K, Tel.: +45 7254 0000 mst@mst.dk www.mst.dk , for the attention of Dorte Balle Hermansen, Chemical Inspection Service
- In 2016 the Danish Environmental Protection Agency has the following resources at its disposal for market surveillance of the chemical properties of toys:
 - o Information and guidance: 0.1 FTE
 - o Checks (monitoring and enforcement): 0.75 FTEs and a budget for analyses etc. of approx. DKK 100 000.

2.3.2. Market surveillance procedures and strategy

Danish Safety Technology Authority

The Danish Safety Technology Authority carries out both reactive and proactive market surveillance. It may impose injunctions, prohibitions and fines.

It cooperates with SKAT [Danish taxation authority] in connection with border checks on products in the sector.

The Danish Safety Technology Authority gladly contributes to the drafting of toy safety rules, etc. in order to afford industry the best conditions for complying with rules and only manufacturing and marketing safe toys. This is done mainly at dialogue meetings held every six months.

The Danish Safety Technology Authority carries out risk assessments of product groups within the toy sector. A particular feature of the toy sector is that it is not possible to obtain overall structured, valid data on products on the market. The Authority has therefore decided to apply a systematised expert model for the risk assessment of product

groups. In the expert model, internal and external experts assess, on the basis of the RAPEX model, one or more injury scenarios for each product group applying the following pre-established parameters: the probability of the injury, its implications, and the number of products on the market. On the basis of the risk assessment, one or more product groups are identified as presenting the greatest risk. The selected product groups then form the basis for the Authority's market surveillance activities for the toy sector.

The Danish Environmental Protection Agency

Market surveillance in this field is risk-based. The efforts undertaken in the form of information, guidance and checks are organised and carried out on the basis of risk assessments, based on:

- knowledge from scientific works and news in the broader sense
- information etc. from cooperation with stakeholders
- information etc. from cooperation with other market surveillance authorities, particularly the Danish Safety Technology Authority
- the age and scope of the rules/consolidated guidance
- the number of reports, including via RAPEX and ICSMS, and the number of infringements detected by checks.

On the basis of the above, prioritisation of the product area may vary over time.

One priority was to follow up on the new toy safety rules with an extraordinary initiative for information, guidance and checks during the period 2013-15. This has been done as part of a special initiative to safeguard children and the very young against problematic chemicals in products marketed for this group.

As a result of the checking campaigns in 2014 and 2015 revealing a disproportionately high number of infringements of the limit values for nitrosamines and nitrosatable substances in balloons, further sample checks of balloons on the Danish market are to be carried out in 2016.

2.3.3. Report on activities carried out under the previous planning period

Danish Safety Technology Authority

In 2014 the Danish Safety Technology Authority carried out an operation for toys placed on the market without the statutory labelling. 200 toy items were withdrawn from distributors or at border checks carried out by SKAT. 57 items were withdrawn by the Environmental Protection Agency in connection with our work on the *Børnekemipakken* (Child Chemicals Package).

The operation revealed that a substantial proportion of the screened toys had faulty labelling. The vast majority of the toys that do not bear the statutory labelling are placed on the market without the trader being able to obtain comprehensive technical documentation of the toy's safety.

In short, it can be concluded that 36 % of the inspected toys complied with the formal requirements for toys. 60 % of the inspected toys were voluntarily withdrawn from the

market or relabelled, while the remaining 8 % were issued with an injunction (Article 45 of the Toys Directive).

The Danish Environmental Protection Agency

Information and guidance initiatives in 2015:

There were no extraordinary operations in 2015.

Inspection operations in 2015:

In 2015, two proactive inspections were carried out on:

- nitrosamines and nitrosatable substances in balloons
- phthalate content in looms and technical evidence that the product is safe.

In addition, a number of reports were received and processed on possibly illegal toys.

2.4. Personal protective equipment – Directive 89/686/EEC

2.4.1. Responsible authority and contact details

Market surveillance is divided up between the Danish Working Environment Authority and the Transport Authority.

The Danish Working Environment Authority – all protective equipment except for personal protective equipment for use in traffic.

- Arbejdstilsynet, Postboks 1228, DK-0900 Copenhagen C. Tel.: +45 7012 1288, email: at@at.dk, website: www.at.dk
- Responsibility for market surveillance lies with the Working Environment Authority's [WEA] market surveillance department at its monitoring centre in southern Denmark [*Tilsynscenter Syd*]. Head of Market Surveillance: Palle Graversgaard.
- All the WEA's market surveillance is carried out by seven FTE monitoring staff, and resource consumption for the individual sectors may be adapted as necessary. In the forthcoming period the WEA is expecting to require 0.25 FTEs for personal protective equipment.

The Danish Transport Authority – personal protective equipment for use in traffic.

- Trafik- og Byggestyrelsen, Edvard Thomsens Vej 14, DK-2300 Copenhagen S, Tel.: +45 72 21 88 00, email: info@tbst.dk, www.tbst.dk. Contact: Martin Larsen
- Budget: approx. DKK 150 000 ≈ 0.2 FTEs

2.4.2. Market surveillance procedures and strategy

Danish Working Environment Authority

The WEA has developed detailed sectoral programmes and procedures available on its website. Its market surveillance procedures are as follows:

[MS-1: Registration in ATIS of MS-cases](#)

[MS-2: Notification to and from EU of dangerous products](#)

[MS-3: Market surveillance programmes](#)

[MS-4: Publication of information on dangerous products](#)

[MS-5: Cooperation with SKAT's customs staff](#)

[MS-6: Processing of market surveillance cases](#)

General coordination with other authorities is handled by the WEA Working Environment Centre in Copenhagen. The area is coordinated with the Danish Transport Authority and SKAT (border checks) at regular and ad hoc meetings as necessary. EU coordination is done mainly through the WEA's involvement in the Administrative Cooperation Group (ADCO) as well as the working group on personal protective equipment.

The overall approach is based on the national market surveillance programme and implemented through sectoral programmes (MS-3 procedure). Resource consumption is determined taking into account overall risk prioritisation in the WEA's areas. Market surveillance of personal protective equipment focuses primarily on products whose use can lead to significant accidents or damage to health if the products are defective. Proactive and reactive checks are carried out, for example, as a result of RAPEX notifications. The WEA also holds additional information sessions for selected target groups where it provides information on the rules and discusses general issues.

Danish Transport Agency

- Both proactive and reactive checks on labelling in actual shops/webshops, as well as verification of documentation.
- Cooperation with the WEA, since we share the same sector.
- In 2014/2015 the Danish Transport Authority initiated preparation of an updated strategy in the field of market surveillance. This is still under preparation.

2.4.3 Report on activities carried out under the previous planning period

Danish Working Environment Authority

The report covers the period from October 2014 to September 2015. A total of four inspections were carried out during this period.

In one case a consignment of gloves was withheld at the border due to unclear information on its documentation. It was released with instructions for relabelling.

Other cases concerned products such as safety catches, gloves, footwear, work clothes, etc.

RAPEX notifications: seven cases relating to personal protective equipment were examined and closed during the period.

A number of information sessions were also held with major importers of work gloves.

There has been continuous cooperation with the Transport Authority on warning clothing for use in traffic.

Danish Transport Agency

As at 1 December 2015 a total of 28 checks on 96 products had been carried out. Irregularities were detected in approximately 25 % of these cases. Fortunately, this is not an area afflicted by many accidents or complaints, nevertheless, it is an area (mainly reflective products) characterised by grey zones and large quantities of cheap third-country products, and so there is a need for more information on the rules and the pitfalls for retail trade. The Danish Transport and Construction Agency therefore launched an information campaign specifically targeting purchasers in the retail sector, to be implemented by mid-December 2015.

2.5. Construction products – Regulation (EU) No 305/2011

2.5.1 *Responsible authority and contact details*

- Trafik- og Byggestyrelsen, Edvard Thomsens Vej 14, DK-2300 Copenhagen S, Tel.: +45 7221 8800, email: info@tbst.dk, www.trafikstyrelsen.dk, www.byggevaerinf.dk
- Centre for construction, market surveillance, mobyg@ens.dk Contact: Ditte Helene Bang, dba@tbst.dk, Tel.: 4178 0509
- Resources in 2016: some DKK 3 million for approx. five FTEs.

2.5.2. *Market surveillance procedures and strategy*

Market surveillance here is two-fold, involving reactive and proactive measures.

Reactive market surveillance is based on communications from citizens and enterprises who suspect the sale, marketing or use of illegal construction products.

Proactive market surveillance implies that each year the Danish Energy Agency carries out two checking operations targeting different construction products, where a number of distributors, producers, importers and construction sites receive a market surveillance visit. Each operation is composed of both an information and a verification aspect. Construction products are selected on the basis of the product's importance for health and safety in construction, the competitive market situation, experience obtained on the basis of external communications, input from the European market surveillance authorities and input from trade organisations.

The sanctions the Danish Energy Agency may impose include injunctions to withdraw or recall a product or remove it if it has already been integrated in a construction. A police report may also be filed.

Two proactive measures are to be launched in 2016.

2.5.3. *Report on activities carried out under the previous planning period*

In 2015 the Danish Energy Agency (as of June 2015 the Danish Transport and Construction Agency) introduced proactive measures for construction products in contact with water intended for human consumption and load-bearing steel structures (hEN

1090). The latter was therefore launched as an information campaign, which will continue in 2016.

