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European standards and the UK

How are business and industry standards developed and used in the European Single Market?

What would be the impact of a UK exit from the EU on the UK's participation and influence in the European standards system?

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Questions and answers about European standards

This document provides the general reader with factual information on the possible impact of a UK decision to exit the European Union as far as this relates to UK participation in the making and use of European standards. It comprises a set of questions and answers that summarizes the role of standards in the European Single Market.

The information in this document has been prepared by BSI (British Standards Institution), which is appointed by the UK Government (HMG) to act as the UK National Standards Body (NSB). In this role, BSI is responsible for the structures that enable the UK to participate in national, European and international standards-making systems and for overseeing the portfolio of those standards adopted in the UK.

No judgement is made nor should be inferred from the information provided in this document over the merits or demerits of UK membership of the EU.

Throughout this document the word 'standards' refers to all standards that:

- are developed through a formal process;
- are managed by the NSB; and
- meet the World Trade Organization (WTO) principles of stakeholder engagement, open public consultation and consensus.

Whether international, European or national, standards play a vital role in the UK market as voluntary codes, guidance and specifications for organizations to use either for their own purposes or to support compliance with contractual or regulatory obligations.

In its work as the NSB, BSI manages around 1,200 committees (comprising over 11,000 members, all volunteers), publishes around 2,500 standards per year and withdraws around 1,000 standards per year that are no longer needed by the market or conflict with

new standards adopted in the UK. Around 95 per cent of BSI's work is on international and European standards.

The paper is presented as a series of five principal questions and answers:

1. What are standards and why are they important for industry?
2. What is the European Single Market?
3. What benefits do European standards bring to the European Single Market?
4. How are these benefits delivered?
5. What would be the impact of a UK exit from the EU in terms of UK participation in the European standardization system?

A summary of the main points is provided in section 6, following which eight supplementary questions are addressed, giving more detail on Questions four and five.

1. What are standards and why are they important for industry?

Standards are effectively a body of knowledge, available to all, that helps build trust and deliver aspirational performance of goods or services. They support trade, interoperability, quality, performance, innovation and market access. Standards may describe good business practices, set out guidance or document technical specifications. They facilitate business-to-business (B2B) and business-to-consumer (B2C) transactions around the world. European standards help businesses and industry trade more easily within the European Single Market.

Standards are developed by industry experts with the involvement of other interested parties (such as societal organizations, academics and regulators). A formal consensus process is used that includes open public scrutiny. Standards are also maintained through a formal committee structure independent of government, commercial or societal interests.

Compliance with a standard is up to the market:

- Where standards are used voluntarily to enable business performance or improvement, then the extent of compliance is a matter for the organization's management to decide.
- Where standards are used by industry to support procurement or sale of goods and services, compliance is a matter for the two parties concerned, buyer and seller.
- Where standards are used in connection with regulation, i.e. where there is a regulatory obligation on a supplier that makes reference to a standard, any obligation to demonstrate compliance will be specified by the regulation. Around a quarter of European standards are associated with legislation and other public policies.

If a buyer of a certain product wants to see evidence of compliance then they may ask the supplier either to declare that their product is compliant (self-declaration), or to provide evidence of independent audit, testing or certification.

Accredited certification is where the supplier's products or services are assessed by a third party organization (a certification body) and a certificate is issued confirming that the product/service passed the assessment. The certification body itself is accredited to certify others

within a certain scope of activity and for a period of time by a national accreditation body. A good example of this is the accreditation of testing laboratories to test and certify products.

International and European standards are written in the same way as national standards. Participation in European and international standards development is arranged by the NSB of each country via their membership of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) or their European counterparts the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC). Standardization is organized on the basis of national delegations, where each delegation contributes the national consensus position of its experts and interested parties. The processes used follow WTO- and EU-recognized principles of transparency, openness, coherence, impartiality, consensus, effectiveness and relevance.

Standards are not the same as regulation: standards are drafted for voluntary use. In the European Single Market the approach to the use of standards follows the definition in the WTO's Technical Barriers to Trade Agreement (WTO TBT)¹, which differentiates between the concept of mandatory technical regulations and voluntary standards. There are a small number of European regulations that refer to industry standards in a way that makes compliance a legal requirement, but these are the exception.

