

National Market Surveillance Programme 2019-2020



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Introduction

In the UK, market surveillance refers to the suite of activities that protect consumers from non-compliant goods, by ensuring the safety of non-food products placed on the market.

This national plan sets out the UK's approach to these activities in 2019-20. It provides an overview of the national surveillance structure, which is comprised of market surveillance authorities (MSAs) who are responsible for enforcing product safety and other product legislation across the UK. It sets out how these organisations communicate and co-ordinate with each other, as well as their co-operation mechanisms for working with Her Majesty's Revenue and Customs (HMRC) and Border Force to ensure the compliance of goods entering the market. It also covers the UK's international co-operation with EU member states and other countries. This plan has been shared with the European Commission in line with the Regulation on Accreditation and Market Surveillance 765/2008.

The plan details the digital information systems that are used to communicate product assessments, as well as to facilitate the exchange of information regarding serious risks and incidents; these systems protect consumers, their property, the market and the environment from non-compliant products. Further to this, it will outline the UK's approach to intelligence-gathering, the powers and sanctions of MSAs, and their activities and procedures.

The latter half of the report outlines the approach and responsibilities of each MSA and includes their contact details to facilitate co-operation at a national and local level.

This report shows how UK market surveillance is organised, the way the system operates, how MSAs share intelligence and best practice, and the procedures through which they enforce product safety and other product legislation to ensure the compliance of goods and to protect consumers.

1. General Market Surveillance Organisation and Infrastructure

1.1 UK market surveillance authorities and their responsibilities

The UK's comprehensive market surveillance system is underpinned by primary and secondary legislation. This is generally organised by sector, although some legislation provides cross-cutting regulatory powers and sanctions, for example: the Consumer Rights Act 2015, the Consumer Protection Act 1987, the Health and Safety at Work Act 1974 and the General Product Safety Regulations 2005. Bespoke powers are also provided within specific pieces of product safety legislation. The market surveillance responsibility for each authority is determined by the subject matter of European-derived legislation.

The UK's <u>Better Regulation Framework</u> and <u>Regulators' Code</u> ensure that the approach to market surveillance is always risk-based and proportionate.

The UK's market surveillance authorities (MSAs) are responsible for market surveillance, co-operating with the Home Office agency Border Force and HMRC, which are responsible for border policies and customs respectively. Details about all UK MSAs can be found in Annex 1.

The Department for Business, Energy and Industrial Strategy (BEIS) has responsibility for the subject matter of most EU Directives and Regulations (regarding the single market for goods). Responsibility for co-ordinating market surveillance activity in the UK is held by The Office for Product Safety and Standards (OPSS), which sits within BEIS. OPSS was established in January 2018 to oversee the regulatory system for product safety and standards, providing for the first time a national regulator for product safety. OPSS provides additional national capacity for product safety, oversight of weights and measures and acts as an MSA for certain areas of product regulation.

Market surveillance is delivered by a range of national and local bodies, including Local Authorities, the Health and Safety Executive (HSE), HSE Northern Ireland (HSENI), the Medicines and Healthcare Regulatory Agency (MHRA), Ofcom, the Marine and Coastguards Agency (MCA), the Driver and Vehicles Standards Agency (DVSA), and the Vehicle Certifications Agency (VCA),

Each MSA has their own budget, and they are individually responsible for setting riskbased priorities and reporting outcomes. National MSAs are accountable to their policy department within government, while local authority regulatory services are accountable to local democratic structures. Section 1.2 contains further information on the co-ordination of MSAs at a regional and national level.

The UK's comprehensive product safety framework and organisational structure aims to ensure that consumers are kept safe from unsafe and non-compliant goods, as well as protecting the environment and wider public interests. The UK will continue to have a robust approach to market surveillance after we exit the EU.

1.2 Co-ordination and co-operation mechanisms between national market surveillance authorities

Market surveillance in the UK is delivered by a range of both national and local authorities that work in particular sectors, and through the Market Surveillance Network (MSNetwork) these authorities come together and develop strategic and operational partnerships.

The MSNetwork was established in 2018 and meets four times a year providing a forum to exchange information, share experiences and understanding. It also allows OPSS to disseminate key market surveillance messages and developments and fosters joint learning which continues outside the formal meetings.

By co-operating and collaborating this network has looked at online sales and issues relating to other non-traditional routes of supply such as direct imports and product fulfilment businesses. There is a working group that looks at the data sources each authority uses and how intelligence can best be shared between the different MSAs.

There are over 200 local regulators collaborating across the UK, in addition to national MSAs and Government Departments with regulatory responsibility. The National Product Safety Group, established in 2012, co-ordinates the activity between MSAs with responsibility for consumer product legislation and construction products. It comprises regional Trading Standards representatives from across the UK, OPSS, the Health and Safety Executive, and lead officers for product safety from the Ministry for Housing, Communities and Local Government (MHCLG) and the Chartered Trading Standards Institute (CTSI). They share best practice, review market surveillance issues and discuss regulatory challenges, enabling co-ordination where more than one regulator is responsible for market surveillance of a sector.

The enforcement of legislation covering workplace goods is undertaken by the Health and Safety Executive's network of 'virtual' product safety teams across Great Britain. In these teams, product safety specialists take the lead on supply issues that arise following the initial findings of inspectors, who carry out more general responsibilities. Because of the migration of professional goods towards the non-professional consumer, the HSE and local authorities co-operate closely, particularly in relation to products such as personal protective equipment, machinery and gas appliances.

