Department for Business Innovation & Skills

Review and Assessment of the Functioning of Market Surveillance Pursuant to Article 18(6) of Regulation (EC) No 765/2008: 2010 - 2013

United Kingdom

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Contents

Overview of general market surveillance activities

A. Review of general market surveillance activities

The United Kingdom's current National Market Surveillance Programme for the period January 2014-2015 which describes the structure of its market surveillance and how it operates has been placed on the European CIRCA website. There have been no changes to the underlying structure. It still remains the case that UK Market Surveillance Authorities (MSAs) are always Public Authorities. The basic split in responsibilities in Great Britain is between the Health and Safety Executive (HSE) who have responsibility for products in the workplace (or HSENI in Northern Ireland) and Local Authorities' Trading Standards Departments who have responsibility for consumer product safety, with specialist agencies of Central Government Departments who also undertake market surveillance, such as the National Measurement Office, who are part of the Department for Business, Innovation and Skills, who have responsibility for weights and measures, and the Medicines Healthcare products Regulatory Agency (MHRA), part of the Department for Health, for medical devices and medical products. Further to these details, there have been updates to the information given in the current national market surveillance programme with regard to product safety strategy, the mechanism of co-ordination and co-operation with customs. These details are given in this report.

The National Market Surveillance Programme described the setting up of an Intelligence Hub to foster co-operation and to facilitate import surveillance on non-food products entering the UK from outside the EU. The Hub acts as a Single Point of Contact (SPoC) for the liaison between all UK MSAs, HM Revenue and Customs and the Border Force for the border controls of unsafe and/or non-compliant products entering the UK. Following its creation, the SPoC is now a well-established mechanism. Benefits of the SPoC include 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 leadership and strategic direction to MSAs in border controls, practice and processes.

A new development during the reporting period of RAMs was the change to HMRC processes that required entries subject to MSAs controls for non-food products to be sent directly to the SPoC rather than previously via HMRC's National Clearance Hub (NCH). This new change in direction helps to maximise efficiencies and further reducing disruption to legitimate businesses. 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 any risk-based and targeted approach to border controls. Customs has a limited but crucial role to play whilst allowing the MSA to take a more

flexible approach based on their established working practices. Customs clearance of all non EU commercial imports continues to be handled at a single HMRC national entry processing unit, the 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 published a commitment to working together, encouraging their staff to take positive action to facilitate close working activity at the UK border.

With regards to international co-operation and co-ordination, the UK continued to have a policy of attending all Administrative Co-operation and other similar groups when appropriate to do so. HSE, through the Machinery ADCO Working Group, has contributued to the development of a “Good Practice Guidance on Market Surveillance”, which is used as an important source documents 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 have ensured that UK industry is supported through its ability to shape and define consistent approaches to market surveillance. The UK also participated 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 MSA 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. HM Revenue and Customs and Border Force continued to play a key role in EU Customs related meetings.

In relation to Trading Standards, there was also engagement with organisations within the EU set up to facilitate partnership working which included PROSAFE. A representative from the Trading Standards Institute (TSI) attended these meetings and reported back through to the Trading Standards Product Safety Focus Group. The UK was 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 AQSIQ, CIQ departments, some test laboratories and manufacturers to learn about Chinese approaches and processes. The UK were also present at the return visit to Rotterdam where the Chinese delegation were shown how the Netherlands and EU Member States approach safety and border controls.

RAMs 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, which had been used voluntarility by the HSE since 2006, was acquired by the EC and made freely available to all European MSAs for this purpose.

In the UK, ICSMS is used by HSE (who act as the UK administrator for ICSMS), Trading Standards Officers in England, Wales and Scotland and Enviromental Health Officers in

Northern Ireland, the VCA, DVSA and other MSAs. 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), the professional body that represents trading standards officers as an alternative simpler means of access to ICSMS, both for uploading records and searching for existing records.

Information on total resources available for market surveillance activities

All of the UK MSAs are autonomous enforcement bodies i.e. they act independently, set their own planning and outcomes. MSAs are funded in different ways and the UK's view is that ring fencing of their budgets would be contrary to their independence nature. Market surveillance in the UK is generally carried out either in response to complaints about unsafe/non-compliant products and/or proactively using a targeted-risk based approach. Enforcement must be risk based so as to effectively target priority areas. The UK does not introduce regulations without giving proper consideration e.g. that it is proportionate, accountable, consistent and transparent.

As the UK has a diverse market surveillance network with a variety and number 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. Details can be provided in relation to Trading Standards Services, which is the UK's largest MSA.

As described earlier in this report, in the UK Local Authority Trading Standards Services (Trading Standards) discharge the statutory duties of those authorities designated as "weights and measure authorities" to enforce a wide range of legislation including sectorial legislation aimed at protecting consumers. The service enforces the provision of laws based on European Directives in order to achieve uniform standards of consumer protection and fair trade throughout the European Union. There are approximately 210 Local Authority Trading Standards within the UK.

