NEW LEGISLATIVE FRAMEWORK

The General National Market Surveillance Programme for the United Kingdom 2014-15

JANUARY 2014

THE GENERAL NATIONAL MARKET SURVEILLANCE PROGRAMME FOR THE UNITED KINGDOM – 2014-15

Introduction:

This document is the United Kingdom's biennial general National Market Surveillance Programme for 2014-15 for those pieces of legislation that implement Community harmonisation legislation (CHL) as required by Article 18(5) of Regulation (EC) No. 765/2008, setting the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.

General objectives of MS activities:

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 (MSA) are signed up to the Enforcement Concordat ¹which can be found on this link and the Regulators Compliance Code² which can be found on this link. 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 great deal of effort is spent on 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.

Organisation of Market Surveillance in the UK:

This is described in diagrammatic form in Annex A. Further details can be found at BIS website³ on this link.

The broad pattern of surveillance is that consumer safety and related aspects 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. 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 – Incorporating the Drivers Standards Agency and the Vehicle & Operator Services Agency.

As indicated in the diagram, non safety legislation is enforced by a number of other sector-specialist enforcement bodies e.g. The National Measurement

¹ http://www.berr.gov.uk/files/file10150.pdf

² http://www.berr.gov.uk/files/file45019.pdf

³ http://www.berr.gov.uk/files/file53488.pdf

Office 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 has a role in Ecodesign, RoHS, Tyres and Timber.

The UK's responsibilities under Articles 27-29 continue to be fulfilled by the UK's Market Surveillance Authorities (MSA), working in co-operation with the Customs and Border authorities. The UK developed legislation that took effect on 10 August 2012 which allows customs and market surveillance authorities to share information about product safety matters. The Customs Disclosure of Information and Miscellaneous Amendments Regulations 2012 were made as a result of the requirement in Article 27 (2) of EU Regulation No. 765/2008 which requires these authorities to share information. The effect of the UK Regulations is that it allows the relevant enforcement authorities to take action against the relevant economic operators in respect of unsafe or otherwise non-compliant imports.

Further details about the Regulations can be found at http://www.legislation.gov.uk/uksi/2012/1848/pdfs/uksi_20121848_en.pdf

The Department of Business, Innovation and Skills (BIS) has co-ordinated responsibility for the policy on EU Single Market Directives on product safety related issues. BIS also has legal responsibility for the implementation of EU single market Directives and Regulations in areas where they fall within BIS's areas of responsibilities.

General Approach:

The UK continues to adopt the following general approach as regards monitoring and intervention. The MSA investigate complaints of alleged non compliance and follow them up as appropriate taking into account the principle of proportionality. The MSA 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 MSA by the principles of better regulation.

A key feature of the UK's system is that the MSA are expected to develop a good understanding of the regulated businesses and apply their powers appropriately. Most MSA make their enforcement policy widely known to business via the internet and this includes the types of sanctions that they have available for non-compliance with legislation together with an explanation of their rights. An example from the MHRA is available at: http://www.mhra.gov.uk/Howweregulate/Devices/Enforcementpolicy-Complianceinspectionandaction-Yourrights/index.htm. A detailed explanation of how Regulation (EC) No 765/2008 applies to a given sector can also be found on this site.

Priority Setting:

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 MSA 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.

General Principles governing the evaluation of risks:

The UK takes a risk based approach in accordance with the established principles of better regulation as developed by the Hampton Report in 2005. http://www.bis.gov.uk/files/file22988.pdf This prescribes that market surveillance should be targeted against deliberate non-compliance so that resources are not wasted on inefficient routine inspections and that compliant business does not face unnecessary burdens as a result. This can be encapsulated as 'no inspection without a reason.'

Risk assessments are undertaken by the MSA in accordance with best practice. MSA will apply the most appropriate risk assessment for their sector of activity. For consumer goods the General Product Safety Directive (GPSD) risk assessment may be used.

Co-operation and Co-ordination

The UK's National Market Surveillance Coordination Committee, which the Government set up in 2009, is now a well established forum for cooperation and coordination. Its Terms of Reference are included in Annex B. In conjunction with this, it has also established an MSCC Stakeholders Group for the purpose of dialogue between the members of the MSCC and business and other interested parties.

The UK's two largest MSA, - 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, the UK established the Product Safety Focus Group 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, is a member of "PROSAFE".

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

The Government has also established the National Trading Standards Board (NTSB) as part of changes to the consumer protection landscape and an enhanced role for trading standards. The NTSB consists of a group of senior and experienced local government heads of Trading Standards, representing all trading standards services across England and Wales.

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 will 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.

The UK Customs authorities (HM Revenue and Customs and the UK 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 the Customs authorities and the UK MSA is imperative for 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.

To foster co-operation and to facilitate import surveillance activities on non food products entering the UK from outside the EU, the UK has established

an Intelligence Hub. It acts as a Single Point of Contact (SPoC) for the liaison between all Market Surveillance Authorities, HM Revenue and Customs and the Border Force for the border controls of unsafe and/or non compliant products entering the United Kingdom.

