

Department for Business, Energy & Industrial Strategy

UK NATIONAL MARKET SURVEILLANCE PROGRAMME

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1. General Market Surveillance Organisation and Infrastructure

1.1 Identification and responsibilities of national market surveillance authorities

The United Kingdom has a comprehensive system of market surveillance underpinned by primary and secondary legislation. Market surveillance in the UK is organised on a European Directive/Regulation specific basis. The UK usually implements European Directives into UK law individually, and for European Regulations, the UK then establishes the market surveillance regime in national implementing Regulations. The subject matter of the European legislation will determine what market surveillance is put in place, including proportionate powers of enforcement and sanctions. Often such powers will derive from the Consumer Rights Act (2015), the Consumer Protection Act (1987), the Health and Safety at Work Act 1974 or bespoke powers will be provided within the specific legislation e.g. where there is no "safety" rationale or where Directives require the provision of specific powers (e.g. GPSD).

The broad pattern of surveillance is that consumer safety and construction products are the responsibility of the UK's Local Authorities (Trading Standards in Great Britain and District Councils in Northern Ireland), exercised within the framework of local democratic autonomy. There are over 200 local authorities in the UK.

The safety of goods for workplaces and related matters are the responsibility of the Health and Safety Executive (HSE) in Great Britain and the Health and Safety Executive for Northern Ireland (HSENI).

Medical Devices Regulations and related legislation (which includes products for professional use) are enforced by the Department for Health's (DH) specialist Medicines and Healthcare products Regulatory Agency (MHRA).

Automotive related products are the responsibility of the Driver & Vehicle Standards Agency (DVSA).

Other non-safety legislation is enforced by a number of other sector-specialist enforcement bodies e.g. The National Measurement and Regulation Office (NMRO) provides market surveillance delivery services for several Government Departments covering a range of environmental protection and fair trading legislation. They operate across five public bodies and have responsibility for the regulations which cover Ecodesign, Energy Labelling, RoHS, Batteries, the Labelling of Tyres, Timber, Heat Networks, Noise Emissions, Waste, electrical and electronic equipment, ELVs, Weights and Measures and finally Gas and Electricity meters. The UK's responsibilities for market surveillance continue to be fulfilled by the UK's Market Surveillance Authorities (MSAs), working in co-operation with HM Revenue and Customs (HMRC) and Border Force, who have responsibilities for customs and border force policies respectively. The Department of Business, Energy and Industrial Strategy (BIES) has legal responsibility for the implementation of most EU single market Directives and Regulations. However, implementation of the Construction Products Regulation lies with the Department for Communities and Local Government (DCLG).

All of the UK MSAs are autonomous enforcement bodies i.e. they act independently and set their own planning and outcomes. The UK's view is that ring fencing of their budgets would be contrary to their independent nature. As the UK has a diverse market surveillance network with a range of market surveillance authorities, it is not feasible for these organisations to provide detailed data about the overall resources at their disposal such as budget, staff and technical means. As an example, it is very difficult to given an accurate estimation of the number of staff working on market surveillance in the UK; there are hundreds of staff engaged on market surveillance activities within local authorities and the amount of time which each of these officers is committed to spending on market surveillance will vary by team and by organisation, according to local priorities which are in turn coordinated at regional and national level.

1.2 Coordination and cooperation mechanisms between national market surveillance authorities

The UK carries out coordination between its market surveillance authorities through a number of mechanisms and this will continue during 2016-17. As previously reported, the Market Surveillance Coordination Committee (MSCC), established in 2009 to take a coordinated and strategic approach towards market surveillance activities in the UK, is now a well-established forum for cooperation and coordination. It meets twice per year and comprises all UK Government Departments and representative organisations with responsibility for market surveillance, including BIES, DCLG, HSE, OfCom (the Communications Regulator), MHRA, NMRO and representatives from Trading Standards. In line with our commitment to improving market surveillance, we are nevertheless reviewing MSCC to ensure that it continues to provide the UK and consequently our EU partners with the most effective market surveillance support mechanism possible.

Another well- established forum is the sub-group of the MSCC on ports and borders. This comprises representatives from UK Government Departments, agencies and authorities with responsibility for market surveillance and/or customs controls at points of entry to the UK, including the Department for Business, Energy and Industrial Strategy (BIES), the Department for Communities and Local Government (DCLG), Her Majesty's Revenue and Customs

(HMRC), UK Border Force and Local Authorities with responsibility for a specific port or border. The sub- group meets 3 to 4 times a year and acts as an intelligence task and coordination group for the UK's market surveillance authorities. The two main aims of the sub-group are to agree national/local priorities for the targeted and risk-based approach to the control of products at the UK's points of entry and to identify post importation data requirements for assisting inland market surveillance controls on products imported from 3rd countries.

