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BMTA Position Paper: The Implications of 'Brexit' for UK Notified Bodies.

Summary

S1. There are currently 189 UK based Notified Bodies (NB) listed in the EU database, but some of these are inactive. The Department for Business, Energy and Industrial Strategy (BEIS) estimates that 4,500 people work in the UK NB sector which has 20,000 customers and is a £2bn industry. NBs' function is to test products' compliance with regulatory requirements and then to issue Certificates of Conformity to manufacturers seeking to place products on the European Market. The quality, safety and performance of the products concerned are regulated by 22 different EU product Directives. Compliant products are marked with the CE mark.

S2. These 22 EU Directives are transcribed into UK law in the form of Regulations under various Acts of Parliament and the European Communities Act 1972 (ECA). Under the proposed 'Great Repeal Bill' the ECA will be repealed upon Brexit and the Regulations in question will continue in their provisions and requirements but shorn of reference to the EU at least for the short to medium term. This will have two immediate outcomes:
(1) UK NBs will cease to exist since NBs can only be established within the EU or under a Mutual recognition agreement (MRA):
(2) Product manufacturers intending to place products on the European market will need to obtain a Certificate of Conformity from a NB within the EU and will not be able to use UK NBs.

S3. This is an existential threat to UK NBs. They are likely to lose business as many of their customers turn to European NBs. Some smaller and specialised UK NBs may close down entirely. This is likely to mean the loss of skilled jobs and loss of revenue for the UK with up to 4,500 jobs and £2bn per annum income to the UK at risk.

S4. Manufacturers are likely to face increased costs of conformity assessment as they will have to seek the services of European NBs. They face possible higher costs of shipping their products for testing, higher fees for testing (although in some eastern European countries fees for testing could be significantly lower) and a poorer service in terms of technical quality, speed and reliability.

S5. There appears to be five main possibilities for regulation post Brexit:
(1) That the UK regulations continue virtually unchanged. UK manufacturers continue to indicate conformity with UK and EU regulations. UK NBs continue to award EU Conformity Assessment certificates for products for use in the UK only or by means of an MRA for products to be sold in Europe.
(2) That the UK regulations remain technically unchanged but refer to a UK Conformity Assessment mark (UKCA mark).
(3) That the UK regulations remain technically unchanged but without the requirement for a mark.
(4) That the UK over a period of time introduces a completely new set of regulations and Conformity Assessment regime along with its own Conformity Assessment mark.
(5) The UK abandons product performance and safety regulation altogether.

S6. Option (1) is the simplest but might not be acceptable to the EU. It might be possible for the UK to negotiate a Mutual Recognition Agreement (MRA) with the EU whereby UK NBs could

continue in business and issue European Certificates of Conformity which would be valid in both the UK and Europe. There are precedents for this in the USA, Japan and Canada. There are 113 'European' NBs in non-EU countries.

S7. Option (2), introduction of a UKCA mark which is virtually identical to the CE mark in its requirements is a variation on option (1) but could only be realised through an MRA with the EU. A simpler MRA which sought equivalence of the UKCA mark and the CE mark throughout Europe based on identical conformity assessment procedures would be very attractive. It would be virtually the same as the first option but would allow use of both the UKCA mark and CE mark in Europe. UK NBs would be able to maintain their current levels of business.

S7 Option (3) would reduce the regulatory burden for manufacturers but would weaken consumer protection and product safety in the UK. Any product intended solely for the UK market would not need to be marked. Any product intended for export to the European single market would need to carry the CE marking either by reference to a European NB or preferably to a UK conformity assessment body which has been recognised under a UK/EU MRA. In the absence of an MRA UK NBs would cease to exist.

S8. Option (4), the UK develops its own product regulations which diverge from those of the EU and Option (5), that the UK deregulates products entirely, are not favoured. The first because it would increase costs for manufacturers who would face dual testing for compliance with different regulations in the EU and UK as well as additional costs of dual marking. Option (5) whilst superficially reducing the burden of EU regulation risks the UK becoming a dumping ground for poor quality, unsafe products. It would also reduce significantly consumer and environmental protection, food safety and the safety of medical devices in the UK.

S9. Resources for enforcement of product regulations and market surveillance in the UK namely through HM Customs and Revenue and Local Authority Trading Standards Departments will need to be strengthened post Brexit on the presumption that the UK is no longer part of the Customs Union.

