Department for Business Innovation & Skills

PRODUCT SAFETY AND MARKET SURVEILLANCE PACKAGE

Proposals for two new European Regulations aimed at improving consumer product safety and the functioning of the European Internal Market through effective market surveillance

JULY 2013

Content

1. Product Safety and Market Surveillance Package: Proposals for two new European Regulations aimed at improving consumer product safety and the functioning of the European Internal Market through effective market surveillance.

This consultation seeks views on the European Commission's Proposals ("the Package") for two new European Regulations aimed at improving consumer product safety and the functioning of the European Internal Market through effective market surveillance. A copy of the two Proposals and the Commission's Impact Assessment can be downloaded at:

http://ec.europa.eu/consumers/safety/psmsp/index_en.htm

The current rules on market surveillance are spread across a number of pieces of legislation and are fragmented, which has led to overlaps, gaps and confusion. The proposed Package aims to simplify the legislation, by enabling greater coherence of the rules regulating consumer product safety, improving product identification and traceability, improving coordination of the way authorities check products, ensuring regulatory compliance and market surveillance, and better enabling a level playing field in the European Internal Market.

The Government supports the Commission's overarching objective of simplifying existing legislation and those specific provisions that will clearly enable that objective to be achieved. However, there are a number of areas where the Government has identified potential difficulties, or where the benefits to the UK are not obvious and/or where there is potential to disproportionately increase burdens on British businesses.

We are asking for your views on whether you have any concerns over the Package, what could be done to address these concerns and what can be done to improve it.

Issued: 10 July 2013

Respond by: 4 September 2013

Enquiries to:
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This consultation is relevant to manufacturers, importers, distributors, retailers, consumers, government departments, enforcement authorities, trade associations, but welcome suggestions from others who may wish to be involved in the consultation process.

2. Executive Summary

This consultation seeks views on the European Commission's Proposals ("the Package") for two new European Regulations aimed at improving consumer product safety and the functioning of the European Internal Market through effective market surveillance. The two Proposals are:-

(i) Proposal for a Regulation of the European Parliament and of the Council on Consumer Product Safety and repealing Council Directive 87/357/EEC and Directive 2001/95/EC ("The Regulation on Consumer Product Safety Regulation")

(ii) Proposal for a Regulation of the European parliament and of the Council on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EU) No 305/2011, Regulation (EC) No 764/2008 and Regulation (EC) No 765/2008 of the European Parliament and of the Council ("The Regulation on Market Surveillance")

The EU Single Market allows the free circulation of goods, services, people and capital. EU legislation on Product Safety and Market Surveillance is designed to ensure a level playing field for businesses whilst ensuring that the products they bring on to the market are compliant with EU legislation and are safe to use. For the purposes of these proposals market surveillance means the activities carried out and the measures taken to ensure that products circulating on the EU's Internal Market are compliant with relevant EU legislation.

The above Proposals form part of the Package that was adopted by the European Commission on 13th February 2013. The Package also contains a multi annual plan of non-legislative measures on market surveillance; they are intended to simplify and strengthen the rules on market surveillance and to revise the current General Product Safety Directive (2001/95/EC). The two Proposals are interdependent.

The Proposal for a **Regulation on Consumer Product Safety** applies to all non-food consumer products (new and used except for antiques) including products that are used by consumers but not intended for them currently covered by the General Product Safety Directive 20051/95/EC ("GPSD"), but will extend to products that are made available to the consumer through a service provider. It therefore has a very broad application.

The key elements of the Proposal include:

- broadening the scope to subsume food-imitating products (products that resemble food but which instead have another purpose) and an extension to products that are made available to consumers via a service provider;

- greater traceability of products through the supply chain (for example distributors and manufacturers will need to include an indication of the country of origin of a product or, where that is not possible due to the size or nature of the product an indication that is included in the documentation or packaging of the product);

- clearer and more detailed obligations on businesses;

- adoption of common definitions used in EU product legislation (following the New Legislative Framework Model);

- simplified rules for the development of supporting standards, and;

- the use of delegated and implementing acts to support some aspects of the Regulation.

The Proposal for a **Regulation on Market Surveillance** applies to all products covered by EU harmonisation legislation (i.e. that which contains provisions on the Single Market for goods) currently covered by the Regulation on Accreditation and Market Surveillance 765/2008 (“RAMS”) but will extend to non-harmonised consumer products (i.e. those covered by the proposal on Consumer Product Safety), with the exception of food products and certain other exemptions. There are also some significant exclusions concerning medicines and medical devices. It is mainly addressed to Member States and their Market Surveillance Authorities but also to Economic Operators (manufacturers, distributers and importers). Therefore it also has a very broad application.

The key elements of the Proposal include provisions on:

- obligations for the organisation and conduct of market surveillance activity in Member States;

- rules on the controls and checks on products entering the European Union from 3rd countries and;

- the organisation and co-ordination of information on market surveillance activity between Member States and their Market Surveillance Authorities; and the control of products which present a risk.