The service was delivered by a number of means, including

- Visits to trade premises to check for compliance
- Investigation of complaints
- Sampling and testing of goods and services
- Provision of advice and guidance to consumers and business
- Taking enforcement action such as suspending the supply of dangerous goods, prosecuting offenders and seeking injunctions against repeated unfair or illegal practices.

The two tables attached at **Annex A and B** respectively provide data for 2011 (approximately 60% of Trading Standards responded) and 2012 (approximately 93% of Trading Standards responded) on UK enforcement and market surveillance activities related to product safety under the GPSD, and European Union harmonisation legislation (plus vehicles). There is no requirement for Trading Standards to collate this information centrally. This data has also been presented in the European Commission's annual Consumer Markets Scoreboard, a tool to help assess the performance of consumer markets across Europe.

B. Assessment of the functioning of market surveillance activities

During this reporting period of RAMs, the UK continued 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 held workshops with its stakeholders on these issues. A continuing key feature of the UK's system is that the MSA has developed a good understanding of the regulated businesses and apply their powers appropriately. MSAs made their enforcement policy widely known to business via the internet and this included the types of sanctions that they have available for non-compliance with legislation together with an explanation of their rights. Through its various co-ordination mechanisms i.e. through the Market Surveillance Coordination Committee, its sub-group, which focused on border controls in relation to market surveillance, and the Product Safety Focus Group, the Department for Business, Innovation and Skills discussed relevant market surveillance issues, including priorities, both national and local, intelligence, and risk assessed targeting for the control of products.

It was during these co-ordination mechanisms, that Trading Standards raised a matter with BIS about an issue concerning fulfilment houses as to whether or not they were an economic operator under RAMs. BIS, UK MSAs and the European Commission are looking at ways to try to resolve this issue.

Within this reporting period of RAMS, BIS has provided targeted funding for specific market surveillance projects. The funding BIS provides for these projects goes to local authority trading standards (TS) departments to allow them to carry out tests on high risk consumer products that might not otherwise be tested. Typically the BIS funding is between £5K to £10K per project, which allows the local authority to buy a range of the products in question and then to contract a testing houses to carry out the necessary tests. The authority then produces its own analysis of the results and this with the test results are made available to the wider national TS network via the knowledge hub operated by the Products Safety Focus Group.

In the call for funding for 2014/15, BIS received 23 bids totalling some £200K. After each was evaluated BIS took forward 8 projects with a total budget of £85K. The projects were as follows: EETSA cycle helmets; Hampshire small craft; LoTSA skin lightening creams; LoTSA sunbed salons; North Yorkshire baby bling; CENTSA halogen heaters. There were several requests for two main product groups – furniture and E-cigs. BIS decided to take this forward as two large projects encompassing several authorities each. They are SWERCOTS (Dorset) E-cigs; Cwm Taf furniture.

BIS are encouraging authorities to look at more 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 before, there is separate funding for testing products at ports via the National Trading Standards Board (NTSB). BIS requires in return a report covering the activities and the analysis of the outcomes. BIS will expect the outputs from successful projects to be made available for all UK Trading Standards Departments via the NTSB Information Hub and other interested bodies.

BIS is also continuously reviewing the UK market surveillance structure with its relevant stakeholders and MSAs. From a workshop organised by BIS earlier in 2014 with these bodies, BIS asked representatives of UK MSAs for their views such as improving enforcement, more effective communication, funding and training. The workshop informed a follow-up exercise where a questionnaire, based on break-out session outcomes, was sent to those who attended. The outputs from these activities have now been summarised by BIS with priority actions identified on how BIS will work together with UK MSAs to improve how the UK's market surveillance regime operates.

In late 2014, BIS commenced an independent review of the UK's consumer product recall system and will expect a report to be with BIS Ministers in Autumn 2015.

Market surveillance activities in specific sectors

Market surveillance in the UK was generally carried out either in response to complaints about unsafe/non-compliant products and/or proactively using a targeted-risk based approach. Enforcement must be risk based so as to effectively target priority areas.

Sector: 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. The MHRA met this obligation in four basic ways:

1. considered any complaints about CE-marked products that are drawn to their attention
2. looked at areas that presented a problem in terms of non-compliance and proactively targeting the devices identified
3. monitored the activity of notified bodies designated by the MHRA to assess the compliance of manufacturers of, in the main, higher risk devices
4. undertook proactive investigations as a result of vigilance reports or intelligence which indicated a potential problem either with an individual device or range of devices.