36 reactive cases were received in 2015. 19 proactive cases are expected. 24 RAPEX notifications have been processed.

2.6. Aerosol dispensers – Directive 75/324/EEC

2.6.1. Responsible authority and contact details

- Arbejdstilsynet, Postboks 1228, DK-0900 Copenhagen C. Tel.: +45 7012 1288, email: at@at.dk, website: www.at.dk
- Responsibility for market surveillance lies with the Working Environment Authority's [WEA] market surveillance department at its monitoring centre in southern Denmark [*Tilsynscenter Syd*]. Head of Market Surveillance: Palle Graversgaard.
- All the WEA's market surveillance is carried out by seven FTE monitoring staff, and resource consumption for the individual sectors may be adapted as necessary. In the forthcoming period the WEA is expecting to require 0.1 FTE for the Aerosols Directive.

2.6.2. Market surveillance procedures and strategy

The WEA has developed detailed sectoral programmes and procedures that are available on its website. Its market surveillance procedures are as follows:

[MS- 1: Registration in ATIS of MS cases](#)

[MS- 2: Notification to and from EU of dangerous products MS-3: Market surveillance programmes](#)

[MS-4: Publication of information on dangerous products](#)

[MS-5: Cooperation with SKAT's customs staff MS-6: Processing of market surveillance cases](#)

General coordination with other authorities is handled by the WEA's Working Environment Centre in Copenhagen. This area is coordinated with SKAT (border checks) at regular and ad hoc meetings as necessary.

The overall approach is based on the national market surveillance programme and implemented through sectoral programmes (MS-3 procedure). Resource consumption is determined by taking account of overall risk prioritisation in the WEA's areas of action. Market surveillance of aerosol dispensers focuses primarily on products whose use can lead to significant accidents or damage to health if the products are defective. Reactive checks are also carried out, e.g. as a result of RAPEX notifications. Finally, the WEA holds information sessions for traders, where it provides information on the rules and general issues.

2.6.3 Report on activities carried out under the previous planning period

The report covers the period from January 2015 to November 2015.

This period saw the implementation of information and monitoring activities for aerosol dispensers and their contents. In the first half of the year the aerosols operation involved 12 information sessions for suppliers to the car and construction industry. The second half of the year saw the implementation of product checks on suppliers at a number of the establishments visited.

Aerosol dispensers were examined with a visual check for defects and shortcomings under the Aerosols Directive. No organisational shortcomings have as yet been found.

In the second half of the year product checks covered 10 enterprises and approx. 20 products. These checks have included rules under the REACH and CLP Regulations as well as the Aerosols Directive. The checks have been carried out in cooperation with the Danish Environmental Protection Agency. The operation has not yet been concluded at the time of writing.

2.7. Simple pressure vessels and pressure equipment – Directives 2009/105/EC and 97/23/EC

2.7.1. Responsible authority and contact details

- Arbejdstilsynet, Postboks 1228, DK-0900 Copenhagen C. Tel.: +45 7012 1288, email: at@at.dk, website: www.at.dk
- Responsibility for market surveillance lies with the Working Environment Authority's [WEA] market surveillance department at its monitoring centre in southern Denmark [*Tilsynscenter Syd*]. Head of Market Surveillance: Palle Graversgaard.
- All the WEA's market surveillance is carried out by seven FTE monitoring staff, and resource consumption for the individual sectors may be adapted as necessary. In the forthcoming period the WEA is expecting to require 0.9 FTE for simple pressure vessels and pressure equipment.

2.7.2. Market surveillance procedures and strategy

The WEA has developed detailed sectoral programmes and procedures that are available on its website. Its market surveillance procedures are as follows:

[MS- 1: Registration in ATIS of MS cases](#)

[MS- 2: Notification to and from EU of dangerous products MS-3: Market surveillance programmes](#)

[MS-4: Publication of information on dangerous products](#)

[MS-5: Cooperation with SKAT's customs staff MS-6: Processing of market surveillance cases](#)

General coordination with other authorities is handled by the WEA's Working Environment Centre in Copenhagen. This area is coordinated with SKAT (border checks) at regular and ad hoc meetings as necessary. EU coordination is done mainly through the WEA's involvement in the Administrative Cooperation Group (ADCO) as well as the working group on pressure equipment.

The overall approach is based on the national market surveillance programme and implemented through sectoral programmes (MS-3 procedure). Resource consumption is determined by taking account of overall risk prioritisation in the WEA's areas of action. Market surveillance of simple pressure vessels and pressure equipment focuses primarily on products whose use can lead to significant accidents or damage to health if the products are defective. In the forthcoming period both proactive and reactive checks will be carried out, for example, as a result of RAPEX notifications. Finally, the WEA holds information sessions for traders, where it provides information on the rules and general issues.

2.7.3 Report on activities carried out under the previous planning period

The report covers the period from October 2014 to September 2015.

During this period two cases of inadequate fitting of pressure equipment were closed. A number of queries submitted by advisers, notified bodies and manufacturers of pressure equipment were processed.

Of the activities concerning equipment covered by the Directive the following aspects may be highlighted:

- the project concerning boiler units, including PED (portable electronic device) requirements for manufacturers and notified bodies. Five companies were selected for checks on documentation, and subsequent visits to the user enterprises where the inspected equipment was installed.
- Follow-up to a steam explosion in a boiler circulating pump at a power plant in Germany. Similar pumps are installed at a number of power stations in Denmark.

There have been no cases concerning simple vessels.

2.8. Transportable pressure equipment - Directive 2010/35/EU

2.8.1. Responsible authority and contact details

- Arbejdstilsynet, Postboks 1228, DK-0900 Copenhagen C. Tel.: +45 7012 1288, email: at@at.dk, website: www.at.dk
- Responsibility for market surveillance lies with the Working Environment Authority's (WEA) market surveillance department at its monitoring centre in southern Denmark [*Tilsynscenter Syd*]. Head of Market Surveillance: Palle Graversgaard.
- All the WEA's market surveillance is carried out by seven FTE monitoring staff, and resource consumption for the individual sectors may be adapted as necessary. In the

forthcoming period the WEA is expecting to require 0.1 FTE for transportable pressure equipment.

2.8.2 Market surveillance procedures and strategy

The WEA has developed detailed sectoral programmes and procedures that are available on its website. Its market surveillance procedures are as follows:

[MS- 1: Registration in ATIS of MS cases](#)

[MS- 2: Notification to and from EU of dangerous products](#) [MS-3: Market surveillance programmes](#)

[MS-4: Publication of information on dangerous products](#)

[MS-5: Cooperation with SKAT's customs staff](#) [MS-6: Processing of market surveillance cases](#)

General coordination with other authorities is handled by the WEA's Working Environment Centre in Copenhagen. This area is coordinated with SKAT (border checks) at regular and ad hoc meetings as necessary. EU coordination is done mainly through the WEA's involvement in the Administrative Cooperation Group (ADCO).

The overall approach is based on the national market surveillance programme and implemented through sectoral programmes (procedure MS-3). Resource consumption is determined by taking account of overall risk prioritisation in the WEA's areas of action. Market surveillance of transportable pressure equipment focuses primarily on products whose use can lead to significant accidents or damage to health if the products are defective. In the forthcoming period primarily reactive checks will be carried out, for example, as a result of RAPEX notifications. Finally, the WEA holds information sessions for traders, where it provides information on the rules and general issues. The WEA is not planning to carry out proactive checks during the period because it will be giving priority to resources in other sectors.

2.8.3 Report on activities carried out under the previous planning period

The report covers the period from October 2014 to September 2015.

A number of submissions from the notified body have been processed concerning the handling of TPED bottles, *inter alia* concerning their labelling.

During this period, a number of queries regarding ADR rules for Class 2 gas cylinders were answered.

A number of queries falling within this area were also addressed.

Of the activities concerning equipment covered by the Directive the following aspects may be highlighted: in the light of several accidents with composite gas bottles from the manufacturer Composite Scandinavia, proceedings are ongoing involving several of the other Nordic authorities.

2.9. Machinery – Directive 2006/42/EC

2.9.1. Responsible authority and contact details

- Arbejdstilsynet, Postboks 1228, DK-0900 Copenhagen C. Tel.: +45 7012 1288, email: at@at.dk, website: www.at.dk
- Responsibility for market surveillance lies with the Working Environment Authority's (WEA) market surveillance department at its monitoring centre in southern Denmark [*Tilsynscenter Syd*]. Head of Market Surveillance: Palle Graversgaard.
- All the WEA's market surveillance is carried out by seven FTE monitoring staff, and resource consumption for the individual sectors may be adapted as necessary. In the forthcoming period the WEA is expecting to require four FTEs for machinery.

2.9.2 Market surveillance procedures and strategy

The WEA has developed detailed sectoral programmes and procedures available on its website. Its market surveillance procedures are as follows:

[MS- 1: Registration in ATIS of MS cases](#)

[MS- 2: Notification to and from EU of dangerous products](#) [MS-3: Market surveillance programmes](#)

[MS-4: Publication of information on dangerous products](#)

[MS-5: Cooperation with SKAT's customs staff](#) [MS-6: Processing of market surveillance cases](#)

General coordination with other authorities is handled by the WEA's Working Environment Centre in Copenhagen. This area is coordinated with SKAT (border checks) at regular and ad hoc meetings as necessary. EU coordination is done mainly through the WEA's involvement in the Administrative Cooperation Group (ADCO) and the machinery working group.