¹ https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

1.1 The single standard model that underpins the European Single Market

The single standard model supports the European Single Market as it means that there is only one standard in use across all the countries of the single market on any given issue. The model is favoured by industry because it reduces the number of standards that an enterprise may have to consider in order to trade across borders. It also reduces cost and increases choice for consumers by making it easier for goods and services to be traded. Businesses gain the benefits of market-driven good practice developed by broad communities of experts through robust and open standardization processes.

All European standards respond to the needs of the European Single Market. This can include public policy. There are European standards for products, testing methods, business processes (such as procurement) and increasingly, for services.

Governance of European standards is managed by the European Standardization Organizations CEN and CENELEC (known as ESOs²) whose membership comprises the NSBs of 33 European countries – including all the Member States of the European Union (EU) and other countries that are part of the European Single Market³. It is a condition of membership of both CEN and CENELEC that all European standards are adopted identically by all members.

Around 25 per cent of European standards are developed following a European Commission (EC) request, and the resulting standards support public policy in a variety of ways. The majority of these standards specifically respond to harmonized regulatory requirements across the single market. The single standard model means that – where standards are used in this way by policy makers – only one standard is needed to meet a specific aspect of regulation (Question 4 provides more detail on how standards work with European regulation). One national member will lead the activity and other countries will participate depending on industry interest. Such standards are known as 'harmonized standards' and are given the designation 'hEN'. They provide one means of meeting the regulatory requirement while remaining voluntary.

The 75 per cent of European standards that are not developed to meet European Commission requests meet other market needs and include test methods, terminologies, specifications for products and services, business process standards and guidance on good practice.

² There are three ESOs in total. The third ESO is ETSI, an organization that specializes in telecommunications standards and uses a different participation model to CEN and CENELEC. It carries out a range of activities in addition to its obligations as an ESO. ETSI's membership includes global industry players as well as NSBs and others. As with CEN and CENELEC, ETSI is subject to EU Regulation 1025/2012 in relation to its activities as an ESO.

³ A full explanation of the European Single Market can be found at the answer to Question 2.

1.2 Withdrawal of conflicting standards – a fundamental principle

CEN and CENELEC rules require that when work is started on a European standard, a 'standstill' procedure applies and members cannot start or continue national work on the same subject. Once a European standard is published, CEN and CENELEC members are required to implement the European standard as a national standard and withdraw any pre-existing standards that conflict with the new European standard. National standards development has to be reported at least annually by each NSB under the European Union Regulation (EU) No. 1025/2012 on European standardization to provide transparency on the national work programmes. In the case of harmonized standards, standstill and withdrawal have regulatory force.

Voting on a new standard broadly follows the principles of the EU Treaties, with weighted voting by the member countries based on a series of parameters, principally population. The UK currently has just over 7 per cent of votes at the main stages of the development process of each CEN and CENELEC standard.

The ESOs are the only organizations authorized to create European standards. Around 19,000 European standards have been created by CEN and CENELEC, and this has resulted in the withdrawal of around 160,000 national standards as the single market has grown.

Figure 1, Standards in the European Single Market, shows different types of standards and their market uses. It also shows the relationship with EU product legislation and illustrates the primary role of standards in supporting business and industry and their secondary role in supporting European or national public policy.

It is the policy of the European Commission, supported by CEN and CENELEC and their members, that there should be a primacy of international standards in Europe. In other words, the ESOs do not develop European standards unless there is a specific European need. Instead CEN, CENELEC and their members including BSI prefer to work at an international – as opposed to European – level (through ISO and IEC) and then adopt those standards in Europe as ENs. The most common reason to develop a European or national standard in the absence of an international standard is to support a European or national regulatory requirement.

Standards are also used in national markets as a way to deliver national government policies.

The UK currently has just over 7 per cent of votes at the main stages of the development process of each CEN and CENELEC standard.

2. What is the European Single Market?

The European Single Market comprises the 28 Member States of the EU, with over 500 million consumers, plus the four members of the European Free Trade Association (EFTA): Norway, Iceland, Liechtenstein and, through bilateral agreements, Switzerland. The influence of the European Single Market is further extended by the customs union with Turkey; EU accession negotiations with Albania, FYROM, Montenegro and Serbia; and negotiations with other countries under the European neighbourhood policy.

The European Single Market is based on the principle of free trade without barriers and with the simplest possible trading conditions. The legal requirements and standards within the single market aim at ensuring the free movement of goods while ensuring a high level of health and safety and other relevant protection for citizens.

