

***NATIONAL MARKET SURVEILLANCE
PROGRAMME***

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United Kingdom

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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 augmented by primary and secondary legislation. Market surveillance in the UK is organised on a European Directive/Regulation specific basis. When the UK implements a European Directive into UK law, 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 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).

As indicated in the diagram attached to this report at Annex A, other non-safety legislation is enforced by a number of other sector-specialist enforcement bodies e.g. The National Measurement Office (NMO) provides market surveillance delivery services for several Government Departments covering a range of environmental protection and fair trading legislation. They operate across four public bodies and have responsibility for the regulations which cover Ecodesign, RoHS, batteries, the labelling of tyres, timber and the energy labelling of energy related products such as fridges and vacuum cleaners. 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. The Department of Business, Innovation and Skills (BIS) has legal responsibility for the implementation of most EU single market Directives and Regulations. However, implementation of 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 data about the overall resources at their disposal such as budget, staff and technical means. As an example, there are hundreds of staff engaged on market surveillance activities within local authorities, which organise their work locally with regional and national co-ordination.

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 2015-16. 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. Another well-established forum is the sub-group of the MSCC, with representatives from the Department for Business, Innovation and Skills (BIS), DCLG, HMRC, Border Force and MSAs which focuses on border controls in relation to market surveillance. The sub-group meets 3 to 4 times a year. It acts as an intelligence task and co-ordination 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 MSAs in the sub-group consist of Trading Standards, HSE, VCA, Ofcom, NMO and MHRA. Their terms of reference are attached at Annex B to this report.

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. They co-ordinate as follows:

For products subject to consumer safety legislation, and construction products, the UK continues to have in place the Product Safety Focus Group (PSFG) which was established in 2012 with Trading Standards representatives from all regions of the UK, plus representatives from the Trading Standards Institute (TSI). TSI, a professional body representing Trading Standards Officers, 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 work.

The National Trading Standards Board (NTSB), 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 meet two to three times a year to discuss issues and formulate policies on consumer safety and market surveillance. The NTSB 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. The NTSB issues grants and funds national and regional initiatives such as Scambusters, the Illegal Money Lending Teams in England and Wales, the Safety at Ports Project and the National e-Crime Centre.

In the UK, responsibility for market surveillance tends to be conferred on those existing public authorities with specific competence for enforcement in a particular sector and as such businesses are used to dealing with them and their enforcement powers and procedures. This is illustrated in the attached diagram at Annex A. For example, in the area of consumer safety, Local Authorities (Trading Standards Services in Great Britain) will enforce legislation. Trading Standards are funded by their own local authorities although they may receive funding for product safety projects from BIS 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 Product Safety Team which has created a network of ‘virtual’ product safety teams across Great Britain. These teams involve 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, particularly in areas such as Personal Protective Equipment, Machinery and Gas Appliances.

Further details of co-ordination and co-operation are given in this report on pages 5,6,10, and 11. Details of sector specific cooperation are given under section 2.1.2 in this report.

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 non-compliant 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, 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.

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. Co-operation 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 230 local Trading Standards are the market surveillance/enforcement authority that submits RAPEX notifications to the UK contact point 'RAPEX Unit' which falls within the responsibility of the Department for Business, Innovation and Skills (BIS).

The Rapex Unit plays an important role to ensure that notifications submitted meet the criteria of Rapex; advising Trading Standards on the type of information that is required with 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 advise Trading Standards on procedures in submitting reactions to 'validated' notifications issued by other EU Member States; to inform whether the notified dangerous product was found on the UK market; what measures were taken to restrict its marketing and distribution. The unit also advise 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.

1.5 ICSMS information system

The Regulation for Accreditation and Market Surveillance (EC Regulation 765/2008) introduced the general obligation for 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 by the Health and Safety Executive, (who act as the UK administrator for ICSMS), Trading Standards Officers in England, Wales and Scotland and Environmental Health Officers in Northern Ireland, and other UK MSAs such as the VCA and the DVSA. Trading Standards continue to use ICSMS through the interface

between their national database and ICSMS which was created with BIS 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.