S10. The harmonised European Standards which underpin the 22 'New Approach' Directives are unlikely to change due to Brexit. Hence there will be no pressure from a standardisation point of view for revision of regulations. BSI is the UK member of CEN, CENELEC, ISO and IEC, none of which is an EU organisation. BSI's ambition is that its membership status of these organisations will not change post Brexit although there may need to be a change of statute in CEN and CENELEC to make this happen.

S11. EU NBs are required to be accredited by their National Accreditation Bodies to assure customers and markets of the robustness of the Conformity Assessment process and to build confidence in it. If UK NBs are to continue to provide European Conformity Assessment services by means of a MRA they will be required to maintain their accreditation. Should UK NBs be restricted to operations in the UK only post Brexit the same benefits of accreditation would be realised albeit restricted to the UK, which would be important in establishing the credibility of the UKCA mark and confidence in the UK CA process.

S12. UKAS is the UK National Accreditation Body. Its authority is derived from EU Regulation 765/2008. Post Brexit this Regulation will no longer apply in the UK and theoretically other Accreditation Bodies could be set up in the UK as an alternative to UKAS. We consider that a competitive market for accreditation in the UK would lead ultimately to a lowering of standards in a 'race to the bottom'. We would therefore urge that the requirements of Regulation 765/2008 are

brought into UK law via the Great Repeal Bill and that the Government confirms UKAS' status as the sole UK National Accreditation Body post Brexit.

S13. Post Brexit the larger international Notified Bodies may simply transfer work to their European laboratories and offices and close or reduce their UK operations. This will mean the loss of skilled jobs and income to the UK.

S14. Smaller and mid-sized specialist NBs strongly favour negotiation of an MRA with the EU whereby they can continue to provide conformity assessment services in the EU. This would require that UK product regulations remained unchanged from the present EU Directives. If this is not possible and the EU will not permit application of the CE mark by a UK NB then negotiation of an MRA which would permit UK NBs to provide Conformity Assessment certificates for a UKCA mark which was to all intents and purposes the same as the CE mark and recognised globally would be desirable. This would retain some skills, jobs and income in the UK.

S15. Other options for smaller NBs include: Moving their operations to an EU country; partnering with an EU NB; setting up a front office in an EU country but undertaking testing work in their UK premises, or closing the business. None of these is particularly attractive and apart from closure, would add cost for little benefit.

S16. **Recommendations**

In light of the foregoing BMTA recommends the following:

1. That the Government seeks to negotiate an MRA with the EU which would allow UK NBs to continue to issue European Conformity Assessment Certificates as they do now. The CE mark would be retained in the UK and UK NBs could retain their global European CA business. Product regulation in the UK would remain virtually unchanged. UK regulations would mirror EU Directives and Regulations and would be updated in future to maintain equivalence. EN Standards harmonised in the EU journal would be accepted as providing a presumption of conformity with requirements of the regulations.

2. If an MRA on the basis of (1) is not possible then the Government should seek to negotiate an MRA with the EU whereby UK NBs for products intended for the UK market issue CA certificates for a UKCA mark which is in all respects identical in its requirements to the CE mark and would be recognised within the EU as such. UK NBs could still award European CA certificates for products intended for sale in the EU. UK product regulations would remain aligned with those of the EU as now.

3. If the UK adopts its own Conformity Assessment mark resources for enforcement and market surveillance namely HM Customs and Revenue and Local Authority Trading Standards Departments will need to be strengthened to ensure that the mark is effective.

4. The UK should ensure that UK product regulations remain aligned closely with those of the EU. A divergence of regulation would raise costs significantly for UK manufacturers wishing to sell products in Europe by having to make separate variants of the product for the European and UK markets as well as face costs for dual testing to different regulations and dual conformity marking. This would be clearly disadvantageous to manufacturers, would confuse customers and disrupt markets.

5. The UK should not deregulate products safety and performance in an attempt to remove burdensome EU regulation. This would destroy UK Notified bodies business in the UK, risks

the UK becoming a dumping ground for poor quality and dangerous products and is not in the best interests of consumers, the environment, food or medical safety.

6. The Government should bring the requirements of Regulation 765/2008 in to UK law and continue to recognise the United Kingdom Accreditation Service (UKAS) as the sole UK National Accreditation Body post Brexit, rather than allow a competitive market for accreditation in the UK which could lower standards. UKAS is a globally respected Accreditation Body which adds value to Notified Bodies' (and other Laboratories') work through an independent third party appraisal process.