The European Single Market is the largest free trade area in the world and the most sophisticated in terms of the role and governance of standards.

The EU is now focusing on the advancement of the single market, looking in particular at the free movement of services, one of the four essential freedoms (see Question 3 below). There remain many restrictive national practices in terms of trade in services across borders. For example, lawyers in Austria are prevented from practising in Germany, despite the common language and close proximity. There are also plans to reflect the emergence of the digital economy through a digital single market.

Figure 1 Standards in the European Single Market



Types of standards for products, services and business processes:



25% of European and national standards also serve public policy needs

European public policies are supported through:		UK national public policies are supported through:		
Co-regulation	Self-regulation	Co-regulation	Self-regulation	Earned recognition
Example: New Approach	Example: e-accessibility	Example: Plugs and sockets regulations	Example: use of Prequalification questionnaires	Example: DECC Energy Savings Opportunities Scheme

3. What benefits do European standards bring to the European Single Market?

The European Single Market is fundamental to the 'four freedoms' of the EU Treaty: freedom of movement of people, goods, services and capital. It involves the removal of tariff and non-tariff ('technical') barriers to trade (known as TBT).

Removing non-tariff barriers means minimizing technical trading differences across all participating countries. This is achieved in three ways: through mutual recognition of national requirements and through EU regulatory harmonization (see Question 4), as well as through European standardization.

The elimination of tariffs and TBTs brings lower costs throughout the supply chain, thus increasing competitiveness. That in turn brings benefits of lower costs and greater choice for consumers, along with an agreed level of consumer protection.

There are a number of benefits to the single market for business and industry that come from standards and a set of single, or mutually recognized, legal requirements:

- A product placed anywhere on the single market has free circulation.
- There is no need to have different product variants for different markets.
- There are economies of scale in production with lower unit costs.
- There are no additional testing costs to enter other states within the market.

4. How are these benefits delivered?

The single market is delivered through regulatory and voluntary measures at European and national level, primarily through either mutual recognition or a process of harmonization.

The single market for products is based on the principle of mutual recognition: unless there is specific national legislation or harmonization then the mutual recognition of national legislation applies. Figure 2, EU regulatory models in the single market for products, shows how products either fall under the non-harmonized area, where national legislation or mutual recognition applies, or under the harmonized area, where standards are used in a variety of ways to support legislation.

Harmonization can take different forms: it can be minimum harmonization or one of several types of 'total' harmonization. These are referred to as the New and Old Approaches. There is also legislation that combines elements of both (called here 'mixed approach'). One of the examples shown here is the Construction Products Regulation (CPR) where voluntary standards developed by industry and other stakeholders are made mandatory by regulation.