The overall approach is based on the national market surveillance programme and implemented through sectoral programmes (MS-3 procedure). Resource consumption is determined by taking account of overall risk prioritisation in the WEA's areas of action. Market surveillance of machinery focuses primarily on products whose use can lead to significant accidents or damage to health if the products are defective. In the forthcoming period both proactive and reactive checks will be carried out, for example, as a result of accidents and RAPEX notifications. Finally, the WEA holds information sessions for traders, where it provides information on the rules and general issues.

2.9.3. Report on activities carried out under the previous planning period

The report covers the period from October 2014 to September 2015.

During the period 32 cases were closed, all dealing with machinery which was inadequately equipped in terms of the requirements of the Directive.

A number of queries falling within this area were also addressed.

Of the activities concerning equipment covered by the Machinery Directive the following aspects may be highlighted.

In 2015, market surveillance focused on cooperation with SKAT with a view to developing effective border checks for selected products. 11 checks were carried out, where the Market Surveillance Department was in contact with the manufacturer/importer and where corrective measures were taken. Two products were withheld for more than three days. Experience has shown that manufacturers and importers are quick to react when SKAT/WEA market surveillance withholds products that fail to comply with CE-marking rules.

In 2015 market surveillance conducted an information campaign about the rules on equipping industrial robots. The aim has been to better publicise these rules throughout the industry. The background to this is that industrial robots are designed as unique items of machinery, i.e. as robot applications adapted to the individual user enterprises' requirements. For this reason they must bear the CE marking and be risk-assessed in relation to their specific installation and use.

There have to date been eight events involving approx. 330 professionals and more than 150 enterprises in the robotics and automation sector.

The events were organised in cooperation with DIRA (Danish Industrial Robot Association), the Danish Technological Institute, Safety of Machinery, Bowitek, Danish Standards, Universal Robots and KJV, all key operators in the robotics industry.

DIRA has since produced a leaflet on rules for industrial robots. This leaflet has been published and made available to the industry.

In 2014 the WEA was informed by *Arbetsmiljöverket* (Swedish Work Environment Authority) of two fatal accidents in Sweden, which occurred during the repair and servicing of feed mixers for livestock farming, produced by a Danish manufacturer. The WEA had contacted the manufacturer in Denmark. The problem was identified as the possibility of certain parts of the machine inadvertently being set in motion while other parts were suspended for repair. The cause was a defective electrical installation in setting up the feed mixer. The WEA also pointed out a problem with access to internal parts of the machine. The manufacturer identified all the customers of the mixer in question, approx. 300 in Europe, all of whom were visited by the manufacturer's fitter. The defect was found in the electrical installations of approx. 50 % of customers, who were offered help to remedy the deficiency. The manufacturer also amended the information in the instruction manual concerning the set-up and requirements for electrical installations. A meeting was held between the WEA, the Swedish Work Environment Authority and the manufacturer whereupon the case was closed.

In the light of the case an operation on this issue is planned for 2016.

2.10. Lifts – Directive 1995/16/EC

2.10.1. Responsible authority and contact details

- Arbejdstilsynet, Postboks 1228, DK-0900 Copenhagen C. Tel.: +45 7012 1288, email: at@at.dk, website: www.at.dk

- Responsibility for market surveillance lies with the Working Environment Authority's (WEA) market surveillance department at its monitoring centre in southern Denmark [*Tilsynscenter Syd*]. Head of Market Surveillance: Palle Graversgaard.
- All the WEA's market surveillance is carried out by seven FTE monitoring staff, and resource consumption for the individual sectors may be adapted as necessary. In the forthcoming period the WEA is expected to require 0.1 FTEs for lifts.

2.10.2. Market surveillance procedures and strategy

The WEA has developed detailed sectoral programmes and procedures that are available on its website. Its market surveillance procedures are as follows:

[MS- 1: Registration in ATIS of MS cases](#)

[MS- 2: Notification to and from EU of dangerous products](#) [MS-3: Market surveillance programmes](#)

[MS-4: Publication of information on dangerous products](#)

[MS-5: Cooperation with SKAT's customs staff](#)

[MS-6: Processing of market surveillance cases](#)

General coordination with other authorities is handled by the WEA's Working Environment Centre in Copenhagen. This area is coordinated with SKAT (border checks) at regular and ad hoc meetings as necessary. EU coordination is done mainly through the WEA's involvement in the Administrative Cooperation Group (ADCO) and the lifts working group.

The overall approach is based on the national market surveillance programme and implemented through sectoral programmes (MS-3 procedure). Resource consumption is determined by taking account of overall risk prioritisation in the WEA's areas of action. In the forthcoming period primarily reactive checks will be carried out, for example, as a result of RAPEX notifications. Finally, the WEA holds information sessions for traders, where it provides information on the rules and general issues. The WEA is not planning to carry out proactive checks during the period because it will be giving priority to resources in other sectors.

2.10.3. Report on activities carried out under the previous planning period

The report covers the period from October 2014 to September 2015.

During this period only one case was launched concerning the inadequate installation of a lift. A lift was inspected in connection with a serious accident. The cause of the accident was found to be insufficient maintenance and inspections, combined with faults in the construction of the lift. There are around seven such special lift constructions in Denmark, and presumably none in any other EU country. The file remains open.

2.11. Cableway installations – Directive 2000/9/EC

2.11.1. Responsible authority and contact details

- Arbejdstilsynet, Postboks 1228, DK-0900 Copenhagen C. Tel.: +45 7012 1288, email: at@at.dk, website: www.at.dk
- Responsibility for market surveillance lies with the Working Environment Authority's (WEA) market surveillance department at its monitoring centre in southern Denmark [*Tilsynscenter Syd*]. Head of Market Surveillance: Palle Graversgaard.
- All the WEA's market surveillance is carried out by seven FTE monitoring staff, and resource consumption for the individual sectors may be adapted as necessary. In the forthcoming period the WEA is expected to require 0 FTEs for cableway installations. This is assuming that, as far as is known, no new cableway installations are under construction.

2.11.2 Market surveillance procedures and strategy

The WEA has developed detailed sectoral programmes and procedures that are available on its website. Its market surveillance procedures are as follows:

[MS- 1: Registration in ATIS of MS cases](#)

[MS- 2: Notification to and from EU of dangerous products](#) [MS-3: Market surveillance programmes](#)

[MS-4: Publication of information on dangerous products](#)

[MS-5: Cooperation with SKAT's customs staff](#) [MS-6: Processing of market surveillance cases](#)

General coordination with other authorities is handled by the WEA's Working Environment Centre in Copenhagen. The WEA does not participate actively in EU coordination, as the market for cableway installations is virtually non-existent in Denmark, but it does follow developments in the area as a passive member of the ADCO group.

The overall approach is based on the national market surveillance programme and implemented through sectoral programmes (MS-3 procedure). Resource consumption is determined by taking account of overall risk prioritisation in the WEA's areas of action. In the coming period, reactive checks will be carried out only if there are problems in this area.

2.11.3. Report on activities carried out under the previous planning period

There were no market surveillance activities in this area during the period from October 2014 to September 2015.

2.12. Noise emission in the environment by equipment for use outdoors - Directive 2000/14/EC

2.12.1. Responsible authority and contact details

- Miljøstyrelsen, Strandgade 29, 1401 Copenhagen K. Acting Head: Steen Pedersen. Contact at the Environmental Protection Agency: Frank Pedersen, engineer. Tel.: +45 7254 4560, email: frape@mst.dk
- Approx. 0.02 FTE in 2016

2.12.2 Market surveillance procedures and strategy

In 2016, no specific funds are expected to be set aside for market surveillance based on the Order on machine noise /Directive 2000/14/EC.

The Environmental Protection Agency is primarily expecting to carry out monitoring in response to the irregularities which were brought to its notice in connection with the Directive.

The Agency is expecting to receive no more than five queries per year concerning non-compliance with the Order on machine noise pursuant to Directive 2000/14/EC.

2.12.3. Report on activities carried out under the previous planning period

The Agency receives very few queries - less than five per year - concerning non-compliance with the Order on machine noise/Directive 2000/14/EC. In 2015 it did not perform any inspections on its own initiative or carry out any enforcements.

2.13. Equipment and protective systems intended for use in potentially explosive atmospheres (ATEX) – Directive 1994/9/EC

2.13.1. Responsible authority and contact details

Market surveillance is divided up between the Danish Working Environment Authority and the Danish Safety Technology Authority.

The WEA – non-electrical equipment and protective systems intended for use in potentially explosive atmospheres.

- Arbejdstilsynet, Postboks 1228, DK-0900 Copenhagen C. Tel.: +45 7012 1288, email: at@at.dk, website: www.at.dk
- Responsibility for market surveillance lies with the Working Environment Authority's market surveillance department at its monitoring centre in southern Denmark [*Tilsynscenter Syd*]. Head of Market Surveillance: Palle Graversgaard.
- All the WEA's market surveillance is carried out by seven FTE monitoring staff, and resource consumption for the individual sectors may be adapted as necessary. In the forthcoming period the WEA is expected to require 0.2 FTE for the ATEX sector.