Co-ordination at points of entry

Market surveillance work at points of entry into the country is of vital importance in ensuring that consumers are protected. OPSS has responsibility for developing national capacity for product safety in the UK; a key component of this is a robust, intelligence-led mechanism for targeting unsafe goods as they enter the UK.

Over the last year, OPSS has improved the effective use of intelligence through the forming of a single UK intelligence hub for product safety. This has involved funding and providing strategic direction to the Ports and Borders Single Point of Contact (SPoC). This team will shortly transfer into the OPSS Intelligence team. Prior to April 2019, the SPoC was funded via the National Trading Standards programme which operates in England and Wales; however, the changes introduced by OPSS will enable this to operate in all parts of the UK. This will enhance the capability of Trading Standards Services operating at ports and key points of entry, to improve how they target their resources based on risk.

As part of OPSS, the SPoC will be able to use its expertise in customs procedures to provide strategic direction to MSAs in relation to border controls, practice and processes. SPoC referrals to ports and airports enable the identification of a diverse range of unsafe and non-compliant goods, ranging from electrical goods to cosmetics. The benefits of the SPoC include the ability to identify national emerging trends and threats; to identify high risk economic operators working across areas within the legislative competence of different MSAs; and to ensure consistency of approach at border points in line with developing best practice across the EU.

OPSS also funds UK Border Force staff to provide intelligence and referrals to local authorities about fast parcels entering the UK via the airport. This will help ensure a consistent approach to product safety between goods arriving via ports and airports.

Examples of MSA collaboration

A recent example of collaboration between MSAs has been the national test-purchasing Sampling Programme coordinated by OPSS. Local Authority Trading Standards Services throughout the UK participated in purchasing items for testing, providing a comprehensive assessment of the safety of certain products – with enforcement action now being taken where appropriate.

MSAs have also worked together in a cross-cutting and collaborative manner to review compliance in the white goods sector in the UK market. This multi-agency initiative took a holistic approach to business engagements to allow compliance with Eco-Design, Restriction of Hazardous Substances (RoHS), and the Electrical Equipment Safety Regulations to be considered together. This approach included visits in partnership with Trading Standards and primary authorities followed by market surveillance testing and the review of technical documentation. Consideration was given to routes to market, general approach to compliance, quality control systems, approach to research and development, methods of product testing, compliance with conformity assessment procedures and compliance with the <u>Code of Practice</u> on consumer product recall.

1.3 Co-operation between national market surveillance authorities and customs

In the UK, HMRC and the Border Force are not designated as MSAs but they have a significant role to play in market surveillance, given the data and documentation they hold relating to imports from third countries. The information contained within customs declarations and the supporting documents can be profiled to target products and economic operators that are likely to present the greatest risk to users. The SPoC develops risk-based criteria using intelligence and works with HMRC and Border Force to set up alerts when consignments meet these criteria. Co-operation between HMRC and Border Force and UKs MSAs is an important element of the risk-based and targeted approach to border controls. Co-operation involves sharing intelligence and knowledge and the provision of access to inspection facilities for non-food products.

HMRC's National Clearance Hub (NCH) is the single national site that handles the movement of third-country goods and processes goods transiting the EU. The NCH is the only centralised clearance hub in the EU, processing around 360,000 import and export declarations each year. The service is available 24 hours a day, every day of the year.

1.4 Digital information systems – RAPEX and ICSMS

The General Product Safety Directive 2001/95/EC (GPSD) provides the legal framework for RAPEX (now publicly known as Safety Gate) which is a Rapid Alert System for non-food, dangerous products. RAPEX facilitates the rapid exchange of information between the national authorities of 31 countries and the European Commission on dangerous products found on the market. In the UK, OPSS holds responsibility for the GPSD and therefore also for RAPEX.

OPSS provides the National Contact Point Service (the 'RAPEX Unit'), which plays a key role in ensuring that notifications submitted meet the criteria of RAPEX. It advises MSAs on the information that is required and the documentation that is needed in order to ensure submissions to the European Commission are consistent and meet necessary time scales. The UK typically submits over 100 notifications a year to the European Commission and ensures that statistics on UK notifications are recorded in a timely fashion.

On request, the RAPEX Unit advises Trading Standards regarding the procedures they should follow when submitting reactions to 'validated' notifications issued by other EU member states, including: the way in which they should provide information on whether the notified dangerous product was found on the UK market, and what measures were taken to restrict its marketing and distribution. The RAPEX Unit also advises on what information is required when there is a divergence in the risk assessment of a UK supplied product notified by other member states. Furthermore, the Unit deals with enquiries about procedures for identifying risk and information requests on products notified on RAPEX from EU member states, UK authorities and UK companies.

The Regulation for Accreditation and Market Surveillance (EC Regulation 765/2008) introduced the general obligation for information sharing on market surveillance activity by all European MSAs with each other and with the European Commission via the Information and Communication System for Market Surveillance (ICSMS). BEIS holds policy responsibility for ICSMS and HSE acts as the UK administrator for the system. All UK MSAs have access to ICSMS, either directly or through national co-ordinators.

The UK is currently in the process of developing a new dedicated UK product safety database to securely exchange data between MSAs within the UK internal market. The new system will ensure we are able to quickly identify new threats, mount co-ordinated and rapid responses to those threats and to target the interception of high-risk products, including imports.