1. Background

1.1 This Position Paper is the output from a meeting organised by BMTA with Notified Bodies to discuss the implications of Brexit for UK Notified Bodies held in central London on 30 March 2017. The working assumptions were that in light of the Prime Minister's speech and the Government's White Paper on the subject, the UK would not be part of the Single Market or the Customs Union after 2019.

1.2 Notified Bodies (NBs) are essential elements of the UK and European Conformity Assessment infrastructure. They are for the most part testing laboratories engaged in testing consumer products and products for industry and commerce for example, toys, lifts, batteries, domestic electrical goods, medical devices and beer glasses for the purpose of applying the CE (Conformité Européene) mark through the process of conformity assessment.

1.3 The CE mark is not a quality or a safety mark. It simply attests that a product conforms to the Essential Requirements of the relevant European Directive or Regulation concerning the performance of the product in question. The Essential Requirements refer to harmonised European standards for product performance, which usually offer the most straightforward route to compliance while remaining voluntary, and which in many cases cover issues of product safety. The harmonised European standards are for the most part identical to International (global) Standards for products promulgated by the International Standards Organisation (ISO) and/or International Electrotechnical Commission (IEC). The EU publishes lists of harmonised EN standards. These provide a recognised way of meeting the essential requirements of relevant EU Directives and Regulations. A manufacturer from anywhere in the world, or the importer of a product to which the relevant European Directive applies must ensure that the product meets the EU regulatory requirements and indicates this by placing a CE mark on it before it can be placed on the European market. In many, but not all cases this will require testing by a Notified Body from within the EU. When a product meets the necessary test requirements a NB will issue an EU Certificate of Conformity.

1.4 NBs are themselves approved by the 'National Competent Authority' (CA) and must be accredited by the National Accreditation Body (NAB). In the UK the CA function is delivered by Government Departments including The Department for Business, Energy, and Industrial Strategy, (BEIS) and The Department of Health, (DH). The United Kingdom Accreditation Service (UKAS) is the NAB. The CE mark may be awarded for a given product on the recommendation of any Notified Body within the EU which is approved for Conformity Assessment of the product type. In essence, some 1500 NBs across Europe compete for Conformity Assessment business. There are currently 189 UK NBs registered on the EU database but not all of them are active. BEIS conducted a survey of UK NBs early in 2017. Based on a 40% response (72 people) BEIS believed that 4,500 people work in the UK NB sector which has 20,000 customers and is a £2bn industry. BEIS is carrying out detailed follow up discussions with 10 NBs.

2. The issues

2.1 There are 22 EU product Directives (collectively referred to as 'New Approach' Directives) which require products to be CE marked before they can be placed on the European market. These are transcribed into UK law in the form of Regulations under various Acts of Parliament and the European Communities Act 1972 (ECA). Under the proposed 'Great Repeal Bill' the ECA will be repealed upon Brexit and the Regulations in question will continue in their provisions and requirements but shorn of reference to the EU at least for the short to medium term. This will have two immediate outcomes:
(1) UK NBs will cease to exist since NBs can only be established within the EU or under a Mutual recognition agreement (MRA):

(2) Product manufacturers intending to place products on the European market will need to obtain a Certificate of Conformity from a NB within the EU and will not be able to use UK NBs.

2.2 The consequences of this are likely to be that UK NBs will lose business as many of their customers turn to European NBs. Some smaller and specialised UK NBs may close down entirely. This is likely to mean the loss of skilled jobs and loss of revenue for the UK with up to 4,500 jobs and £2bn per annum income to the UK at risk. Larger organisations which already operate on a global basis face less of a problem in that they could simply transfer their UK operations to one of their European laboratories without significant loss of business overall. In all probability they would still downsize their UK operation or even close it entirely with consequent loss of skilled UK jobs. A possible mitigating factor might be if a multinational organisation had a highly capital intensive and technically complex test facility in the UK which was very expensive to relocate and none in Europe. They might 'front' the business through their European NB but carry out the testing work in their UK facility.

2.3 Manufacturers are likely to face increased costs of conformity assessment as they will have to seek the services of European NBs. They face possible higher costs of shipping their products for testing, higher fees for testing (although in some eastern European countries fees for testing could be significantly lower) and a poorer service in terms of technical quality, speed and reliability. There is some anecdotal evidence that some European NBs place non-European products seeking conformity assessment at the back of the queue behind local or other European products. In general UK NBs have been very successful in winning conformity assessment business from around the world because of their high technical quality, speed and high standards of customer service and competitive prices.