The UK's two largest MSAs, Local Authorities and the Health and Safety Executive, require greater co-operation because of their size and the large number of competing priorities for their activities. The Product Safety Focus Group (PSFG) was established in 2012 to coordinate activity between authorities with responsibility for consumer product safety legislation, and construction products. It comprises Trading Standards representatives from all regions of the UK, the HSE, BEIS and the Chartered Trading

Standards Institute (CTSI). CTSI is a professional body representing Trading Standards Officers, and continues to be a member of PROSAFE.

The PSFG meets 3 times a year. The purpose of the Group is to act as strategic liaison between local authorities, regions, central government and other stakeholders on product safety, compliance, enforcement and co-ordination issues. Its functions include: providing guidance to facilitate consistency of enforcement; to encourage engagement with EU bodies and agencies; acting as a forum for discussion of enforcement issues; exchange of ideas and liaison between local authorities, regions and central government; and promoting local authority product safety and compliance work.

The National Trading Standards Board (NTS), which consists of a group of senior and experienced local government heads of Trading Standards, representing all trading standards services across England and Wales, continues to meets two to three times a year to discuss issues and formulate policies on consumer safety and market surveillance. NTS was established by the Government in 2012 to improve the enforcement of laws intended to tackle rogue traders operating both regionally and nationally who are causing harm to consumers and legitimate businesses. NTS issues grants and funds national and regional initiatives such as Scambusters, the Safety at Ports and Borders Teams, and the National Trading Standards e-Crime Team.

In the UK, responsibility for market surveillance is usually conferred on public authorities with specific competence for enforcement in a particular sector. For example, in the area of consumer safety, BEIS has policy responsibility for most product safety legislation, and Trading Standards will enforce the legislation. Trading Standards are funded by their own local authorities although they may receive funding for product safety projects from BEIS in response to national priorities or as a result of joint action and cooperation with other MSAs e.g. the Health and Safety Executive.

The enforcement of legislation covering workplace goods is undertaken by the HSE's Product Safety Team which is a 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. Because of the migration of professional goods towards the non-professional consumer, HSE and Local Authorities co-operate closely, particularly in areas such as Personal Protective Equipment, Machinery and Gas Appliances.

To foster co-operation and to facilitate import surveillance activities on non-food products entering the UK from outside the EU, the UK established an Intelligence Hub in 2012. It acts as a Single Point of Contact (SPoC) for the liaison between all Market Surveillance Authorities, HMRC and Border Force for the border controls of unsafe and/or noncompliant products entering the United Kingdom. It has responsibility for setting, managing and evaluating risk based and intelligence led controls and is now well-established in this role.

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 all 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. A new development is the change to HMRC processes relating to the legal paperwork which agents are required to submit on non-food products, which accompanies these products. The paper work for non-food products which are subject to MSA controls is now sent directly by the agents to the SPoC rather than previously via HMRC's National Clearance Hub (NCB), who in turn would submit it to the SPoC. This change in direction helps the agents as it maximising efficiencies and further reducing disruption to legitimate businesses.

The SPoC recently underwent an independent review which found that the SPoC continues to deliver good value for money and has a key role in preventing the circulation of illegal and dangerous products in the UK.

1.3 Cooperation between national market surveillance authorities and customs

HMRC and the Border Force are not designated with an MSA function because they have no competence in the area of enforcing against single market legislation. They do, however, have unique access to the documentation relating to imports from third countries. The information contained within customs declarations and the supporting documents can be profiled in order to target products that are likely to present a risk to users etc. Cooperation between HMRC and Border Force and the UK MSAs is an important element of the risk-based and targeted approach to border controls. Co-operation involves intelligence and knowledge sharing and access to inspection facilities by trading standards for non-food products.

Customs clearance of all non-EU commercial imports continues to be handled at a single HMRC national entry processing unit, the National Clearance Hub (NCH). The NCH also provides the single point of contact for importers and other enforcement agencies for freight clearance queries. In September 2014, the Director General of Border Force and the Chairman of National Trading Standards jointly published a commitment to working together, encouraging their staff to take positive action to facilitate close working activity at the UK border.

1.4 Rapid Information Exchange System – RAPEX

The General Product Safety Directive 2001/95/EC (GPSD) provides the legal framework for RAPEX. In the UK, the Local Authority Trading Standards Departments have the necessary powers to take measures to prevent or restrict the marketing or use of dangerous products. The UK's local Trading Standards teams are the market surveillance/enforcement authorities that submit RAPEX notifications to the UK contact point 'RAPEX Unit' which falls within the responsibility of the Department for Business, Energy and Industrial Strategy (BEIS).