1.5 General description of market surveillance activities and relevant procedures

Market surveillance in the UK is designed to ensure the free circulation of safe and compliant products, and to protect consumers by intervening where products are unsafe or non-compliant. The UK's approach to regulation and enforcement supports business and business growth, provides high levels of consumer and environmental protection, and promotes consumer choice.

All MSAs are required to consider the UK's Better Regulation Framework and the Regulators' Code. Additionally, national MSAs have a statutory duty to consider the desirability of promoting economic growth, alongside the delivery of protections covered in relevant legislation. They are required to consider taking regulatory action only when it is proportionate and needed, in order to promote economic growth.

Engagement with businesses

A key component of the UK's market surveillance approach is providing information, guidance and advice to business on applicable legislation, in order to prevent and address non-compliance. As such, a high priority is given to business communication and engagement activities by all MSAs.

The Regulators' Code came into statutory effect on 6 April 2014. It provides a clear, flexible and principles-based framework for how regulators should engage with those they regulate. Regulators in scope of the Code must have regard to it when developing policies and procedures that guide their regulatory activities. It covers the transparency of policies; accessibility of information and guidance; and provisions which require regulatory activities to be based on risk. By promoting the development of an open and constructive relationship between regulators and those they regulate, the Regulators' Code gives businesses greater confidence to invest and grow as they have greater certainty over the way that regulations will be enforced. It helps regulators to better target their resources by basing activity on risk.

Businesses also have the opportunity to form a legally recognised partnership with one local authority, which then provides robust and reliable advice to the business on matters of regulatory compliance. Known as 'Primary Authority', this is a means for businesses to receive assured and tailored advice on meeting environmental health, trading standards or fire safety regulations through a single point of contact. This ensures start-ups get it right at the outset and enables all businesses to invest with confidence in products, practices and procedures, knowing that the resources they devote to compliance are well spent. There are approximately 90,000 businesses that currently benefit from Primary Authority and these range from single site independents to large multi-site corporations. Primary Authority enables businesses to take an innovative approach to compliance and it also promotes national conversations in areas of regulation that are either contentious or require clarification. For further information about Primary Authority, please see: www.gov.uk/government/publications/primary-authority-overview.

Ensuring that regulators and policy departments better understand the views of the business community (in relation to regulatory policy and delivery) is a key goal for BEIS, which has a Business Reference Panel. This panel is dedicated to regulatory issues and is comprised of experts from over 150 business organisations, trade associations and professional bodies; collectively, these represent over 1.5 million businesses. The panel helps to ensure that the voices of business are heard by giving the opportunity to feedback on Government ideas and proposed work programmes, airing priorities and concerns. The panel meets four times a year, and 'expert panels' are established intermittently to focus in detail on specific regulatory issues.

Proactive interventions

The proactive work of MSAs is based on risk assessment, which utilises data and intelligence from a range of sources, including other MSAs. This information is used to establish strategic priorities and to identify specific products, businesses or supply chains to target for market surveillance activities. These activities may include checking products, technical files and incident data, but can also involve raising awareness to help consumers make informed choices and to ensure businesses are aware of their obligations.

MSAs are expected to have a thorough understanding of the businesses that they regulate and to apply their powers proportionately. MSAs are therefore able to tailor the type of interventions they use to the business and to the context of the situation, to arrive at the best outcome.

Reactive interventions

Complaints about alleged non-compliant products are received by MSAs through a variety of routes including consumer bodies, trade associations, other regulators and direct reports to the MSA through their website, telephone or other communication tools. MSAs also receive product safety and compliance alerts through RAPEX and 'baton passing' of cases through ICSMS that have been initiated in other EU countries. Complaints are assessed as they are received against each MSA's intelligence model to identify the risks and to determine the priority of response that is required.

MSAs generally conduct a mixture of proactive and reactive activities, and the balance of resource allocated to each is a matter for the individual MSA to determine in response to the risks that are present. The MSA will also determine the proportionate approach to the risk, checking labelling and instructions, reviewing documents, assessing technical files or undertaking some form of product testing.

Alerts about hazardous products

Consumers can access information about hazardous products that have been recalled using the government website <u>https://productrecall.campaign.gov.uk/</u>. The appropriate route to alerting consumers depends on the product type. For work equipment, HSE has a system of safety alerts and bulletins for dealing with products that pose a serious risk, which can be found at <u>http://www.hse.gov.uk/safetybulletins/</u>. For domestic appliances, consumers can register their appliance with the manufacturer to receive alerts. This can be done with the manufacturer directly or through a website run by the Association of Manufacturers of Domestic Appliances: <u>https://www.registermyappliance.org.uk</u>. Consumers may also choose to sign up for alerts from RAPEX. UK MSAs share alerts with each other, and with EU MSAs through ICSMS and RAPEX.

Powers and sanctions

UK MSAs have an extensive range of statutory powers to investigate and deal with contraventions, set out in UK legislation.

MSAs have enforcement policies, guidelines or strategies that outline their approach to non-compliance and explain business's legal obligations and rights. These reflect the UK Government's expectations of regulators, as set out in the Regulators' Code, and are published online and through social media.

If MSAs find a product to be non-compliant, they will usually first seek voluntary compliance from the business, providing support, guidance and advice to help them become compliant. If a business does not voluntarily bring the product into compliance, MSAs will issue formal notices that require businesses to take appropriate corrective action.

Where it is considered proportionate to take punitive action, MSAs have a range of sanctions available; for example, this might involve imposing a monetary penalty determined by the MSA, or potentially prosecution in court. Prosecutions can result in financial penalties being imposed by the Courts or, in the most serious cases, imprisonment.