The Safety Technology Authority – electrical equipment and protective systems intended for use in potentially explosive atmospheres.

- Sikkerhedsstyrelsen, Nørregade 63, 6700 Esbjerg, Tel. +45 33732000, sik@sik.dk, website www.sik.dk
- Resources: 1 FTE.

2.13.2. Market surveillance procedures and strategy

Danish Working Environment Authority

The WEA has developed detailed sectoral programmes and procedures that are available on its website. Its market surveillance procedures are as follows:

[MS- 1: Registration in ATIS of MS-cases](#)

[MS-2: Notification to and from EU of dangerous products](#) [MS-3: Market surveillance programmes](#)

[MS-4: Publication of information on dangerous products](#)

[MS-5: Cooperation with SKAT's customs staff](#) [MS-6: Processing of market surveillance cases](#)

General coordination with other authorities is handled by the WEA's Working Environment Centre in Copenhagen. This area is coordinated with the Danish Safety Technology Authority and SKAT (border checks) at regular and ad hoc meetings as necessary. EU coordination is done mainly through the WEA's involvement in the Administrative Cooperation Group (ADCO) and the ATEX working group.

The overall approach is based on the national market surveillance programme and implemented through sectoral programmes (MS-3 procedure). Resource consumption is determined by taking account of overall risk prioritisation in the WEA's areas of action. Market surveillance of ATEX focuses primarily on products whose use can lead to significant accidents or damage to health if the products are defective. In the forthcoming period primarily reactive checks will be carried out, for example, as a result of RAPEX notifications. Finally, the WEA holds information sessions for traders, where it provides information on the rules and general issues. The WEA is not planning to carry out proactive checks during the period because it will be giving priority to resources in other sectors.

Danish Safety Technology Authority

The Danish Safety Technology Authority carries out both reactive and proactive market surveillance. It may impose injunctions, prohibitions and fines.

It participates in various ATEX fora. In the EU context this means the ATEX ADCO and ATEX WG. In addition, we are involved at national level in the standardisation group DS S- 531, in an ERFA group together with other authorities and testing institutes. We are also involved in the Danish Standard DS ATEX Forum. We cooperate with the other Nordic countries in the NKS ATEX.

2.13.3 Report on activities carried out under the previous planning period

Danish Working Environment Authority

A total of three inspections were carried out during the period October 2014 to September 2015. The inspections did not give rise to any decisions.

In the same period, around 10 cases were concluded, all about comprehension of either the ATEX Directive's equipment rules or the interaction between the Machinery Directive and the ATEX Directive's rules.

This is considered to have contributed to the equipment concerned being arranged in accordance with the requirements of the relevant Directives.

Furthermore, the WEA estimates that it answered 10 to 15 questions arising from telephone calls from manufacturers and notified bodies. These issues were not such that a case needed to be opened.

Danish Safety Technology Authority

During the period no proactive measures were performed, instead it was primarily reactive cases that were processed within the sector.

2.14. Pyrotechnic articles – Directive 2007/23/EC – Directive 2013/29/EU

2.14.1. Responsible authority and contact details

- Sikkerhedsstyrelsen, Nørregade 63, 6700 Esbjerg, Tel. +45 33732000, sik@sik.dk, website www.sik.dk
- Resources: four FTEs and DKK 19 000.

2.14.2. Market surveillance procedures and strategy

The Danish Safety Technology Authority carries out both reactive and proactive market surveillance.

The proactive measures carried out by the Authority involve selecting a sample of a number of fireworks every year. The Authority targets its checks so that the documentary inspection covers a higher proportion of the products checked than in the past. A number of fireworks undergo tests, analyses and checks. The products are primarily selected from the importers. The selection itself is based on a risk assessment and the number of articles in stock.

The Authority cooperates with the police and SKAT on implementing a campaign targeting Danish consumers, specifically aimed at the age group with the highest number of firework accidents.

The Authority participates in the European working groups under the Fireworks Directive. The sanctions it may impose are injunctions, prohibitions and reporting to the police for a fine and possible imprisonment.

2.14.3. Report on activities carried out under the previous planning period

The Danish Safety Technology Authority participated in an information campaign in December 2014. The campaign was aimed at school children aged 10 to 15 years.

In 2015 the Authority carried out market surveillance on 57 articles, divided into 25 articles for function tests, 21 articles for documentary checks and 11 articles for NEM inspection.

Following the tragic deaths which occurred on New Year's Eve 2014, the Authority carried out a number of inspections of approved firework manufacturers licensed to store professional fireworks. The inspections revealed that a number of these manufacturers failed to meet the legislative requirements for storage records etc.

The Authority also intends to focus on inspections of firework manufacturers in future.

2.16. Gas appliances – Directive 2009/142/EC

2.16.1. Responsible authority and contact details

- Sikkerhedsstyrelsen, Nørregade 63, 6700 Esbjerg, Tel. +45 33732000, sik@sik.dk, website www.sik.dk
- Resources: four FTEs and DKK 70 000.

2.16.2. Market surveillance procedures and strategy

The Danish Safety Technology Authority carries out both reactive and proactive market surveillance. The sanctions it may impose are injunctions, prohibitions and reporting to the police for a fine.

The Authority participates in various fora, in association with the approved gas suppliers. At EU level we participate in the GAD [Gas Appliances Directive] ADCO and the GAD Commission working group. We are also involved at national level in the standardisation group DS S-245. We also have close Nordic cooperation in the forum SAMGAS. In this forum we have carried out joint proactive market surveillance activities on a number of occasions.

2.16.3. Report on activities carried out under the previous planning period

During this period we participated in a Nordic project in which we jointly examined liquefied petroleum gas regulators (LPG, type G56).

2.17. Measuring instruments, non-automatic weighing instruments and prepackaged products – Directive 2004/22/EC and 2009/23/EC, Directive 2014/32/EU and 2014/31/EU; Directives 2007/45/EC, 75/107/EEC and 76/211/EEC; Directive 80/181/EEC

2.17.1. Responsible authority and contact details

- Sikkerhedsstyrelsen, Nørregade 63, 6700 Esbjerg, Tel.: 33732000, sik@sik.dk, web: www.sik.dk
- Resources: 0.5 FTE.

2.17.1. Market surveillance procedures and strategy

The Danish Safety Technology Authority carries out both reactive and proactive market surveillance. It organises information campaigns and participates in information meetings targeting the industry, laboratories and notified bodies, etc. It may impose injunctions, prohibitions and fines. Prior to any verification activities, it usually carries out an information campaign for the industry concerned. The selection of focus areas/checking operations is always based on a risk assessment.

The Danish Safety Technology Authority works together with other EU Member States, in particular through WELMEC within the sector.

In 2016 the Authority will participate in two EU projects: the NAWI [non-automatic weighing instruments] project is expected to be completed by January 2016. The consumption meter project is expected to be completed by late April 2016.

A national initiative for market surveillance of gold scales is being launched at the start of 2016 and is expected to be completed by September 2016.

2.17.1. Report on activities carried out under the previous planning period

Reactive cases: In 2013 nine reactive cases concerning water meters were examined in the light of consumer complaints. As this is a relatively small number of complaints in comparison with the number of meters installed in Danish homes, and as there is no evidence of any use of illegal meters, there are currently no plans for any proactive measures concerning water meters.

Screening of gold scales in 2013: Screening of 50 scales used for the purchase and sale of gold and silver was undertaken to verify compliance with the regulations in this area. None of the scales was correctly labelled. Only one set of scales indicated the accuracy class. None of the scales was verified in accordance with the national rules. 11 scales were not sealed. The zeroing function was in order for all instruments.

The Authority only had the power to penalise manufacturers which marketed the scales, and had no legal basis for sanctioning the owners of such instruments. The existing Order 1143 of 15 December 2003 has therefore subsequently been amended, so that breaches of rules can result in injunctions and be penalised.

EU project on consumption meters in 2014 and 2015: The Authority purchased and tested six consumption meters. The cases were dealt with in 2015.

EU NAWI project, 2014 and 2015: The project was not supported by EU funds, but it was decided to implement the project under the aegis of WELMEC. The Authority decided to participate in the project. Screening of the labelling on the scales was carried out in 2015.

2.18. **Electrical equipment in accordance with the Directive on electromagnetic compatibility – Directive 2004/108/EC – Directive 2014/30/EU**

2.18.1. *Responsible authority and contact details*

- Energistyrelsen, Amaliegade 44, 1256 Copenhagen K, Tel.: +45 3392 6700, email: ens@ens.dk, website: www.energistyrelsen.dk
- Department responsible: Centre for Tele
- For 2016 the Danish Energy Agency has a budget of EUR 149 400 for market surveillance activities in the EMC area. 1.5 FTEs are allocated to specific tasks in this area.

(Note: In mid-2015 there was a change of portfolios and this remit was transferred from the Danish Business Authority to the Danish Energy Agency.)