2.4 There is also a question about validity of current Conformity Assessment certificates issued by UK NBs. These might be invalidated at a stroke on exit from the EU, or more likely they would remain valid until their expiry date after which manufacturers would have to obtain new certificates from a European NB. It is vital for manufacturers that this is agreed with the EU before Brexit.

3. The future of Conformity Assessment in the UK post Brexit

3.1 Consequent upon the passage of the 'Great Repeal Bill' it is expected that current UK regulations implementing conformity assessment procedures for award of the CE mark to products will continue in substance albeit without reference to EU institutions or law. This raises a conundrum: Will the revised regulations refer to the CE mark or will they refer to an UK specific mark of conformity (UKCA mark)? For simplicity of argument this could be akin to the 'Crown Stamp' which used to appear on beer glasses and weighing machines prior to the implementation of the EU Measuring Instruments Directive in 2004. However, the form of a UKCA mark would be the subject of discussion between government, industry and other stakeholders.

3.2 There appears to be five main possibilities for regulation post Brexit:
(1) That the UK regulations continue virtually unchanged. UK manufacturers continue to indicate conformity with UK and EU regulations. UK NBs continue to award Conformity Assessment certificates for products and award CE marks for use in the UK only or by means of an MRA for products to be sold in Europe.
(2) That the UK regulations remain technically unchanged but refer to a UK Conformity Assessment mark (UKCA mark).
(3) That the UK regulations remain technically unchanged but without the requirement for a mark.
(4) That the UK over a period of time introduces a completely new set of regulations and Conformity Assessment regime along with the UKCA mark.
(5) The UK abandons product performance and safety regulation altogether.

3.3 (1) Continued use of the CE Mark.
This is the simplest option. But it is questionable whether the EU would permit use of its mark by a non-European country. It is also questionable whether this would be acceptable to the UK 'Brexiteers' as being an instance of unwelcome EU regulation. It would be rather pointless if the UK were to continue to use the CE mark if it were not recognised in Europe, unless manufacturers wished to place their products on the UK market only. It might be possible for the UK to negotiate a Mutual Recognition Agreement (MRA) with the EU whereby UK NBs could continue in business and issue European Certificates of Conformity which would be valid in both the UK and Europe. There are precedents for this in the USA, Japan and Canada. There are 113 'European' NBs (more correctly termed Designated Bodies) in non-EU countries.

3.4 This possibility was strongly favoured by the majority of persons attending the BMTA Discussion meeting. It has the advantage of continuity, enabling UK NBs to maintain viable businesses thus retaining skilled jobs and income in the UK. Manufacturers could avoid the costs of dual testing for the UK and European markets separately and still enjoy the high quality service provided by UK NBs. A disadvantage is that since the UK would no longer be a member of the EU we would lose influence in the future development of Directives on product performance and safety with which our regulations are aligned.

3.5 The possibility for EU Certificates of Conformity to be recognised as fulfilling UK legal requirements whilst the reciprocal of UK certificates not being recognised in Europe would spell disaster for UK NBs and was considered to be unacceptable by the meeting.

3.6 *(2) A UK Conformity Assessment mark*
This possibility is really a variant of the first, but instead of awarding CE marks UK NBs would provide Certificates of Conformity for award of the UKCA mark which would be valid for the UK only. Whilst superficially attractive as a mark of UK regulation, rather than European, it would have several important disadvantages. It would require manufacturers wishing to place their products on both the UK and European markets to undertake dual testing, once by a UK NB and virtually identical tests by a European NB. Whilst this could be a bonanza for UK NBs it would increase manufacturers' costs significantly and would in all probability be strongly resisted by them. Some manufacturers might simply choose to ignore the UK market altogether.

3.7 The CE mark is misinterpreted by consumers who tend to view it as a safety or quality mark. Should the UK adopt its own CA mark the meaning of this mark needs to be clearly explained in a national campaign resourced by government.

3.8 An MRA with the EU whereby the testing regime for the UKCA mark and the CE mark were identical, but which allowed UK NBs to issue EU Certificates of Conformity for products intended to be placed on the European market and, using the same test criteria and results to issue Certificates of Conformity to UK regulations and the UKCA mark for products to be placed on the UK market would obviate the need for dual testing, would allow UK NBs to remain in business whilst meeting sensitivities in both the EU and UK about use of the CE and UKCA marks respectively. Manufacturers intending to place products on both markets would face a small increase in costs arising from the need for (physically) dual marking, albeit not for dual testing.