The Rapex Unit plays an important role in ensuring that notifications submitted meet the criteria of Rapex, and providing advice to Trading Standards on the type of information that is required, and the correct documentation to ensure information issued to the European Commission is consistent and meets necessary time scales. The UK submits over a 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.

The Rapex Unit advises Trading Standards on the procedures they should follow for in 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 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. The RAPEX contact point is also responsible for dealing with enquires from other EU member states, UK authorities and UK companies enquiring about RAPEX procedures or to request information on products notified on the RAPEX system.

The work by the European Commission to modify to RAPEX to make it more usable for construction products is welcomed, as is the initial work establishing the feasibility of RAPEX/ICSMS convergence.

1.5 ICSMS information 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 the European Commission. In 2012 the existing ICSMS database was acquired by the European Commission and made freely available to all European MSAs for this purpose.

In the UK, ICSMS is used regularly by the Health and Safety Executive, (who act as the UK administrator for ICSMS), Environmental Health Officers in Northern Ireland, as well as other UK MSAs such as the DVSA and NMRO. Many Trading Standards officers also use the ICSMS system, however several also use local systems. In addition some Trading Standards officers continue to use ICSMS through the interface between their national database and ICSMS which was created with BEIS funding in 2013 by Trading Standards Institute (TSI). This provides a simpler means of access to ICSMS, both for uploading records and searching for existing records. However, recognising that the use of ICSMS is inconsistent in the UK, BEIS has recently made the decision to cease funding the interface and instead to work with HSE to encourage Trading Standards Officers to use ICSMS exclusively, rather than any local systems which might be in place. BEIS anticipates that the transition will take at least 5 years.

1.6 General description of Market Surveillance activities and relevant procedures

The general objective of Market Surveillance in the UK is to ensure the free circulation of safe and compliant products in the Single Market, in a way that supports business and business growth, promotes consumer choice, and provides adequate consumer protection. To that end we believe that legislation on consumer product safety should be proportionate, consistent and transparent with only the minimum regulatory burdens required to achieve this goal. All Market Surveillance Authorities (MSAs) are signed up to the Regulator's Code (www.gov.uk/government/publications/regulators-code), excluding OfCom which is an economic regulator. 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. This can also include activities that encourage compliance by those businesses that are found to be non-compliant. For example, BEIS meets with Industry representatives on a very regular basis to discuss the application of sector-specific regulations, and through its Better Regulation Delivery Office (BRDO) offers clear links to businesses which require support in this area.

MSAs undertake proactive work on the basis of risk assessment. Where legislation prescribes the precautionary principle, this is taken into account however the UK's standard policy is to rely on risk-based assessment as the most efficient and effective basis for action, and that this complements the principles underpinning better and smart regulation.

A continuing key feature of the UK's system is that MSAs develop a good understanding of the businesses which they regulate, and apply their powers proportionately. MSAs make their enforcement policy widely known to business including via the internet, as well as other communication channels such as twitter. This includes the types of sanctions that MSAs have available for non-compliance with legislation and an explanation of business's rights.

1.7 How MSAs follow up complaints

UK MSAs investigate complaints of alleged non-compliance and follow them up as appropriate taking into account the principle of proportionality. MSAs follow up complaints in a number of ways. Some examples are given below.

Driver & Vehicle Standards Agency

The Driver & Vehicle Standards Agency (DVSA) have responsibility for the automotive sector. Consumers who have concerns about the safety of an automotive product can register a complaint with the DVSA's Vehicle Safety Branch who will consider the concern and where justified raise and investigate it in cooperation with the relevant producer in line with a published Code of Practice.

Health and Safety Executive

HSE has an established system of dealing with complaints/concerns relating to product supply and safety matters. There are 4 HSE 'Product Safety Teams' which are tasked with reactive and proactive Market Surveillance activities, following up referrals from field staff (including inspectors visiting workplaces, eg when investigating injuries arising from product use) and external referrals, and information from others, including product users and other authorities. Further details can be found at: www.hse.gov.uk/work-equipment-machinery/hse-role-market-surveillance-authority.htm and www.hse.gov.uk/work-equipment-machinery/report-defective-product.

National Measurement and Regulation Office

Complaints made to the National Measurement and Regulation Office (NMRO) Enforcement Directorate can take many forms; those arising from market surveillance, industry (business to business) information and from the public. All complaints are taken seriously and are assessed objectively.