New provisions include the possibility that:

- Market Surveillance Authorities may charge fees for their activities;
- new rules on the operation of the Rapid Exchange of Information System (RAPEX) and Information and Communication System for Market Surveillance (ICSMS);
- the creation of a European Market Surveillance Forum (EMSF), and;
- the designation of Union reference laboratories to support market surveillance activity and resolve disputes between Member States.

This is a UK-wide consultation and is aimed at manufacturers, importers, distributors, retailers, consumers, government departments, enforcement authorities, trade associations etc, but we also welcome suggestions from others who may wish to be involved in the consultation process.

We are interested in your views on the content of the Proposals any other concerns you might have regarding the two regulation proposals. The responses received will help to shape the UK line in negotiations on the two Regulation Proposals. Negotiations have already started and are likely to continue into 2014.

Responses to the consultations are required by 4 September 2013.

3. How to respond

Please state whether you are responding as an individual or representing the views of an organisation. If you are responding on behalf of an organisation, please make it clear who the organisation represents by selecting the appropriate interest group on the consultation form and, where applicable, how the views of members were assembled.

Please make it clear whether you are responding on the proposal for the Regulation on Consumer Product Safety, or the proposal for the Regulation on Market Surveillance of Products, or both.

The consultation response form is available electronically on the consultation page: (until the consultation closes). The form can be submitted online/by email or by letter or fax to:

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A list of those organisations and individuals consulted is in Annex 2. We would welcome suggestions of others who may wish to be involved in this consultation process.

The consultation begins on 10 July 2013 and ends on 4 September 2013 which is the last date for responses.

If you have any concerns about the way the consultation is being run please refer to the contact in Annex 1.

You may make printed copies of this document without permission.

Other versions of the document in Braille, other languages or audio-cassette are available on request.

4. Confidentiality & Data Protection

Information provided in response to this consultation, including personal information, may be subject to publication or release to other parties or to disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004). If you want information, including personal data that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence.

In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

5. Help with queries

Questions about the policy issues raised in the document can be addressed to:

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The consultation principles are in Annex 1.

6. The proposals

Current provisions on consumer product safety – The General Product Safety Directive (2001/95/EC)

The General Product Safety Directive contains the core safety provisions that must be met for many non-food consumer products i.e. products intended for use by consumers or reasonably foreseeably used by consumers. It does not cover consumer products subject to specific harmonisation legislation which include provisions covering the same aspects relating to the safety of products.

It requires that consumer products within scope are safe, provides for standard setting, imposes obligations on Member States and national market surveillance authorities and lays down procedures for the exchange of information and for rapid intervention in relation to dangerous products. However, the Commission and other stakeholders believe that the Directive needs to be revised to update its product safety rules to align them, as far as possible, with those in place for harmonised products (e.g. Toys). In particular, the obligations of businesses involved in the supply of consumer products (especially requirements relating to product identification and traceability) should be strengthened to enable market surveillance authorities to carry out their activities.

The GPSD also contains some rules on market surveillance, as do several pieces of sector-specific legislation. These market surveillance provisions and emergency procedures amongst others are now to appear in the broader Market Surveillance Proposal.

Please note that for each Proposal we have tried to summarise below the main elements, rather than focus on each individual Article.

However, comments are welcome on any provision within the proposals.
Proposal for a Regulation on Consumer Product Safety and Repealing Council Directive 87/357/EEC and Directive 2001/95/EC (“The Proposal on Consumer Product Safety”)

This proposal is for an EU Regulation which will replace the General Product Safety Directive which requires that all non-food consumer products are safe (with limited exemptions). It also subsumes and repeals Directive 87/357/EEC concerning food imitating products. It should be noted that the legislative model has changed which will have substantial implications for how it will apply in the United Kingdom. EU Regulations have direct effect and do not require transposition into UK law save in respect of creation of offences for enforcement. The main features of the Proposal are set out below:

Chapter I

This Chapter sets out the general provisions including the objective and the scope of the Proposal. It sets out the general safety requirement and provisions for how safety is to be assessed. It also includes a new requirement for an indication on a product of its geographic origin.

Article 2 – Scope

General Scope – The Proposal applies to non-food consumer products not subject to any Union product safety legislation with certain exceptions (see article 2(3)). It also applies to those products subject to specific safety legislation that harmonises the conditions for supply in the EU e.g. toys and cosmetics. Where products are subject to safety requirements in harmonised product safety legislation only Chapters I and IV apply.

Scope extension: The scope of the Proposal has been extended beyond the remit of the GPSD to cover products to which consumers are exposed in the context of a service provided to them. The GPSD only covered such products that were used by the consumer themselves in the context of a service. This therefore is a scope extension because it covers all products provided via a service except equipment on which consumers travel or ride (operated by a service provider see Article 2(3)(f)). It is not clear how wide this scope extension applies but it has potential to apply to products such as tattoo inks, dermal fillers, teeth whitening products, sun beds and many other products used by service providers.