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 otherwise compliant product in our part of the Internal Market with the minimum regulatory burden on economic operators commensurate with that purpose. In particular the activities of the Market Surveillance authorities should be accountable, targeted, proportionate, consistent and transparent. All Market Surveillance Authorities (MSAs) are signed up to the Enforcement Concordat (<http://www.berr.gov.uk/files/file10150.pdf>) and the Regulators Compliance Code (<http://www.berr.gov.uk/files/file45019.pdf>). Prevention of non-compliance by educating 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 communication activities by all of the authorities. This can also include activities that encourage compliance by those businesses that are found to be non-compliant.

The UK continues to adopt the following general approach to monitoring and intervention. The MSAs investigate complaints of alleged non-compliance and follow them up as appropriate taking into account the principle of proportionality. The MSAs undertake proactive work on the basis of risk assessment having regard to the seriousness of potential contraventions and their frequency. Where legislation prescribes the precautionary principle, this is duly taken into account. The UK, however, regards risk assessment as the better basis for action: this is ingrained within the strategies of the MSAs by the principles of better regulation.

A continuing key feature of the UK's system is that the MSAs develop a good understanding of the regulated businesses and apply their powers appropriately. MSAs make their enforcement policy widely known to business via the internet. 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

As described in section 1.6, 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 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: <http://www.hse.gov.uk/work-equipment-machinery/hse-role-market-surveillance-authority.htm> and <http://www.hse.gov.uk/work-equipment-machinery/report-defective-product.htm>

National Measurement Office

Complaints made to the National Measurement Office (NMO) 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 NMO 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 NMO 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 / NMO 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:

- i. Source Evaluation;
- ii. Intelligence Evaluation;
- iii. Projected Impact; and
- iv. 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 NMO 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 Compliance Code, the NMO may offer informal courses of enforcement action. These alternatives may include but are not limited to:

- Verbal warnings
- Written warnings

- Business support

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 a 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. MSAs, however, can issue formal notices to require economic operators to bring about such compliance in the products that they supply. 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 judgements 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 are given below

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: <http://www.hse.gov.uk/safetybulletins/> . HSE also uses ICSMS and RAPEX as a means of alerting other EU MSAs about non-compliant products.

NMO

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

1. ICSMS input
2. Data sharing with UK authorities (local and national)

3. Data sharing with other Member State MSAs (the ADCO) and the European Commission, as appropriate
4. Press releases published on our website with subsequent e-alerts

1.9 MSAs approach to penalties

Duties and offences with the measures and penalties are set out in national legislation that establishes the market surveillance approach for each piece of 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, Innovation and Skills 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.

1.10 Evaluation of market surveillance activities

The UK continues to work with its stakeholders, including businesses and consumer organisations, in the identification of problem areas/priorities and in the evaluation of market surveillance activities. For example, BIS holds workshops with its Market Surveillance stakeholders on these issues.

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

Construction products

For construction products, Trading Standards, work with industry at national, regional and local level using workshops, correspondence and topic-specific meetings to promote understanding of requirements and risks. In addition to the guidance provided by the MSA, industry has produced guidance that reinforces the message from the MSA. This approach also draws attention to the information and FAQs provided on the website of the European Commission.

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: <http://www.hse.gov.uk/work-equipment-machinery/hse-role-market-surveillance-authority.htm>

NMO

The NMO work 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.

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. Much of this information is now web based.

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 BIS 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

Participation in EU market surveillance ADCO groups:

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 NMO 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 NMO 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 NMO are also a key project partner of the Ecompliant project, funded under the Intelligent Energy Europe programme. Aligning 11 project partners, from 10 Member States, Ecompliant 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 Ecompliant 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 NMO 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 which 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. The UK participated in the visit to China to meet with China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ). This is a ministerial level department that has responsibility for the administration of law enforcement, certification, accreditation and standardisation, and other issues. The visit also included test laboratories and manufacturers to learn about Chinese approaches and processes. The UK was also present at the return visit to Rotterdam where the Chinese delegation was shown how the Netherlands and EU Member States approach safety and border controls.

1.15 Evaluation of Market surveillance actions and reporting

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

1.16 Horizontal activities planned for the relevant period

BIS issued an invitation for trading standards to submit product testing funding proposals. BIS has in recent years provided targeted funding for specific market surveillance projects. These projects are typically valued at between £5K-£10K each although larger projects with a budget of £25K have been agreed this year in sectors with issues of National concern (furniture and e-cigarettes). These along with a number of smaller projects covering cycle helmets, small craft, skin lightening creams, sunbed salons, baby bling, and halogen heaters, are well under way.