1.6 Evaluation of market surveillance activities

OPSS coordinates the Market Surveillance Network, which brings together national and local regulators to discuss current issues, share best practice and evaluate how the UK can improve the coordination of its market surveillance. OPSS also engages directly with MSAs, particularly Trading Standards Services, as well as businesses, trade associations and other key stakeholders to understand the challenges, needs and opportunities in delivering effective market surveillance.

The development of a new product safety database will improve the UK's national capability to collate information on unsafe and non-compliant products, which will better enable the monitoring and targeting of market surveillance activity. The integration of ports and borders intelligence into the OPSS Intelligence team will also ensure that the UK has a closer, more integrated understanding of the market surveillance activities that have been taken, which will feed into the UK's intelligence-led approach to targeting unsafe goods.

In 2018/19 OPSS provided additional funding via the existing National Trading Standards Ports and Borders Programme to support a number of local authorities, to increase their delivery capacity. Visits have been taken to each of these local authorities to ascertain how the grant funding has been used and to evaluate outcomes and impact. For information on Ports and Borders activity and outcomes in 18/19, please see the NTS annual report: https://www.nationaltradingstandards.uk/uploads/annual%20report.pdf

Finally, the UK is committed to evaluating whether regulations are achieving their policy objectives, and as part of this has a rolling programme of post-implementation reviews.

1.7 International co-operation with member states and other countries

The UK highly values international cooperation with both member states of the European Union and other countries. The UK has been an active participant in EU level discussions on market surveillance, working with member states to develop common approaches and share best practice.

UK MSAs upload serious risk incidents requiring immediate action to the RAPEX database, as well as providing responses to actions placed on the database by other MSAs throughout Europe. UK MSAs have access to ICSMS and receive and respond to "ICSMS baton passing" of cases from other member states and individual MSAs, where they relate to products which are found to be available on the UK market or to businesses which are located in the UK.

Internationally, OPSS represents the UK at the Organisation for Economic Co-operation and Development (OECD) working party on product safety. This group develops international guidance on issues such as Recall Effectiveness and shares best practice among its members. OPSS is also a member of the United Nations Conference on Trade and Development (UNCTAD) working group on product safety, where it shares information on a wide-reaching international scale.

2. Market Surveillance in specific sectors

2.1 Product sectors and contact details

The Driver and Vehicle Standards Agency (DVSA)

The Driver and Vehicle Standards Agency (DVSA) has responsibility for regulating the automotive sector on behalf of the Department for Transport (DFT). The work covers a wide range of activities aimed at ensuring that vehicles entering the UK market comply with regulations. A robust system of automotive market surveillance is an essential element of DVSA's aim to improve road safety and environmental performance whilst safeguarding and protecting consumer interests. DVSA's Market Surveillance Unit ensures that products in free circulation comply with relevant safety and environmental legislative requirements. The Unit manages a programme of in-service market testing assessments, checking that vehicles meet (in service) type approval requirements and aftermarket components are manufactured to the correct standards. DVSA record any complaints or intelligence and, following initial investigation, will agree with DFT the best course of action.

The DVSA is the UK Competent Authority for automotive and aftermarket component parts and has responsibility for enforcement for vehicles. Enforcement priorities are determined by risks to consumers, the environment and industry. Information is shared with other member states using approved intelligence networks. Enforcement activity is carried out through reacting to complaints, testing of products at approved test facilities, monitoring of information and products at point of sale, and monitoring of advertisements. The form of enforcement action used will differ depending on the nature of the non-compliance, the harm caused and the history of the responsible person or business. DVSA are therefore not restricted to taking the least formal enforcement action in the first instance and will consider what immediate action is needed to protect consumer interests, including where necessary, prosecution.

Contact details:

Market Surveillance Unit Driver and Vehicle Standards Agency Berkeley House Croydon Street Bristol BS5 0DA

+44 (0) 117 954 3300

The Health and Safety Executive (HSE)

HSE has the enforcing authority responsibility for product supply and safety matters, primarily in the workplace, but also for some consumer products such as pyrotechnics and civil explosives.

HSE also plays a significant role in providing guidance to Trading Standards teams who have more general responsibility for consumer products; this is because traditionally workplace-based products such as vehicle lifts, compressors and workplace personal protective equipment (PPE) are increasingly being purchased by consumers for individuals' use.

Intelligence for HSE's market surveillance programme is gathered from concerns and complaints about specific products from external referrals, information collated by HSE staff, and information from other sources including product users and other authorities.

Where HSE undertakes planned market surveillance activities, this is done using a riskbased approach which identifies products through the receipt of information, or where there is a known or suspected issue (e.g. laser products, PPE used at work).

HSE's market surveillance work is undertaken by six teams, three working on a geographical basis and three nationally:

- Northern Product Safety team;
- Central Product Safety team;
- Southern Product Safety team;
- National Construction team;
- National Explosives Regulatory team;
- National Chemical Regulatory team.

HSE has a national Concerns and Advisory team who receive the majority of concerns and complaints that come into HSE. As well as workplace concerns, they also take the details of concerns relating to product safety and pass these to the relevant teams for further action, where necessary.

HSE Inspectors can also refer issues where they are identified during inspections or as part of accident investigations. If there are concerns about the safety of products, or where there is suggestion that an accident has been caused by faulty design or supply, then the relevant product safety teams are informed so that follow-up action can be taken.

