Department for Business, Energy & Industrial Strategy

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To whom it may concern:

Delivering the deal negotiated with the EU remains the Government's top priority. This has not changed. However, the Government must prepare for every eventuality, including a 'no deal' scenario.

I am therefore writing to inform you about your status as a Notified Body, Recognised Third Party Organisation (RTPO), User Inspectorate (UI) or Technical Assessment Body (TAB) and how that will be impacted in the event that the UK leaves the European Union without a deal agreed by both Parties on 29 March 2019.

This letter refers to UK Notified Bodies, RTPOs, UIs and TABs collectively as 'conformity assessment bodies.' For the purposes of this letter, this term does not include any other types of conformity assessment body. This letter covers conformity assessment activity mandated in the EU legislation listed in Annex A.

Legal framework for UK conformity assessment bodies

If the UK leaves the EU without an agreed deal on 29 March 2019, the European Union has made clear that UK conformity assessment bodies will no longer be recognised as competent to carry out conformity assessment processes for products due to be placed on the EU market.

The Government, however, is putting in place a domestic legal framework that will enable UK conformity assessment bodies to continue operating for most products being placed on the UK market. Under this framework, UK conformity assessment bodies which are currently recognised by the EU will be converted into a UK Approved Body or a UK-recognised RTPO, UI or TAB respectively so that they can continue to carry out compliance processes for the UK market.

The UK product safety framework will mirror the existing EU framework as far as possible and the technical requirements for becoming a UK Approved Body or a UK-recognised RTPO, UI or TAB will be broadly the same as they are now.

Conversion of conformity assessment bodies

On 29 March 2019, if there is no agreed deal between the UK and the EU, most conformity assessment bodies in the UK (excluding Medical Devices and Transportable Pressure Equipment – see below for further detail) will automatically have their status converted by the Government under the new UK framework. UK-based accredited Notified Bodies will automatically become UK Approved Bodies, and RTPOs, UIs and TABs will become UK-recognised RTPOs, UIs and TABs respectively.

You do <u>not</u> need to take any action to be transferred under this arrangement.

UK conformity assessment statuses will be automatically converted by the Government unless you decide before exit day to cease operating. If you no longer intend to carry out conformity assessment, decide to cease operating, or change the scope of the services that

you offer, you will need to follow the usual procedures. In most cases, this means informing UKAS, who will then inform the relevant government department.

If you choose to cease providing services under any particular area of legislation, you will be asked to either retain the relevant documents, transfer them to another body, or provide them to the relevant government department.

The following will apply to all those bodies who are converted to UK Approved Bodies, or UK-recognised RTPO, UI or TABs:

The Government is setting up a new UK database which will replace, for domestic purposes, the EU's NANDO database. You can check the details of your company which are currently published on the NANDO database here: http://ec.europa.eu/growth/tools-databases/nando/index.cfm.

We would be grateful if you could notify us of the company contact details that you would like to be published on the new UK version of the NANDO database. Please send these details to goodsregulation@beis.gov.uk, using the subject line 'Approved Bodies Database Details' at your earliest convenience. We are keen to ensure that the UK equivalent of the NANDO database has accurate data on which UK bodies have been accredited to assess products under these MRAs. If you currently operate under one of the EU Mutual Recognition Agreements with third countries, you should provide these details in the same email.

Updated letters of appointment or designation will be sent out soon after 29 March 2019 to confirm your new status and the conditions attached to your appointment. The United Kingdom Accreditation Service (UKAS) will also update your schedules of accreditation as needed.

You do not need to wait for receipt of a letter of appointment or designation in order to be able to carry out conformity assessment for the UK market. You will also be able to apply the new UK marking to products (or, where relevant, the UK replacement for the Wheel Mark). Further guidance on the new marking is available here: Using the UKCA marking. Converted UK bodies will also, subject to obtaining any additional accreditation necessary, be able to assess the conformity of products for export to third countries where the UK has secured ongoing mutual recognition of conformity assessment.

Any certificates you issued to your clients before exit day will continue to be valid for the UK market and will be treated as if they had been issued under the new UK framework. This means you do not have to reissue certificates, but your clients who continue to rely on a certificate you hold would need to use the relevant new UK conformity marking after exit day for products which are not ready for placing on the market immediately after 29 March 2019.