BIS 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 Board (NTSB).

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

BIS is also continuously reviewing the UK market surveillance structure with its relevant stakeholders and MSAs. A workshop and follow-up questionnaire organised by BIS in 2014 with these bodies, asked for their views on improving enforcement, more effective communication, funding and training. The outputs from these activities have now been summarised by BIS with priority actions identified for how we will work together to improve how the UK's market surveillance regime operates.

BIS has also commissioned an independent review of the UK's consumer product recall system and will expect a report to be with our Ministers in autumn 2015.

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: Regulatory Affairs & Compliance- Medical Devices, Medicines and Healthcare Products Regulatory Agency, 151 Buckingham Palace Road, London SW1W 9SZ. The contact details are :- Devices.compliance@mhra.gsi.gov.uk 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.

MHRA's Market surveillance procedures and strategy

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:

1. considering any complaints about CE-marked products that are drawn to our attention
2. looking at areas that are presenting a problem in terms of non-compliance 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 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

Trading Standards have enforcement responsibility for these Directives, 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, 6, 10 and 11.

Personal Protective Equipment, Pressure Equipment, Transportable Pressure Equipment, Machinery, Lifts, Pyrotechnics, Explosives for Civil Use, Appliances Burning Gaseous Fuels, 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. Details of HSE and Trading Standards market surveillance activities are described in this document on pages 5-7 and 4-5, 8-9 and 14 respectively.

HSE’s planned activities are not based on industries or sectors – but is a risk- based approach identifying machinery/equipment where there is a known or suspected problems, 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). HSE also works with ADCOs and the European Commission in relation to undertaking 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.

HSE NI 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: cyril.anderson@hse.gov.uk

Electrical and electronic equipment under RoHS, Eco-design and Energy Labelling, Tyre labelling, Batteries and Accumulators (Placing on the Market), EU Timber Regulation

The NMO have responsibility for these Directives. They employ approximately 30 fulltime experts in their capacity as a market surveillance authority responsible for the above pieces of legislation on behalf of four UK government departments. They operate from a purpose built facility which allows secure evidential control on all items purchased under their annual inspection plan and which are subsequently held as part of an investigation. NMO also have the capacity (in terms of technical expertise and in-house testing facilities) to carry out a degree of testing and screen testing. However, they are not accredited and products are generally sent to external, accredited test facilities.

The NMO focus their own initiatives on products or businesses that need support or advice in meeting their regulatory obligations, in particular reviewing new products, and identifying companies that have expanded into our areas of responsibility. These are conducted by one, or a combination of inspections, testing, reviewing of processes and records of the manufacturer or distributor.

Contact Details

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

www.gov.uk/nmo/enforcement

Noise Emissions for Outdoor Equipment, Non-road mobile machinery, End of Life Vehicles, Passenger Car (Fuel Consumption and CO2 Emissions Information) and the Electrical and electronic equipment under WEEE and batteries.

The Vehicle Certification Agency (VCA) is the authority responsible for carrying out market surveillance in these sectors across the United Kingdom.

The VCA has a team of 15 staff distributed across the UK with a wealth of experience and resources to enable industry to expand whilst still meeting their regulatory obligations. The VCA provides support and advice to industry, through tradeshows and presentations, encouraging them to develop, whilst ensuring that industry meets its regulatory obligations. They address complaints in a proportionate but effective manner keeping all parties informed of enquiries and outcomes.

The Enforcement priorities are determined by risk, on consumers, environment, and industry. They react quickly to findings from other members' states and likewise share concerns/findings with them and other internal MSAs using approved intelligence networks as detailed in this report.

The VCA focus their own initiatives on products or businesses that need support or advice in meeting their regulatory obligations, in particular reviewing new products, and identifying companies that have expanded into their areas of responsibility. These are conducted by one, or a combination of inspections, testing, reviewing of processes and records of the manufacturer or distributor.

