

# The Brexit Papers



## Technical Regulations and Product Standards Paper 14



Bar Council Brexit  
Working Group  
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**THIRD  
EDITION**



## **Brexit Paper 14: Technical regulations and product standards**

### **Introduction**

1. The UK's departure from the EU will create significant challenges in the area of technical regulations and product standards. Although the Government has declared its intention to use the EU acquis as the starting point for Brexit, difficulties will emerge subsequently as divergences arise.

### **Standards and the New Approach measures**

2. Some of the major economic gains of the European single market have stemmed from the removal of the non-tariff barriers embodied in different national technical regulations and product standards. By adopting harmonised standards, EU member states were able to permit free circulation of highly sensitive products without jeopardising public interest concerns such as the protection of health, safety or the environment. Full harmonisation of product standards has evolved over time into what has become known as the "New Approach".

3. The New Approach is based on the following key principles:

3.1. Legislative harmonization at the EU level is limited to the adoption of "essential" safety requirements. Products must meet these essential requirements in order to be marketed and enjoy free movement throughout the EU. There are around 30 harmonising "New Approach" directives covering a range of products, including toys, construction products, low-voltage electrical equipment, machinery, pressure equipment, medical devices, and lifts.

3.2. The more detailed harmonised technical specifications underpinning the 'essential requirements' are drawn up by the European Standards bodies,

principally CEN and CENELEC<sup>1</sup> whose membership extends beyond the national standards bodies of the EU member states to include EEA and other major trading partners. Although CEN-CENELEC technical specifications are voluntary, if products have been manufactured in conformity with them, they will be presumed to meet the ‘essential requirements’ of the relevant EU Directive<sup>2</sup>. This gives producers a choice of manufacturing in conformity with CEN-CENELEC technical standards, or by an alternative method. However, in the latter case the manufacturer has an obligation to prove that his products conform to the ‘essential requirements’ of the Directive and the affixing of a ‘CE’ mark on the product’s label represents the manufacturer’s assurance to buyers and users that this is the case.

3.3. Beyond the mandatory New Approach measures, CEN and CENELEC,<sup>3</sup> also produce a great many voluntary European standards which facilitate the marketing of products across the EU and beyond. However these have no legislative force.

4. The work of drafting and amending CEN-CENELEC standards is done by technical committees made up of representatives of the national standards bodies. The main burden is usually borne by the national body that provides the secretariat of the particular committee. The British Standards Institute (BSI) has been a major contributor to this work and provides the secretariat for some 80 technical committees, and supplies a chairperson for several hundred others.

5. CEN and CENELEC operate largely by consensus, but there are rules on voting for the adoption or amendment of standards. As a general rule, adopted standards must be implemented by all members, even by those who abstained or voted against<sup>4</sup>. The exception to this majority procedure of CEN-CENELEC standards is known as an ‘A-deviation’. This covers circumstances in which existing national regulations differ from proposed European standards and cannot easily be altered.<sup>5</sup> An A-deviation is considered to be exceptional, and a step towards adoption over

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<sup>1</sup> CEN (European Committee for Standardisation) has a general competence; CENELEC (European Committee for Electrotechnical Standardisation) is concerned with electrical products. The two bodies are legally distinct. They are not EU institutions but comprise the national standards bodies of all EU/EEA members as well as Switzerland, Turkey, Serbia and Macedonia.

<sup>2</sup> The system is elaborated in Regulation (EU) No 1025/2012. The Commission’s requests for standards are not limited to the New Approach measures. About a third of the present work of CEN-CENELEC is in response to mandates from the EU/EFTA: CEN-CENELEC [Quarterly Statistical Pack](#) 2016Q4, p. 25.

<sup>3</sup> CEN-CENELEC [Quarterly Statistical Pack](#) 2016Q4, p. 19.

<sup>4</sup> CEN-CENELEC Internal Regulations Part 2:2017, Clause 6.3.

<sup>5</sup> CEN-CENELEC [Internal Regulation Part 3:2017](#) (E), clause 3.5.4, defines an A-Deviation as a “modification of, addition to or deletion from the content of an EN (and HD for CENELEC) reflecting a national situation due to regulations the alteration of which is for the time being outside the competence of the CEN-CENELEC national member.”

time rather than a permanent derogation.<sup>6</sup> This presumption against permanent derogations from harmonised standards applies to all CEN-CENELEC members, even non-EU members.

6. Product standard harmonisation also takes place at an international level. All of the national standards bodies (such as the BSI) that make up CEN-CENELEC membership are also members of the corresponding international standards-making bodies, the ISO and the IEC.<sup>7</sup> As a result there is a significant overlap between European and International standards (about 30 percent of CEN standards and 70 percent of CENELEC standards).