Where the health and safety of users is put at risk, appropriate action is taken, with priority for those cases presenting serious risk. HSE inspectors have a range of enforcement tools, including: requiring product compliance; requiring the withdrawal of products from the market, and where necessary, recall; and instituting legal proceedings under criminal law in the most serious cases (where the financial penalties may be unlimited). All enforcement action is subject to HSE's own enforcement policy, as well as the provisions of the UK Regulators' Code and the UK Code for Crown Prosecutors, following the principle of proportionality, impartiality and without bias.

Further details can be found at:

www.hse.gov.uk/work-equipment-machinery/hse-role-market-surveillance-authority.htm www.hse.gov.uk/work-equipment-machinery/report-defective-product.htm http://www.hse.gov.uk/explosives/market-surveillance.htm http://www.hse.gov.uk/enforce/enforcepolicy.htm

Contact Details:

Safety Unit Health & Safety Executive Redgrave Court Merton Road Bootle Merseyside L20 7HS

Safety.Unit@hse.gov.uk Surveillance.explosives@hse.gov.uk

The Health and Safety Executive for Northern Ireland (HSENI)

HSENI is the enforcing authority responsible for product supply and safety matters, primarily in the workplace, but also for a limited number of consumer products. HSENI has one product safety team, based in Belfast, which covers the whole of Northern Ireland, and has systems in place to deal with complaints/concerns received by HSENI from the public, from industry, and from HSENI inspectors. The product safety team conducts reactive market surveillance, following up external referrals, issues identified by HSENI's inspectors from visiting workplaces, and information from other sources such as product users and other MSAs. The team is also tasked with proactive market surveillance. For example, in 2019, an ongoing market surveillance programme regarding the importation of catering equipment from third countries will continue. HSENI Inspectors have a range of enforcement powers including requiring product compliance, the withdrawal of products from the market if non-compliant, as well as recall where necessary – with all enforcement action being subject to HSENI's own policies.

HSENI works with other market surveillance authorities in Northern Ireland, including local authorities, for example in providing support on work products which increasingly private consumers can and do obtain. HSENI has an in-house UKAS Accredited Laboratory which provides technical advice and guidance to the product safety team as required.

Contact Details:

The Health and Safety Executive for Northern Ireland (HSENI) 83 Ladas Drive Belfast BT6 9FJ

0800 0320 121

mail@hseni.gov.uk

Local Authority Regulatory Services

Local authority regulatory services (Trading Standards officers in Great Britain and District Council Environmental Health officers in Northern Ireland) have frontline enforcement responsibility for consumer product safety at a local level – excluding medical devices and vehicles – and are supported by OPSS as a national regulator. They also have frontline enforcement responsibility for construction products, with policy responsibility resting with the Ministry of Housing, Communities and Local Government.

OPSS supports local authorities in their market surveillance work by providing learning and development opportunities and access to product safety testing at no cost to the local authority. The product safety testing is aimed at products that are sampled from businesses with producer responsibility to ensure that any corrective action can be taken throughout the supply chain should any non-compliance be found.

Local authorities publish enforcement policies that set out their individual approach to regulatory activity. They use intelligence to inform their activities and ensure business compliance by acting proportionately and co-operate on a national scale through established mechanisms. One example of this is Primary Authority, which enables businesses to build relationships with local authorities to receive tailored advice on meeting trading standards, environmental health or fire safety regulations. The primary authority then acts as a single point of contact for the business and across local authorities, in order to ensure they can work together effectively and avoid duplication of effort.

Local authority Trading Standards in Great Britain and the Northern Ireland Trading Standards Service (part of the Department for the Economy) are responsible, alongside other MSAs, for market surveillance in relation to weights and measures legislation. Every six months the Metrology Expert Panel – consisting of regional Trading Standards representatives from across the UK, experts from OPSS and CTSI lead officers for metrology – meets to review market surveillance issues, discuss regulatory challenges, and share best practice. There is a four-monthly meeting of the National Product Safety Group, covered in Section 1.2 of this report, that meets to discuss consumer product safety.

There are over 200 local authorities in the UK. Contact the Trading Standards Liaison team in OPSS for further details.

Contact Details:

Office for Product Safety & Standards Lower Ground Floor Victoria Square House Victoria Square Birmingham B2 4AJ

+44 (0)121 345 1201

OPSS.enquiries@beis.gov.uk

The Office for Product Safety and Standards (OPSS)

The Office for Product Safety and Standards (OPSS) was created in January 2018 as part of the Department for Business, Energy and Industrial Strategy, to provide national capacity and expertise on product safety, identifying consumer risks and managing responses to large-scale product recalls and repairs. OPSS is guided by the three following principles:

- Working in active partnership with organisations across the safety landscape, to build a more resilient system, and create a shared understanding of risk and the right mitigating interventions.
- Prioritising interventions by focusing on risk, cost and benefits.
- Providing practical tools, tested with users, to enable all those with a role in delivering safety to better fulfil their roles and deliver improved protection.

OPSS is responsible for national capacity for product safety and for the development of products that support small business growth. It works at the front line with businesses, local and national regulators and consumers to improve regulatory protections for consumers and support compliant businesses.

OPSS is also responsible for capacity building for enforcement in relation to the safety of consumer products, working closely with Trading Standards Services and other partners across the product safety landscape. OPSS works to maximise the strengths of local enforcement whilst providing additional capacity to tackle national threats and address novel, contentious and complex cases. OPSS also applies these principles and activities to the area of legal metrology and works closely with local authority regulators to ensure that market surveillance is effective by providing co-ordination, competency training and technical expertise.