Across the varied enforcement streams, VCA has worked with industry to maintain and improve on its high-level of national compliance. They have maintained this by conducting no notice risk based inspections across the UK, attending and presenting at Trade shows, meeting and addressing concerns raised by industry. Most importantly by reacting quickly where products are identified as giving incorrect information or not meeting minimum standards, thereby limiting the damage to consumer confidence and the competitiveness of the market. VCA will continue in this proactive approach to global activities where we deliver value for money and support the aims of the legislation.

The VCA Point of contact (POC) details for the Directives on Noise emissions for outdoor equipment Directive, Non-road mobile machinery, End of Life Vehicles, 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](tel:+441179524169)

The VCA Point of contact (POC) for the Electrical and electronic equipment under WEEE and batteries is:-

VCA Midlands Centre
Watling Street
Nuneaton
Warwickshire
CV 10 OUA
Tel:+44 (0) 247 6642795

Electrical Equipment under EMC, Radio and Telecom Equipment under RTTE, Electrical Appliances and Equipment under LVD

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 2014/15 is £117m and currently has 785 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 complaint 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 make 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 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. On an annual basis, Ofcom works in collaboration with other EU member states on market surveillance campaigns and actively participates in choosing the target product, creating the codes of practice and drafting the final report.

To modernise current legislation, Ofcom are in the process of introducing secondary legislation in relation to electrical products causing interference to wireless telegraphy apparatus. During the 2014 period, Ofcom received 114 complaints of interference to wireless telegraphy apparatus (radio) caused by EMC products.

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)

2.1.2 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 workplan 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.

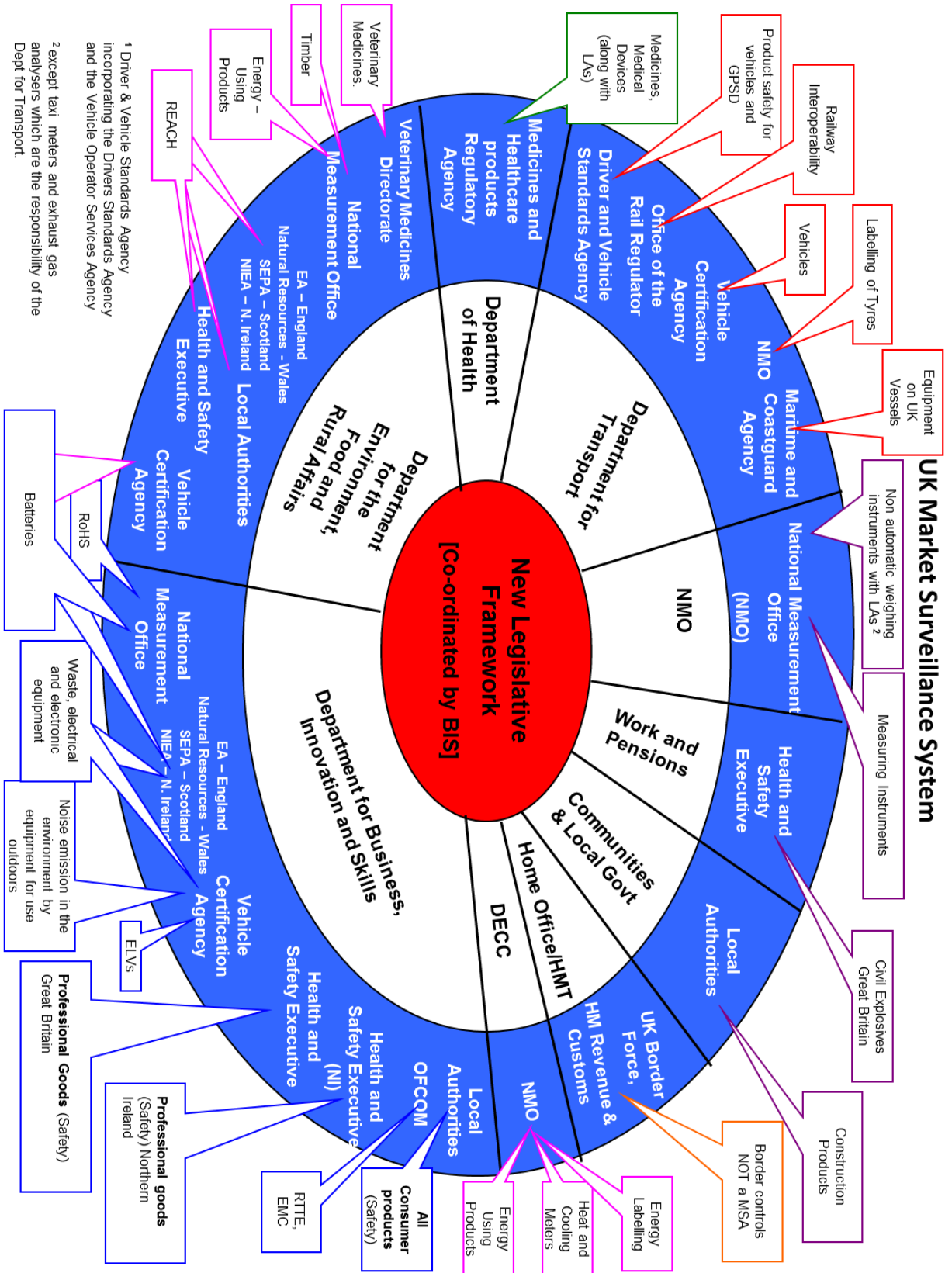
There are organised programmes of work by those MSAs which are established on a national basis. In the case of the Local Authorities with responsibility for Consumer Safety, BIS will supplement existing resources to finance projects to address national and European priorities - especially those that emerge from sector ADCOs and the RAPEX network.

