

BIS | Department for Business
Innovation & Skills

NEW LEGISLATIVE FRAMEWORK

**The General National Market
Surveillance Programme for the
United Kingdom 2010**

DECEMBER 2009

THE GENERAL NATIONAL MARKET SURVEILLANCE PROGRAMME FOR THE UNITED KINGDOM - 2010

Introduction:

This document is the United Kingdom's annual general National Market Surveillance Programme 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 products 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 MSA 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 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 website (<http://www.berr.gov.uk/files/file53488.pdf>).

The broad pattern of surveillance is that consumer safety and related aspects are the responsibility of the UK's Local Authorities, 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 Department for Transport's Vehicle and Operator Services Agency (VOSA). As indicated in the diagram, non safety legislation is enforced by a number of other sector-specialist enforcement bodies e.g. for weights and measurements, environmental protection and related CHL.

The UK's responsibilities under Articles 27-29 will be fulfilled by the UK's Market Surveillance Authorities (MSA), working in co-operation with the Customs and Border authorities. Work is in hand to develop practical co-operation arrangements for a systematic structure for the information gateway.

General Approach:

The general approach as regards monitoring and intervention is as follows: The MSA **investigate complaints** of alleged non compliance and follow them up as appropriate taking into account the principle of proportionality. The MSA undertakes **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 engrained within the strategies of the MSA by the better regulation principles.

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 at: <http://www.mhra.gov.uk/Howweregulate/Devices/MarketSurveillanceandAccreditationRegulationsECNO7652008/index.htm>

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. 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. It will be a priority task for the UK's new MSCC to develop this further in 2010 (see below for more details).

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. 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 but in areas where standards are prevalent a less formal approach will be used (an example of the approach used by HSE for the Machinery Directive is at Annex B).

Co-operation and Co-ordination

The UK has established a national Market Surveillance Co-ordination Committee (MSCC). Its Terms of Reference are included in Annex C. 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, co-ordination of the individual Trading Standards services is undertaken by the Local Authorities' Co-ordinators of Regulatory Services (LACORS). The statutory body, Local Better Regulation Office (LBRO) is responsible for, inter alia, agreeing the National Priorities for Local Authorities. The Trading Standards Institute is a professional body representing Trading Standards Officers and ensuring their professional skills. Both LACORS and TSI are members of PROSAFE.

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, both organisations 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 Agency) 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.

The UK has a policy of attending all ADCOs and other similar groups. Often these groups are attended by both policy officials and those from an MSA. Policy staff attend because of their overview of the legislation and the MSA attend because it is they who are expected to co-operate in cross border activities and on practical enforcement issues etc.

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 is developing a workplan for the further integration of the system into all MSA.

Duration of the Programme:

This is the annual programme for 2010.

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.

Inspection visits to a business premises or a trade fair can be helpful in encouraging compliance by the enforcement officers imparting information on what is required. Such inspection visits are often risk based to maximise the efficiency of the resources used.

Where a particular product or category of product poses a known risk, the following route can be taken: Safety Notices are developed and disseminated to industry contacts. Press Notices are developed to inform consumers of particular risks. Guidance is developed for economic operators and available from the BIS website for circumstances in which a product recall is undertaken (whether as voluntary or as a result of an enforcement action). The guidance can be found at: <http://www.berr.gov.uk/files/file22713.pdf> .

General Approach when Products are found to present a Risk:

All MSA will 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.

It is proposed to introduce legislation that will add to the powers of certain MSA in priority areas, where this is judged appropriate by reference to the provisions of Chapter III of Regulation (EC) No. 765/2008 (see below).

Priority Features of the General Programme for 2010:

As referred to above, the horizontal (across the board) strategic priorities for 2010 will be as follows:

1. To ensure that the organisational arrangements in support of the flow of information between MSA and the UK's Customs and Border authorities enable the MSA to fulfil the UK's obligations under Article 27 of Regulation (EC) No 765/2008.
2. To propose legislation to ensure that certain MSA have strengthened powers to deal with products that present a serious risk in accordance with Article 16 and 20 of Regulation (EC) No 765/2008 and to ensure that the UK's legislative framework meets our obligations under that Regulation.
3. 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.
4. To ensure the wider usage of ICSMS (the Article 23 General Information Support System) by UK MSA. This will involve training and potentially the alignment of national interface with the ICSMS system.
5. The UK will take an active role in the management of ICSMS through the new International Non Profit Association.
6. To extend the role of the RAPEX National Contact Point to ensure that the new requirements under Article 22 are established and operational.
7. A pilot project (funded by DH) will be undertaken by the South West Public Health Observatory to carry out research into the feasibility of the collection of home and leisure injury data in order to help the UK meet its obligation under Article 18(2)(b) of Regulation (EC) No 765/2008.
8. The Consumer White Paper, published in July 2009, will make available new resources to strengthen product safety work undertaken by Local Authorities at the Ports. Also the UK will make a separate fighting fund available for Local Authorities to utilise, to support major investigations.
9. We will continue to review the UK's market surveillance system, through the MSCC, to ensure that all of its component parts are operating in line with the requirements of the Regulation.
10. The UK will continue to take part in expert exchange visits and TAIEX visits (e.g. Croatia) in accordance with Articles 25 and 26 of the Regulation.
11. The UK will participate in the expected CE marking campaign in order to strengthen the EU regulatory system.

