



Department for
Business, Energy
& Industrial Strategy

UK National Market Surveillance Programme January 2018 – January 2019



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Introduction

Market surveillance is the set of activities within the UK which, in co-ordination and collaboration with the other member states of the EU, ensures the safety and compliance of non-food products placed on the market.

This national plan fulfils the obligation to publicise market surveillance activities and share with the European Commission the national activities under the Regulation on Accreditation and Market Surveillance 765/2008. It outlines the structure of surveillance in the UK through the national and local organisations which are responsible for and enforce the different pieces of legislation; how those organisations work together, share information with similar authorities in the rest of the EU and engage with Her Majesty's Revenue and Customs (HMRC) and Border Force to manage the products which enter the market.

The plan describes the digital systems which are used to communicate product assessments as well as serious risks and incidents which require immediate responses from authorities to ensure consumer safety, the protection of property and other objectives such as the protection of the market and the environment.

The report explains the role of the Market Surveillance Co-ordination Committee, managed by the Office for Product Safety and Standards, in drawing together the UK's surveillance authorities, disseminating information, sharing best practice, intelligence and specific case issues, particularly where products are regulated by more than one piece of legislation or authority.

The report also explains the wider relationship between economic operators and regulators in the UK through the Regulators' Code which embeds the concepts of risk, transparency and proportionality into the UK's systems of supervision.

Finally, it provides practical information and contact details for the market surveillance authorities in the UK to facilitate a more effective level of national and international co-operation.

1. General Market Surveillance Organisation and Infrastructure

1.1 UK Market Surveillance Authorities and their responsibilities

The United Kingdom has a comprehensive system of market surveillance underpinned by primary and secondary legislation. Market surveillance in the UK is organised according to individual Directives and Regulations and the relevant implementing measures. The subject matter of the European legislation determines which authority is responsible and what market surveillance activities are established or applicable. Market surveillance is additionally informed by the UK's Principles of Good Regulation and the statutory Regulators' Code and Growth Duty which ensure that no matter which authority is responsible, the approach is always proportionate and risk-based.

The UK has a comprehensive framework of powers, sanctions and corrective actions. Powers derive from the Consumer Rights Act 2015, the Consumer Protection Act 1987, the Health and Safety at Work Act 1974 or bespoke powers are provided within the specific legislation e.g. where there is no "safety" rationale or where Directives require the provision of specific powers, such as the General Product Safety Regulations 2005.

The UK's responsibilities for market surveillance continue to be fulfilled by the UK's Market Surveillance Authorities (MSAs), working in co-operation with HMRC and the Home Office agency Border Force, which have responsibilities for customs and border policies respectively. The Department for Business, Energy and Industrial Strategy (BEIS) has legal responsibility for the implementation of most of the EU's single market for goods Directives and Regulations. Practical information about all the UK MSAs can be found in Annex 1.

The Office for Product Safety and Standards (OPSS) is responsible for co-ordinating market surveillance activity in the UK. OPSS is part of BEIS and was established in January 2018 to provide additional national capacity for product safety activity. OPSS takes forward the responsibilities of the previous Regulatory Delivery directorate within BEIS, including the responsibility to ensure co-ordination of all market surveillance activity, oversight of weights and measures as well as acting as an MSA for some areas of product regulation.

Budgets for each MSA are set individually and the MSA is responsible for setting risk-based priorities and reporting on outcomes. National MSAs are accountable to their policy department within government, whilst local authority regulatory services are accountable to their local democratic structures. Co-ordination at regional and national levels is discussed in section 1.2.

Through the co-ordinated enforcement activities of MSAs, the UK has a strong history of protecting consumers (and other end users) from unsafe and non-compliant products, protecting the environment and wider public interests, both within our domestic market and the markets of our trading partners. We intend this to continue after our exit from the EU.

1.2 Co-ordination and co-operation mechanisms between national Market Surveillance Authorities

The UK co-ordinates its market surveillance activities through several established mechanisms; these are led by OPSS. The Market Surveillance Co-ordination Committee (MSCC) was established in 2009 and provides central co-ordination and strategic direction. It meets four times a year. It comprises representatives from all UK Government Departments and representative organisations with responsibility for market surveillance (see Annex 1). The operation of the MSCC is currently being reviewed to further improve its focus and strategic direction.