Article 3 – Definitions: These are different to the GPSD because the aim of the Proposal is to align itself as close as possible to the New Legislative Framework (Decision 768/2008 on a common framework for the marketing of products). The definitions are mirrored as appropriate in the Proposal on market surveillance. Other definitions refer to the Standardisation Regulation (1025/2012).

Article 5 – Presumption of Safety: This differs from the GPSD in so far that it now provides a hierarchy of situations where a presumption of conformity to the general safety requirement is provided. Under the GPSD each situation listed provided a presumption of conformity or deemed conformity with the requirements.

Article 7 – Indication of Origin: This is a new provision and requires manufacturers and importers to ensure that all consumer goods bear a marking indicating the country of origin of the product. The proposal provides that country of origin marking should be placed on the product itself (or the packaging or accompanying document) and should be placed there in accordance with the non-preferential origin rules in the Community Customs Code (2913/92). EU manufactured products may refer to either the EU or the specific Member State. The costs and benefits of this provision were not addressed in the Commission's Impact Assessment.

Chapter II

This Chapter sets out the obligations on economic operators (manufacturers, authorised representatives, importers, distributors). Note that this Chapter does not apply to products subject to harmonised consumer product safety legislation. It will apply to products regulated under domestic legislation in the same way as the GPSD but will be directly applicable.

Article 8 – Obligations of Manufacturers: This is similar in concept to the provisions of the New Legislative Framework, but not identical. There is a significant requirement for manufacturers to draw up technical documentation for each product "proportionate to possible risks". Such documentation should entail a general description and its essential properties; an analysis of the possible risks and the solutions used to mitigate them; and where relevant the standards used to meet the general safety requirement.
The expression "proportionate to possible risks" we understand means that where a product presents a low risk then the documentation may be more limited in nature than a more complex product that may presents more serious risks. This documentation must be kept by the manufacturer for 10 years. Other provisions appear to remain similar to existing product safety legislation and cover traceability requirements etc.

Article 10 – Obligations of importers: This is new and aligns well with the concepts in the New Legislative Framework. However, there is also a requirement where products are manufactured outside of the EU for the EU based importer to keep the technical documentation (as required by Article 8) for 10 years. This is not aligned with the New Legislative Framework where the emphasis is on the manufacturer retaining the technical file.

Article 13 – Exemption from obligations of manufacturers, importer and distributors
This provides powers for the Commission to decide when the obligations to inform the market surveillance authorities do not apply by implementing act subject to the examination procedure. This will enable member states to contribute to the decision. This also delegates power to the Commission to decide what products do not require to be marked as required under articles 8(7) and 10(3) by way of delegated acts. While experts in member states may be consulted in this process, the final decision is that of the Commission.

Article 15 – Traceability of Products: This provision allows the Commission through delegated acts to establish a system of traceability for certain high risk products, using new technology such as barcoding, in order to be able to trace products back through a supply chain. The Commission may by implementing act subject to the examination procedure determine the type of data carrier. These powers are similar to the UK system of secondary legislation. It is envisaged that Commission Impact Assessments will be undertaken ahead of any proposed acts.

Chapter III

This Chapter sets out the requirements for the development of European standards that provide a presumption of conformity with the general safety requirement as set out in Article 5. It also provides a mechanism for the formal objection to such standards.

Article 16 – Standards: This enables the Commission to request the European Standards Organisations to develop reference standards to support the general safety requirement. This is very similar to the provisions in the EU Standardisation Regulation (1025/2012) and is intended to speed up the development of standards to assist businesses.

Chapter IV
This Chapter contains the general final provisions which set out requirements for Member States to establish rules on penalties for infringements of the proposed Regulation. It lays down the procedure for the Committee and revokes the existing superseded legislation. It also sets out the transitional provisions and for an evaluation of the legislation. It should be noted that both Proposals in the product safety and market surveillance package will come into effect on the same date.

Current provisions on Market Surveillance- Regulation on Accreditation and Market Surveillance

The Regulation on Accreditation and Market Surveillance (RAMS, Regulation No EC/765/2008, which took effect on 1 January 2010) introduced, amongst other things, a legal framework for market surveillance and new rules for the control of products entering the EU market from third countries. The market surveillance framework applies to products subject to harmonisation legislation (including products used by consumers and those designed for professional use) whilst the border control provisions apply to any products subject to EU legislation (the wider scope of “EU Legislation” means that it includes non-harmonised consumer products covered by the GPSD). Sectoral harmonisation legislation also exists which contains stand alone provisions on market surveillance.