Sector Specific Elements of the NMSP:

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 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:

Although similar to the above these are purely 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 transposed directive. Normally based on areas of greatest risk to the consumer/user, enforcement will 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 at Trade Fairs where large numbers of exhibitors can be targeted with information campaigns.

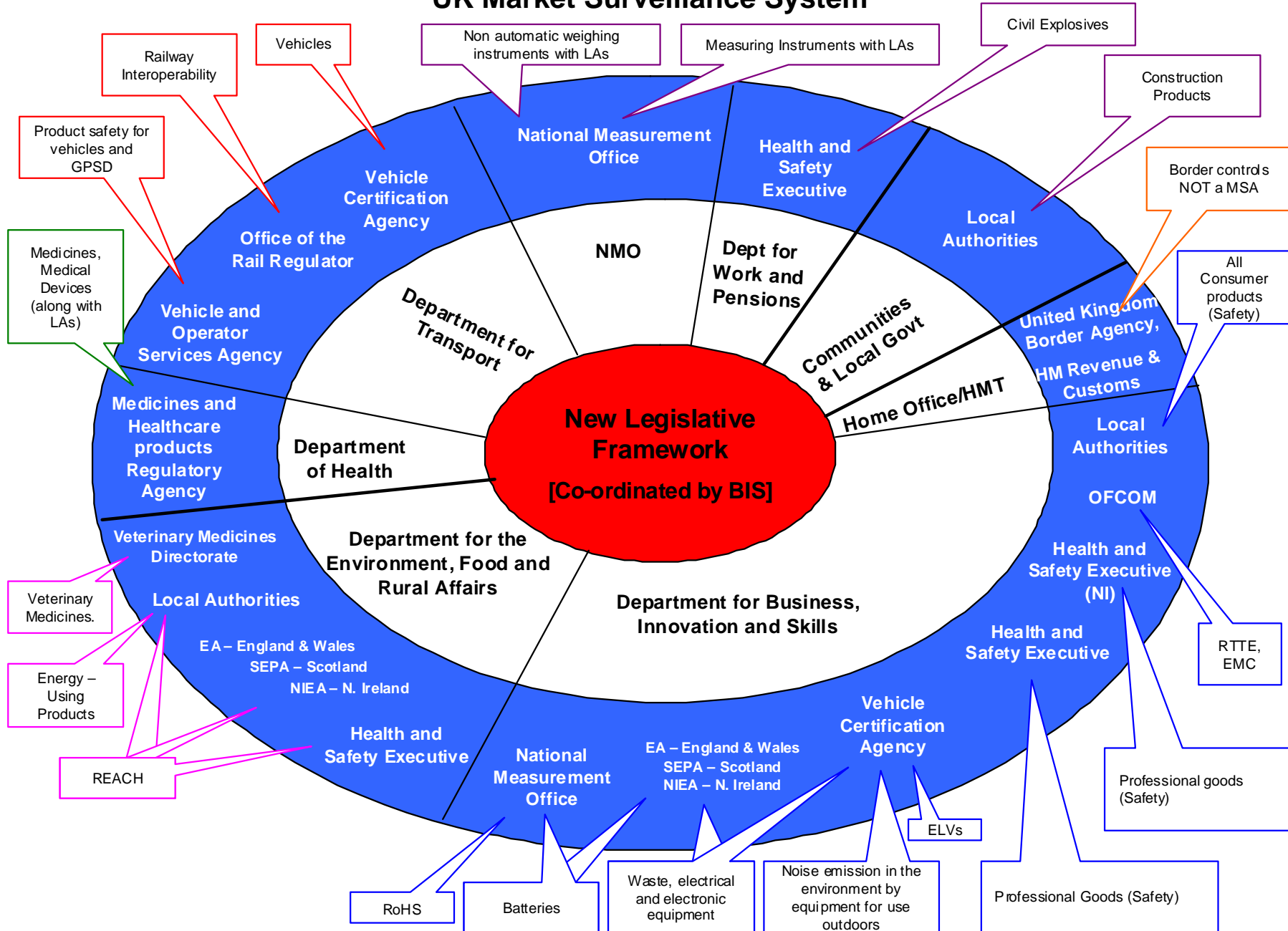