OPSS is the enforcement authority for a range of product regulation areas, namely relating to energy efficiency and environmental pollution. These regulations aim to deliver positive environmental outcomes to reduce energy consumption and greenhouse gas emissions; minimising the level of hazardous substances entering the environment; maximising recycling; reducing noise pollution; and ensuring responsible sourcing of natural resources and protection of biodiversity. In addition, OPSS has enforcement responsibility for regulation that ensures accurate metering of electricity and gas usage. The OPSS Enforcement team enforces these regulations in four key ways:

- 1. Providing information, guidance and advice to support businesses and other organisations to comply with regulations and to encourage good practice;
- 2. Operating approval processes, in relation to requirements to make a notification or submit information to OPSS;
- 3. Risk-based market surveillance activities such as inspections and product testing that aim to identify whether regulatory requirements are being met;
- 4. Responding in a proportionate manner to non-compliance.

The OPSS Enforcement team operates across the UK from sites in Birmingham, Bristol and Teddington. The Enforcement team also draws on the wider resources of OPSS as required, including an Intelligence Unit and a central helpdesk which handles business and consumer enquiries, as well as technical expertise in areas such as assessment, laboratory testing facilities and legal expertise. Resources are divided between the provision of support for compliance; the detection of non-compliance; and measures to deal with non-compliance.

Proactive checks on compliance, whether through inspection of compliance documentation or product testing, may focus on products that are newly in scope of the regulation; product areas that have not been recently examined; or product areas that have been identified (for example, through intelligence) as presenting a high risk of non-compliance. Should non-compliance be found, the OPSS Enforcement team is committed to dealing with non-compliance in a manner proportionate to the nature, seriousness and circumstances of the offence; the aim being to deliver enforcement that is fair and objective while also being robust, credible and consistent with the intentions of the legislation.

Further details can be found at: <u>www.gov.uk/government/organisations/office-for-product-safety-and-standards</u>.

Contact Details:

Office for Product Safety & Standards Lower Ground Floor Victoria Square House Victoria Square Birmingham B2 4AJ

+44 (0)121 345 1201

OPSS.enquiries@beis.gov.uk

The Maritime and Coastguard Agency (MCA)

In the UK, Marine Equipment Directive (MED) market surveillance is carried out by the Maritime and Coastguard Agency (MCA) on behalf of the Secretary of State for Transport.

The MCA carries out risk-based inspections and other investigatory work. They consider factors such as, but not limited to: the number of complaints received regarding a product type; the number of non-compliant articles previously found; the size and nature of the equipment; and the number of products produced and/or placed on board ships, as well as the potential consequence of such equipment failing to operate correctly.

The sample checking of marine equipment offered for supply in the UK will take place in the following ways:

- Owners, superintendents, or masters of ships and vessels reporting any equipment that they are offered to the MCA if they do not consider it to comply with the MED, or to meet applicable standards.
- Ships' chandleries or other marine equipment outlets, including manufacturers of equipment, reporting objective evidence regarding equipment not in compliance with the MED.
- MCA personnel visiting chandleries, marine equipment suppliers, distributors and importers, and manufacturers' storage facilities to inspect the finished products available. This includes verifying details relevant to any approval which has been issued that is pertinent to the MED, and assessing the overall safety, performance or compliance of the product (where practicable).

The International Maritime Organisation Conventions requires operational performance tests for safety and/or pollution prevention equipment; in line with these requirements, equipment may be evaluated after installation on board a UK ship, though not in the case that this would duplicate conformity-assessment procedures already carried out by a notified body. This aspect of market surveillance will be undertaken by:

- MCA surveyors and inspectors undertaking general inspections or safety surveys.
- Owners, superintendents or masters reporting problems with equipment after installation, leading to the MCA undertaking follow-up action if necessary.
- Recognised Organisation surveyors conducting surveys on behalf of the MCA and reporting their findings to the MCA, which will then undertake follow-up action if necessary.
- Small Commercial Vessel Certifying Authority surveyors conducting surveys on behalf of the Certifying Authority they represent.

Contact Details:

Marine Equipment Quality Assurance Ship Standards Maritime and Coastguard Agency Bay 2/27 Spring Place 105 Commercial Road Southampton SO15 1EG

MEQA@mcga.gov.uk

The Medicines and Healthcare products Regulatory Agency (MHRA)

The Medicines and Healthcare products Regulatory Agency (MHRA) is the competent authority for medical devices in the UK. MHRA is responsible for setting UK policy on medical devices, and also for undertaking market surveillance activities as an executive function.

Sector-specific legislation on medical devices is set at EU level in the form of the EEC Medical Devices Directives, which have been implemented in UK law as the Medical Devices Regulations 2002. It is MHRA's duty to enforce these regulations on behalf of the Secretary of State for Health and Social Care, and has delegated responsibility for England, Scotland, Wales and Northern Ireland.

When medical devices are also consumer products, they are required to meet certain aspects of the General Product Safety Regulations 2005 (GPSR) in addition to the Medical Devices Regulations 2002. To ensure that these elements of GPSR are appropriately enforced in relation to medical devices, the MHRA actively works with local authorities.

The MHRA has several legal notices and powers at their disposal which are found within the Consumer Protection Act 1987, Consumer Rights Act 2015, GPSR 2005, Medical Devices Regulations 2002 and EU Regulation for Accreditation and Market Surveillance (RAMS).