In the context of the EU Timber Regulation (EUTR), people have the right to report a substantiated concern to the NMRO as the acting competent authority. This means that it is essentially a concern raised by any third party, to an MSA, about compliance with the regulation. There is no standardised format or method for presenting the concern.

Substantiated concerns only differ from other complaints in that the NMRO has an obligation to endeavour to investigate by statute. However, they are treated in the same manner as other complaints via the following process:

The complaint is received (via telephone / email / post / NMRO dedicated enquiry line/ in person etc.). The receiving officer completes a 'complaint form' template, with recommendations made (typically initiate activity, make test purchase or retain and record with no direct action at this time). The template is based on the National Intelligence model and comprises four key elements:

- Source Evaluation
- Intelligence Evaluation
- Projected Impact
- Handling Code

The template is sent to the Officer in Charge (typically the Director of Enforcement) for review. The recommendations made are either endorsed or other actions suggested. The case is allocated as appropriate to an enforcement officer to progress.

Where an offence has been committed and after considering all of the evidence available and all of the actions of the economic operator concerned, the NMRO will consider issuing some form of sanction as well as any other preventative or remedial action as deemed appropriate. This may include requiring economic operators to pay for the costs of testing, if it is proven that their product is non-compliant.

Where appropriate and in keeping with the Regulators Code, the NMRO may offer informal courses of enforcement action. These alternatives may include but are not limited to:

- Verbal warnings
- Written warnings
- Business support

Complaints raised under other NMRO regulations regarding Weights and Measures are dealt with by the Regulation Directorate who deal on a case by case basis with the organisations or persons concerned usually in an advisory way.

Trading Standards

With regard to Trading Standards services of local authorities in England, Scotland and Wales, and Environmental Health departments of district councils in Northern Ireland, enforcement action may be taken in cases of formal non-compliance such as inappropriate CE marking, or in cases where the enforcement authority has reason to believe that the product, for example a toy, presents a risk to the safety and health of persons. The local authority enforcement authority may issue a compliance notice in the case of formal non-compliance or where this notice is not complied with, or a safety risk exists, the operator may be required to withdraw the product from the market or undertake a recall. Where the required technical documentation cannot be produced, Trading Standards enforcement authorities have the power to require, for example, toys to be tested at the supplier's own expense.

All MSAs have an extensive range of statutory powers to deal with contraventions. MSAs will always seek voluntary compliance from an economic operator when a product is found to contravene legislation. However MSAs can issue formal notices to require economic operators to bring about compliance. Where the significance of non-compliances makes it appropriate MSAs can take more rigorous action, including preventing economic operators from supplying the goods until the non-compliances have been rectified or until a judgement has been made in the courts. Successful prosecutions can result in monetary penalties or, in the most extreme cases, imprisonment.

The nature of the market surveillance action will be taken by reference to the risk assessment – the severity and frequency of the hazards identified – and to other considerations, such as any significant history of contraventions by the suppliers concerned.

1.8 Details of how some MSAs alert users of hazardous products

DVSA

For the DVSA, automotive producers will contact vehicle owners to alert them of hazardous products. Where this is an automotive vehicle DVSA will arrange for the release of vehicle keeper information from the national database to help the producers identify and promptly contact the correct vehicle owner.

HSE

HSE has system of safety alerts/bulletins for dealing with products/work equipment which pose a serious risk, see: <u>www.hse.gov.uk/safetybulletins/</u>. HSE also uses ICSMS and RAPEX as a means of alerting other EU MSAs about non-compliant products.

NMRO

The NMRO use four main platforms for alerting users of hazardous products:

- ICSMS input
- Data sharing with UK authorities (local and national)
- Data sharing with other Member State MSAs (the ADCO) and the European Commission, as appropriate
- Press releases published on its website with subsequent e-alerts

1.9 MSAs' approach to penalties

Duties and offences, and the associated measures and penalties are set out in the individual pieces of national legislation which give effect to European legislation. The level of the financial penalty imposed is a matter for the Courts. Examples of some MSAs approach to penalties are given below.

DVSA

The DVSA work to an agreed code of practice which requires and promotes cooperation between Producers and the authority. They would only use their enforcement powers and any penalties in extreme and urgent cases and only after promoting voluntary action.

Trading Standards

Trading Standards' approach to penalties reflects the strategic direction set by the Department for Business, Energy and Industrial Strategy i.e. support/guidance/advice to businesses to help them become compliant. For businesses that continue to operate outside relevant legislation this is supported by Enforcement Notices and, as a last resort, prosecution in court.

