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Llywodraeth Cymru
Welsh Government

Ein cyf/Our ref MA-L/EM/0222/19

Mick Antoniw AM
Chair, Constitutional and Legislative Affairs Committee
National Assembly for Wales
Cardiff

01 March 2019

Dear Mick,

I am writing to bring your attention to an SI laid in Parliament, The Conformity Assessments (Mutual Recognition) Regulations 2019. This SI relates to EU Exit, but it is made under s.2(2) of the European Communities Act 1972 and therefore does not fall within the scope of SO30C. Therefore I am writing to you instead of laying a written statement, in the spirit of keeping the Committee informed of developments.

This SI is a trade related SI concerning product safety, which is a reserved matter. However the SI has a broad scope, which extends to some products within devolved competence, specifically blood products and biocides. The Welsh Ministers are not designated to make regulations under s.2(2) for the products within devolved competence that would be affected by this SI.

It would not be possible for the Welsh Ministers to make this legislation in Wales, due to the reserved nature of product safety. This SI does not transfer any functions, nor does it amend any existing operational delivery systems. As this SI legislates in a reserved area, it does not affect the legislative competence of the National Assembly. Kelly Tolhurst MP, Minister for Small Business, Consumers & Corporate Responsibility, wrote to me as a courtesy, seeking my agreement to proceed with this SI because of its potential impact on areas devolved to Wales. I have written in return confirming that the Welsh Ministers have no objections to this SI being laid in Parliament.

This instrument will provide explicit recognition in UK legislation for conformity assessment (product safety approval) against EU regulations carried out by bodies in third countries that have entered into a Mutual Recognition Agreement (MRA), or a trade agreement including provisions on conformity assessment (collectively referred to as Agreements), with the European Union. The countries with Agreements covered by this measure are Australia, New Zealand, Canada, USA, Japan, Switzerland, Turkey, South Korea and Israel.

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The purpose of product safety legislation is to ensure that products that are placed on the market are safe and compliant. To this end, UK legislation places obligations on economic operators throughout the supply chain (manufacturers, importers, distributors and authorised representatives). The key obligations are that products are safe or accurate and meet certain requirements. Sometimes there is a requirement that products are assessed (conformity assessments) to demonstrate compliance with the relevant regulations prior to being placed on the market. Should products be found to be unsafe or otherwise non-compliant, corrective action will be required and they ultimately may have to be withdrawn from the market.

In the case of product-specific legislation, UK legislation follows a framework developed at EU level and applied with adaptations to many product areas. This SI forms part of maintaining that framework after EU Exit, as an interim measure until more permanent measures are put in place with the third countries in question.

In order to reduce potential disruption to businesses and consumers, the UK Government has decided to adopt a continuity approach for goods which meet EU regulations in a no deal scenario. This means that the UK will continue to accept goods made and assessed by EU bodies against EU regulations for a time-limited period. This SI states that results of conformity assessment by bodies covered by the Agreements should be treated as if issued by an EU body. This will ensure that the continuity approach described above also applies to conformity assessment carried out by specific third country bodies in a no deal scenario. This will mean that products that follow this process will be recognised as valid for sale on the UK market. This SI will also recognise existing Authorised Representatives (legal entities that perform certain statutory functions on behalf of a manufacturer) based in Switzerland and Turkey, where the respective Agreements allow for this.

Without this instrument there could be legal uncertainty for these third countries, meaning it is possible that the availability of products from these countries in the UK could diminish. A reduction in the availability of biocides would negatively affect the Welsh farming industry. A reduction in the availability of blood products could be detrimental to the health and wellbeing of individuals who rely on these products, as well as increase costs for the Welsh health services. Failing to make this SI by exit day would disadvantage citizens in Wales. It is also in line with the Welsh Government's policies of continuity after exit day.

Yours sincerely,

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