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

The MHRA adopted the statutory principles of the Regulators' Code in carrying out its regulatory functions. Effective and proportionate enforcement was recognised as being critical to the MHRA and was a major contributor to the achievement of the MHRA's responsibilities for safeguarding public health. An Agency Enforcement Strategy was published which covered medicines, medical devices and blood products. This stated that in all cases where enforcement action was deemed to be the appropriate course, the MHRA ensured that it was intelligence-led and applied in a fair, consistent, transparent and proportionate manner.

RAMS also applied to medical devices and so the principle of cooperation with other Member States was well established. MHRA was co-Chair of the EU Compliance and Enforcement Working Group (COEN) which served 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 also led a proactive EU-wide project under COEN's new programme of market surveillance activity for 2014/15. Furthermore, 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 was allocated to communicating key messages to members of the public, manufacturers and healthcare professionals about medical device compliance. An example of such activity was 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. MHRA have also worked in cooperation with them when issues arose, such as the selling of counterfeit devices via these outlets.

Sectors: 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. Each local authority acted independently setting its own priorities. The "Home Authority" principle operates among local authorities. The Home/Lead Authority Partnerships helped councils to 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.

In relation to the Toy Safety Directive, the UK provided a report to the European Commission in 2014 which gave an account of how they applied the Directive. For construction products, Trading Standards work with industry at both 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.

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.

Sectors: 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. Generally, HSE's 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 worked with ADCOs and the European Commission in relation to joint (EU) enforcement action (e.g. Machinery – motor vehicle hoists, chainsaws).

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 other inspectors who carry out more general responsibilities working across business. Because of the migration of professional goods towards the consumer, HSE and Local Authorities co-operate, particularly in areas such as Personal Protective Equipment, Machinery and Gas Appliances.

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

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.

Sectors: 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 allow us to secure evidential control on all items purchased under our 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.

The NMO work in partnership with business and industry as it is vital in achieving higher levels of compliance. This created and maintained 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. NMO communicating and engaging with businesses (both SME's and multinationals) is fundamental to the realising the effectiveness of the legislation that NMO are responsible for enforcing. It is a proven enforcement tool that increases businesses understanding of legislative obligations and helps to achieve higher levels of compliance.

Sectors: 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 an effective 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 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.

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 they deliver value for money and support the aims of the legislation.

The VCA works 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.

Sectors: 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 compliant was made, spectrum assurance engineers carry out investigative techniques to source the cause of interference. If that cause was a non-radio electrical product then Ofcom generally contacted 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.

Annex A: Trading Standards Data for 2011

	Total	Toys	Electrical appliances	Cosmetics	Childcare articles
Number of inspections	9674	1665	1453	1749	328
Number of inspections concerning products sold over the internet	524	92	77	19	128
Number of products inspected	87302	45517	38950	19436	4185
Number of products tested in labs	1867	696	331	132	77
Number of non-compliant products found on the market	75026	2195	51376	15165	175
Number of dangerous products posing a serious risk	10317	353	9590	12008	105
Number of administrative decisions taken	1129	561	137	138	17
Number of products withdrawn from the market	1055	690	415	52	150
Number of products recalled from the market	55	8	4	8	22
Number of decisions taken by authorities in charge of external border controls to suspend products at the border	252		2	1	
Number of decisions to reject products at the border	2		2	1	
Number of products destroyed	9543	827	9295	77	
Number of voluntary measures taken by companies	529	347	63	25	14
Number of voluntary withdrawals	417	135	81	59	10
Number of voluntary recalls	78	32	18	7	4
Number of sanctions imposed	94	18	27	10	

Annex B: Trading Standards Data for 2012

	Total	Toys	Electrical appliances	Cosmetics	Childcare articles	Vehicles	Others
Number of inspections	11141	1299	1588	906	440	461	4617
Number of inspections concerning products sold over the internet	487	62	123	76	32		114
Number of products inspected	111095	8806	77866	9677	1282	7	10940
Number of products tested in labs	2603	570	735	442	70		477
Number of non-compliant products found on the market	9317	955	3272	1336	55	199	2723
Number of dangerous products posing a serious risk	3005	149	2408	42	18	184	366
Number of administrative decisions taken	361	36	59	22	24		278
Number of products withdrawn from the market	2234	67	348	558	28		1083
Number of products recalled from the market	125	33	14		34	184	8
Number of decisions taken by authorities in charge of external border controls to suspend products at the border	414	160	122	7	2		5
Number of decisions to reject products at the border	15		10				4
Number of products destroyed	2928	451	463	373	21		1272
Number of voluntary measures taken by companies	754	76	78	33	12	242	66
Number of voluntary withdrawals	464	34	40	9	11	6	40
Number of voluntary recalls	105	28	28	2	8	210	14
Number of sanctions imposed	234	37	23	6			46
Number of total pieces of advice offered to all in supply chain	3453	335	409	189	221		708

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