As an example of UK MSA collaboration, the OPSS Enforcement team has liaised with the Medicines and Healthcare products Regulatory Agency (MHRA) in relation to a project examining compliance in the growing e-cigarettes sector. The project, concerned with compliance in the sector in relation to restrictions on hazardous substances in electrical and electronic products, benefitted from MHRA's substantial knowledge of the sector, as the competent authority for the notification scheme for e-cigarettes and refill containers under the Tobacco Products Directive in the UK.

The MSCC has received and shared information on collaboration between MSAs to address the enforcement challenges presented by non-traditional routes of supply, such as direct import by consumers and the implications of products regulated by more than one Directive or MSA.

The National Product Safety Group was established in 2012 to co-ordinate activity between authorities with responsibility for consumer product safety legislation, and construction products. It comprises local authority representatives from all regions of the UK, the Health & Safety Executive (HSE), BEIS, the Ministry of Housing, Communities and Local Government (MHCLG), and the Chartered Trading Standards Institute (CTSI), which is a professional body representing Trading Standards Officers. The group actively produces guidance and shares information about activity carried out by local authorities.

The enforcement of legislation covering workplace goods is undertaken by the HSE's network of 'virtual' Product Safety Teams across Great Britain. These teams comprise product safety specialists who take the lead on product supply issues that arise from the initial findings of inspectors who carry out more general responsibilities working across business sectors. 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.

Market surveillance work at points of entry to the country is of vital importance in ensuring consumers are protected.

National Trading Standards (NTS), a government funded organisation set up to improve local enforcement of laws intended to tackle rogue traders operating regionally and nationally and causing harm to consumers and legitimate business, operates a Safety at Ports and Borders Team.

To foster co-operation and to facilitate import surveillance activities on non-food products entering the market from outside the EU, the team run an Intelligence Hub covering points of entry in England and Wales. This acts as a Single Point of Contact at ports and borders (SPoC) for liaison between MSAs, HMRC and Border Force for the border control of unsafe and/or non-compliant imported products. The team has responsibility for setting, managing and evaluating risk-based on intelligence-led controls and is well established in this role, providing information to individual MSAs and reporting on ports and borders intelligence and activities to the MSCC.

The benefits of the SPoC include the ability to identify national emerging trends and threats; to identify high risk economic operators operating across legislative areas within the competence of different MSAs; and to ensure consistency of approach at border points and in line with developing best practice across the EU. The SPoC has developed expertise in customs procedures which enables it to provide strategic direction to MSAs in border controls, practice and processes.

SPoC referrals to ports/airports enable the identification of many unsafe and non-compliant goods ranging from electrical goods to cosmetics. Officers working at the SPoC continue ongoing liaison with officials from OPSS and local authority Trading Standards Officers and provide advice via a range of working groups within Government.

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 have access to 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 the UK's 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 by Trading Standards 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.

Border Force and NTS have an ongoing commitment to work together to encourage their staff to take positive action to facilitate close working activity at the UK border.

1.4 Digital information systems – RAPEX and ICSMS

The General Product Safety Directive 2001/95/EC (GPSD) provides the legal framework for RAPEX, which is a Rapid Alert System for non-food, dangerous products. It facilitates a 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, responsibility for the GPSD, and therefore for RAPEX, falls to OPSS which also provides the National Contact Point service (the 'RAPEX Unit').

The RAPEX Unit plays an important role in ensuring that notifications submitted meet the criteria of RAPEX. It provides advice to MSAs on the type of information that is required, and the correct documentation needed to ensure information issued to the European Commission is consistent and meets necessary time scales. The UK generally submits over 100 notifications a year to the European Commission and ensures that the statistics on notifications issued by the UK are recorded in a timely fashion.

On request, the RAPEX Unit advises Trading Standards on the procedures they should follow when submitting reactions to 'validated' notifications issued by other EU member states - how 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 the information required when there is a divergence in the risk assessment of a UK supplied product notified by other member states. Additionally, the Unit is responsible for dealing with enquires from other EU member states, UK authorities and UK companies enquiring about procedures for identifying risk or to request information on products notified on the RAPEX system.

The Regulation for Accreditation and Market Surveillance (EC Regulation 765/2008) introduced the general obligation for the sharing of information on market surveillance activity by all European MSAs with each other and with the European Commission. BEIS holds policy responsibility for ICSMS and HSE acts as the UK administrator for the system. In 2012, the existing ICSMS database was acquired by the European Commission and made freely available to all European MSAs for this purpose. 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 infrastructure to exchange secure data between MSAs within the UK internal market. The new system will ensure we are able to quickly identify new threats, to mount co-ordinated and rapid responses to those threats and to target the interception of high-risk products, including imports. The first phase of this system is due to be released in March 2019.