3.9 A simpler MRA which sought equivalence of the crown stamp and the CE mark throughout Europe and global recognition based on identical conformity assessment procedures would be very attractive. It would be virtually the same as the first option but would allow use of both the crown stamp and CE mark in Europe. UK NBs would be able to maintain their current levels of business.

3.10. These forms of MRA were also supported by the discussion meeting participants.

3.11 (*3) No UK Conformity Assessment mark.*
This option would reduce the regulatory burden for manufacturers but would weaken consumer protection and product safety in the UK. It would mean that any product intended solely for the UK market would not need to be marked (the act of placing on the market would represent an undertaking that the product meets the requirements, including any conformity assessment requirements, as it did in the UK before the advent of the CE marking). Any product intended for export to the European single market would need to carry the CE marking either by reference to a European NB or preferably to a UK conformity assessment body which has been recognised under a UK/EU MRA. In the absence of an MRA UK NBs would cease to exist.

3.12 *(4) The UK develops its own product regulations*
Whilst initially following the passage of the 'Great Repeal Bill' UK regulations would remain much as they are now, in the fullness of time they might diverge significantly from EU regulations. This would require that all products intended to be placed on the UK market would require UK Conformity Assessment certificates for the UKCA mark. This would mean dual testing and marking of products intended to be placed on the European market as well which would raise manufacturers' costs significantly. Furthermore manufacturers could well be faced with producing two variations of the same product, one to comply with UK regulations and another to comply with EU regulations. This could effectively be a technical barrier to trade and not allowable under WTO rules. It might generate business for UK NBs but would be clearly unattractive to manufacturers both in the UK and the rest of the World.

3.13 The general view of the discussion meeting was that this position was untenable.

3.14 *(5) UK deregulation of products.*
The UK might choose to deregulate product performance and safety which would thus require no process of Conformity Assessment at all. This would clearly be fatal for UK NBs as they would have no business unless through an MRA with the EU they were still allowed to test and issue Conformity Certificates for the EU. There might simply be a general regulation for placing a duty of care on manufacturers to produce 'safe' products although what constitutes a 'safe' product is likely to have to be tested in the UK Courts. This approach is closer to that of the USA and Canada where there is a less consistent approach to product safety regulation than in the EU with different regulations for different types of product. Deregulation would reduce consumer protection, food and medical safety, and environmental protection significantly. It would leave the UK exposed to dumping of cheap, unsafe or poor quality products from around the world. It would not benefit UK manufacturers seeking to sell products overseas but could instead prove disadvantageous by destroying the home market.

3.15 Whilst this course might be seen as an example of the UK doing away with burdensome EU regulation, overall the negative effects are likely to outweigh the benefits to the UK.

4. **Enforcement issues post Brexit**

4.1 Apart from total deregulation any form of UK Conformity Assessment will require enforcement if it is to be effective in preventing unsafe or poor quality products being placed on the market. This is the function of market surveillance which checks that products which are on the market are compliant with the relevant regulations.

4.2 Market surveillance in the UK is undertaken by HM Customs and Revenue who check products entering the UK at ports and airports. Local authority Trading Standards Officers check products at the point of sale as well as looking for counterfeit goods. Other enforcement agencies such as HSE and BEIS/RD (formerly NMRO) for industrial equipment are also involved. HMRC, HSE and LA Trading Standards Departments have been significantly cut back in recent years. If the UK is to have its own product regulatory system an increase in resource will be required to police it.

4.3 It is worth noting that the efficacy of the CE mark and European Market Surveillance practices have been criticised. Enforcement of CE marking regulations is poor in some EU countries, leading to a lower level of conformity than is desirable. Manufacturers are themselves responsible for placing the CE marking on products, and for producing a declaration of conformity stating that the products meet EU health and safety requirements.

4.4 The Netherlands Court of Audit conducted an audit on the European system of CE marking and published a report on 19 January 2017. It indicates that consumers buying a toy car, contact lenses, a smartphone or a bicycle helmet with the letters CE on it cannot assume that the product is safe, healthy or environmentally friendly. On average, 800 products subject to the CE system have to be withdrawn from the European market every year because they are neither safe nor healthy.