Accreditation

UKAS will continue as the UK's appointed national accreditation body. Its role in accrediting UK Approved Bodies will be the same as its current role for UK-based Notified Bodies.

The EU's position is that UKAS accreditation for appointment of conformity assessment bodies will no longer be valid under EU legislation. However outside of relevant EU regulatory requirements UKAS accreditation will still be recognised and accreditation certificates will continue to be valid. The UK Government has confirmed that UKAS' role as the national accreditation body including for most UK conformity assessment bodies will remain as it is now.

UKAS also expects to maintain its membership of the European Cooperation for Accreditation (EA) and will continue to provide accreditation of other types of assessment bodies (e.g. test houses and laboratories) against recognised international standards.

UKAS' membership of the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC) will be unaffected if the UK leaves the EU on 29 March 2019 without a deal agreed by both Parties.

Medical Devices and Transportable Pressure Equipment

Due to the complexity of medical devices regulation, these products will not be subject to the new UK framework, and separate arrangements will apply. If you carry out notified body activities for medical devices, please contact the Medicines and Healthcare products Regulatory Agency (Margarida Carlos, margarida.carlos@mhra.gov.uk). As detailed in the technical notice, UK Notified Bodies would retain a legal status in the UK meaning all existing product certificates would remain valid for medical devices on the UK market.

In addition, the Department for Transport intends to consult later this year with industry on the approach being taken on transportable pressure equipment (TPE). This will include whether a separate UK conformity mark for use in the domestic market should be introduced and UK notified bodies for TPE recognised as appointed or approved bodies listed on the new UK database. Responsibility for appointment of inspection bodies for transportable pressure equipment under the UN Agreements concerning the International Carriage of Dangerous Goods by Rail (RID) and by Road (ADR) is unaffected and remains with DfT.

In summary

In the event, that the UK leaves the EU without a deal on 29 March 2019, most organisations which currently operate in the UK as accredited Notified Bodies, RTPOs, UIs or TABs will be automatically converted to UK approved bodies, UK RTPOs, UIs and TABs. You do not need to take any action, unless you decide to cease operating, or change the scope of the services that you offer**.**

If the Withdrawal Agreement is ratified in the UK and the EU, then the processes set out above will not come into effect. The Withdrawal Agreement includes an Implementation Period, during which time the ability of UK conformity assessment bodies to assess products for the EU market will remain unchanged throughout this period.

Further information

For more information, please consult the technical notices and other guidance on gov.uk and if you have any further questions, please contact goodsregulation@beis.gov.uk.

Yours faithfully,

Blake Bower
Europe Director

Annex A – EU legislation in the scope of this letter

Toy Safety - Directive 2009/48/EU

Transportable pressure equipment - Directive 2010/35/EU

Construction products - Regulation (EU) No 305/2011

Pyrotechnic Articles - Directive 2013/29/EU

Recreational craft and personal watercraft - Directive 2013/53/EU

Civil Explosives - Directive 2014/28/EU

Simple Pressure Vessels - Directive 2014/29/EU

Electromagnetic Compatibility - Directive 2014/30/EU

Non-automatic Weighing Instruments - Directive 2014/31/EU

Measuring Instruments - Directive 2014/32/EU

Lifts - Directive 2014/33/EU

ATEX - Directive 2014/34/EU

Radio equipment - Directive 2014/53/EU

Pressure equipment - Directive 2014/68/EU

Marine Equipment - Directive 2014/90/EU

Personal protective equipment - Regulation (EU) 2016/425

Gas appliances - Regulation (EU) 2016/426

Machinery Directive 2006/42/EC

Directive 2008/57/EC interoperability of the rail system within the Community

2009/750/EC: European Electronic Toll Service and its technical elements

Outdoor Noise Directive 2000/14/EC

Directive 92/42/EEC hot-water boilers

Regulation (EU) 2016/426 appliances burning gaseous fuels

Active implantable medical devices (90/385/EEC)

Medical devices (93/42/EEC)

In vitro medical devices (98/79/EC)

Ecodesign directive – (2009/125/EC)