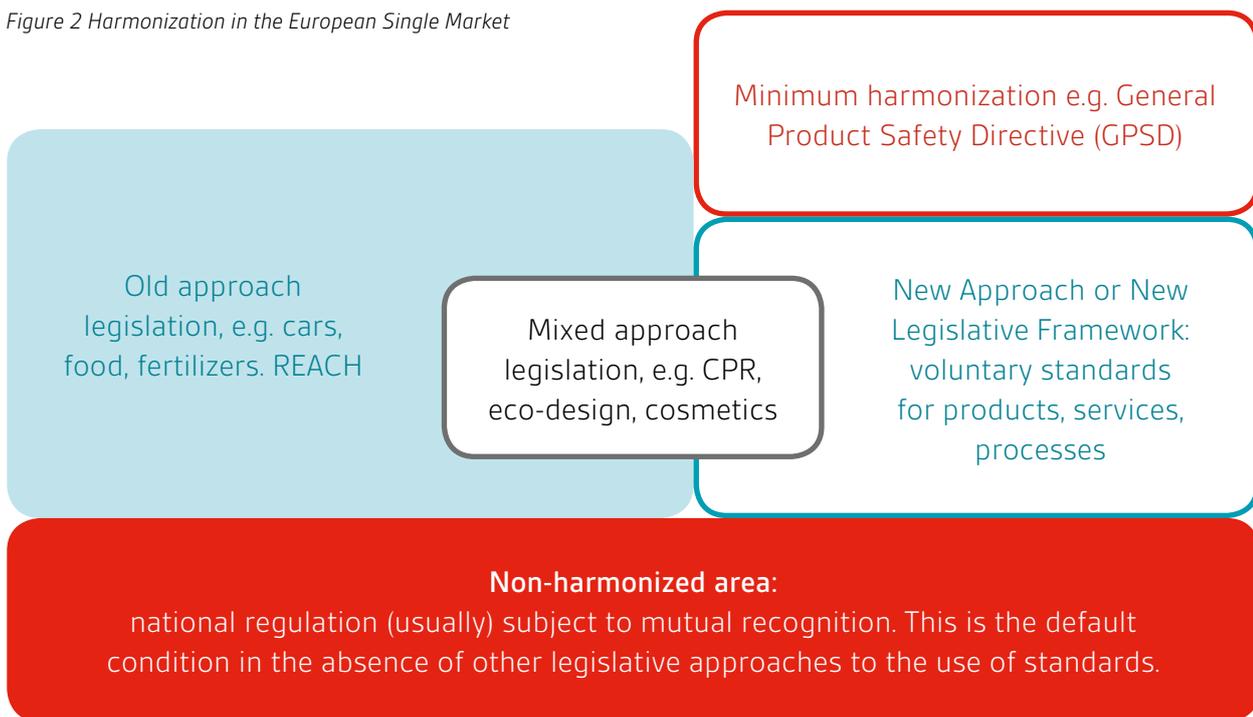
Only around 25 per cent of European standards are associated with public policies and legislation. Under the New Approach, where individual standards are specifically identified, they are referenced as a means of compliance, not the means of compliance. Use of standards referenced in this way is voluntary. The responsibility for complying with the requirements of the regulation rests with the supplier of the goods or services.

A description of harmonization in the EU, with a focus on the New Approach, is contained in the European Commission's authoritative 'Blue Guide on the implementation of EU product rules'⁴.

More information on the benefits of standards is available in the 'More details' section at the end of this document, specifically addressing the questions:

- 4.1 What is mutual recognition of legislation and how does it relate to standards?
- 4.2 Can national legislation override mutual recognition and legitimately cause barriers to trade?
- 4.3 How does harmonization of regulation apply to the single market?
- 4.4 What is the New Approach/New Legislative Framework?
- 4.5 What is the Old Approach and where is it still used?
- 4.6 Is there any overlap between the New Approach and the Old Approach?
- 4.7 What does Minimum Harmonization mean?

Figure 2 Harmonization in the European Single Market



⁴ <http://ec.europa.eu/DocsRoom/documents/11502>

5. What would be the impact of a UK exit from the EU in terms of UK participation in the European standardization system?

This section explains how a possible UK exit from the EU would affect UK participation in the European standardization system. Should the referendum on 23 June 2016 result in the UK leaving the EU, it is reasonable to assume that there would be an urgent re-negotiation of trade agreements with both the EU and other countries. There would be a number of impacts on BSI in its role as the UK NSB, most importantly on its role to represent UK interests in the development and use of standards by business and industry for trade, interoperability, quality, performance, innovation and market access (see Question 1). Clearly the precise impacts would depend on a range of political choices that would be made by HMG, some of them in conjunction with the EU and/or EFTA countries.

5.1 What would be the impact of UK exit from the EU on the UK memberships of CEN, CENELEC, ETSI, ISO and IEC?

Membership of ISO, IEC, CEN and CENELEC has been essential to the UK's participation in international trade as a member of the WTO, and to fulfilling its obligations as a member of the European Single Market. In the event of the UK leaving the EU, there would be consequences for the UK's eligibility to participate in CEN and CENELEC. These impacts would depend on the political decisions made over future trade agreements. A range of options are considered here to illustrate the impacts:

1. The UK applies for membership of EFTA and then seeks to sign the European Economic Area (EEA) agreement (like Norway and Iceland).
2. The UK applies for membership of EFTA but remains outside the EEA, negotiating bilateral trade agreements with the EU (like Switzerland).
3. The UK relies on the WTO TBT Agreement to protect the UK in international trade.
4. The UK negotiates bilateral trade agreements with the EU without being an EFTA member.

The House of Commons paper of February 2016⁵ presents two scenarios that encompass the list above:

- EU exit without a free trade agreement (as 3 above);
- EU exit under a negotiated arrangement, including an EEA and Swiss arrangement (as 1, 2 and 4 above).