2.18.2. *Market surveillance procedures and strategy*

The Danish Energy Agency performs reactive checks on products covered by the EMC Directive further to complaints or information received from consumers, traders and manufacturers on the market, etc. The Agency also conducts reactive monitoring in relation to RAPEX notifications, where the market is explored for relevant products on the basis of notifications from other EU countries. The Danish Energy Agency carries out proactive monitoring of EMC products by performing random checks on the premises of traders and importers, etc. (retail and wholesale level). In addition, participation in a common European market surveillance campaign under the aegis of ADCO EMC is being considered. This monitoring is also proactive. The Danish Energy Agency's market surveillance can, in the event of a breach of the relevant legislation, lead, for instance, to a ban on the marketing of products that fail to comply with the provisions laid down in the legislation. Manufacturers, distributors or other persons who place products on the market which do not comply with the legislation could be reported to the police.

The Danish Energy Agency takes part in ADCO EMC, which is a forum for exchanging experience between European market surveillance authorities. In 2016, the Danish Energy Agency will focus largely on risk-based market surveillance, and has, in this context, developed an inspection database in order to improve the basic information for carrying out risk-based checks. Furthermore, 2016 will see an enhanced focus on guidance for economic operators who market or produce EMC products.

2.18.3. *Report on activities carried out under the previous planning period*

In 2014-2015, the Danish Business Authority (and now the Danish Energy Agency) focused resources essentially on random checks at retail and wholesale level. In the

context of this market surveillance, there have been only a few infringements of the relevant legislation, and the Agency considers that checks have functioned effectively.

2.19. Radio and telecommunications equipment in accordance with the Directives on radio and telecommunications terminal equipment – Directive 1999/5/EC – Directive 2014/53/EU

2.19.1. Responsible authority and contact details

- Energistyrelsen, Amaliegade 44, 1256 Copenhagen K, Tel.: +45 3392 6700, email: ens@ens.dk, website: www.energistyrelsen.dk
- Department responsible: Centre for Tele
- For 2016 the Danish Energy Agency has a budget of EUR 149 400 for market surveillance activities in the EMC area. 1.5 FTEs are allocated to specific tasks in this area.

(Note: In mid-2015 there was a change of portfolios and this remit was transferred from the Danish Business Authority to the Danish Energy Agency.)

2.19.2. Market surveillance procedures and strategy

The Danish Energy Agency performs reactive checks on products covered by the radio and telecommunications terminal equipment Directive further to complaints or information received from consumers, traders and manufacturers on the market etc. The Agency also conducts reactive monitoring in relation to RAPEX notifications, where the market is explored for relevant products on the basis of notifications from other EU countries. The Danish Energy Agency carries out proactive monitoring of radio equipment by undertaking random checks on the premises of traders and importers, etc. (retail and wholesale level). In addition, participation in a common European market inspection campaign under the aegis of ADCO R&TTE is being considered. This monitoring is also proactive. The Danish Energy Agency's market surveillance can, in the event of a breach of the relevant legislation, lead, for instance, to a ban on the marketing of products that fail to comply with the provisions laid down in the legislation. Manufacturers, distributors or other persons who place products on the market which do not comply with the legislation could be reported to the police.

The Danish Energy Agency takes part in ADCO R&TTE, which is a forum for exchanging experience between European market surveillance authorities.

In 2016, the Danish Energy Agency will focus largely on risk-based market surveillance, and has, in this context, developed an inspection database for carrying out risk-based checks. Furthermore, 2016 will see an enhanced focus on guidance for economic operators who market or produce radio equipment.

2.19.3. Report on activities carried out under the previous planning period

The Danish Energy Agency (now the Danish Business Authority) conducted random checks in 2014-2015 at the retail and the wholesale levels in order to assess whether the

radio equipment and telecommunications terminal equipment complies with the requirements of the legislation.

In 2014-2015 the Danish Energy Agency (now DBA) also focused on the placing on the market of repeaters, and on compliance with the requirements for CE marking, etc. of these appliances.

2.20. **Electrical appliances and equipment under the Low Voltage Directive – Directive 2006/95/EC – Directive 2014/35/EU**

2.20.1. *Responsible authority and contact details*

- Sikkerhedsstyrelsen, Nørregade 63, 6700 Esbjerg, Tel. +45 33732000, sik@sik.dk, website www.sik.dk
- Resources: 11 FTEs and DKK 200 000 for tests on products.

2.20.2. *Market surveillance procedures and strategy*

The Danish Safety Technology Authority carries out both reactive and proactive market surveillance. It may impose injunctions, prohibitions and fines.

The Authority, in cooperation with the Environmental Protection Agency, is planning an information campaign on children's use of electrical products. It cooperates with SKAT in connection with border checks on products in the sector. The Authority participates in the LVD-ADCO working group and the Nordic cooperation group NSS. In addition, the Authority participates in standardisation work in relation to household appliances, lighting and home electronics. In 2015 and 2016 the Authority is participating in the LVD-ADCO project on CFL and LVD lighting.

The Authority selects its proactive market surveillance operations using a risk-based approach. It expects to carry out the following checking operations in 2016:

- Power Bank or Pocket Power with a built-in rechargeable 5V lithium battery, for connecting to the equipment to be charged.
- Electrical equipment such as table lamps, kitchen lighting and clock radios fitted with chargers for operating and charging portable electrical equipment.
- Wireless chargers, where charging takes place by induction in a charging pad.

2.20.3. *Report on activities carried out under the previous planning period*

In 2014 the Danish Safety Technology Authority carried out a proactive operation concerning electrical equipment for livestock and pets.

The aim was to clarify the safety situation regarding electrical products used for pets and livestock, etc. A preliminary study showed that there was a reasonable suspicion of problems with safety.

An assessment showed that certain sections of the industry were not sufficiently familiar with the laws and rules applicable in this area. The objective of the operation was, among other things, to help raise the industry's awareness of the electrical risks that may occur with this type of product and to make importers ensure that they are in possession of the correct documentation from the manufacturer.

Following implementation of this operation, as the market stands in 2014 the following conclusions may be drawn:

- The products generally demonstrate a satisfactory level of safety. Out of 13 products examined, one was closed without remarks, eight were closed with a recommendation to correct minor defects and shortcomings and two cases were closed with an injunction to withdraw a product, one was closed with an injunction to recall a product from the end-user and one involved the voluntary suspension of sales.
- The visits to physical shops showed that the owners give priority to safety and that they have sufficient knowledge of the industry to safeguard their supplies from established wholesalers. There was only one shop which had itself imported a small share of the product range. After the visit, the owner was aware of the rules, and was able to produce sufficient documentary evidence for the products, which, moreover, demonstrated an adequate level of safety.
- Some Internet retailers buy their supplies from authorised wholesalers where the level of safety is satisfactory. A small share of the shops import the products themselves. It was only possible to obtain a few examples of these types of product.

The products examined demonstrated a satisfactory level of safety.

The five largest wholesalers were sufficiently familiar with the rules and requirements on safety, and could readily provide technical documentation. One of the more minor importers was marketing a dangerous product, and failed to produce technical documentation.

In 2014 the Danish Safety Technology Authority carried out a proactive survey of rules and legislation on safety for electrical batteries

The aim of this exercise was to establish which safety requirements cover electrical batteries; the survey covered safety requirements in standards and clarified whether the batteries may also be covered by other authorities and their legislation.

30 different batteries and the accompanying user manuals and safety advice were screened.

This screening exercise showed that the labelling on batteries was very varied and unclear, with some items having virtually no labelling and others exhibiting both text and pictograms.

Nor was it clear from the user manuals or packaging which standard the batteries were tested under.

Batteries are subject to a relatively extensive number of laws, and the authorities concerned were contacted to establish whether they had carried out any inspection measures in this field. The WEA and the Danish Emergency Management Agency (DEMA) [*Beredskabsstyrelsen*] have not run any operations concerning batteries but the

Environmental Protection Agency did undertake minor operations in 1998, 2007 and 2012, which involved looking at the chemicals in batteries. Overall there has been very little focus on batteries.

All these authorities are interested in hearing whether we intend to carry out any measures in this field.

The information available was taken to the Nordic cooperation group NSS at its meeting in Iceland in November 2014 with the expectation of consultation with the other Nordic countries on what they have done in this area. Unfortunately, there was not very much to take back as they have not as yet undertaken any form of action on batteries.

In 2014 the Danish Safety Technology Authority carried out a proactive operation concerning children's lamps (portable and night lights)

The aim was to obtain an overview of the market for children's lamps and also to gain an insight into whether such lamps comply with safety requirements.

The operation encompasses both portable lamps, lighting chains and night lights.

All 30 selected children's lamps were assessed internally by the Danish Safety Technology Authority on the basis of criteria such as safety, appeal to children and play value.

Nine of the lamps were subsequently tested by an external test laboratory which resulted in the elimination from the market of dangerous children's lamps.

Sales were suspended for seven lamps and two were recalled from consumers.

As regards documentation for children's lamps, not all importers were aware of the requirements for electrical products to comply with the Low Voltage Directive's rules on electrical safety documentation, i.e. that they must be able to produce a declaration of conformity.

On the first request for documentation, 25 were unable to produce a correct declaration of conformity, but following a dialogue and upon closer examination, the outcome was that eight did not have a correct declaration of conformity.