Proposal for a Regulation of the European parliament and of the Council on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EU) No 305/2011, Regulation (EC) No 764/2008 and Regulation (EC) No 765/2008 of the European Parliament and of the Council ("The Regulation on Market Surveillance")

This Proposal is for an EU Regulation which will replace the market surveillance provisions of the Regulation on Accreditation and Market Surveillance (RAMS - Regulation (EC) No 765/2008), the General Product Safety Directive (GPSD – 2001/95 EC) and a number of sector-specific harmonisation legislation.
Although RAMS is relatively new, there is a strong argument to streamline, simplify and improve market surveillance rules and procedures to make it easier for national authorities and business to apply and understand them. In order to achieve this the Proposal on market surveillance requires the operation of market surveillance at the local/national level to be improved to exploit synergies and ensure cost efficiencies where they exist. It also requires national market surveillance authorities to cooperate better within their own territories and with their counterparts in other Member States, and that market surveillance action must be more targeted and coordinated across the Union. This could include greater resource-sharing, better IT tools and more targeted external controls at the borders of the EU

The main features of the Proposal are set out below:

Chapter I

This chapter sets out the general provisions including the objective (which is to set out a framework to verify that products within scope met high level of safety), the scope and the definitions of the proposal.

Article 2 – Scope

The scope of the Proposal is more explicit than the scope set out in RAMS and other legislation that it replaces. Chapters I, II, III, V and VI apply to products within scope of the Consumer Product Safety Proposal. Medicinal products and medicinal devices are excluded from chapters II, III and IV of the proposal and the proposal as a whole will not apply to food and food safety, rules laying down animal health requirements or rules on protective measures against pests of plants. It also contains a number of other exclusions. Chapters I and IV and article 23 shall apply to all products covered by Union legislation to the extent that other Union legislation does not contain specific provisions relating to the organisation of external border controls or to cooperation between authorities in charge of external border controls.

Article 3 - Definitions

These are different to previous legislation because the purpose is to align itself as closely as possible to the New Legislative Framework (Decision 768/2008). The definitions are mirrored as appropriate in the Proposal on Consumer Product Safety. In particular, the article defines "economic operator" in addition to "manufacturer", "authorised representative", "importer" and "distributer" – a term which is used throughout the proposal. It also defines "product presenting a risk" and "product presenting a serious risk."

Chapter II

This chapter sets out the general obligations on market surveillance authorities, including on their organisation, and the general obligations of economic operators. The majority of the obligations fall on Market Surveillance Authorities (rather than to Member States, as is the case in previous legislation) and has direct effect as this is a Regulation.

Article 4 Market surveillance obligation

This article sets out the overarching market surveillance obligation and includes provisions for market surveillance authorities to report on their activities and controls, and provide statistical information on this to the Commission every year. It is proposed that this information shall be communicated to all Member States and that Member States may make a summary of the information available to the public.

Article 6 – General obligations of market surveillance authorities

This sets out the general obligations of market surveillance authorities. They shall be obliged to perform "appropriate checks" on products and with "adequate frequency". This article also outlines the type of checks that should be made on a product. The article provides that the Commission may adopt implementing acts by way of examination procedure to establish the conditions for carrying out these checks where a known or emerging risk is present. It also sets out a number of other methods of operation for market surveillance authorities and powers to carry these out including a power of entry to the premises of economic operators.

Article 7 – Market surveillance programmes

This article is largely concerned with how Member States should organise their market surveillance programmes. It says that market surveillance authorities shall draw up a general market surveillance programme and review and update it (if necessary) at least every four years. These would include a variety of information including on the competence of the authorities that Member States designate to conduct market surveillance activity, the resources attributed to the activity and mechanisms for coordination and participation in the exchange of information among and between authorities.

Article 8 – General obligations of economic operators

This article concerns the general obligations of economic operators. It contains a provision for economic operators to provide documentation and information to market surveillance authorities to enable the authorities require to carry out their activities "in a language which can be easily understood by them". This includes information providing for traceability and identification of products.

Chapter III

This chapter is concerned with the control of products within the European Union – in particular in relation to risk. It describes the measures which Market Surveillance Authorities should take against products which present a risk and how products should be risk-assessed.

Article 9 – Products presenting a risk

This article sets out a process for identifying the extent to which products present a risk (risk assessment process is set out in article 13). It attempts to introduce a hierarchy of risk and the action that may be taken against such products, illustrating the difference between action which should be taken in relation to non-compliant products, those which also present a risk, and those which also present a serious risk.

Article 10 – Measures taken by market surveillance authorities

This article sets out the measures which market surveillance authorities may take if the identity of the economic operator can not be ascertained or where the economic operator fails to take the corrective action set out in article 9. It also introduces the possibility for market surveillance authorities to charge fees on economic operators to cover the cost of their activities, which is a new provision.

Article 11 – Union assessment for products controlled within the Union and subject to harmonisation legislation

This article provides that Member States may object to the Measures taken by another Member State in relation to non compliant products, the circumstances under which the objection might be made and the measures that the Commission might take in relation to these. It includes the possibility that the Commission may decide by implementing acts without committee procedure whether the national measures are justified and determine whether all Member States should take a similar action

Article 12 – Union action against products presenting a serious risk

This article is about the measures that the Commission may take if a serious risk is presented in relation to a compliant product that is used in accordance with its purpose or under reasonably foreseeable circumstances if that risk

can not be satisfactorily contained by a Member State. It provides the Commission with the power to prohibit, suspend or restrict the placing or making available on the market of such products. These measures may be adopted by way of implementing acts subject to the examination committee procedure and may be adopted urgently where necessary.