1.5 General description of Market Surveillance activities and relevant procedures

The objective of market surveillance in the UK is to ensure the free circulation of safe and compliant products in the context of the EU Single Market, and to intervene where products are unsafe or non-compliant. The UK has an overarching approach to regulation and enforcement that supports businesses and business growth, promotes consumer choice, and provides high levels of consumer and environmental protection.

All MSAs are required to have regard to the Principles of Good Regulation and to the Regulators' Code¹ The Regulators' Code provides a principles-based framework for how regulators including MSAs should engage with those they regulate, including provisions which require regulatory activities to be based on risk, transparency of regulators' policies, and accessibility of information and guidance. National MSAs are also under a statutory duty to have regard to the desirability of promoting economic growth², alongside the delivery of protections set out in relevant legislation. They are required to consider the importance, for growth, of taking regulatory action only when it is needed, and when the action taken is proportionate.

Engagement with businesses

The prevention and reduction of non-compliance by educating and consulting with business about the applicable legislation is a key component of the UK's approach to market surveillance and as such a high priority is given to business communication and engagement activities by all MSAs.

BEIS is committed to ensuring that regulators and policy departments better understand the views of the business community regarding regulatory policy and delivery, and has a Business Reference Panel dedicated to regulatory issues. The panel is made up of regulatory experts from over 150 business organisations, trade associations and professional bodies which collectively represent over 1.5 million businesses. The panel, which meets four times a year, helps to ensure that the business voice is heard, by giving feedback on Government ideas and proposed work programmes ensuring that business priorities and concerns are understood. The panel establishes 'expert panels' from time to time to focus in detail on particular regulatory issues.

Proactive interventions

MSAs undertake proactive work based on risk assessment using data and intelligence from a range of sources, including from other MSAs, to establish strategic priorities and specific products, businesses or supply chains to target for market surveillance activities. This may include checking products, technical files, incident data and risk assessments, but will also involve awareness raising to ensure businesses understand their obligations, and to help consumers make informed choices.

MSAs are expected to have a good understanding of the businesses which they regulate and apply their powers proportionately. This understanding means that UK MSAs are able to tailor the type of interventions they use to best effect.

Reactive interventions

Complaints about alleged non-compliant products are received by MSAs through a range of routes and will feed into each MSA's intelligence picture. As is consistent with a risk-based approach, UK MSAs do not necessarily investigate all complaints, but instead assess these against risk-based criteria, including by reviewing existing records and intelligence, to establish what intervention is required. Some examples of reactive interventions are given in Section 2.

¹ www.gov.uk/government/publications/regulators-code

² <https://www.gov.uk/government/publications/growth-duty>

Generally, MSAs will conduct a mixture of proactive and reactive activities. The balance of resource allocated to each is a matter for each individual MSA.

Alerts about hazardous products

Consumers can access information about hazardous products that have been recalled using the government website <https://productrecall.campaign.gov.uk/>. This provides links to consumers dependent on the product type. The appropriate route to alerting consumers depends on the product type. For vehicles, where registration details are available, the Driver and Vehicle Standards Agency (DVSA) will contact manufacturers and/or distributors and inform them of any next steps or actions as a matter of priority. DVSA will work with manufacturers to ensure that, where necessary, vehicles owners are notified of relevant issues. DVSA has a system which publishes any vehicle safety recall and for the majority of cars owners DVSA has an online system where they can see if a recall specifically affects their vehicle. For work equipment, HSE has a system of safety alerts/bulletins for dealing with products/work equipment which pose a serious risk, which can be found here <http://www.hse.gov.uk/safetybulletins/>. 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 – <https://www.registermyappliance.org.uk>. OPSS are working on improving information alerts in relation to consumer product safety. 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 the UK legislation which gives effect to European legislation.

MSAs set out their approach to dealing with non-compliance in their enforcement policies, which reflect the UK Government's expectations of regulators, as set out in the Regulators' Code. These enforcement policies are made widely known to businesses by MSAs, including via the internet as well as other communication channels such as Twitter e.g [HSE](#). These enforcement policies include the types of sanctions that MSAs have available for non-compliance with legislation and an explanation of business's rights.

For an example of an MSA enforcement policy see:

<https://www.gov.uk/government/publications/safety-and-standards-enforcement-enforcement-policy>.

MSAs will usually first seek voluntary compliance from an economic operator when a product is found to contravene legislation, often providing support, guidance or advice to businesses to help them become compliant. Where appropriate remedial action is not delivered voluntarily, MSAs will issue formal notices to require economic operators to bring about compliance.