The UK continues to have a policy of attending all ADCOs and other similar groups when appropriate to do so. The National Measurement Office (NMO) chair two ADCOs and co-chair a third. The UK has subscribed to the Information and Communication System for Market Surveillance (ICSMS) since 2005 and uses the tool to help foster co-operation and communication with other Member States and their authorities. It continues to apply its workplan for the further integration of the system into all MSA.

The Competent Authorities and Market Surveillance Authorities aim to promote a close and continuing relationship with business and other key stakeholders. This is done bilaterally by the authorities referred to in the pie chart at Annex A and on a coordinated basis through the Market Surveillance Coordination Committee's Stakeholders' Group, which meets at least on an annual basis to influence market surveillance priorities.

Duration of the Programme:

As stated above, this is the biennial programme for 2014-15.

General Approach to Inform Relevant Parties of the Risk from a Product:

The UK has a preference for a preventive route towards enforcement. In our view most companies are (or seek to be) law abiding with only a small minority of economic operators who seek deliberately not to comply with the applicable legislation. Most non-compliance is therefore as a result of not having access to the available information or understanding what is required (a particular issue for SMEs who do not have the resource to keep track of regulatory developments). The UK therefore puts a lot of effort into ensuring that the information on our websites is as up to date and as informative as possible. This consists of information on the legislation, guidance material, reports of expert working groups in the European institutions and other relevant material.

Market Surveillance Authorities enforcement officers make visits to trade fairs or to business premises to encourage compliance. Such inspection visits are risk based to maximise the efficiency of the resources used.

General Approach when Products are found to present a Risk:

All MSA have an extensive range of statutory powers to deal with contraventions. MSA will always seek voluntary compliance from an economic operator when a product is found to contravene legislation. MSA, however, can issue formal notices to require duty holders to bring about such compliance in the products that they supply. Where the significance of non-

compliances makes it appropriate, MSA can take more rigorous action, including preventing duty holders 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.

Priority Features of the General Programme for 2014-15

The horizontal (across the board) strategic priorities for 2014-15 will be as follows:

- 1. To continue the work of the UK's Single Point of Contact (SPoC) which facilitates border controls of non-food products entering the UK from outside the EU.
- Transition of oversight of BIS managing the SPoC to the National Trading Standards Board.
- 3. To continue to take part in co-operative action with certain other Member States to develop surveillance at seaports or at centres holding goods prior to their release for free circulation in order to develop and widely disseminate skills and knowledge in the field of Customs/MSA co-operation. This includes continued UK participation in "Customs 2013".
- 4. The UK to chair two ADCOs and co-chair a third.
- 5. To ensure the wider usage of ICSMS (the Article 23 General Information Support System) by UK MSA. This will involve further training of MSAs.
- 6. To take an active role in EU meetings in the facilitation of the EC's ICSMS.
- 7. To continue to support the smooth transition of trading standards records direct onto RAPEX and maintain a RAPEX Single Contact point.
- 8. To continue to work with the National Trading Standards Board on the Safety at Ports workstream.
- To continue the Product Safety Focus Group which acts to liaise between local authorities of trading standards departments, central Government and other stakeholders on product safety issues.
- 10. To continue to monitor and review the UK's market surveillance system, through the MSCC, to ensure that all of its component parts are operating efficiently and effectively in line with the requirements of current legislation and best practice.
- 11. To ensure that MSAs and Government Departments continue to engage with business in order to reflect business strength and priorities for market surveillance, to draw on Business experience and knowledge, and to enable resource sharing.
- 12. Wider usage of the e-training package on consumer safety to MSAs.

Sector Specific Elements of the National Market Surveillance Programme:

Examples of sector specific market surveillance programmes or projects can fit into the following categories:

Cross-border exercises:

Normally arranged via ADCOs or with like minded MSA in other Member States, the project will look at specific risks related to products. Some of these may be supported financially by the Commission (in areas where there is a Community budget) but invariably they are funded directly by Member States. Such projects can be project managed either by a volunteer Member State or by a third party.

National projects:

These are compliance monitoring and enforcement projects in key areas where there are perceived risks. These projects are often funded by Central Government and may be undertaken by individual authorities working alone or collaboratively with other authorities or regional groups of Local Authorities. Often they will focus on a particular type of product and a range of such products will be sampled from the market to ascertain compliance. This can also be linked in to assessments of the test bodies to assess how well they respond to requests for testing services etc.