### **The Impact of Brexit**

7. Once the UK has left the EU, divergence in product standards might arise:

7.1 If the BSI does not follow updates and changes to technical specifications supporting harmonised standards made by CEN-CENELEC; or

7.2. If a new harmonising New Approach directive is adopted or an existing directive amended by the EU and not transposed into UK law.

8. Although post-Brexit, the UK could simply choose to transpose New Approach EU directives and CEN-CENELEC standards, this does not reflect UK government statements of policy to date. As a result manufacturers in the UK and abroad would most likely then need to produce different versions of products destined either for the UK or for the EU internal market to reflect these divergences in standards. In the case of products produced in small numbers, such as medical devices, the manufacturer might even decide that producing a special version for the UK market was not cost effective.

9. Where divergence in product standards has occurred, the CE mark would cease to provide a reliable indication that a product satisfied the relevant UK technical regulations. The UK could then put forward a rival mark indicating that the product satisfied the relevant UK rules, but this would place a further cost burden on manufacturers and consumers.

10. Divergence in product standards would create problems for the BSI, as well as for manufacturers, distributors and consumers. As a member of CEN-CENELEC, the BSI is obliged, subject to a few exceptions, to implement all the standards that these institutions adopt, including those made under the New Approach measures.

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<sup>6</sup> CEN, '[National regulations – Possible conflict with CEN work \(A-deviations\)](#)'.

<sup>7</sup> The International Organisation for Standardisation, and the International Electrotechnical Commission.

Furthermore, members undertake to do nothing “which could prejudice the harmonization intended and, in particular, not to publish a new or revised national standard which is not completely in line with an existing EN”.<sup>8</sup> The BSI could therefore only supply the latest version of each CEN-CENELEC standard. It would not be able to offer an alternative UK standard whilst remaining a member of CEN-CENELEC. CEN-CENELEC members undoubtedly place a high value on the continued participation of the BSI, and, of course, the New Approach standards constitute only a part of their activities, albeit in the most sensitive areas. Nonetheless, accommodating such divergence would involve a fundamental departure from the present CEN-CENELEC constitution.

11. The BSI has adopted an optimistic tone, saying that:

11.1. “The single standard model does not depend on harmonized regulation; divergence of regulation over time can be accommodated within a single international or European standard model. Such a solution provides maximum flexibility for the UK economy”.<sup>9</sup>

11.2. But it is hard to see how significant divergences could be accommodated, given the CEN-CENELEC constitution and internal regulations and the prevailing attitude towards A-deviations.

12. There are possibilities for BSI participation in CEN-CENELEC that fall short of full membership. Under the present rules it could become a Companion Standardisation Body (CSB), which would enable it to act as an observer in specific technical committees. It would then be obliged to adopt only the standards produced by those Committees. This would represent a radical reduction in the role the BSI has previously played in European product standards, and would not solve the problem of how to adopt measures which diverged from the New Approach measures.

13. International standards, in the form of ISO/IEC standards would not necessarily offer a satisfactory alternative since these are, in many cases, identical to CEN-CENELEC instruments. Brexit will not prevent the BSI continuing to be an active ISO/IEC member, but these organisations will remain strongly influenced by the standards organisations of the 30 or so EU and EFTA countries who are also in CEN-CENELEC.

14. Finally, the UK Government could move away from using standardisation bodies to draw up technical regulations and adopt an approach of incorporating all requirements in regulations. The EU uses this approach for certain particularly

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<sup>8</sup> CEN-CENELEC Internal Regulations Part 2:2017, clause 5.

<sup>9</sup> BSI, [What Brexit means for Industry standards](#), March 2017.

sensitive products such as medicines and chemicals (e.g. REACH). But this would inevitably increase the divergences between EU New Approach measures and the UK regulations, and aggravate the problems facing manufacturers who seek to supply both markets.

### **Conformity assessment**

15. Common product standards are supported by 'conformity assessment', which combines self-certification by a manufacturer that their product complies with any essential requirements<sup>10</sup> (most obviously by affixing the CE mark), together with market surveillance by trading standards agencies, or their equivalents, in different member states<sup>11</sup>. This approach is supported by the EU Commission's online Rapid Alert System (RAPEX) which circulates information about dangerous or risky products<sup>12</sup> and is underpinned by a requirement on manufacturers to retain detailed technical files on all the products they supply to the European market which are covered by product standards.