Where it is considered proportionate to take punitive action, MSAs have a range of penalties available, as set out in the various legislation. 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 extreme cases, imprisonment.

The legislation may provide for the MSA to accept a commitment by the economic operator to take steps to offset any detriment caused to third parties by the non-compliance and in this circumstance, punitive action may not be taken. An example of this sort of sanction is the Energy Information Regulation Enforcement Undertaking.

1.6 Evaluation of Market Surveillance activities

The UK works with stakeholders, including with MSAs, business and consumer groups on a continuous basis to evaluate and improve its market surveillance activities. This is a key feature of meetings with business and trade representatives and consumer groups.

The co-ordinating bodies for market surveillance review the way in which the UK organises its market surveillance and enforcement activity with the aim of ensuring that the co-ordination activities it is involved in work as effectively as possible within the current resource constraints and respecting the EU obligations on enforcement and penalties.

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 other Member States and non-Member States

The UK places great importance on co-operation with both member states and non-member states. The UK has actively participated in Administrative Co-operation Groups (ADCOs). During the early part of 2018, OPSS continued its role in providing the Chair and secretariat for each of the three Restriction of Hazardous Substances, Ecodesign and Energy Labelling ADCOs. This has involved working closely with the European Commission on the future of market surveillance, inviting appropriate industry bodies for multilateral discussions, and initiating ADCO group projects. The role of OPSS in these groups has enabled them to shape and define consistent and co-ordinated approaches to market surveillance and has also enabled UK participation in working groups of the Internal Market for Products- Market Surveillance Group focusing on key performance indicators, the conduct of market surveillance activities and the review of framework guidance such as risk assessment methodologies. UK engagement in ADCOs is considered on a case by case basis and participation can be through policy responsibility or operationally from the MSA.

OPSS participates in the Consumer Safety Network (CSN), an EU level meeting hosted by the Commission which meets in Brussels three times per year. In this group, OPSS updates other member states on UK market surveillance activities, puts forward suggestions and areas of concern, and shares best practice and current challenges that UK MSAs face. MSAs have access to ICSMS and can facilitate the upload of 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. The UK receives and responds to “ICSMS baton passing” of cases from other member states and individual MSAs where they relate to businesses that are located in the UK or products which are found to be available on the UK market.

The UK has also focused on developing the framework documents which support market surveillance activities and engaging in the development of the EU enforcement and compliance proposals to ensure the most effective outcomes. In support of these activities, the UK is participating and chairing a working group developing guidance to support the use of ICSMS and has been fully engaged with the development of new RAPEX guidance.

Internationally, the UK participates in the Organisation for Economic Co-operation and Development (OECD) working party on consumer product safety, contributing to awareness campaigns, data collection and research into key topics such as behavioural insights and distributed ledger tools. It will also participate fully with the European Commission and OECD in the 2018 “consumer week”, attending the various international sessions and contributing to the consumer campaigns.

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 of vehicle. 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) / The Health and Safety Executive for Northern Ireland (HSENI)

The Health and Safety Executive (HSE)

HSE has enforcing authority responsibility for product supply and safety matters, primarily in the workplace, but also some consumer products eg pyrotechnics and civil explosives. Where workplace products are used by consumers in a personal capacity, Trading Standards have enforcement responsibility. The majority of HSE's market surveillance activity is intelligence based and reactive. Intelligence is gained from concerns/complaints about specific products, from external referrals, information gained by HSE staff and information from others, including product users and other authorities. HSE uses this breadth of intelligence to assist in prioritising its interventions.

Where HSE undertakes planned market surveillance activities this is based on a risk-based approach identifying products where there is a known or suspected issue, or based on information received about products (e.g. laser products, personal protective equipment used at work). Where relevant, HSE works with other MSAs, especially Trading Standards, for example in providing support on work products which, increasingly, private consumers can and do obtain (eg motor vehicle lifting machinery).

HSE has six 'Product Safety Teams' – three geographical teams and three national teams, dealing with the separate issues of construction specific equipment, explosives and chemicals regulations respectively. HSE has an established system of dealing with complaints/concerns received by HSE's national Concerns and Advisory Team'. All the teams are tasked with reactive and proactive market surveillance, following up external referrals, issues identified by HSE's staff (including inspectors visiting workplaces, e.g. when investigating injuries arising from product use), and information from others, including product users and other authorities.

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 Regulator's 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 responsibility 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, Industry, and HSENI inspectors.