1.10 Evaluation of market surveillance activities

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

In addition BEIS is managing an internal review of how the UK organises its enforcement activity with the aim of ensuring that the coordination activities it is involved in work as effectively as possible within the current resource constraints.

BEIS also manages a multi-stakeholder workshop on Fulfilment Houses to ensure that our approach to this difficulty is joined-up, and are shortly due to respond to a review of the product recall system which it commissioned independently.

1.11 Some examples of how MSAs work with businesses and consumer organisations in this area

HSE

HSE is the UK market surveillance authority for the safety of products in the workplace. Information on how HSE carries out its market surveillance work can be found here: www.hse.gov.uk/work-equipment-machinery/hse-role-market-surveillance-authority.htm.

NMRO

For the environmental regulatory area NMRO works in partnership with business and industry to achieve high levels of compliance. Creating and maintaining sustainable 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 SME's, via event attendance and regular project work, as well as reactive support via enquiry lines.

For other regulatory areas such as Weights and Measures NMRO works closely with its enforcement partners in local authorities, particularly Trading Standards, who they meet and liaise with regularly. There is an annual meeting with the Local Government Metrology Expert Panel which consists of regional Trading Standards representatives from across the UK and the CTSI Lead Officers for Metrology.

Trading Standards

Trading Standards provide assistance through the Home Authority scheme and Primary Authority scheme to all businesses in their respective administrative areas on a wide range of consumer protection issues. The Primary Authority scheme allows businesses to be involved in their own regulation. It enables them to form a statutory partnership with one local authority or fire and rescue authority, which then provides robust and reliable advice for other local regulators to take into account when carrying out inspections or addressing non-compliance. Further information about Primary Authority can be found at: www.gov.uk/government/publications/primary-authority-overview.

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

The UK continues to have a policy of attending all ADCOs and other similar groups when appropriate to do so. The UK also participates in a number of international meetings on market surveillance. For example, the SPoC has undertaken a number of tasks in its capacity as the UK's MSAs expert in border controls. This has included contributing to EU consultations, attending relevant EU meetings and representing BEIS at the USA, EU and China tripartite meeting on RAPEX alerts. Details of specific MSAs international activities are given below.

1.13 MSAs international activities

The UK continues to play an active part in the Administrative Cooperation Groups, which facilitates the sharing of best practice, the identification of barriers to enforcement and the resolution of legislative grey areas. For example, HSE, through the Machinery ADCO Working Group, has contributed to the development of a "Good Practice Guidance on Market Surveillance", which is now being used as an important source document for a new horizontal European guide to market surveillance in the industrial sector.

The NMRO have provided the Chair and secretariat for the RoHS and Energy Labelling ADCO (as well as the co-chairmanship of the Ecodesign ADCO) for several years. They have set the strategic direction of these groups by working closely with the European Commission on the future of market surveillance, by inviting appropriate industry bodies for multilateral discussions, and by initiating ADCO group projects (both internally and externally funded and visible). This approach has allowed the ADCOs to mature, has improved the accessibility and increased attendance. In doing so NMRO have ensured that UK industry is supported through its ability to shape and define consistent approaches to market surveillance.

1.14 Participation in coordinated EU projects

The NMRO are also a key project partner of the Ecopliant project, funded under the Intelligent Energy Europe programme. Aligning 11 project partners, from 10 Member States, Ecopliant aims to develop and validate a range of best practices to improve the collaboration between EU MSAs, through monitoring, verification and enforcement exercises. The objective of Ecopliant is to help deliver the intended economic and environmental benefits of the Ecodesign Directive by strengthening market surveillance and so increasing compliance with the Directive. Working closely with other Member State MSAs, enables NMRO to be far more effective when operating across borders

In relation to Trading Standards, there is also engagement with organisations within the EU to facilitate partnership working, particularly with PROSAFE. A representative from the Trading Standards Institute (TSI) attends these meetings and reports back through to the Product Safety Focus Group. The UK is also one of the ten Member States in the core group of the Joint Action China project. This is an on-going project to identify and implement methodologies that would enable EU Member States to have confidence in Chinese inspection/export processes. The aim would be that if this confidence can be

achieved, then it would be possible to identify those consignments which would not need to be checked at the EU border.

1.15 Evaluation of Market surveillance actions and reporting

As previously reported, the UK evaluates its market surveillance activities through the BEIS co-ordination mechanisms, ie the MSCC, MSCC sub-group and the Product Safety Focus Group.

1.16 Horizontal activities planned for the relevant period

BEIS has in recent years provided targeted funding for specific market surveillance projects. These projects are typically valued at between £5K-£20K.