4.5 A Study by the International Federation of Inspection Agencies (IFIA) in 2014 and updated in 2015 and 2016 showed that 78% of CE marked consumer electrical equipment sold in the EU was non-compliant, some dangerously so. They calculated that in 3 out of 4 households in the EU there is a CE marked domestic appliance that is not compliant. In one out of every 8 households there is a CE marked domestic appliance which is dangerous. This contrasts with the regulatory situation in the USA where such products need to undergo third party independent testing, rather than relying on self-declaration which is permitted in the EU. Only 26% of consumer electrical equipment in the USA was non-compliant and none dangerously so. This clearly demonstrates the value of testing by an independent Notified Body and is a powerful argument against deregulation or self-declaration of conformity by manufacturers.

4.6 An opportunity therefore presents itself for an independent UK to move towards greater reliance on conformity assessment by Notified Bodies and relying less on self-declaration by manufacturers.

5. Standards post Brexit.

5.1 The harmonised European standards which underpin the 22 ‘New Approach’ Directives are unlikely to change due to Brexit. Hence there will be no pressure from a standardisation point of view for revision of regulations. BSI is the UK member of CEN, CENELEC, ISO and IEC, none of which is an EU organisation. BSI’s ambition is that its membership status of these organisations will not change post Brexit, although there may need to be a change of statute in CEN and CENELEC to make this happen.

5.2 ISO, IEC, CEN and CENELEC are together responsible for international standards. CEN and CENELEC are the European Bodies charged with the development of European standards, including a minority (about 20%) which are harmonised European standards that enable compliance with EU regulations. They are not EU institutions so BSI’s role within them will not need to change post Brexit noting that technical changes to the statutes of CEN and CENELEC might be required. The UK will continue have a strong influence at the technical level and hence on the technical aspect of product regulation. BSI provides hundreds of Chairs of Technical Committees in CEN and CENELEC and 80 Secretariats of Technical Committees. The standards themselves may undergo periodic

revision but this will be on a global basis through CEN and CENELEC, linked where needed to ISO and IEC, and will apply equally in the EU and UK.

6. Accreditation post Brexit

6.1 EU NBs are required to be accredited by their National Accreditation Bodies to assure customers and markets of the robustness of the Conformity Assessment process and to build confidence in it. If UK NBs are to continue to provide European Conformity Assessment services by means of a MRA they will be required to maintain their accreditation. Should UK NBs be restricted to operations in the UK only post Brexit the same benefits of accreditation would be realised albeit restricted to the UK, which would be important in establishing the credibility of the UKCA mark and confidence in the UK CA process.

6.2 UKAS is the UK National Accreditation Body. Its authority is derived from EU Regulation 765/2008. Post Brexit this Regulation will no longer apply in the UK and theoretically other Accreditation Bodies could be set up in the UK as an alternative to UKAS. But UKAS is highly regarded globally and is widely seen as a world leader in Accreditation. It is a core member of the European Co-operation on Accreditation (EA) chairing numerous of its committees. It is a signatory to the EA MRA which means that UKAS Accreditation is recognised throughout Europe. EA is not an EU body although it does receive some funding from the EU. Non-EU countries are members of EA and UKAS is in the process of discussing with EA its continued membership post Brexit. UKAS is a member of the International Accreditation Forum (IAF) and of the International Laboratory Accreditation Cooperation (ILAC). It is a signatory to the ILAC MRA which ensures global recognition of its accreditations. It is widely respected by the UK laboratory community, over 1500 laboratories and test facilities in the UK having been accredited by UKAS.

6.3 Accreditation adds value to Notified Bodies and other Laboratories through a process of independent third party appraisal of quality processes and procedures. It is BMTA's view that post Brexit it will be highly beneficial for UK Notified Bodies to retain their Accreditation by UKAS rather than seek an alternative of lesser authority and status. In our view UKAS accreditation would be the best way of ensuring the robustness of UK Notified Bodies and a UKCA mark post Brexit. We consider that a competitive market for accreditation in the UK would lead ultimately to a lowering of standards in a 'race to the bottom'. For these reasons we would urge that the Government confirms UKAS' status as the sole UK National Accreditation Body post Brexit.

7. What can UK NBs do?

7.1 It is clear that UK Notified Bodies face an existential threat following Brexit. This will be felt most keenly by the smaller and medium sized specialist NBs who are based in the UK but undertake significant business overseas. Larger multinational companies who may operate more than one UK NB and have well established operations elsewhere in Europe can simply transfer business to one of their European branches thus avoiding significant loss of business overall. They may well choose to close their UK operations however.