The product safety team is tasked with reactive and proactive market surveillance, following up external referrals, issues identified by HSENI's inspectors from visiting workplaces, information from others, including product users and other authorities.

HSENI Inspectors have a range of enforcement powers including requiring product compliance, the withdrawal of products from the market, and where necessary recall, with all enforcement action being subject to HSENI's own policies.

HSENI works with other MSAs 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 on request.

HSENI are the enforcing authority for machinery, lifts, cableways, electrical and pressure equipment (including simple pressure vessels), transportable pressure equipment³, appliances burning gaseous fuels, chemicals, and personal protective equipment.

³ HSENI are the enforcing authority for transportable pressure equipment in Northern Ireland as the VCA, who have responsibility for transportable pressure equipment in Great Britain, do not operate in Northern Ireland.

HSENI 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 and environmental health) have frontline enforcement responsibility for consumer product safety excluding medical devices and vehicles (see Annex 1 for detailed list) and weights and measures, supported by OPSS as a national regulator. They are also responsible for market surveillance on construction products, reporting to MHCLG (see Annex 1).

Each local authority publishes an enforcement policy, which sets out its approach to regulatory activity. This includes using intelligence to inform regulatory activities and acting proportionately to ensure businesses compliance. Local authority regulatory services have established mechanisms for co-operating across regions and nationally. For example, Primary Authority enables a business or group of businesses to form a statutory partnership with a local authority to receive assured advice on regulatory compliance. That primary authority can then act as the single point of contact for the business and other local authorities, ensuring that local authorities can work together effectively and avoid duplication of effort. Further information about Primary Authority can be found at: www.gov.uk/government/publications/primary-authority-overview.

Local authority trading standards in Great Britain and the Northern Ireland Trading Standards Service (part of the Department for the Economy) are responsible for market surveillance in relation to weights and measures legislation. There is a six-monthly meeting of the Metrology Expert Panel which consists of regional trading standards representatives from across the UK, OPSS and the CTSI lead officers for metrology. They share best practice, review market surveillance issues and discuss regulatory challenges.

The Office for Product Safety and Standards as the national regulator for product safety and metrology

The OPSS was launched in January 2018, to strengthen national capacity for product safety. The vision for product safety is a trusted product safety system that delivers protection for consumers, fairness for business and a competitive market place defined by outcomes of safety and public confidence. OPSS will drive action in four areas (analyse, inform, enforce and build), as set out in the 'Strengthening national capacity for product safety: Strategy 2018-2020'⁴.

⁴ <https://www.gov.uk/government/publications/strengthening-national-capacity-for-product-safety-strategy-2018-2020>

OPSS is strengthening the market surveillance system for consumer products and legal metrology by creating centralised technical and scientific capability to support effective decision making and to help co-ordinate the activity of local authorities and the businesses that they regulate.

OPSS enables the UK to meet evolving challenges – responding to expanding international trade, the growth in online retail and the increasing rate of product innovation. It will also help the UK to put in place the most effective system for regulation and enforcement of product safety and legal metrology in preparation for our exit from the European Union.

OPSS is building the capacity to:

- provide incident management capability to respond to national product safety issues;
- improve the information available to consumers on the Government's product recall website;
- provide central scientific and technical expertise on product safety and legal metrology issues;
- provide support for local regulators throughout the UK
- support checks at UK borders and the interception of unsafe imports;
- provide improved intelligence and risk analysis to guide enforcement activities; and,
- work with UK business to ensure they are able to meet their compliance requirements.

OPSS has an operating budget of around £12 million per year for product safety when it is fully operational and is in the process of recruiting additional staff to focus on providing national capacity for product safety.

OPSS is guided by the three following principles: OPSS will work in active **partnership** with organisations across the safety landscape to build a more resilient system. OPSS want to create a shared understanding of risk and the right interventions to mitigate and control risk. The OPSS know that not every issue will need intervention and we will prioritise by focusing on risk, cost and benefits. OPSS will provide **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 also apply these principles and activities to the area of legal metrology and work closely with local authority regulators to ensure that market surveillance is effective providing co-ordination, competency training and technical expertise.

OPSS holds contact details for the Heads of Service for all local authority regulatory services. Contact details for OPSS are below.

Office for Product Safety and Standards (Enforcement Team)

OPSS also has responsibility for the enforcement of a range of product regulation areas relating to energy efficiency and environmental pollution (see Annex 1).