16. Post-Brexit and outside the single market, the UK would not be included in RAPEX<sup>13</sup>, potentially exposing UK consumers to risks from products which have been removed from European market. Divergence in standards could also increase conformity assessment costs to manufacturers who supply products to both the UK and the EU, since they would need to maintain two separate sets of technical files to reflect the different standards to which they were operating.

17. The production of more sensitive products e.g. medical devices, is subject to more stringent oversight by external assessment bodies, ranging from design control, through to full production process approval and ongoing quality assurance through periodic checks by conformity assessment bodies, including unannounced factory visits and production sampling.<sup>14</sup>

18. External conformity assessments are carried out by bodies that are authorised by governments. For the New Approach measures the EU Commission maintains an online database (NANDO) of notified assessment bodies.<sup>15</sup> Post-Brexit, the UK would need to reach separate agreement to remain part of this system. However in the

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<sup>10</sup> A set of modules of conformity assessment suitable for inclusion in New Approach measures is established in Decision No 768/2008/EC.

<sup>11</sup> See Regulation (EC) No 765/2008.

<sup>12</sup> Directive 2001/95/EC, Article 12 and Annex II.

<sup>13</sup> The system is at present limited to the EEA countries; Switzerland is not a participant. An EU Commission database of notifications is available [online](#).

<sup>14</sup> Directive 98/79/EC, Annex IV, Sections 5 and 6.

<sup>15</sup> <http://ec.europa.eu/growth/tools-databases/nando/index.cfm>

absence of such an agreement, UK manufacturers could still obtain EU conformity assessment for their products by using a notified body in another EU member state.

19. The EU has a number of MRAs on product conformity assessment with third countries, for example Australia.<sup>16</sup> These agreements enable equivalent assessment bodies outside the EU to confirm that particular products satisfy the relevant *EU* essential requirements. This allows such products to bear the CE mark, and avoid the need for further examination on export to the EU. Following Brexit equivalent arrangements would be helpful to UK manufacturers.

### **WTO rules**

20. As a WTO member, the UK is a party to the Agreement on Technical Barriers to Trade (TBT Agreement). Even though standards-making bodies, as non-governmental entities, are not bound by WTO obligations, Article 4.1 of the TBT Agreement explicitly recognises their role and sets out a Code of Good Practice which applies to these bodies via national level commitments:

20.1. "(WTO Members)...shall take such reasonable measures as may be available to them to ensure that local government and non-governmental standardizing bodies within their territories, as well as regional standardizing bodies of which they or one or more bodies within their territories are members, accept and comply with this Code of Good Practice. In addition, Members shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such standardizing bodies to act in a manner inconsistent with the Code of Good Practice".

21. Most of the provisions in the Code of Good Practice concern the procedures by which standards are adopted. However, it also contains the following rule in paragraph H:

*The standardizing body within the territory of a Member shall make every effort to avoid duplication of, or overlap with, the work ... of relevant international or regional standardizing bodies.*

22. The rule does not explicitly address the issue of national standards that differ from those developed at the regional level, but for a national standardising body, such as the BSI, to produce such standards would almost inevitably involve "duplication" or "overlap".

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<sup>16</sup> The legal authority is found in Articles 207 and 218 of the TFEU.

23. Like the standardisation bodies of most WTO members, the BSI has formally accepted the Code. The relevant regional standardising body is CEN-CENELEC. The extent of the obligation to ‘make every effort to avoid duplication, etc.’ is not clear. However, it would hardly be compatible with this rule for a national body to engage in producing rival standards.

24. Furthermore, the UK could be held to be acting inconsistently with Article 4.1 if it encouraged the BSI to promote different standards from those adopted by CEN-CENELEC. It could then be held accountable through the WTO’s dispute settlement procedures. Furthermore, although the obligation stated in Article 4.1 (above) is merely to take “reasonable measures”, the dispute settlement clause of the Agreement says that the procedure “can be invoked in cases where a Member considers that another Member has not achieved satisfactory results under ... [Article 4] ... and its trade interests are significantly affected”.<sup>17</sup> WTO members do not lightly invoke these procedures, but they regularly raise such matters in meetings of the WTO committee that oversees the TBT Agreement and call on the governments concerned to give a justification for their actions. Any post-Brexit move away from CEN-CENELEC approaches could therefore have wider consequences in the WTO.

### **Recommendation**

25. The closer the UK can remain to the CEN-CENELEC system of standard setting and conformity assessment, the better the outcome will be for manufacturers and consumers, the more influence the UK will retain over European and international product standards and the less likely any trade related challenges will be mounted against the UK in this area.

### **Brexit Working Group**

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<sup>17</sup> TBT Agreement, Article 14.4.