BREXIT UPDATE: DOES THE FUTURE REGULATION OF PRODUCTS IN THE EU AND UK CONTINUE TO MEAN "DOUBLE THE TROUBLE" FOR BUSINESSES?

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The UK Government's long-awaited negotiating position for Brexit was published on 12 July 2018 by way of a White Paper (the "Chequers Paper"). In addition to critical issues such as security and trade, the Chequers Paper also sheds light as to what the UK is seeking in terms of the regulation of various industries post-Brexit. If an agreement is reached between the UK and EU, the new intended regulatory regime for products would likely come into force after a transition period at the end of 2020. However, if no agreement is struck, businesses should prepare for the eventuality of "hard-Brexit" on 29 March 2019, when all EU rules would cease to apply to UK manufacturers, importers and distributors, having a significant impact on global supply chains and causing numerous products placed on the EU market to be in breach of EU legislation.

TECHNICAL RULES AND STANDARDS APPLIED TO PRODUCTS

In the Chequers Paper, the Government rejects membership of the single market or entering into a customs union with the EU, but instead advocates for a "*Facilitated Customs Arrangement*", which would allow for the free trade of products between the UK and EU, without custom checks, controls, tariffs, quotas or rules of origin for goods. It would ensure (i) a "common rulebook" between the EU and UK for manufactured goods, and (ii) permit the UK to participate in the work of the EU agencies that regulate products being placed on the EU market.

Under the common rulebook model, a common set of technical rules would apply across the EU and UK, ensuring "*frictionless trade*" at the borders. Identical rules would be applied in each jurisdiction that govern (i) the testing of products, so manufacturers would only be required to undergo one series of tests for both jurisdictions, (ii) an agreed framework for the accreditation of conformity assessment bodies as well as manufacturing and quality assurance processes for manufacturers, (iii) agreed licencing regimes, and (iv) the continued use of nominated individuals who would interact with authorities, for example lead registrants under the REACH regime.

In addition, where a common rulebook applies to a category of products, any relevant EU standard will prevail over any domestic UK standard. This maintains the current policy of the "*single standard model*", as implemented by the British Standards Institution, whereby any product manufactured or imported into the UK must meet the

standards set by the EU. As an example, the Chequers Paper specifically addresses how the common rulebook may apply to the type approval of vehicles and vehicle components. By implementing a common rulebook for these products, the UK Government intends for the system currently in place to continue post-Brexit, whereby (i) vehicles and their components, when approved by a UK approval authority, may be lawfully sold in the EU and vice-versa i.e. mutual recognition of approvals, and (ii) UK approval authorities are recognised by each Member State and vice-versa. The UK Government are also seeking to implement common rulebooks for agriculture, food and fisheries products. These common rulebooks are designed to ensure the products they relate to can continue to be easily traded between the EU and UK.

CENTRALISED REGULATION OF PRODUCTS

Under the UK Government's proposals for products regulated at the EU level, including chemicals, aviation products and medical devices, the UK would fully subscribe to the requirements set by the relevant EU agencies. The Government wishes to maintain the one-stop shop approval system and to obtain access to the IT systems of the EU regulators, such as REACH-IT for chemicals or the Device Online Registration System for medical devices.

Specifically for chemicals, the Government seeks to maintain the current practice of UK businesses registering substances with the European Chemicals Agency to continue post-Brexit. For medicines and medical devices, the UK is seeking for its domestic regulators to maintain their positions as leading authorities in conducting technical work for the assessment of medicines, ongoing safety monitoring and participation in the upcoming clinical trial framework. Finally, for aviation products, the UK is looking to be categorised as a third country member via the route already established under Article 66 of the European Aviation Safety Agency basic regulation, following the example of Switzerland.

The UK Government has not specifically addressed its plans for other types of centrally registered or notifiable products, such as whether the UK would participate in the Cosmetic Product Notification Portal or the Register for Biocidal Products. In this regard, the Government states that its intention is that all authorisations, approvals, certifications, notifications and any agency activity under EU law, completed prior to Brexit, would be recognised as valid by both the EU and UK.