The OPSS Enforcement Team of over fifty staff operates across the UK from sites in Birmingham, Bristol and Teddington. The Enforcement Team draws on the wider resources of OPSS, including scientific, technical and legal expertise; an Intelligence Unit; and a central helpdesk which handles business and consumer enquiries.

The OPSS Enforcement Team resources are divided between the provision of support for compliance; the detection of non-compliance; and measures to deal with non-compliance.

The OPSS Enforcement Team allocates its resources on the basis of risk-based prioritisation. Where there are low levels of awareness or understanding of the regulation, as can often be the case where the scope of regulation is extended or where novel products are being brought to market, the initial focus will be on engagement with economic operators - raising awareness and providing guidance and support to help businesses in meeting their regulatory obligations. As an example, low levels of awareness of the Restriction of Hazardous Substances (RoHS) regulations, have been identified as an issue in the growing e-cigarettes sector and, as a result, manufacturers and importers in this sector has been identified as a priority for this year. Priorities for this year in relation to the RoHS regulations also include a focus on raising awareness amongst those economic operators whose products will be impacted by the extension of the regulations to four additional substances in 2019.

OPSS works in partnership with businesses to achieve high levels of compliance. Creating and maintaining relationships with trade associations that have direct access to large groups of businesses, which are often difficult to either define or identify, is key in facilitating positive industry interaction. This is achieved by:

- Identifying and contacting trade associations and businesses as appropriate
- Maintaining direct engagement through meetings, seminars and conferences
- Providing overarching and specific guidance on relevant legislative issues and obligations
- Providing access to support materials via external communication platforms
- Providing high level proactive engagement to smaller businesses, via event attendance and regular project work, as well as reactive support via enquiry lines.

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. Information about potential non-compliance can take many forms, including; allegations received from industry (business to business), consumers or non-governmental organisations (NGO's); referrals from other MSAs; and, information gathered by OPSS through its proactive market surveillance activities. Information about potential non-compliance is critically assessed against a range of criteria before a decision is taken to undertake an investigation or not. 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.

OPSS provides a detailed website covering all of the legislative areas and their activities www.gov.uk/government/organisations/office-for-product-safety-and-standards.

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, the 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 will carry out its inspections and other investigatory work using a risk-based system. This will consider considerations 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 / 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:

- By MCA personnel visiting chandleries, marine equipment suppliers, distributors and importers, and manufacturers' storage facilities to inspect finished products available; verifying details relevant to any approval issued pertinent to the MED and assess the overall safety, performance or compliance of the product (where practicable).
- By owners, superintendents or masters of ships and vessels reporting to the MCA, any equipment they are offered which they consider does not meet the applicable standards or otherwise does not comply with the MED.
- By ships' chandleries or other marine equipment outlets, including manufacturers of equipment, reporting objective evidence regarding equipment not in compliance with the MED.

Equipment may be evaluated after installation on board a UK ship providing that only operational performance tests required by the International Maritime Organization Conventions for safety and / or pollution prevention equipment are conducted and do not duplicate the conformity-assessment procedures already carried out by a notified body. This aspect of market surveillance will be carried out by:

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

- Small Commercial Vessel Certifying Authority surveyors conducting surveys on behalf of the Certifying Authority they represent.

Contact Details:

Marine Equipment Quality Assurance
Marine Technology Branch
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 UK competent authority for medical devices. MHRA has responsibility for setting UK policy on medical devices as well as carrying out 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. These directives have been implemented into UK law in the form of the Medical Devices Regulations 2002. MHRA has a duty to enforce these regulations on behalf of the Secretary of State for Health and has the delegated responsibility for England, Wales, Scotland and Northern Ireland.

As well as the Medical Devices Regulations, medical devices that are also consumer products are required to meet certain aspects of the General Product Safety Regulations 2005. The MHRA therefore takes an active role in working with local authorities to ensure that these regulations are appropriately enforced in relation to medical devices.

To fulfil its duty as the UK competent authority for medical devices, the MHRA has approximately nine full time experts working on medical device compliance/market surveillance issues. Their primary goal is to work with economic operators to bring them into compliance with the requirements of the medical devices legislation. These experts are supported by the MHRA's Intelligence Unit who help develop a detailed understanding of the practices relating to high profile or common non-compliant market practices.

In cases where a non-compliant / counterfeit device poses a high risk of harm it may be considered necessary to undertake a criminal investigation. Such cases are referred to the MHRA's Enforcement Operations Unit. This unit will work with the medical device compliance/market surveillance experts to ensure a satisfactory conclusion is reached, appropriate sanctions are imposed, and that public health is appropriately safeguarded.