7.2 The smaller UK NBs strongly favour negotiation of an MRA with the EU whereby they can continue to provide conformity assessment services in the EU. This would require that UK product regulations remained unchanged from the present EU Directives. This is the 'no change' option.

7.3 If this is not possible and the EU will not permit application of the CE mark by a UK NB then negotiation of an MRA which would permit UK NBs to provide Conformity Assessment certificates for a UKCA mark which was to all intents and purposes the same as the CE mark and recognised globally would be desirable. This would retain some skills, jobs and income in the UK.

7.4 If an MRA cannot be agreed UK Notified bodies could relocate to an EU Country. The Republic of Ireland and the Netherlands might be popular choices due to geographic proximity, the fact that English is widely spoken and that both countries are significant trading partners with the UK. This would still result in a loss of skilled jobs and income to the UK. It would be necessary for the Competent Authority of the chosen country to approve the NB in that country.

7.5 If relocation to Europe is not feasible the NB might be able to partner with a European NB whereby the European NB transferred work to its UK partner. This would at least retain some skills and jobs in the UK and would allow the UK NB to issue European Conformity assessment certificates albeit under the banner of its European Partner. It would however require approval by the Competent Authority in the European NB's country.

7.6 Alternatively a UK NB or a group of UK NBs might set up a small 'front office' in a European Country whist undertaking the work in its UK laboratories. The certificates issued would be European ones from the country in which the front office was located. Again this would require approval by the Competent Authority of the European Country in which the front office was based.

7.7 If none of these options is viable the UK NB would be left with only offering CA services to the UK market. It is questionable whether this greatly reduced volume of work would be sufficient to maintain the NB as a going concern.

7.8 Action needs to be taken swiftly. There is anecdotal evidence that some of the global players are already transferring business to their European laboratories. Some UK NBs are already looking at transferring their operations to another EU country or setting up a branch office elsewhere on the Continent. There is also evidence that EU NBs are already trying to poach work from their UK counterparts by telling customers that the UK NBs will soon be out of business.

8. Recommendations

In light of the foregoing BMTA recommends the following:

1. That the Government seeks to negotiate an MRA with the EU which would allow UK NBs to continue to issue European Conformity Assessment Certificates as they do now. The CE mark would be retained in the UK and UK NBs could retain their global European CA business. Product regulation in the UK would remain virtually unchanged. UK regulations would mirror EU Directives and Regulations and would be updated in future to maintain equivalence. EN Standards harmonised in the EU journal would be accepted as providing a presumption of conformity with requirements of the regulations.

2. If an MRA on the basis of (1) is not possible then the Government should seek to negotiate an MRA with the EU whereby UK NBs for products intended for the UK market issue CA certificates for a UKCA mark which is in all respects identical in its requirements to the CE mark and would be recognised within the EU as such. UK NBs could still award European CA certificates for products intended for sale in the EU. UK product regulations would remain aligned with those of the EU as now.

3. If the UK adopts its own Conformity Assessment Mark resources for enforcement and market surveillance namely HM Customs and Revenue and Local Authority Trading Standards Departments will need to be strengthened to ensure that the mark is effective.

4. The UK should ensure that UK product regulations remain aligned closely with those of the EU. A divergence of regulation would raise costs significantly for UK manufacturers wishing to sell products in Europe by having to make separate variants of the product for the

European and UK markets as well as face costs for dual testing to different regulations and dual Conformity marking. This would be clearly disadvantageous to manufacturers, would confuse customers and disrupt markets.

5. The UK should not deregulate products safety and performance in an attempt to remove burdensome EU regulation. This would destroy UK Notified bodies business in the UK, risks the UK becoming a dumping ground for poor quality and dangerous products and is not in the best interests of consumers, the environment, food or medical safety.

6. The Government should bring the requirements of Regulation 765/2008 into UK law and continue to recognise the United Kingdom Accreditation Service (UKAS) as the sole UK National Accreditation Body post Brexit, rather than allow a competitive market for accreditation in the UK which could lower standards. UKAS is a globally respected Accreditation Body which adds value to Notified Bodies' (and other Laboratories') work through an independent third party appraisal process.

Dr J W Llewellyn on behalf of the BMTA Council
President & Chief Executive
BMTA

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