Chapter IV

This Chapter sets out the obligations on Member States and their border authorities in relation to the control of products entering the European Union and includes provisions on checks, the release of products, and personal imports.

Article 14 – Checks and suspension of release

This article requires authorities at in charge of the control of products at the borders of the Union to carry out “appropriate documentary and, where necessary, physical and laboratory checks” on products before they are released for free circulation. It allows them to suspend products from release if they believe the product carries a risk.

Article 15 – Release

This article is concerned with the actions which authorities in charge of external border controls must take in relation to the release of products which do not present a risk due to formal non-compliance. It says that test reports or certificates attesting conformity shall raise an assumption that a product does not present a risk. However, if these authorities have evidence that, despite such compliance, the product does in fact present a risk they may continue to withhold it.

Article 16 – Refusal to release

This article sets out the measures which Market Surveillance Authorities must employ where they conclude that products present a risk and should not be released including marking, destroying or rendering the product inoperable. It includes the possibility for market surveillance authorities to charge fees on economic operators to cover the cost of their activities, including testing carried out for risk assessment. This is a new provision.

Article 17 – Personal imports

This article attempts to make a distinction between products entering the market and personal imports and provides that dangerous products should be prevented from entering the Union.

Chapter V

This chapter sets out the systems which Member States should use to communicate information about risk and market surveillance.

Article 19 – Union Rapid Information Exchange System – RAPEX

This article provides that the system for the rapid exchange of information (RAPEX) should be used to exchange information about products presenting a risk. It does not specify whether these should be serious risks. It also provides that participation in RAPEX should be based on reciprocity and include provisions on confidentiality.

Article 21 - Information and communication system for market surveillance

This article specifies that an information and communication system for market surveillance (ICSMS) should be used to collect and store information on issues relating to market surveillance. ICSMS already exists, however it is not currently specifically designated for this function in Union legislation.

Chapter VI

This chapter sets out how Member States and Market Surveillance Authorities should cooperate with each other on matters relating to market surveillance.

Article 23 – Mutual assistance

This provides for market surveillance authorities to provide information, carry out checks or investigations and report to a requesting authority in another Member State. This is required to be processed quickly by electronic means.

Articles 25 – 27 – European Market Surveillance Forum

These articles establish a European Market Surveillance Forum (EMSF); its procedure and conduct and set out its tasks and provide for participation by the Commission. The purpose of the EMSF is for experts within Member States to exchange information on products presenting a risk and on risk assessment, and to promote training and greater understanding of market surveillance activity in the European Union. Participants will be designated by Member States according to their particular knowledge and experience. The EMSF may establish sub-groups which shall include the administrative cooperation groups for market surveillance set up for the implementation of Union harmonisation legislation. The EMSF is new and does not already exist.

Article 28 – European Union reference laboratories

This article provides for the designation of European Union reference laboratories by way of implementing act by the Commission. This is not

subject to any committee oversight. European Union reference laboratories will carry out tasks relating to specific products or categories or groups of products or for specific risks related to a category or group including product testing, resolve disputes between Member States, economic operators and conformity assessment bodies, and provide independent technical or scientific advice to the Commission and to Member States. This is a new provision.

Chapter VII

This chapter addresses the financing activities of the European Union in relation to the application of the Regulation. It provides for measures to be taken by the Commission and the European Anti-fraud Office to protect the Union's financial interests.

Chapter VIII

This chapter contains final provisions on penalties, the committee procedures that would be used in relation to implementing acts, evaluation of the application of the Regulation, amendments to existing harmonised product safety legislation and RAMS, transitional provisions and entry into force.
The following provisions are deleted:

The following provisions are deleted:

(a) Article 18 of Directive 2011/65/EU;

(b) Article 7 of Council Directive 89/686/EEC;

(c) Paragraphs 2 and 3 of Article 7 and Article 8 of Directive 93/15/EEC;

(d) Article 7 of Directive 94/9/EC;

(e) Article 7, paragraph 4 of Article 10 and Article 11 of Directive 94/25/EC;

(f) Articles 7 and 11 of Directive 95/16/EC;

(g) Articles 8, 16 and 18 of Directive 97/23/EC;

(h) Article 9 of Directive 1999/5/EC;

(i) Articles 14, 15 and 19 of Directive 2000/9/EC;

(j) Article 5 of Directive 2000/14/EC;

(k) Paragraphs 2 and 3 of Article 6 and Articles 8, 9, 10, 11, 12 and 13 of, and Annex II to, Directive 2001/95/EC;

(l) Articles 10 and 11 of Directive 2004/108/EC;

(m) Paragraphs 3 and 4 of Article 4 and Articles 11, 17 and 20 of Directive 2006/42/EC;

(n) Article 9 of Directive 2006/95/EC;

(o) Paragraphs 5 and 6 of Article 14 and Articles 15, 16 and 17 of Directive 2007/23/EC;

(p) Paragraph 5 of Article 13 and Article 14 of Directive 2008/57/EC;

(q) Articles 39, 40, 42 to 45 of Directive 2009/48/EC;

(r) Articles 7, 15 and 17 of Directive 2009/105/EC;

(s) Articles 7, 11 and 12 of Directive 2009/142/EC;

(t) Articles 56 to 59 of Regulation (EU) No 305/2011.