MHRA meets its obligation to ensure that only compliant devices are allowed onto the UK market in four basic ways:

1. Considering any allegations of non-compliance or counterfeiting of medical devices that are drawn to our attention;
2. Looking at areas that are presenting a problem in terms of non-compliance/ counterfeiting and proactively targeting the devices identified;
3. Monitoring the activity of notified bodies designated by the MHRA to assess the compliance of manufacturers of, in the main, higher risk devices;
4. Undertaking proactive investigations because of intelligence indicating a potential problem either with an individual device or range of devices.

The MHRA carries out a risk-based analysis to prioritise and carry out investigations. The investigations detailed in points 1, 2 and 4 above will normally be initiated and resolved in writing by requesting technical and other information for documentary review. Inspection visits will generally only be undertaken where the documentation available indicates it is merited to confirm compliance, or where technical documentation can only be properly reviewed on site, as for custom-made devices. Where a breach of the Regulations is identified, manufacturers will normally be given the opportunity to come into compliance voluntarily. Immediate enforcement action will only be taken where necessary to protect public health.

Effective and proportionate enforcement is recognised as being critical to the MHRA and is a major contributor to the achievement of the MHRA's responsibilities for safeguarding public health. An Agency Enforcement Strategy is published which covers medicines and medical devices; this states that in all cases where enforcement action is deemed to be the appropriate course, the MHRA will ensure it is intelligence-led and applied in a fair, consistent, transparent and proportionate manner.

MHRA is an influential member of the EU Compliance and Enforcement Working Group which serves to promote collaboration, consistency and information-sharing across EU member states on the market surveillance of medical devices. As part of this group, MHRA has been involved in several proactive projects, such as a review of instructions for use for sterilisable devices and associated education activity for manufacturers in this sector.

Education is a key aspect of MHRA's role and a significant amount of resource is allocated to communicating key messages to members of the public, manufacturers and healthcare professionals about medical device compliance. An example of such activity is the education of the dangers of counterfeit dental equipment. This has involved MHRA enforcement and regulatory experts attending dental trade fairs and association events to exchange information with industry experts and healthcare professionals to enable a collaborative strategy in tackling this growing problem. MHRA has also fostered excellent relationships with major online auction and retail sites and it is able to work in co-operation with them when issues arise, such as the selling of counterfeit devices via these outlets.

Contact Details: -

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

devices.compliance@mhra.gsi.gov.uk

Ofcom

Ofcom is the communications regulator in the UK, with responsibility for the TV and radio sectors, fixed line telecoms, mobiles, postal services, plus the airwaves over which wireless devices operate. They are an enforcing authority for the Electrical Equipment under EMC and Radio Equipment under RED Directives. Ofcom operates under several Acts of Parliament, including the Communications Act 2003 and the Wireless Telegraphy Act 2006. The Communications Act says that Ofcom's principal duty is to further the interests of citizens and of consumers and ensure optimal use of the radio spectrum. Ofcom's operating budget for the period 2018/19 is £124.2m and it has approximately 800 employees. Ofcom has radio test laboratories, field engineers and dedicated market surveillance and enforcement officers with responsibilities for these Directives.

Ofcom responds to complaints of interference to radio communications and may investigate to identify the cause. Where non-compliant equipment is identified, Ofcom can investigate the making available and putting into service of the equipment. Ofcom can suspend sales, require the recall or withdrawal of equipment and sanction economic operators under the UK criminal law enforcement regime.

Ofcom works in collaboration with other UK MSAs and with the Commission and EU member states through Administration and Co-operation Groups and cross border and national market surveillance campaigns targeting resources where the risk is greatest. Ofcom engages with stakeholders including online sales platforms to remove non-compliant equipment from the market.

Contact Details:

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

0300 123 3333

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.

VCA are also the relevant agency for the Passenger Car (Fuel Consumption and CO2 Emissions Information) Regulations. The primary aim of the Regulations is to ensure that clear and accurate information on the fuel consumption and CO2 emissions of new passenger cars is readily available to potential purchasers, in particular at the points of sale.