UK'S INVOLVEMENT IN RULE MAKING AND THE CJEU'S ROLE

While the Government wants the UK actively to engage in the process of drafting the technical rules that make up the common rulebook and participate in the EU's centralised regulatory frameworks, it does not foresee the UK having any voting rights in regards to either. Under the proposals, Parliament could refuse to implement certain rules. However, given the severe consequences this would bring, such as restriction of access to the EU market, border frictions and reduced security cooperation, it would be questionable whether Parliament would exercise such powers.

The role of the Court of Justice of the European Union ("CJEU") has been a red line for both the EU and the UK in discussions regarding regulation post-Brexit. The EU has refused to permit the UK to remain a participant in the EU regulatory frameworks unless the CJEU remains the highest court. The UK's position is that the CJEU should no longer bind UK courts and EU law should cease to have direct effect in the UK. However, the UK Government now intends, where products are subject to the common rulebook, that the CJEU would continue its role as the highest court and the UK courts would have to "*pay due regard to CJEU case law*". Where a product is regulated at the EU level, disputes between a UK business and an EU agency would also need to be resolved by the CJEU. Thus, the post-Brexit relationship between the CJEU and the UK in relation to products as set out in Chequers Paper is similar to the current position.

LIKELIHOOD OF HARD-BREXIT

The regulatory framework detailed in the Chequers Paper and summarised above is not yet agreed between the UK and the EU. On 26 July 2018 Michel Barnier, the EU's chief Brexit negotiator, categorically ruled out the arrangements put forward by the UK Government in the Chequers Paper, stating that the UK could not maintain its involvement in the EU's customs policy and rules post-Brexit. This is in line with the position previously set out by the EU on 22 January 2018 in its Notice to Stakeholders entitled "Withdrawal of the UK and EU Rules in the Field of Industrial Products", which envisages the UK becoming a third country, with "*EU rules in the field of non-food and non-agricultural products […] no longer apply[ing] to the United Kingdom*". Thus a "*no-deal, hard-Brexit*" remains as likely an outcome as the UK Government's proposals set out in the Chequers Paper, although both the EU and UK have now recognised the harm that could be done to UK and EU manufacturers (as well as distributors and end users) if this turns out to be the case.

Two of the EU regulatory authorities, European Chemicals Agency and European Medicines Agency, continue to urge UK and EU businesses to prepare for the "*no-deal*" outcome, while the EU Commission has since released a communication on Brexit on 19 July 2018, reiterating the advice it provided in the Notice that all businesses need to make preparations for a "*cliff-edge, no-deal*" scenario. Further to this, the Commission has begun to introduce legislation designed to limit the impact a "*hard-Brexit*" outcome may have on industry and trade; for example, a transitional regime that permits vehicle manufacturers to register products with EU authorities which will continue to be recognised in the EU market post-Brexit (see proposal 2018/0220 (COD)). The UK Governmental departments also appear to be preparing for "*hard-Brexit*", planning emergency measures for the supply of medical devices. The Department for Environment, Food and Rural Affairs (DEFRA) is also developing its own regulatory regime for chemicals separate from the EU, dubbed UK-REACH (see our previous article, "Back to the drawing board: Brexit to result in UK-REACH. How can UK importers and manufacturers best prepare?").

WHAT NEXT?

The post-Brexit regulatory environment remains uncertain, including how (if at all) individual Member States may enforce regulation against UK manufacturers operating within the EU. UK businesses should ensure they are adequately prepared for all outcomes of Brexit, so as to minimise costs, losses or disruption to business. Steps

UK manufacturers can take include ensuring they have an EU base which they can operate out of post-Brexit, obtaining insurance, inserting appropriate protections into contracts with those with whom they trade and conducting advocacy with the EU Parliament and Council in relation to specific regulatory regimes. K&L Gates has experienced teams of lawyers in offices in London, Brussels and across the EU and is well placed to assist you with any of these steps.