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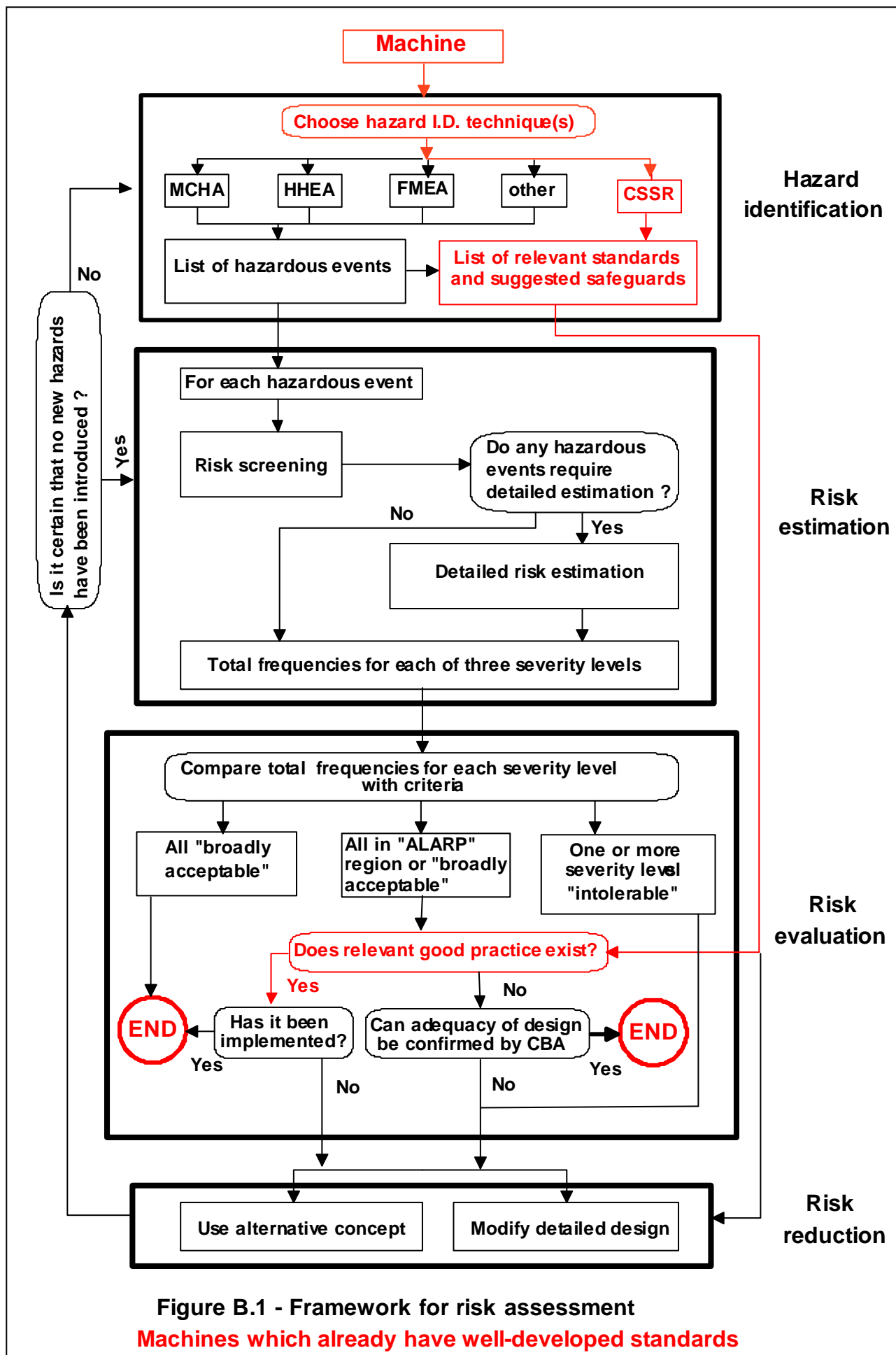
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UK Market Surveillance System





Glossary of Acronyms:

Hazard Identification:

MCHA – Machinery Centred Hazard Analysis

HHEA – Hazardous Human Error Analysis

FMEA – Failure Mode and Effect Analysis

CSSR – Concept Safety Standards Review

Risk Evaluation:

ALARP – As Low as is Reasonably Practicable

CBA – Cost Benefit Analysis (in relation to ALARP)

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
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