7. Consultation questions

The following questions will assist us in understanding stakeholder views on the Proposals, however we would welcome additional comments and information in addition to the points raised below. If you are able to provide information about the costs and benefits of the proposals it would help our estimation of the impact on stakeholders if you could specify whether these are likely to be transitory or recurring.

Proposal for a Regulation on Consumer Product Safety

1. Scope – Does the proposal give enough clarity on which products are covered? If not, what are the specific issues of concern in relation to the uncertainty?

2. Extension of scope – What in your estimation are the products affected by the scope extension (to cover product to which consumers are exposed in a service)? What are the implications of this extension for you in terms of costs/benefits?

3. Definitions – Do you consider that some of the terms used throughout the Proposal should be defined? If so, which ones?

4. Presumption of safety – Will the hierarchical structure cause difficulties in demonstrating compliance e.g. that simply complying with national regulation will not automatically confer a presumption of safety where this does not reference published European standards?

5. Indication of origin – If you are a manufacturer or importer, do you agree with mandatory requirements for all consumer products to bear an indication of origin? Can you gauge the cost of the provision? If you are an enforcement authority, in your estimation, will this improve the traceability of products?

6. Obligations of Manufacturers – What implications/benefits/disadvantages might there be in requiring manufacturers to first establish and then hold technical documentation relating to their products for 10 years? Does the requirement that this is “proportionate to the possible risks of a product” help to simplify the obligation? Are there any costs associated with this, and if so what are these likely to be?

7. Given the extremely broad scope of the Proposal and the vastly differing nature of risks, are there alternative and better ways of improving the safety of products than requiring all products to have a technical file, which would not pose additional burdens on businesses? Could you give examples of these?

8. Obligations of importers – What implications/benefits/disadvantages might there be in requiring EU-based importers to hold technical documentation

relating to products manufactured outside of the EU for 10 years? Which costs (if any) will be associated with this?

9. Exemptions from obligations to mark – Is this a matter you are content should be decided by the Commission given its cost implications or are these cases so obvious that the end result is acceptable?

10. What are the potential costs associated with the implementation of a system of traceability for high risk products? What are the advantages and disadvantages of this provision? Do you consider there should be more involvement by member states in the decision making process?

11. If you are an SME, do you expect that this proposal will have a particular impact on your business?

12. Do you have suggestions for improving the Proposal?

13. Do you envisage any unintended consequences from the approach taken by the Commission in the Proposal?

14. Do you have any general comments on any aspect of the Proposal?

Proposal for a Regulation on Market Surveillance

1. Does the scope give enough clarity on the cover provided by market surveillance activity on certain products? Is the scope sufficiently detailed?

2. Are the terms “product presenting a risk” and “product presenting a serious risk” sufficiently clear and detailed? Would it be useful to include other definitions of risk?

3. Are other terms required to be defined?

4. Are the obligations on Market Surveillance Authorities and Member States in relation to their organisation and in relation to the provision of information to the Commission proportionate? Are you able to gauge the cost of providing this information to the Commission?

5. Are the obligations on economic operators sufficiently clear? Do you think they are justified, and can you provide any evidence to support your conclusions?

6. Is the different course of action in relation to non-compliant products and products presenting a risk sufficiently clear? Is it easy to distinguish what action should be taken in relation to non-compliant products, products which present a risk, and products which present a serious risk? Are these proportionate responses to the risks in question? Why?

7. Should Market Surveillance Authorities have the ability to charge cost-recovery fees on economic operators to cover the cost of their activities? What impact do you think this will have, and can you quantify this?

8. Is the inclusion of a provision on personal imports necessary for the effective application of this Regulation? Is the wording sufficiently clear, especially in relation to what constitutes personal use?

9. Should all types of risk be reported, and if so, is it necessary for RAPEX be used? Are the obligations for reporting under RAPEX clear?

10. Is it appropriate to designate ICSMS as the European Union's system for collecting and storing information related to market surveillance activity?

11. Is the obligation to assist requesting authorities potentially onerous or would it assist in identifying and eliminating breaches in compliance so that the result is proportionate to the resources expended? Can you specify what impact this will have on you?

12. Do you support the principle of the EMSF? Do you support its composition and the range of its activities? How do you envisage this working?

13. Do you support the principle of European Union designated Reference Laboratories? Are you content that the decision relating to their application to specific products/risks is left to the Commission? To what extent might these laboratories be useful? Do you have any examples to support your view?

14. If you are an SME, do you expect that this proposal will have a particular impact on your business?

15. Do you have any suggestions for improving the Proposal?

Impact Assessment for both Proposals

1. Are you able to provide an analysis of the costs and benefits to your organisation of all or any of the provisions within both Proposals?