BEIS encourages authorities to look at ambitious strategic projects and projects which involve authorities working in partnership to deliver the outputs. Project proposals should be for products which have been placed on the market i.e. not products intercepted at ports as there is separate funding for testing products at ports via the National Trading Standards (NTS).

The main output of each project is a report covering the testing activities and an analysis and conclusions based on the outcomes. BEIS requires the outputs from projects to be made available for all UK Trading Standards Departments via the NTS Information Hub.

This year the projects will cover work on LED Floodlights, Nightwear, Telescopic Leaning Ladders, Childcare Articles (nappy sacks and slings), and second-hand Electrical Goods. The latter project will be taken forward as 3 individual market surveillance across 3 different regions, reporting jointly.

As already mentioned above in section 1.10 BEIS has also commissioned an independent review of the UK's consumer product recall system. We expect the report and the Government's response to be published soon.

2. Market Surveillance in specific sectors

2.1 Product Sectors and contact details

Medical Devices

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.

Contact Details:-

Regulatory Affairs & Compliance Medical Devices Medicines and Healthcare Products Regulatory Agency 151 Buckingham Palace Road London SW1W 9SZ.

Email: <u>Devices.compliance@mhra.gsi.gov.uk</u> Telephone +44203 080 6311

MHRA have approximately 9 full time experts working on medical device compliance/market surveillance issues. They also have a further 40 full time experts in the form of enforcement officers, making it a unique model compared with European counterparts where it is the only medicines and devices regulatory authority (and one of very few worldwide) that has its own dedicated Intelligence Unit and distinct Operations Unit responsible for criminal investigations. Where appropriate, the agency seeks compliance or brings criminal prosecutions against suspects involved in illegal activities concerning medicines and devices and their availability through manufacture, import, sale, supply, counterfeiting, diversion or theft.

Sector-specific legislation on medical devices is set at EU level; the EEC medical devices directives are implemented in the UK by the Medical Devices Regulations (2002). The 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. The General Product Safety Regulations 2005 also apply to certain medical devices which are deemed to be consumer products, for example sticking plasters and condoms. MHRA's role involves establishing that both sets of Regulations have been complied with and ensuring that the appropriate action is taken wherever necessary to prohibit or restrict unsafe products being placed on the market and/or put into service.

The MHRA meets this obligation in four basic ways:

- Considering any complaints about CE-marked products that are drawn to our attention
- Looking at areas that are presenting a problem in terms of non-compliance and proactively targeting the devices identified
- Monitoring the activity of notified bodies designated by the MHRA to assess the compliance of manufacturers of, in the main, higher risk devices
- Undertaking proactive investigations as a result of vigilance reports or intelligence indicating a potential problem either with an individual device or range of devices.

MHRA carries out a risk-based analysis to prioritise and carry out investigations. The investigations detailed in 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.

The MHRA adopts the statutory principles of the Regulators' Code in carrying out its regulatory functions. 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, medical devices and blood products; 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.

The Regulation on Accreditation and Market Surveillance (RAMS) also applies to medical devices and so the principle of cooperation with other Member States is well established. MHRA is co-Chair of the EU Compliance and Enforcement Working Group (COEN) which serves to promote collaboration, consistency and information-sharing across EU Member States on the market surveillance of medical devices. Under this umbrella, MHRA has been involved in a number of proactive projects, such as a review of instructions for use (IFUs) for resterilisable devices and associated education activity for manufacturers in this sector. MHRA is also currently leading a proactive EU-wide project under COEN's new programme of market surveillance activity for 2014/15. Further, MHRA enforcement experts have been seconded to other Member States in an effort to share knowledge and resource on medical device market surveillance. There are plans for further secondments to take place in 2015.

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 we are able to work in cooperation with them when issues arise, such as the selling of counterfeit devices via these outlets.

Cosmetics, Toys, Construction Products, Aerosol Dispensers, Personal Protective Equipment, Appliances Burning Gaseous Fuels (consumer products only); LVD; EMC; RTTE; RCD Machinery (consumer products)

Trading Standards have enforcement responsibility for these Directives and Regulation, and also for Simple Pressure Vessels when it is a consumer product. Trading Standards are part of Local Authorities, of which there are over 200 in the UK. It is therefore not possible to list individual contact details. Each local authority acts independently setting its own priorities. The "Home Authority" principle operates among local authorities. The Home/Lead Authority Partnerships help councils work together effectively and avoid duplication of effort when regulating businesses who trade across local council boundaries, and support them by providing contact points for advice and guidance in order to maintain high standards of public protection and develop a consistent approach to enforcement. Further details of Trading Standards market surveillance activities have been described in this document on pages 5 - 8.