The House of Commons paper comments that: 'Membership of the EEA or the negotiation of bilateral agreements analogous to those in Switzerland would also require the UK to continue to adopt EU product standards (and other regulations) across the whole economy.'

Each of these scenarios would have different impacts on BSI's membership of CEN and CENELEC and hence on the UK's ability to influence the European standardization system.

In the first two options above (1 and 2), it is anticipated that BSI would retain membership of CEN and CENELEC without challenge. BSI would meet both the membership requirements of the CEN and CENELEC statutes and the criteria for membership (ways of working). In these circumstances, the impacts would be minimal in terms of the UK's membership rights within CEN and CENELEC.

⁵ House of Commons Library Briefing Paper No 07213 *Exiting the EU: Impact in key UK policy areas*, 12 February 2016

However there would be impacts in terms of relationships with partner countries and on the ability of the UK's NSB to influence regulatory policy at European level (see Question 5.2).

In the case of options 3 and 4, BSI would need to argue for the continuation of UK membership of CEN and CENELEC. Continuing membership in these circumstances would depend upon other CEN and CENELEC members agreeing to change the statutes in order to create a category of membership fitting the UK situation. Arguments could include historical membership, economic significance, commitment to and involvement in the system. Acceptance of these arguments would probably depend on whether the UK continued to commit to the adoption of all European

standards (on a voluntary basis as a non-member of the EU) and to the fundamental principles of standstill and withdrawal (see Question 1.1 and 1.2). Without such a commitment, it is likely that the UK membership of CEN and CENELEC would be challenged on the grounds of a lack of commitment to reciprocity of market access.

BSI's membership of ETSI would not be affected as its rules of membership are different.

An EU exit would not affect the UK's membership of the two main international standardization organizations, ISO and IEC, but it would potentially affect relations with strategic international partner countries such as China and Japan, see Question 5.2.

5.2 General impacts on standardization in the UK of EU exit

It is possible that the UK's standing and influence in the regional and international standardization organizations would decline in the event that the UK left the EU.

Relations with other major European NSBs (particularly Germany and France), with whom BSI collaborates closely at present, would be affected. The UK benefits from its strong relationships with France and Germany, forged in part because of the common challenges the three countries face in the evolution of the European standardization system and the single market.

Discussions with European regulators are frequent and the informal exchange of information with the European institutions provides an opportunity to influence the direction of European regulation and the way in which European standards may be developed to support the delivery of policy. The UK's influence in these discussions would be reduced were the UK no longer an EU member.

Similarly, the strength of BSI's bilateral relations with trading partners such as China or Japan would potentially be diminished as the UK would not have the same level of influence on the use of standards in the European Single Market as it did as a member of the EU.

No longer being an EU member, the UK might seek to interact with the EU in one of the four ways identified in Question 5.1 (EFTA and EEA membership; EFTA membership only; reliance on WTO TBT Agreement; or bilateral agreements without EFTA membership). In each of these cases, the power of the UK to influence EU policy and legislation in the European Commission, the European Parliament and in the Council would be curtailed.

It might be possible for the UK to exert influence at an early stage in Commission discussions on new proposals for legislation, but the UK would not have the voting power currently held that is critical to achieving desired outcomes in any situation, see Question 5.3. It is worth noting in this context that the influence over EU legislation of the EEA nations has reduced with the increase in power of the European Parliament (as co-legislator) following recent European Treaty changes.

This issue of loss of influence where standards interface with public policy and regulation is probably the most serious negative impact for the UK of an exit from the EU. Specifically in terms of standardization, the UK would lose influence over:

- a. the EU regulatory framework for standardization;
- b. any EU legislation that relies on standards (such as New Approach technical harmonization legislation for most products on the market, also consumer safety and energy efficiency);
- c. European Commission standardization requests (formerly known as 'mandates');
- d. the publication of references of 'harmonized standards' in the EU Official Journal that confers a presumption of conformity with legislation;
- e. formal objections against standards, made by the European Commission or Member States that can remove this 'presumption of conformity'.

One possible scenario is that the UK could have to accept European regulation and the harmonized European standards that support it as a condition of reciprocal market access. The alternative (which is effectively a refusal to adopt European standards and to withdraw conflicting national standards) would create additional barriers to the export of UK products and services as different standards could be needed for domestic and European markets.