8. What happens next?

After the closing date the responses will be collated and summarised. These will be published on the BIS website. The Government will aim to publish the results of this consultation and provide a response by 4 September 2013.

Annex 1: The Consultation Principles

The principles that Government departments and other public bodies should adopt for engaging stakeholders when developing policy and legislation are set out in the consultation principles.
http://www.cabinetoffice.gov.uk/sites/default/files/resources/Consultation-Principles.pdf

Comments or complaints on the conduct of this consultation

If you wish to comment on the conduct of this consultation or make a complaint about the way this consultation has been conducted, please write to:

John Conway,
BIS Consultation Co-ordinator,
1 Victoria Street,
London
SW1H 0ET

Telephone John on 020 7215 6402
or e-mail to: john.conway@bis.gsi.gov.uk

However if you wish to comment on the specific policy proposals you should contact the policy lead (see section 4).

Annex 2: List of Individuals/Organisations consulted

Agricultural Engineers Association
Aromatherapy Trade Council
Association of Manufacturers of Domestic Appliances
B&Q
Baby Products Association
BBSA
Bolton Consultancy
Boots Group Plc
British Adhesives and Sealants Association
British Aerosol Manufacturers Association
British Cables Association
British Chambers of Commerce
British Coatings Federation Ltd
British Electrical and Allied Manufacturers Association
British Fragrance Association
British Furniture Federation
British Marine Federation
British Plastics Federation
British Retail Consortium
British Rubber Polyurethane Products Association
British Safety Industry Federation
British Shops and Stores Association Ltd
British Toy & Hobby Association
BSI
CAPT
Catering Equipment Supplies Association
CBI
Charity Retail Association
Chemical Industries Association
Chemical Industries Association
Clifford Chance
CO-Gas Safety
Construction Equipment Association
Construction Products Association
Construction Products Association
Crossing the Boundaries Regional Safety Group
CTPA
DCLG
Department for Environment, Food and Rural Affairs
Department of Health
Electrical Safety Council
Federation of Small Businesses
FIRA
GAMBICA
Gas Safe Register
Health Protection Agency

Home Office
Home Retail Group
HSE
HSENI
IKEA
IntellectUK
IoD
John Lewis
Leisure and Outdoor Furniture Association
Leisure Plan
Local Government Association
Mail Order Traders' Association
Manufacturing Technologies Association
Marks & Spencer
MHRA
Mothercare
National Bed Federation
National Childrenswear Association
National Market Traders Federation
Next
Packaging Federation
Royal Society for the Prevention of Accidents
Royal Yachting Association
Safety Assessment Federation
Sainsbury’s
SATRA
Shop Direct Group Limited
Small Electrical Appliance Marketing Association
Solvents Industry Association
Tesco
The Lighting Industry Association
The Lighting Industry Federation
The Society of Motor Manufacturers & Traders Ltd
Trade Association for the Domestic Heating and Hot Water Industry
Trading Standards Institute
UK Cleaning Products Industry Association
UK Cleaning Products Industry Association
UKAS
UKTLF
Vehicle Certification Agency
VoSA
Which?

Annex 3: The Product Safety and Market Surveillance Package response form

The Department may, in accordance with the Code of Practice on Access to Government Information, make available, on public request, individual responses.

The closing date for this consultation is 4 September 2013.

Name:

Organisation (if applicable):

Address:

Please return completed forms to:

Michael Porter,
Materials, Chemicals & Product Regulation,
4TH Floor, Orchard 1,
Department of Business, Innovation and Skills,
1 Victoria Street,
London SW1H 0ET.
Tel: 020 7215 6078
Fax: 020 7215 6862
Email: productsafetypackage@bis.gsi.gov.uk

Please can you tick a box from a list of options below that best describes you as a respondent.

	Business representative organisation/trade body
	Central government
	Charity or social enterprise
	Individual
	Large business (over 250 staff)
	Legal representative
	Local Government

	Medium business (50 to 250 staff)
	Micro business (up to 9 staff)
	Small business (10 to 49 staff)
	Trade union or staff association
	Other (please describe)

Proposal for a Regulation on Consumer Product Safety

Question 1: Scope – Does the proposal give enough clarity on which products are covered? If not, what are the specific issues of concern in relation to the uncertainty?

Comments:

Question 2: Extension of scope – What in your estimation are the products affected by the scope extension (to cover product to which consumers are exposed in a service)? What are the implications of this extension for you in terms of costs/benefits?

Comments:

Question 3: Definitions – Do you consider that some of the terms used throughout the Proposal should be defined? If so, which ones?

Comments:

Question 4: Presumption of safety – Will the hierarchical structure cause difficulties in demonstrating compliance e.g. that simply complying with national regulation will not automatically confer a presumption of safety where this does not reference published European standards?