2.21. Chemical substances under REACH and Classification and Labelling Regulations – Regulation (EC) No 1907/2006 and Regulation (EC) No 1272/2008

22A. 1.1. Responsible authority and contact details

- Miljøstyrelsen, Strandgade 29, 1401 Copenhagen K, Tel.: +45 7254 0000 mst@mst.dk www.mst.dk, for the attention of Birte Børglum, Chemical Inspection Service
- Monitoring: three FTEs in 2016
- Information: one FTE in 2016

- The WEA monitors selected articles of the REACH Regulation, primarily the obligation to produce safety data sheets. 1 FTE is allocated to this task.

22A.1.2. Market surveillance procedures and strategy

- Cooperation with other Danish authorities: the WEA and SKAT
- Cooperation with EU Member States: Forum monitoring projects and Nordic cooperation on monitoring.
- Inspection campaigns are selected on the basis of risk screening. In 2016 verification is set to continue on the REACH rule for authorisation of the next candidate list of substances (FORUM pilot project). These substances require an authorisation before being placed on the market and used. The CLP requirements for mixtures entered into force on 1 June 2015, meaning that in 2016 there will be a check on the new CLP rules in a Nordic monitoring programme focusing on paints, glues, etc. Monitoring of CLP and aerosols will also continue.
- In 2016, in addition to the general Help Desk support for enterprises on the interpretation of CLP and REACH in general, particular focus will be given to information for enterprises covered by REACH registration requirements for chemical substances manufactured or imported in quantities of between 1 and 100 tonnes per year. In addition, the focus will be on improving and updating information on REACH and CLP on the Environmental Protection Agency's website.

22A.1.3. Report on activities carried out under the previous planning period

- In 2015, in addition to the general Help Desk support to enterprises on the interpretation of CLP and REACH in general, particular focus has been given to providing information to consumers on the entry into force of the new CLP rules for mixtures. In addition, information activities were launched targeting enterprises covered by REACH registration requirements in 2018 for chemical substances manufactured or imported in quantities of between 1 and 100 tonnes per year.
- Market surveillance is carried out as risk-based monitoring in all of the Chemical Inspection Service's areas of responsibility. In 2015 the Agency monitored the REACH rule on the authorisation of the first two candidate list substances. These substances require an authorisation before being placed on the market and used. The CLP requirements for mixtures entered into force on 1 June 2015, meaning that in 2015 checks were carried out on both the old classification rules and the new CLP rules for household chemicals, mixtures for use in public and in aerosols.
- In 2014, the Environmental Protection Agency closed 35 alerts (reactive) on possible infringements of hazard labelling of chemical mixtures, of which five involved no infringement, eight were given guidelines, 12 led to warnings/orders and nine were otherwise closed.
- There has as yet been no statement as to the number of alerts for 2015.

- In the period from October 2014 to September 2015, the WEA completed 12 cases concerning errors and shortcomings in safety data sheets for paint, epoxy and cleaning products. The Environmental Protection Agency was contacted in a number of cases to clarify the rules for CLP. In addition, a number of queries from producers, distributors and advisers were processed.

2.22.B. Other chemicals – Regulation (EC) 648/2004, Directive 2004/42/EC, Regulation (EC) 850/2004, Regulation (EC) 842/2006, Regulation (EU) 517/2014 and Regulation (EC) 1005/2009

22B. 1.1. Responsible authority and contact details

- Miljøstyrelsen, Strandgade 29, 1401 Copenhagen K, Tel.: +45 7254 0000 mst@mst.dk www.mst.dk, for the attention of Birte Børglum, Chemical Inspection Service
- Monitoring: 0.5 FTE in 2016
- Information: 0.3 FTE in 2016

Market surveillance procedures and strategy

- Cooperation with other Danish authorities: the WEA and SKAT
- Cooperation with EU Member States: CLEEN and the Nordic monitoring group.
- Inspection campaigns are selected on the basis of risk screening. In 2016, the focus has been on checks of VOCs in paint. Checks on greenhouse gas emissions in aerosols are also continuing.
- No specific information activities are planned for 2016; there will only be the general information that the Environmental Protection Agency circulates regularly.

22B.1.3. Report on activities carried out under the previous planning period

- In 2015, information regarding the rules was provided on the EPA website and by means of the ongoing assistance supplied to enterprises at their request.
- The chemicals sector, encompassing detergents, VOCs, POPs, greenhouse gases and ozone-depleting substances, etc. covers a very large and diverse product area, since it includes, for example, cleaning products, detergents, paints, fireworks, aerosols, refrigerators, etc.
- Market surveillance is carried out as risk-based monitoring in all of the Chemical Inspection Service's areas of responsibility covered by product legislation. In some years, the above product areas are given priority and in others, priority will be given to other product areas.

- In 2014, the CIS closed 14 alerts on ozone-depleting substances, of which four were given warnings, one was reported to the police, five involved no infringement and four were otherwise closed. Six reports on greenhouse gases were closed, of these three were given guidelines, two were given a warning and one did not involve an infringement. Three cases concerning detergents were closed, of which one was voluntarily rectified and two were otherwise closed.
- There are not yet any statements of reports available for 2015.
- In 2014 and 2015 proactive market surveillance on detergents and cleaning products for professional use was carried out, which included checks on compliance with the rules of the Detergents Regulation.
- In 2015 a proactive check on greenhouse gases in hairspray and in other aerosols was carried out.

2.22. Tyres (labelling) – Regulation (EC) No 1222/2009

2.22.1. Responsible authority and contact details

- Trafik- og Byggestyrelsen, Edvard Thomsens Vej 14, DK-2300 Copenhagen S, Tel.: +45 72 21 88 00, email: info@tbst.dk, www.tbst.dk. Contact: Martin Larsen
- Budget: approx. DKK 150 000 ≈ 0.2 FTEs

2.22.2. Market surveillance procedures and strategy

- Both proactive and reactive checks on labelling are carried out in physical shops/webshops. In addition, documentary checks are carried out on the premises of tyre importers, among others.
- Participation in the ADCO group on tyre labelling.
- In 2014/2015 the Danish Transport and Construction Agency started drawing up an updated strategy in the field of market surveillance. This is still under preparation.

2.22.3. Report on activities carried out under the previous planning period

- As at 1 December 2015, five checks on a total of 52 products had been carried out. Irregularities were detected in approximately 2 % of these cases.

2.23. Recreational craft – Directives 1994/25/EC and 2013/53/EU

2.23.1. Responsible authority and contact details

Market surveillance is divided up between the Danish Maritime Authority [*Søfartsstyrelsen*] and the Danish Environmental Protection Agency.

Danish Maritime Authority

- Søfartsstyrelsen, Carl Jakobsens Vej 31, 2500 Valby, Tel.: 72196000, Email: cfs@dma.dk, website: www.dma.dk. Coordinating Head: Ms Annemette Knagaard
- Resources have been copied from 2014, since the monitoring method is the same: budget of DKK 67 000 and 2.80 FTEs
- Technical facilities: None. (covers both sectors 25 + 26)

The Danish Environmental Protection Agency

- The Environmental Protection Agency is responsible for emissions and noise: Miljøstyrelsen, Strandgade 29, 1401 Copenhagen K. website: www.mst.dk
- No monitoring of emissions and noise is planned for 2016.

2.23.2. Market surveillance procedures and strategy

Overall strategy: Ship inspectors at the Maritime Authority's SKIBE department are in daily contact with seafarers, fishermen, shipowners, shipyards, classification societies and citizens. Through our work and conduct, we help to shape the development of Danish quality shipping. We provide and enforce the Maritime Authority's safety strategies, we provide services to the industry and we help to shape the work of the Authority through day-to-day feedback from our customers.

EU legislation	Sector	Description of product and category	Type of monitoring	Justification/description	Activity
94/25/EC	Recreational craft	Recreational craft	Proactive Reactive	Inspections shall be conducted in connection with dossier processing, campaigns and monitoring.	Inspections Documentary checks
Priority	Start period/date	Cooperation with others	Objectives and initiatives	Project leader	
Intermediate	Ongoing	As and when required	First cross-border RCD market surveillance campaign on small inflatable craft in 2015	Administrator appointed on a regular basis.	

The Danish Environmental Protection Agency

The Environmental Protection Agency cooperates with the Danish Maritime Authority on monitoring. Monitoring has previously been carried out at large boat fairs in Denmark.

2.23.3. Report on activities carried out under the previous planning period

There is an ongoing campaign on small inflatable boats, see the table above, and otherwise market surveillance is undertaken as one of the tasks of the SKIBE department, e.g. health and safety on Danish merchant vessels and fishing vessels, flag state control (statutory and operational inspections), port state control (PSC), monitoring, checks and auditing of the recognised classification societies and authorised enterprises, monitoring and checks within the field of diving, dossier processing within the field of maritime safety and clean seas, assisting the Environmental Protection Agency and the Energy Agency, auditing shipping companies, cooperating with the industry, CE marking of pleasure boats, etc.

The Danish Environmental Protection Agency

In 2011, monitoring was conducted at a boat fair, where four enterprises were contacted, mainly owing to missing or incomplete declarations of conformity. In all, there were 156 different exhibitors at the fair, but not all had engines. No inspections were carried out in 2012-2015.