More detail on this topic is available in the 'More details' section at the end of the document, see Question 5.3 How does the EEA/EFTA operate with the European Single Market rules?

6. Summary of answers

European standards provide a means for business and industry to trade more easily within the European Single Market. They are developed through a consensus process by industry experts and all the other stakeholders likely to be affected by the standards. Standards are maintained for as long as the market needs them through a formal committee structure managed by the national members of CEN and CENELEC. This process is independent of government, commercial or societal interests.

Standards may describe good business practices, set out guidance, or document technical specifications. Standards are effectively a body of knowledge available to all that helps build trust and deliver aspirational performance. They are subject to open public consultation.

Only around 25 per cent of European standards are associated with public policies and legislation. Under the New Approach, where individual standards are specifically identified, they are referenced as a means of compliance, not the means of compliance. Use of standards referenced in this way is voluntary. The responsibility for complying with the regulation rests with the supplier of the goods or services.

Across the European Single Market the single standard model means that there is only one standard for any given issue, whether technical, process or guidance. The withdrawal of any conflicting standards in the countries of the single market is a fundamental principle to ensure that there are no technical barriers to trade. Therefore, where the standard is associated with European regulation, every country must adopt the same regulatory requirement as well as the voluntary standard linked to it.

If the UK were to leave the EU, future UK influence over the European standardization system would depend largely on a range of political choices that would be made by HMG, including whether or not the UK continued to commit to the adoption of European standards and the withdrawal of conflicting national standards.

In this circumstance, even if the UK remained outside the EEA and EFTA, it is likely that BSI's membership representing the UK in CEN and CENELEC would be unaffected. However, if the UK refused to commit to the adoption of European standards (and the associated regulatory framework) then the UK's continued membership of CEN and CENELEC would be in question. In either circumstance, the UK's influence on European standardization policy and on European legislation that makes use of standards would be reduced.

Similarly, BSI's relationships with its opposite numbers among strategic partners in the European standardization system, particularly France and Germany, would be lessened.

Only around 25 per cent of European standards are associated with public policies and legislation

More details

Question 4

The European standardization system

4.1 What is mutual recognition of legislation and how does it relate to standards?

Mutual recognition is the principle of the European Single Market that products lawfully manufactured in one Member State can be marketed freely throughout the single market. Other Member States cannot prohibit their supply without good and explicit reason. This approach is set down in the Treaty for the Functioning of the European Union (TFEU), 2009. There is additional specification in Regulation 764/2008, part of the New Legislative Framework that updated and consolidated the rules for the single market for goods.

Member States are free to legislate in their own territory subject to the principles of mutual recognition in TFEU and to any harmonization legislation.

Mutual recognition applies unless there is harmonization legislation or additional national measures⁶. National measures are permitted only in specific cases outlined in the TFEU Article 36: "public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property". This means that Member States can introduce TBTs, subject to restrictions in the Treaty and to requirements of harmonization.

The additional rules that can be introduced by Member States under TFEU may refer to standards in whichever way the Member State chooses. CEN-CENELEC Guide 30⁷ has examples from France and the Czech Republic of national legislation that refers to standards in a way that leaves them voluntary. The UK also has such examples, although a small number of these make standards mandatory (e.g. the furniture fire safety regulations).

4.2 Can national legislation override mutual recognition and legitimately cause barriers to trade?

Yes. One good example of national legislation creating specific rules that are not subject to mutual recognition is the UK plugs and sockets regulations⁸. These regulations require electrical equipment to be fitted with UK-type plugs and sockets, manufactured and certified in accordance with the British Standard or equivalent.

The regulations ensure that products meet the level of safety and protection expected by the UK Government, but at the same time they create clear TBTs. Manufacturers are required to put different plugs onto electrical equipment for different

parts of the EU market. This necessitates additional product versions and incurs extra costs that are passed on to the consumer.

⁶ See *Blue Guide on the implementation of EU product rules* (link provided in footnote 4).

⁷ ftp://ftp.cenelec.eu/EN/EuropeanStandardization/Guides/30_CENCLCGuide30.pdf

⁸ *The Plugs and Sockets etc. (Safety) Regulations 1994*

4.3 How does harmonization of regulation apply to the single market?

Legislative harmonization is the process of making technical requirements for products identical, or at least similar, to enable the successful running of the single market. This harmonization is neither complete nor systematic; it is a function of specific needs to develop rules where they are required to ensure a free and successful market.