Comments:

Question 5: Indication of origin – If you are a manufacturer or importer, do you agree with mandatory requirements for all consumer products to bear an indication of origin? Can you gauge the cost of the provision? If you are an enforcement authority, in your estimation, will this improve the traceability of products?

Comments:

Question 6: Obligations of Manufacturers – What implications/benefits/disadvantages might there be in requiring manufacturers to first establish and then hold technical documentation relating to their products for 10 years? Does the requirement that this is "proportionate to the possible risks of a product" help to simplify the obligation? Are there any costs associated with this, and if so what are these likely to be?

Comments:

Question 7: Given the extremely broad scope of the Proposal and the vastly differing nature of risks, are there alternative and better ways of improving the safety of products than requiring all products to have a technical file, which would not pose additional burdens on businesses? Could you give examples of these?

Comments:

Question 8: Obligations of importers – What implications/benefits/disadvantages might there be in requiring EU-based importers to hold technical documentation relating to products manufactured outside of the EU for 10 years? Which costs (if any) will be associated with this?

Comments:

Question 9: Exemptions from obligations to mark – Is this a matter you are content should be decided by the Commission given its cost implications or are these cases so obvious that the end result is acceptable?

Comments:

Question 10: What are the potential costs associated with the implementation of a system of traceability for high risk products? What are the advantages and disadvantages of this provision? Do you consider there should be more involvement by member states in the decision making process?

Comments:

Question 11: If you are an SME, do you expect that this proposal will have a particular impact on your business?

Comments:

Question 12: Do you have suggestions for improving the Proposal?

Comments:

Question 13: Do you envisage any unintended consequences from the approach taken by the Commission in the Proposal?

Comments:

Question 14: Do you have any general comments on any aspect of the Proposal?

Comments:

Proposal for a Regulation on Market Surveillance

Question 1: Does the scope give enough clarity on the cover provided by market surveillance activity on certain products? Is the scope sufficiently detailed?

Comments:

Question 2: Are the terms "product presenting a risk" and "product presenting a serious risk" sufficiently clear and detailed? Would it be useful to include other definitions of risk?

Comments:

Question 3: Are other terms required to be defined?

Comments:

Question 4: Are the obligations on Market Surveillance Authorities and Member States in relation to their organisation and in relation to the provision of information to the Commission proportionate? Are you able to gauge the cost of providing this information to the Commission?

Comments:

Question 5: Are the obligations on economic operators sufficiently clear? Do you think they are justified, and can you provide any evidence to support your conclusions?

Comments:

Question 6: Is the different course of action in relation to non-compliant products and products presenting a risk sufficiently clear? Is it easy to distinguish what action should be taken in relation to non-compliant products, products which present a risk, and products which present a serious risk? Are these proportionate responses to the risks in question? Why?

Comments:

Question 7: Should Market Surveillance Authorities have the ability to charge cost-recovery fees on economic operators to cover the cost of their activities? What impact do you think this will have, and can you quantify this?

Comments:

Question 8: Is the inclusion of a provision on personal imports necessary for the effective application of this Regulation? Is the wording sufficiently clear, especially in relation to what constitutes personal use?

Comments:

Question 9: Should all types of risk be reported, and if so, is it necessary for RAPEX be used? Are the obligations for reporting under RAPEX clear?

Comments:

Question 10: Is it appropriate to designate ICSMS as the European Union's system for collecting and storing information related to market surveillance activity?

Comments:

Question 11: Is the obligation to assist requesting authorities potentially onerous or would it assist in identifying and eliminating breaches in compliance so that the result is proportionate to the resources expended? Can you specify what impact this will have on you?

Comments:

Question 12: Do you support the principle of the EMSF? Do you support its composition and the range of its activities? How do you envisage this working?

Comments:

Question 13: Do you support the principle of European Union designated Reference Laboratories? Are you content that the decision relating to their application to specific products/risks is left to the Commission? To what extent might these laboratories be useful? Do you have any examples to support your view?

Comments:

Question 14: If you are an SME, do you expect that this proposal will have a particular impact on your business?

Comments:

Question 15: Do you have any suggestions for improving the Proposal?

Comments:

Do you have any other comments that might aid the consultation process as a whole?

Please use this space for any general comments that you may have, comments on the layout of this consultation would also be welcomed.

Impact Assessment for both Proposals

Question 1: Are you able to provide an analysis of the costs and benefits to your organisation of all or any of the provisions within both Proposals?

Comments:

Thank you for taking the time to let us have your views. We do not intend to acknowledge receipt of individual responses unless you tick the box below. Please acknowledge this reply ☐

At BIS we carry out our research on many different topics and consultations. As your views are valuable to us, would it be okay if we were to contact you again from time to time either for research or to send through consultation documents?

☐ Yes ☐ No

This publication is also available on our website at www.gov.uk/bis

Any enquiries regarding this publication should be sent to:

Department for Business, Innovation and Skills
1 Victoria Street
London SW1H 0ET
Tel: 020 7215 5000

If you require this publication in an alternative format, email enquiries@bis.gsi.gov.uk, or call 020 7215 5000.

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