To ensure that the MHRA can fulfil its duty as the UK competent authority for medical devices, it has approximately nine full time experts working on medical device compliance and market surveillance activities. Their primary focus is to collaborate with economic operators, bringing them into compliance with medical device legislation requirements. In addition to its compliance unit, MHRA also receives support from the Agencies enforcement unit, including intelligence analysts and financial investigators if appropriate.

Where an allegation is made relating to counterfeiting, regulatory fraud or severe risks to members of the public, the enforcement unit will investigate – supported by members of the compliance team – to ensure that appropriate and proportionate action is taken (including sanctions if required).

The MHRA takes a five-pronged approach to ensure that only compliant devices are allowed onto the UK market:

- 1. Investigating allegations of non-compliance or counterfeiting of medical devices using a risk-based approach;
- 2. Focusing on areas that are presenting issues regarding non-compliance and counterfeiting, and proactively targeting the devices identified;
- 3. Monitoring the activity of those notified bodies which have been designated by the MHRA to assess the compliance of manufacturers;
- 4. Ongoing operational activity and education focussing on points of entry to the UK, including air freight, fast parcel and maritime.
- 5. Undertaking proactive investigations informed by intelligence indicating a potential problem, either with an individual medical device or a range of devices.

The MHRA undertakes a risk-based analysis to prioritise and pursue investigations. Those investigations referenced in points 1, 2 and 5 will usually be initiated and resolved in writing by requesting technical and other information for documentary review. It is usually only in cases where the available information indicates a need to confirm compliance, or where technical documentation can only be thoroughly reviewed on-site (as for custom devices), that inspection visits will take place. Where a Regulations breach is discovered, manufacturers will typically be given the chance to come into compliance voluntarily. Immediate enforcement action will only be taken when necessary to protect public health.

Effective and proportionate enforcement is crucial to ensuring that the MHRA meets its responsibility for safeguarding public health. The MHRA has published an Agency Enforcement Strategy which covers medicines and medical devices and makes a commitment that where enforcement action is deemed to be the appropriate course, the MHRA will ensure it is intelligence-led and undertaken in a fair, consistent, transparent and proportionate manner.

MHRA is an influential member of the EU Market Surveillance Working Group, which promotes collaboration, consistency and information-sharing on the market surveillance of medical devices across EU member states. As part of the Working Group, MHRA has been involved in several proactive projects regarding EU compliance, with a recent example being labelling and/or warnings relating to emollient skin creams to ensure the end user is aware of flammability.

Another key part of MHRA's role is education, and significant amount of resource is allocated to communicating important messages about medical device compliance to the public, manufacturers and healthcare professionals. An example of such activity is the ongoing education and collaboration with the dental industry regarding the dangers of counterfeit dental equipment. MHRA enforcement and regulatory experts have attended dental trade fairs and association events to share information with industry experts and healthcare professionals, in order to enable a collaborative, well-informed strategy for tackling this growing problem. MHRA has also been attending several beauty and aesthetic trade shows with a view to educate the sector on the upcoming changes with our new regulations due to come into force in May 2020. The new legislation will cover a range of products that had previously been in a grey area of regulation including dermal fillers, lasers and cosmetic contact lenses amongst others.

Contact Details:

Devices Compliance Unit 10 South Colonnade Canary Wharf London E14 4PU

devices.compliance@mhra.gov.uk

Ofcom

Ofcom is the communications regulator in UK and is an enforcing authority for the Radio Equipment Directive 2014/53/EU (RED) and the Electromagnetic Compatibility (EMC) Directive 2014/30/EU. Ofcom has radio test laboratories, field engineers and dedicated market surveillance and enforcement officers.

Ofcom is proactive in its role to protect and manage the radio spectrum and also responds to complaints of interference to radio communications and may investigate to identify the cause.

Where non-compliant or illegal equipment is identified, Ofcom can investigate the making available and putting into service of the equipment. Ofcom has a range of powers under the UK criminal law enforcement regime to ensure economic operators adhere to the conditions of EU directives.

Ofcom's strategy for the coming year will continue to be based on a proportionate, accountable, consistent and targeted approach to market surveillance, directing resources responsibly and where the risk is greatest. Collaboration with other UK MSAs, the Commission and EU member states via ADCOs, and on cross border and national market surveillance campaigns will continue. Ofcom will continue to engage with stakeholders including online sales platforms to remove illegal and non-compliant equipment from the market.

Contact details:

The Office of Communications (Ofcom) Riverside House 2a Southwark Bridge Road London SE1 9HA

0300 123 333

marketsurveillance@ofcom.org.uk www.ofcom.org.uk

The Vehicle Certification Agency (VCA)

Dangerous goods which are transported by road or rail within Great Britain must comply with the requirements of The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009. These regulations implement the provisions of the European agreements, International Carriage of Dangerous Goods by Road and International Carriage of Dangerous Goods by Rail, and the Transportable Pressure Equipment Directive which, amongst other things, requires that tanks and pressure receptacles are tested, inspected and certified before they are first used and periodically thereafter. Only bodies appointed by the competent authority may undertake these tasks.