Article 26 of the TFEU requires the EU to take measures to ensure the functioning of the internal market: "an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured".

The process of harmonization requires Member States to bring national legislation into line, unless they can justify its existence in line with the TFEU requirements in Article 36 (Question 4.1).

TFEU does not set down specifically how harmonization should be created. As shown in Figure 2, harmonization takes a number of forms and these have developed as the single market has developed. The main approaches are described below.

4.4 What is the New Approach/New Legislative Framework?

The New Approach (which is still most commonly referred to in this way even though it was expanded and updated in 2008 into the New Legislative Framework) entails harmonization legislation created under TFEU Article 114 (sometimes referred to as full or total harmonization).

The New Approach replaces national legislation and Member States can only introduce more stringent provisions on an exceptional basis and only when they will not prejudice the harmonization, or when they are justified on the basis of environmental or workplace needs, or in line with TFEU Article 36 (see Question 4.1).

New Approach legislation may take the form of a regulation, which is directly applicable, such as the CPR, or the current proposals for medical devices regulations, where the Member States do not need to implement the legislation, although they may well need to make provisions for market surveillance.

Only around 25 per cent of European standards are associated with public policies and legislation. Under the New Approach, where individual standards are specifically identified, they are referenced as a means of compliance, not the means of compliance. Use of standards referenced in this way is voluntary. The responsibility for complying with the regulation rests with the supplier of the goods or services.

Alternatively it can be by directive, which requires Member States to implement the legislation at national level within a set timeframe. This gives more flexibility to the Member States as they can reflect the principles of the legislation within their own legal and administrative frameworks.

There are 25-30 New Approach directives, including toys, machinery, electrical equipment (LVD), electromagnetic

compatibility (EMC), gas appliances, medical devices (three directives, currently under revision), cableways, recreational craft, lifts, measuring instruments, non-automatic weighing instruments, personal protective equipment (PPE), pressure vessels, equipment for explosive atmospheres, pyrotechnics etc. The exact number is not certain as there is some blurring at the edges, with several legal texts having some, but not all, elements of the New Approach (see 'Mixed approach' legislation below, Question 4.6).

From a standards' perspective, the key to the New Approach is that the legislator separates the high level 'essential' requirements from the technical specifications needed to manufacture the products. Legislation covers only those essential requirements and the precise means of meeting those requirements is left to the market. One way to meet the requirements – which is voluntary – is by applying 'harmonized standards' (as defined in Regulation 1025/2012: a standard requested by the Commission from the ESOs for the purposes of harmonization legislation). Compliance with such standards, once their references have been published in the EU's Official Journal, confers a presumption of conformity with applicable law.

This harmonization legislation and the use of harmonized standards is the main area where standards are used to support legislation. Around 4,000 hENs serve this purpose.

4.5 What is the Old Approach and where is it still used?

Before the New Approach was introduced in 1985, harmonization followed the model now referred to as the Old Approach. This involved legislation which covered all aspects of regulated products and specified all technical parameters in some detail. The Old Approach continues to be used in a number of areas, such as REACH (for chemicals), batteries and fertilisers. Specific examples are listed below.

4.5.1 Food

Food safety is comprehensively regulated within the EU and this has led to a full range of regulatory food standards being created. The EU legislative process may take standards from the Codex Alimentarius Commission (an intergovernmental body sponsored by the WHO and the Food and Agriculture Organization) and develops them for the EU market, then enacts the provisions. The EU regulation on food controls (178/2002/EC) recognizes the importance of international standards (e.g. Codex): 'Where international standards exist or their completion is imminent, they shall be taken into consideration in the development or adaptation of food law'.

There are similar UK food standards provisions, though most of these have been taken over by European law.

As Old Approach legislation, the EU regulation contains technical specifications for products, such as walnuts.

There are a small number of standards also developed by ISO (e.g. for some herbs and spices) and a large body of international/European/national standards for food test

methods. These test method standards support the use of the Codex standards in national/regional regulation around the world.