Testing Programmes:

These are testing campaigns aimed at assessing the levels of compliance in a particular product area. Such campaigns can be managed by third parties

Strategic enforcement priorities:

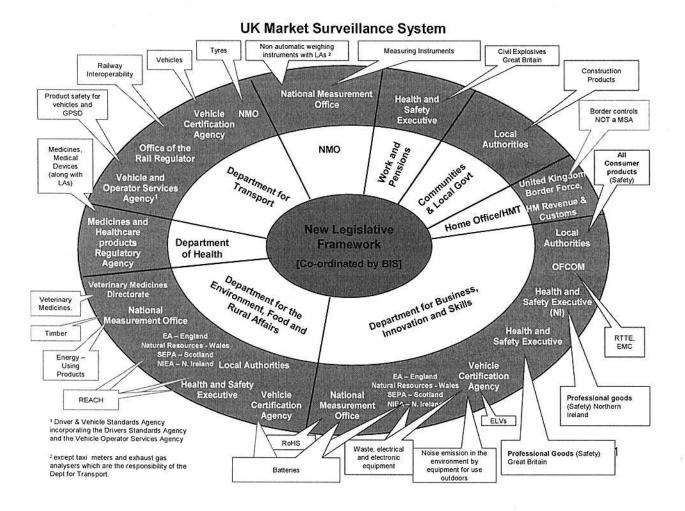
These are the risk based enforcement targets for a given piece of legislation. Normally based on areas of greatest risk to the consumer/user, enforcement with be proactive in these areas whereas in other areas (where there are lower levels of risk) the enforcement will be more reactive in nature.

Knowledge Transfer:

Work streams undertaken to inform economic operators about their obligations under specific pieces of legislation. Projects can be undertaken by and with industry partners, at a national and a local level, and at Trade Fairs where large numbers of exhibitors can be targeted with information campaigns.

Department for Business, Innovation and Skills January 2014

Annex A



UK Market Surveillance Authorities

Department of Enterprise, Trade and Investment (DETNI)

Environment Agency (EA)

Health and Safety Executive (HSE)

Health and Safety Executive Northern Ireland (HSENI)

Local Authorities (Trading Standards in Great Britain and District Councils in Northern Ireland).

Medicines and Healthcare products Regulatory Agency (MHRA)

National Measurement Office (NMO)

Northern Ireland Environment Agency (NIEA)

Ofcom

Office of the Rail Regulator (ORR)

Scottish Environment Protection Agency (SEPA)

Vehicle Certification Agency (VCA)

Driver & Vehicle Standards Agency - Incorporating the Drivers Standards Agency and the

Vehicle & Operator Services Agency

(VOSA)

Veterinary Medicines Directorate (VMD)

UK Customs Authorities

UK Border Force (UKBF)

HM Revenue and Customs (HMRC)

Government Departments

Department for Business, Innovation and Skills (BIS)

Department for Communities and Local Government (DCLG)

Department for the Environment, Food and Rural Affairs (Defra)

Department for Health (DH)

Department for Transport (DfT)

Department for Work and Pensions (DWP)

TERMS OF REFERENCE

THE UK MARKET SURVEILLANCE CO-ORDINATION COMMITTEE

1. Aim:

1.1 To take a co-ordinated and strategic approach to Market Surveillance policies and practices for those products that are marketed in the United Kingdom and subject to Community harmonisation legislation or the General Product Safety Directive. It will fulfil the function of a communication and co-ordination mechanism as envisaged by Article 18(1) of Regulation (EC) No 765/2008 (setting out the requirements for accreditation and market surveillance relating to the marketing of products - RAMS).

2. Main Issues:

- 2.1 In order to comply with Article 18(5) and 18(6), to establish, implement, review and update periodically a UK strategic market surveillance programme which will be made publicly available and communicated to other Member States and the European Commission. Such a programme will include the Committee undertaking the following activities:
 - 2.1.1 To co-ordinate views and approaches on the market surveillance policy issues that emanate from the Institutions of the European Union.
 - 2.1.2 To assess and agree how to deliver on the UK's obligations within Regulation (EC) 765/2008. More specifically this will include but not be limited to:
 - Controls of products entering the Community market at its borders (Chapter III, Section 3 of RAMS)
 - The extension of Community Rapid Information System (RAPEX) to cover industrial products
 - The adoption and use of the General Information Support System
 - Participation in Community market surveillance activities
 - 2.1.3 To encourage where appropriate co-operation across authorities in the area of market surveillance e.g. the development of multi-authority market surveillance projects (which may or may not be linked to EU projects).
 - 2.1.4 To identify, develop and spread best practices in market surveillance.
 - 2.1.5 To assess the UK's model of market surveillance and to address areas where improvements may be necessary, including the appropriateness of the range of different powers and sanctions currently used by the various authorities when applied to market surveillance activity under RAMS.

3. Working Methods:

3.1 Meetings of the Committee will take place 4 times a year. At alternate meetings, a separate, prior, open session will be held with business and other stakeholders to hear

their opinions on how the economic and other benefits of market surveillance can be maximised.

- 3.2 BERR 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 Committee will aim to produce deliverables, which will contribute towards the principles of better regulation and enhanced market surveillance in the United Kingdom. This will be agreed in advance via an annual Action Plan.
- 3.5 Working groups of the Committee (and targeted market surveillance projects) may be set up to work on particular issues or projects and to feed back to the Committee for information/agreement/adoption as necessary.

4. Membership:

4.1 Membership of the Market Surveillance Co-ordination Committee is open to relevant government departments and agencies, public authorities, co-ordinating and professional bodies engaged in or with a policy interest in the market surveillance of products or border controls in the United Kingdom.

5. General:

5.1 This document may be reviewed and varied by the agreement of the Committee.

BERR February 2009

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