2.24. Marine equipment – Directives 96/98/EC and 2014/90/EU

2.24.1. Responsible authority and contact details

- Søfartsstyrelsen, Carl Jakobsens Vej 31 2500 Valby, Tel.:72196000, Email: cfs@dma.dk, website: www.dma.dk. Coordinating Head: Ms Annemette Knagaard
- Resources have been copied from 2014, since the monitoring method is the same: budget of DKK 67 000 and 2.80 FTEs
- Technical facilities: None. (covers both sectors 25 + 26)

2.24.2. Market surveillance procedures and strategy

Overall strategy: Ship inspectors at the Maritime Authority's SKIBE department are in daily contact with seafarers, fishermen, shipowners, shipyards, classification societies and citizens. Through our work and conduct, we help to shape the development of Danish quality shipping. We provide and enforce the Maritime Authority's safety strategies, we provide services to the industry and we help to shape the work of the Authority through day-to-day feedback from our customers.

EU legislation	Sector	Description of product and category	Type of monitoring	Justification/description	Activity
96/98/EC	Marine equipment	Marine equipment	Proactive Reactive	Inspections shall be conducted in connection with monitoring of ships Dossier processing may also arise on the basis of complaints/design/accidents.	Inspections Documentary checks
Priority	Start period/date	Cooperation with others	Objectives and initiatives	Project leader	
Intermediate	Ongoing	As and when required		Administrator appointed on a regular basis.	

2.24.3. Report on activities carried out under the previous planning period

There is an ongoing campaign on small inflatable boats, see the table above, and otherwise market surveillance is undertaken as one of the tasks of the SKIBE department, e.g. health and safety on Danish merchant vessels and fishing vessels, flag state control (statutory and operational inspections), port state control (PSC), monitoring, checks and auditing of the recognised classification societies and authorised enterprises, monitoring and checks within the field of diving, dossier processing within the field of maritime safety and clean seas, assisting the Environmental Protection Agency and the Energy Agency, auditing shipping companies, cooperating with the industry, CE marking of pleasure boats, etc.

2.25. Motor vehicles and tractors – Directive 2002/24/EC and Regulation (EC) No 168/2013; Directive 2007/46/EC; Directive 2003/37/EC and Regulation (EC) No 167/2013

2.25.1. Responsible authority and contact details

- Trafik- og Byggestyrelsen, Edvard Thomsens Vej 14, DK-2300 Copenhagen S, Tel.: +45 72 21 88 00, email: info@tbst.dk, website www.tbst.dk. Contact: Martin Larsen
- Budget: approx. DKK 2 000 000 ≈ 2.0 FTEs

2.25.2. Market surveillance procedures and strategy

Maintenance of type-approval requirements for trucks/buses, and checks on type approvals already issued, in the form of spotchecks or dossier processing. In addition, proactive and reactive monitoring of motor vehicle equipment, including safety equipment for restraining children in cars, and spare parts and accessories, in physical shops/webshops.

Cooperation with SKAT (motor vehicle register), and participation in various EU working groups.

In 2014/2015 the Danish Transport and Construction Agency started drawing up an updated strategy in the field of market surveillance. This is still under preparation.

2.25.3. Report on activities carried out under the previous planning period

As at 1 December 2015, 42 checks on a total of 180 motor-vehicle equipment products had been carried out. Irregularities were detected in approximately 11 % of these cases.

As vehicles are becoming increasingly EU-approved, this is decreasing the need for national checks in the form of type approvals. This will release more resources for general market surveillance. This has, *inter alia*, led to increased market surveillance of safety equipment for children in cars, which has recently been the focus of much political attention.

2.26. Non-road mobile machinery – Directive 97/68/EC

2.26.1. Responsible authority and contact details

- Miljøstyrelsen, Strandgade 29, 1401 Copenhagen K, mst@mst.dk, Environmental technology
- In 2014/15, DKK 200 000 were allocated to surveying the Danish market for machinery, types of engines used in this machinery, requirements for different stages, etc. This work has been delayed and is expected to be implemented and reported on in 2016.
- An estimated 0.2 FTEs are required for these activities.

2.26.2. Market surveillance procedures and strategy

Continuing assistance is being provided to various machinery manufacturers, trade organisations and engine manufacturers (international) on the provisions of Directive 97/68/EC concerning:

- labelling and type approval in conjunction with the requirements of the Directive
- exchange of knowledge on the market with trade organisations
- requirements for different stages in relation to air emissions, dates for entry into force
- imports (components and engines) from non-EU countries
- permits have been issued and guidance provided on labelling for alternative marketing under the flexible scheme for machinery covered by Annex XIII to the Directive.

2016 will also see surveying of the Danish market for machinery, types of engines used in these machines, requirements at different stages, etc.

2.26.3. Report on activities carried out under the previous planning period

No further activities were carried out beyond the ongoing operations described in point 2.26.2.

2.29. Fertilisers – Regulation (EU) No 2003/2003

2.29.1. Responsible authority and contact details

- NaturErhvervstyrelsen [Danish AgriFish Agency], Nyropsgade 30, 1602 Copenhagen V, Tel. + 45 33 95 80 00, naturerhverv@naturerhverv.dk, Inspections Centre, Unit for agricultural inspections, Organic inspections and fertilisers team, Mette Thomsen, Tel. + 45 45 26 37 18, mth@naturerhverv.dk
- In the 2016 budget, 2.8 FTEs have been allocated to inspections of commercial fertilisers, soil improvers, etc., of which 0.8 FTE to the Danish AgriFish Agency's decentralised units. Added to this are the costs of other operations amounting to DKK 2.16 million. This amount includes expenditure on IT support, laboratory costs and other expenditure on support services and overheads.

2.29.2. Market surveillance procedures and strategy

Inspections are carried out based on Regulation (EC) No 2003/2003 as regards fertilisers and liming materials, and Order No 862 of 27 August 2008 as regards commercial fertilisers, soil improvers, growing media, etc. which have so far not been covered by joint legislation.

Within a few years it is expected that there will be common EU rules on the sale of products which have so far been regulated by national provisions, cf. the abovementioned Danish Order.

The Danish AgriFish Agency carries out checks by taking samples and undertaking chemical analysis of the samples, to ascertain whether the products fulfil the declaration that they were sold with. Checks are also carried out on labelling to ensure that it generally complies with the rules.

The check is a continuation of the strategy adopted in the preceding years.

Half the checks/sampling/analyses target the risk based on predefined criteria, including the risk of unwanted heavy metal content. Extra checks are made on products and producers/importers, where the preceding year's checks have revealed divergent results exceeding the average.

The remaining half of the checks are carried out randomly, in order to obtain a realistic picture of the market situation in Denmark.

There has been some cooperation with SKAT with regard to imports and the introduction of fertiliser products. The same is true of cooperation with the police (PET) with regard to the sale of fertiliser products to persons and enterprises which are not entitled to buy certain types of fertiliser. Provisions based on the Regulation on chemicals (REACH).

2.29.3. Report on activities carried out under the previous planning period

Every year the AgriFish Agency publishes the results of the chemical analysis of the samples on its website: www.naturerhverv.dk.

2.30. Biocides – Regulation (EU) No 528/2012

2.30.1. Responsible authority and contact details

- Miljøstyrelsen, Strandgade 29, 1401 Copenhagen K, Tel.: +45 72 54 00 00
mst@mst.dk www.mst.dk, for the attention of Birte Børghum, Chemical Inspection Service
- Monitoring: two FTEs in 2016
- Information: 0.25 FTE in 2016

2.30.2. Market surveillance procedures and strategy

Inspection campaigns are selected on the basis of risk screening. In 2016 the main focus remains on control testing for the presence of active substances in biocidal products, and checks on mixtures that are illegally sold as biocidal products. In addition, the focus will be on monitoring of the use of biocides by pest control operators, monitoring of the use of rat poison, and monitoring under Article 95.

In 2016 there are also plans for an ongoing campaign aimed at small and medium-sized enterprises which will provide information on the Biocide Regulation's authorisation requirements for biocides and how biocidal products and items treated with biocides can legally remain on the market. The campaign is expected to be implemented in the form of an enhanced website, with more guidelines, but also a general introduction to the chemicals sector geared to enterprises. The website is to provide better guidance on which set of rules applies to which type of product, and more factsheets on selected issues. Initiatives in the form of briefing meetings and direct emailing is also envisaged.

Cooperation with other Danish authorities: SKAT

Cooperation with EU Member States: CLEEN and the Nordic monitoring projects.

2.30.3. Report on activities carried out under the previous planning period

In 2015 Denmark carried out an analysis of Danish SMEs' information needs regarding the Regulation in order to be able to plan and target its continued information campaign in 2016 and 2017.

In 2015, there was also a specific campaign providing information on the Biocide Regulation's requirement to register active substance suppliers under Article 95, a requirement that applies to all products, even those which do not as yet require approval. Information was circulated via email, letters, trade organisations and the specialised press on how to meet the requirement, which entered into force on 1 September 2015.

Market surveillance itself is carried out as risk-based monitoring in all of the Chemical Inspection Service's areas of responsibility covered by product legislation.