Pressure Equipment, Transportable Pressure Equipment, Machinery, Lifts, Pyrotechnics, Explosives for Civil Use, LVD, Appliances Burning Gaseous Fuels (non-consumer products only), Equipment and Protective Systems Intended for Use in Potentially Explosives Atmospheres (ATEX)

HSE have enforcement responsibility for these Directives. They also have enforcement responsibility for Simple Pressure Vessels when it is work equipment. Trading Standards have enforcement responsibility when it is a consumer product. HSE does not enforce the PPE Directive but provides technical support and guidance to other MSAs as required.

HSE's planned activities are not based on industries or sectors. Instead they follow a riskbased approach identifying machinery/equipment where there is a known or suspected problem, or based on information received about particular products e.g. PPE (face masks), Machinery (lifting slings, installation instructions for [small] wind turbines, Impact Post drivers, Pressure equipment (small vessels), construction equipment e.g. excavators. HSE also works with ADCOs and the European Commission in relation to joint (EU) enforcement action e.g. Machinery – motor vehicle hoists, chainsaws.

Contact Details:-

Safety.Unit@hse.gsi.gov.uk

The Health and Safety Executive for Northern Ireland (HSENI)

All members of the Manufacturing Group within HSENI have a role in Machinery Safety issues including Market Surveillance along with their roles as Health and Safety Inspectors. Other Inspector colleagues have oversight of and responsibility for other Directives such as the Low Voltage Directive. "In House" UKAS Accredited Laboratory is available to provide some technical advice and guidance.

HSENI Contact Details:-

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

Tel: 028 9024 3249 Mobile: 07879 487848 Email: <u>cyril.anderson@hseni.gov.uk</u>

Ecodesign, Energy Labelling, RoHS, Heat Networks (Energy Efficiency Directive), Timber Regulations, ABS, FLEGT, WEEE (take back provisions), End of Life Vehicles, Batteries and Accumulators (Placing on the market), Batteries (automotive and portable reporting), Noise Emissions for Outdoor Equipment

The NMRO have responsibility for the enforcement of these Directives and is a national regulator, tasked with simplifying technical regulation for the benefit of British businesses. They provide a range of services in addition to their enforcement tasks including policy development in the areas of Weights and Measures and Hallmarking as well as technical services, training and accreditation capability.

NMRO operates throughout the UK with over 50 full time experts in their capacity as market surveillance officers. Many of the staff are based in Teddington, South West London, in a purpose built facility.

NMRO's approach to enforcement follows the principles of the Regulators Code and they divide their resources between engagement with businesses through education, awareness and assured advice, the detection of noncompliance through projects, complaints and case work and a programme of product testing which encompasses screen testing, and internal and external accredited testing.

The NMRO focus their activities on products, businesses and organisations that need support or advice in meeting their regulatory obligations, in particular reviewing new products, and identifying companies that have expanded into new areas. Resources and the tupes of support and engagement are based on market intelligence and the risk of non-compliance.

NMRO provide a detailed website covering all of the legislative areas and their activities hosted on the government website <u>www.gov.uk/nmro</u>.

Contact Details:-

The National Measurement Office (NMRO) Stanton Avenue Teddington Middlesex TW11 0JZ +44 (0)20 8493 7227

Automotive Vehicles and aftermarket components

The Driver and Vehicle Standards Agency (DVSA) is the UK competent authority for automotive and aftermarket component parts. DVSA is responsible for the registration and monitoring of all safety recalls of products within the sector. DVSA has responsibility for carrying out market surveillance activities to ensure compliance within the automotive sector as well as providing educational and mentoring support to "immature" manufacturers who wish to be compliant when entering the sector.

DVSA's Vehicle Safety Branch has a Safety Recalls Scheme Manager and two administrators working on Safety Recall Scheme matters and three engineers who fundamentally are involved in allegations of safety issues with all types of automotive products, tyres and aftermarket component parts fitted to products suitable for use on the public highway.

The agency conducts market surveillance to ensure compliance by producers, distributors and used product retailers to ensure immediate compliance by registration of the issue and commencement of a customer contact and rework programme.

In addition, DVSA has established an early warning notification system to ensure that producers, distributors and their parent companies can give advance notice of issues that will affect their markets. This enables DVSA access to high level information at an early stage and the ability to influence the way forward.

Contact details:-

Vehicle Safety Branch Driver and Vehicle Standards Agency Berkeley House Croydon Street Bristol BS5 0DA

+44 (0) 117 954 3300

Non-road mobile machinery (NRMM) Gaseous Emissions, Passenger Car (Fuel Consumption and CO2 Emissions Information)

The Vehicle Certification Agency (VCA), and the Driver and Vehicle Standards Agency (DVSA) have responsibility for enforcement of vehicle regulations including carrying out market surveillance across the United Kingdom.