4.5.2 Motor vehicles

The EU is a signatory of the 1958 UN ECE agreement on motor vehicles⁹, which operates on the principles of type approval and reciprocal recognition. This agreement has broad international membership, with the notable exception of the US and Canada. The US and Canada are signatories of the 1998 UN ECE agreement¹⁰, which enables the production of United Nations Global Technical Regulations (UN GTRs) and their publication in a UN Global Registry. The 1998 agreement binds members to these regulatory standards. The EU participates in UN ECE international committees to develop the standards that are adopted as EU law. The approach is one of legislative technical specifications for safety of vehicles, i.e. it is Old Approach. Automotive parts are standardized internationally.

⁹ "Agreement concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts which can be fitted and/or be used on wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions" (E/ECE/TRANS/505/Rev.2, amended on 16 October 1995)

¹⁰ "Agreement concerning the Establishing of Global Technical Regulations for Wheeled Vehicles, Equipment and Parts which can be fitted and/or be used on Wheeled Vehicles"

4.5.3 Aeronautics

In aeronautics, the European harmonization of requirements is based on EASA rules, supported by standards that are primarily developed both by EUROCAE in the EU and also in the US. There are also ISO standards for different components or items on aircraft, adopted as ENs with additions for legislative requirements (e.g. the Machinery Directive) where necessary.

Mutual recognition of certification with the US, which enables recognition of safety and airworthiness, is ensured by a bilateral EU-US agreement from 2011¹¹. This approach

has been considered successful and is being progressively extended to other countries, such as Canada and Brazil. Discussions are underway with China.

4.6 Is there any overlap between the New Approach and the Old Approach?

While the EU has committed to the New Approach through the New Legislative Framework, it has never adhered completely to a set formula for harmonization. There are many examples of harmonization legislation that fall between the Old Approach and the New Approach, which are referred to here and figure 2 as 'mixed approach', though this is not a term used by the European institutions.

CPR uses harmonized standards and provides for CE marking but is not truly New Approach legislation, as it does not set essential requirements in the legislation and it makes compliance with standards mandatory.

The Ecodesign Directive is framework legislation that reads as a New Approach directive and requires CE marking, but the implementation measures that are necessary to implement its framework are regulations with specific requirements and limit values; the role of standards is limited to providing test methods.

Other examples of legislation that adopts a mixed approach include the packaging and packaging waste legislation which has harmonized standards but no CE marking. Cosmetics legislation is primarily Old Approach, but follows the New Approach to give a presumption of conformity with regard to good manufacturing practice for compliance with harmonized standards.

4.7 What does Minimum Harmonization mean?

The General Product Safety Directive (GPSD 2001/95/EC), also made under TFEU Art 114, requires that all consumer products on the EU market are safe. The Directive recognizes that national legislation may set legal requirements as to the safety of consumer products that go beyond this general safety requirement. Hence the harmonization is considered to set a minimum level of safety that must be met in all cases.

There are a number of examples in the UK where additional safety requirements have been required by national legislation, one of the most well-known being the furniture fire safety legislation (which makes the relevant British Standard mandatory). Recently another such provision, the nightwear safety legislation, has received media coverage

following the 2015 BBC TV Watchdog investigation into the safety of children's fancy dress.

Generally, the GPSD does not apply to products where there is harmonization legislation in place.

¹¹ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2011.291.01.0001.01.ENG

Question 5

Impact of a UK exit from the EU

5.3 How does the EEA/EFTA operate with the European Single Market rules?

The EEA Agreement enables the EEA EFTA members (Norway, Iceland and Liechtenstein) to have limited influence on EU legislation that is of EEA relevance. These members may participate in European Commission committees that are developing relevant legislative proposals and delegated legislative acts (the latter through procedures run through EC-chaired Member State committees, called comitology). They can submit comments on proposals and thus influence the development of legislation. Once the proposal is adopted by the Commission and enters the legislative process in Council and Parliament, however, there is very little influence. This level of influence has reduced as successive revisions to the EU Treaties have given more power to the European Parliament.

Once legislation is adopted, it is incorporated into the annexes or protocols to the EEA Agreement and then transposed into the legislation of the EEA EFTA members. The transposition is enforced by the EFTA Surveillance Authority, which can instigate infringement procedures against the EEA EFTA states for non-compliance. These are heard by the EFTA Court.

This limited degree of influence is described as “the price that must be paid for participating in a homogeneous Internal Market without actually being a full member of the EU” (The European Economic Area: Past, present and future’, EFTA Bulletin, June 2015).



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