Contact Details:

The Vehicle Certification Agency (VCA) No 1 The Eastgate Office Centre Eastgate Road Bristol BS5 6XX

0300 330 5797

enquiries@vca.gov.uk www.vehicle-certification-agency.gov.uk

Glossary

Α	Administrative Co-operation Group (ADCO)		
В	Department for Business, Energy and Industrial Strategy (BEIS)		
С	Chartered Trading Standards Institute (CTSI)		
D	 Department for Transport (DFT) The Driver and Vehicle Standards Agency (DVSA) 		
Е	European Union (EU)		
G	 General Product Safety Directive 2001/95/EC (GPSD) General Product Safety Regulations 2005 (GPSR) 		
н	 Health and Safety Executive (HSE) Health and Safety Executive for Northern Ireland (HSENI) Her Majesty's Revenue and Customs (HMRC) 		
Ι	Information and Communication System on Market Surveillance (ICSMS)		
Μ	 Maritime and Coastguard Agency (MCA) Market Surveillance Co-ordination Committee (MSCC) Marine Equipment Directive (MED) Market Surveillance Authorities (MSAs) Medicines and Healthcare products Regulatory Agency (MHRA) Ministry of Housing Communities and Local Government (MHCLG) 		
Ν	 National Clearance Hub (NCH) National Trading Standards (NTS) 		
0	 The Office for Product Safety and Standards (OPSS) The Office of Communications (Ofcom) 		
Ρ	Primary Authority (PA)		
R	 Rapid Exchange of Information System (RAPEX) Restriction of Hazardous Substances (RoHS) Regulation on Accreditation and Market Surveillance 765/2008 (RAMS) 		
S	Single Point of Contact at ports and borders (SPoC)		
U	United Kingdom (UK)		
V	Vehicle Certification Agency (VCA)		
V	Vehicle Certification Agency (VCA)		

Annex 1 – Market surveillance authority, regulatory area and policy department/national regulator

Market Surveillance Authority	Regulatory Areas include	Policy Department/ National Regulator
Driver and Vehicle Standards Agency (DVSA) <u>www.gov.uk/government/o</u> <u>rganisations/driver-and-</u> <u>vehicle-standards-agency</u>	 Vehicles Non-road mobile machinery gaseous emissions 	Department for Transport
vehicle-standards-agency Health and Safety Executive (HSE) http://www.hse.gov.uk Health and Safety Executive Northern Ireland (HSENI) www.hseni.gov.uk	 Product safety for workplace use: Appliances burning gaseous fuels Equipment and protective systems used in potentially explosive atmospheres (ATEX) Low voltage electrical equipment Machinery Personal protective equipment Simple pressure vessels and pressure equipment When used in any situation: Pyrotechnics Civil use explosives 	Health and Safety Executive
	Chemicals	Department for Environment, Food and Rural Affairs
	 Cableways Transportable pressure equipment [HSENI only] 	Department for Transport
	Lifts in the workplace	Office for Product Safety and Standards

Market Surveillance Authority	Regulatory Areas include	Policy Department/ National Regulator
Local Authority Regulatory Services:	Product safety for consumer use including:	Office for Product Safety and Standards
For Trading Standards in Great Britain, locate the relevant local authority regulator at: <u>www.tradingstandards.uk/c</u> onsumers/support-advice Environmental Health in Northern Ireland: <u>https://www.health-</u> ni.gov.uk/topics/profession <u>al-medical-and-</u> <u>environmental-health-</u> advice/environmental- <u>health</u>	 Aerosols Appliances burning gaseous fuels Cosmetics Electromagnetic compatibility Equipment and protective systems used in potentially explosive atmospheres (ATEX) Low voltage electrical appliances and equipment Machinery Personal protective equipment Pyrotechnics Radio equipment Recreational craft Simple pressure vessels and pressure equipment Toys 	
	Chemicals	Department for Environment, Food and Rural Affairs
	Construction products	Ministry of Housing, Communities and Local Government
Local Authority Regulatory Services:	Metrology (weights and measures)	Office for Product Safety and Standards
For Trading Standards in Great Britain, locate at: <u>www.tradingstandards.uk/c</u> <u>onsumers/support-advice</u>		
Trading Standards Service Northern Ireland (Department of the Economy): <u>www.economy- ni.gov.uk/topics/consumer- affairs</u>		

Market Surveillance Authority	Regulatory Areas include	Policy Department/ National Regulator
Maritime Coastguard Agency (MCA)	Marine Equipment	Department for Transport
Medicines and Healthcare products Regulatory Agency (MHRA)	Medical devices	Medical and Healthcare Products Regulatory Agency
www.gov.uk/government/o rganisations/medicines- and-healthcare-products- regulatory-agency		
Ofcom <u>www.ofcom.org.uk</u>	 Electromagnetic compatibility Radio equipment 	Office for Product Safety and Standards
Office for Product Safety and Standards (OPSS) Enforcement Team	Outdoor noiseResidential lifts	Office for Product Safety and Standards
www.gov.uk/government/o rganisations/office-for- product-safety-and- standards	Product regulation (energy efficiency) - Eco-design - Energy labelling	Department for Business, Energy and Industrial Strategy
	 Product regulation (environmental pollution) Batteries End of life vehicles Restriction on hazardous substances used in electrical devices 	Department for Environment, Food and Rural Affairs
Vehicle certification agency (VCA) <u>www.gov.uk/government/o</u> <u>rganisations/vehicle-</u> <u>certification-agency</u>	 Transportable pressure equipment [GB only] Passenger cars (fuel consumption and CO₂ emissions information) 	Department for Transport

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Office for Product Safety and Standards

Department for Business, Energy and Industrial Strategy Lower Ground Floor, Victoria Square House, Victoria Square, Birmingham B2 4AJ www.gov.uk/government/organisations/office-for-product-safety-and-standards

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