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 Point of Contact (POC) details for work on NRMM gaseous emissions, Passenger Car (Fuel Consumption and CO2 Emissions Information) is:-

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

Tel: + 44 (0)117 952 4169

Electrical Equipment under EMC, Radio and Telecommunications Equipment under RTTE

Ofcom is the communications regulator in the UK and regulates the TV and radio sectors, fixed line telecoms, mobiles, postal services, plus the airwaves over which wireless devices operate. They have enforcement responsibility for these Directives. Ofcom operates under a number of Acts of Parliament, including in particular the Communications Act 2003. The Communications Act says that Ofcom's principal duty is to further the interests of citizens and of consumers, where appropriate by promoting competition. Ofcom must act within the powers and duties set for it by Parliament in legislation. Ofcom's operating budget for the period 2015/16 is £114m and currently has approximately 780 employees. Ofcom has internal UKAS accredited test laboratories where products under the R&TTE Directive are tested.

Ofcom conducts investigations in response to complaints of interference to the radio spectrum from non-radio electrical devices. Once a compliant is made, spectrum assurance engineers will carry out investigative techniques to source the cause of interference. If that cause is a non-radio electrical product then Ofcom may contact the owner and the manufacturer of the product to may them aware of the issue and if possible, test the product against the harmonised standards listed in the declaration of conformity.

On an annual basis, Ofcom works in collaboration with other EU member states on R&TTE and EMC market surveillance campaigns and actively participates in choosing the target product, creating the codes of practice and drafting the final report. A pro-active approach is adopted by Ofcom and online sites, such as eBay and Amazon, are checked on a daily basis for non-compliant products. A joint approach by Ofcom and the online store allows this item to be removed from the site.

To modernise current legislation, Ofcom are in the process of introducing secondary legislation in relation to electrical products that have not been maintained and deteriorated

from their state when initially placed on the market such that they are now causing interference to wireless telegraphy apparatus.

Contact Details:-

The Office of Communications (Ofcom) Riverside House 2a Southwark Bridge Road London SE1 9HA Tel: 0300 123 3333

www.ofcom.org.uk

Andy Cutting (andrew.cutting@ofcom.org.uk)

2.2 Market surveillance procedures and activities

As mentioned in this document under part 1, Market Surveillance Authorities in the UK are often (but not always) designated by the implementing legislation. They are all public authorities and tend to be independent of the competent authority (except in sectors such as medical devices where the competent authority is also the market surveillance authority). As enforcement of legislation falls within their competence, they cannot be directed by the competent authority but they often co-operate closely on how the legislation is implemented. All will have a strategic work plan which will relate to local and/or national priorities. Priority areas will include a speedy response to credible complaints on the basis of risk assessment.

There are organised programmes of work by those MSAs which are established on a national basis. In the case of the Local Authorities with responsibility for Consumer Safety, BEIS has a budget which can be used to supplement existing resources to finance projects to address national and European priorities - especially those that emerge from sector ADCOs and the RAPEX network - and emergency requests. For example following concerns with regard to flammability of children's fancy dress BEIS funded a project lead by The City of Newcastle Trading Standards on behalf of The North East Trading Standards Association, and involving a large number of Trading Standards services across the UK, to determine whether the fancy dress costumes being made available were compliant with the currently accepted standard. Some 300 samples of fancy dress were assessed and reassuringly the number of samples that failed to meet current flammability was considered to demonstrate a high level of compliance. The project was also able to provide feedback to the British Standards Institute (BSI) on issues relating to the use of the standard along with some suggestions for improvement.

Structured enforcement is used when addressing border controls (notably at the UK's principal container port at Felixstowe) to good effect. There is a chronological structure for products enforcement ahead of the peak periods of demand e.g. fireworks, Christmas, Easter etc. The market surveillance officers investigate complaints of alleged non-compliance and follow them up as appropriate taking into account the principle of proportionality. Enforcement officers undertake proactive work on the basis of risk assessment having regard to the seriousness of potential contraventions and their

frequency. Details of other specific sector activities have been described in this document under part 2.1.

2.3 Report from activities carried out under the previous planning period

The report above describes the UK's generic market surveillance activities for 2016 as it is not possible to forecast future funding allocations or to predict emerging priorities until the start of the financial year, which in the UK begins in April. However we will provide more detail on the ad hoc activities which we will carry out in this calendar year at the end of March 2017.



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