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.

2.1.3 Report from activities carried out under the previous planning period

The activities of the UK market surveillance authorities are described in this document.

ANNEX A DIAGRAM - UK MARKET SURVEILLANCE SYSTEM



¹ Driver & Vehicle Standards Agency incorporating the Drivers Standards Agency and the Vehicle Operator Services Agency

² except taxi meters and exhaust gas analysers which are the responsibility of the Dept for Transport.

ANNEX B MSCC SUB-GROUP TERMS OF REFERENCE

TERMS OF REFERENCE

THE UK MARKET SURVEILLANCE CO-ORDINATION COMMITTEE

SUB-GROUP ON BORDER CONTROLS

1. Aim:

1.1 With regard to the requirements set out in Articles 27-29 of Regulation (EC) No 765/2008 (setting out the requirements for accreditation and market surveillance relating to the marketing of products - RAMS):

1.1.1 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;

1.1.2 To act as a intelligence task and co-ordination group for the UK's market surveillance authorities;

2. Main Issues:

2.1 In order to comply with Chapter III, Section 3 (Articles 27-29) of RAMS, and to take account of the Better Regulation principles of risk-based, proportionate enforcement, to undertake the following activities:

2.1.1 To co-ordinate the national priorities for the control of products from third countries taking account of current national market surveillance plan objectives and latest EU emergency decisions;

2.1.2 To foster co-operation between the market surveillance authorities that operate at points of entry;

2.1.3 To ensure that the co-operation mechanisms between the customs and the market surveillance authorities work effectively and efficiently;

2.1.4 To establish best practice in targeting non-compliant products from 3rd countries using intelligence led risk based controls commensurate with the resources available from all authorities involved in the implementation of RAMS.

2.1.5 To share intelligence and to advocate the use of IT tools to enhance market surveillance activities.

3. Working Methods:

3.1 Meetings of the Committee will take place 3 to 4 times a year.

3.2 BIS officials will chair the meetings, provide the Secretariat for the Committee and will arrange meetings, produce the agenda and an agreed record of the meetings.

3.3 Subject to Freedom of Information and other legal obligations, the meetings will operate on the basis that discussions and materials produced will be of a private nature, unless joint public statements or other public documents are agreed by the members.

3.4 The Sub-Group will aim to produce deliverables, which will contribute towards the principles of better regulation, enhanced market surveillance and trade facilitation in the United Kingdom.

3.5 The Sub-Group will report on a regular basis to the MSCC via the Chair or other members.

4. Membership:

4.1 Membership of the Sub-Group is open to MSCC members, market surveillance authorities (as defined by RAMS), and those with a customs authority function in the United Kingdom.

5. General:

5.1 This document may be reviewed and varied by the agreement of the Sub-Group.

BIS

December 2009