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

A	<ul style="list-style-type: none"> Administrative Co-operation Group (ADCO)
B	<ul style="list-style-type: none"> Department for Business, Energy and Industrial Strategy (BEIS)
C	<ul style="list-style-type: none"> Chartered Trading Standards Institute (CTSI)
D	<ul style="list-style-type: none"> Department for Transport (DFT) The Driver and Vehicle Standards Agency (DVSA)
E	<ul style="list-style-type: none"> European Economic Area (EEA) European Union (EU)
G	<ul style="list-style-type: none"> General Product Safety Directive 2001/95/EC (GPSD)
H	<ul style="list-style-type: none"> Health and Safety Executive (HSE) Health and Safety Executive for Northern Ireland (HSENI) Her Majesty's Revenue and Customs (HMRC)
I	<ul style="list-style-type: none"> Information and Communication System on Market Surveillance (ICSMS)
M	<ul style="list-style-type: none"> 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) Member of Parliament (MP) Ministry of Housing Communities and Local Government (MHCLG)
N	<ul style="list-style-type: none"> National Clearance Hub (NCH) National Trading Standards (NTS) Non-Governmental Organizations (NGOs)
O	<ul style="list-style-type: none"> The Office for Product Safety & Standards (OPSS) The Office of Communications (Ofcom)
P	<ul style="list-style-type: none"> Primary Authority (PA)
R	<ul style="list-style-type: none"> Rapid Exchange of Information System (RAPEX) Restriction of Hazardous Substances (RoHS) Regulation on Accreditation and Market Surveillance 765/2008 (RAMS)
S	<ul style="list-style-type: none"> Single Point of Contact at ports and borders (SPoC)
U	<ul style="list-style-type: none"> United Kingdom (UK)
V	<ul style="list-style-type: none"> Vehicle Certification Agency (VCA)

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

Market Surveillance Authority	Regulatory Areas	Policy Department/ National Regulator
Driver and Vehicle Standards Agency (DVSA) www.gov.uk/government/organisations/driver-and-vehicle-standards-agency	<ul style="list-style-type: none"> - Vehicles - Non-road mobile machinery gaseous emissions 	Department for Transport
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: <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - Pyrotechnics - Civil use explosives 	Health and Safety Executive
	Chemicals	Department for Environment, Food and Rural Affairs
	<ul style="list-style-type: none"> - Cableways - Transportable pressure equipment [HSENI only] 	Department for Transport
	Lifts in the workplace	Office for Product Safety and Standards

<p>Local Authority Regulatory Services:</p> <p>Trading standards in Great Britain</p> <p>MSAs and individuals can locate the relevant local authority regulator at www.tradingstandards.uk/consumers/support-advice</p> <p>Environmental Health in Northern Ireland</p> <p>https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-advice/environmental-health</p>	<p>Product safety for consumer use, including:</p> <ul style="list-style-type: none"> - Aerosols - Appliances burning gaseous fuels - Cosmetics - Electromagnetic compatibility - Equipment and protective systems used in potentially explosive atmospheres (ATEX) - Low voltage electrical appliances and equipment - Lifts - Machinery - Personal protective equipment - Pyrotechnics - Radio equipment - Recreational craft - Simple pressure vessels and pressure equipment - Toys 	<p>Office for Product Safety and Standards</p>
	Chemicals	Department for Environment, Food and Rural Affairs
	Construction products	Ministry of Housing, Communities and Local Government
<p>Local Authority Regulatory Services:</p> <p>Trading standards in Great Britain</p> <p>www.tradingstandards.uk/consumers/support-advice is the CTSI authority locator</p> <p>Trading Standards Service Northern Ireland (Department of the Economy)</p> <p>www.economy-ni.gov.uk/topics/consumer-affairs</p>	<p>Metrology (weights and measures)</p>	<p>Office for Product Safety and Standards</p>

Medicines and Healthcare products Regulatory Agency (MHRA) www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency	Medical devices	Medical and Healthcare Products Regulatory Agency
Ofcom www.ofcom.org.uk	<ul style="list-style-type: none"> - Electromagnetic compatibility - Radio equipment 	Office for Product Safety and Standards
Office for Product Safety and Standards (OPSS) Enforcement Team www.gov.uk/government/organisations/office-for-product-safety-and-standards	Outdoor noise	Office for Product Safety and Standards
	Product regulation (energy efficiency) <ul style="list-style-type: none"> - Eco-design - Energy labelling 	Department for Business, Energy and Industrial Strategy
	Product regulation (environmental pollution) <ul style="list-style-type: none"> - Batteries - End of life vehicles - Restriction on hazardous substances used in electrical devices 	Department for Environment, Food and Rural Affairs
Vehicle certification agency (VCA) www.gov.uk/government/organisations/vehicle-certification-agency	<ul style="list-style-type: none"> - Transportable pressure equipment [GB only] - Passenger cars (fuel consumption and CO₂ emissions information) 	Department for Transport



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