In 2015, proactive market surveillance was carried out in the form of control testing for active substances in biocidal products, monitoring of pest control operators, possession and storage of biocidal products and checks on mixtures that are illegally sold as biocidal products, including repellents against martenes and insects.

In 2014, the Environmental Protection Agency closed reports (reactive market surveillance) on 69 possibly illegal biocidal products. Of these cases, two were closed with no infringement, one was given guidelines, three were voluntarily rectified, 35 received a warning or an order, 15 were reported to the police and 13 were otherwise closed.

There has as yet been no statement as to the number of reports for 2015.

2.31. Textiles (labelling) – Regulation (EC) No 1007/2011

2.31.1. Responsible authority and contact details

- Konkurrence- og Forbrugerstyrelsen [Danish Competition and Consumer Authority], Carl Jacobsens Vej 35, 2500 Valby. Tel.: +45 4171 5000, email: kfst@kfst.dk, website: www.kfst.dk. Centre for Policy and preparing legislation.
- 0.5 FTE in 2015

2.31.2. Market surveillance procedures and strategy

The Danish Competition and Consumer Authority [*Konkurrence- og Forbrugerstyrelsen*] is the competent authority for Regulation (EC) No 1007/2011. The Authority participates in meetings of expert groups at EU level and is in dialogue with the European Commission for discussions on the scope etc. of the Regulation. The Competition and Consumer Authority's market surveillance under the Regulation is initiated on the basis of queries from citizens, businesses, etc., and is therefore reactive market surveillance.

The Consumer Ombudsman is the enforcement authority, and the Competition and Consumer Authority therefore cooperates with the Consumer Ombudsman on any cases of infringements of the Regulation. The Danish Competition and Consumer Authority has also been in cooperation with the Danish Environmental Protection Agency.

2.31.3. Report on activities carried out under the previous planning period

In the period 2014-2015 the Danish Competition and Consumer Authority received three queries from citizens and enterprises, enquiring as to the content of the Regulation.

2.32. Labelling of the materials used in the main components of footwear — Directive 94/11/EC

2.32.1. Responsible authority and contact details

- Konkurrence- og Forbrugerstyrelsen, Carl Jacobsens Vej 35, 2500 Valby. Tel.: +45 4171 5000, email: kfst@kfst.dk, website: www.kfst.dk. Centre for Policy and preparing legislation.

2.32.2. Market surveillance procedures and strategy

The Danish Competition and Consumer Authority [*Konkurrence- og Forbrugerstyrelsen*] is the competent authority for Directive 94/2011/EC.

The Authority participates in meetings of expert groups at EU level and is in dialogue with the European Commission for discussions on the scope etc. of the Directive. The Authority's market surveillance under the Directive is initiated on the basis of queries from citizens, businesses, etc., and is therefore reactive market surveillance.

The Consumer Ombudsman is the enforcement authority, and the Competition and Consumer Authority therefore cooperates with the Consumer Ombudsman on any cases of infringements of the Directive.

2.32.3. Report on activities carried out under the previous planning period

During the period 2014-2015 the Danish Competition and Consumer Authority and the Consumer Ombudsman did not receive any queries concerning the Directive.

2.33. Labelling of crystal glass – Directive 69/493/EEC

2.33.1. Responsible authority and contact details

- Konkurrence- og Forbrugerstyrelsen, Carl Jacobsens Vej 35, 2500 Valby. Tel.: +45 4171 5000, email: kfst@kfst.dk, website: www.kfst.dk. Centre for Policy and preparing legislation.

2.33.2. Market surveillance procedures and strategy

The Danish Competition and Consumer Authority is the competent authority for Directive 69/493/EEC.

The Authority participates in meetings of expert groups at EU level and is in dialogue with the European Commission for discussions on the scope etc. of the Directive. The Authority's market surveillance under the Directive is initiated on the basis of queries from citizens, businesses, etc., and is therefore reactive market surveillance.

The Consumer Ombudsman is the enforcement authority, and the Competition and Consumer Authority therefore cooperates with the Consumer Ombudsman on any cases of infringements of the Directive.

2.33.3. Report on activities carried out under the previous planning period

During the period 2014-2015 the Danish Competition and Consumer Authority and the Consumer Ombudsman did not receive any queries concerning the Directive.

2.34. Food Contact Materials – Regulation (EU) No 1935/2004

2.34.1. Responsible authority and contact details

Fødevarestyrelsen, Stationsparken 31-33, 2600 Glostrup, Tel. 72 27 60 00, www.fvst.dk.
Chemistry and Food Quality

In market surveillance of food contact materials the Chemistry and Food Quality specialist office shares inspection units, one of the DVFA's own laboratories and the National Food Institute's laboratory.

2.34.2. Market surveillance procedures and strategy

Enterprises which either manufacture, import or are wholesalers of food contact materials must be registered with the DVFA and are subject to their checks. This is undertaken by monitoring the enterprise, which involves carrying out checks on the documentation for food contact materials, and by taking samples that are analysed for contamination with chemical substances during inspection projects and campaigns. In the event of non-compliance with these rules the enterprises will be penalised.

The rules on food contact materials are harmonised within the European Union.

The DVFA's monitoring of enterprises is risk-based.

2.34.3. Report on activities carried out under the previous planning period

Every year the Danish Veterinary and Food Administration checks approx. 600 enterprises which either manufacture, import or are wholesalers of food contact materials. In addition, 10 annual inspection projects and campaigns were undertaken in 2014 and 2015.

ANNEX: REFERENCE LIST OF PRODUCT SECTORS

Product sectors	Relevant legislation ^{14 15}
1. Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)	Directives 93/42/EEC, 98/79/EC and 90/385/EEC
2. Cosmetic products	Regulation (EC) No 1223/2009
3. Toys	Directive 2009/48/EC
4. Personal protective equipment	Directive 89/686/EEC
5. Construction products	Regulation (EU) No 305/2011
6. Aerosol dispensers	Directive 75/324/EEC
7. Simple pressure vessels and pressure equipment	Directive 2009/105/EC and Directive 97/23/EC; Directive 2014/29/EU and Directive 2014/68/EU
8. Transportable pressure equipment	Directive 2010/35/EU
9. Machinery	Directive 2006/42/EC
10. Lifts	Directives 1995/16/EC and 2014/33/EU
11. Cableway installations	Directive 2000/9/EC
12. Noise emission in the environment by equipment for use outdoors	Directive 2000/14/EC
13. Equipment and Protective Systems intended for use in potentially explosive atmospheres	Directives 1994/9/EC and 2014/34/EU
14. Pyrotechnic articles	Directives 2007/23/EC and 2013/29/EU
15. Explosives for civil uses	Directives 93/15/EEC and 2014/28/EU
16. Gas appliances	Directive 2009/142/EC
17. Measuring instruments, non-automatic weighing instruments and prepackaged products, and units of measurement	Directives 2004/22/EC and 2009/23/EC; Directives 2014/32/EU and 2014/31/EU; Directives 2007/45/EC, 75/107/EEC and 76/211/EEC; Directive 80/181/EEC
18. Electrical equipment under the EMC Directive	Directives 2004/108/EC and 2014/30/EU
19. Radio and telecommunications equipment under the RTTE Directive	Directives 1999/5/EC and 2014/53/EU
20. Electrical appliances and equipment under the LVD	Directives 2006/95/EC and 2014/35/EU
21. Electrical and electronic equipment under the Directive on RoHS and WEEE	Directives 2011/65/EU, 2002/96/EC and 2006/66/EC

¹⁴ For ease of reference this table indicates established EU legislation. New legislation replacing that listed in the table should also be taken into account for the period concerned if it is relevant.

¹⁵ For ease of reference, in some cases (e.g. eco-design, energy labelling) this table only indicates EU framework legislation, but is intended to cover product-specific EU legislative acts too.

and batteries	
22./A Chemical substances under REACH and Classification and Labelling Regulations	Regulations (EC) Nos 1907/2006 and 1272/2008
22. /B Other chemicals (Detergents, Paints, Persistent Organic Pollutants, Fluorinated greenhouse gases, Ozone Depleting Substances, etc.)	Regulation (EC) No 648/2004, Directive 2004/42/EC, Regulation (EC) No 850/2004, Regulation (EC) No No 842/2006 and Regulation (EU) No 517/2014, Regulation (EC) No 1005/2009
23. Eco-design and Energy Labelling; Efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels	Directives 2009/125/EC and 2010/30/EU; Directive 1992/42/EEC
24. Tyre labelling	Regulation (EC) No 1222/2009
25. Recreational craft	Directives 1994/25/EC and 2013/53/EU
26. Marine equipment	Directives 96/98/EC and 2014/90/EU
27. Motor vehicles and tractors	Directive 2002/24/EC and Regulation (EU) No 168/2013; Directive 2007/46/EC; Directive 2003/37/EC and Regulation (EU) No 167/2013
28. Non-road mobile machinery	Directive 97/68/EC
29. Fertilisers	Regulation (EC) No 2003/2003
30. Other consumer products under the GPSD (optional)	Directive 2001/95/EC
31. Biocides	Regulation (EU) No 528/2012
32. Labelling of textile products and footwear	Regulation (EC) No 1007/2011 and Directive 94/11/EC
33. Crystal glass	Directive 69/493/EEC
34. Food contact materials	Regulation (EC) No 1935/2004