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Brexit: The Great Repeal Bill and the EU's Chemicals, Emissions, and Medicines Regimes

As discussed in our recent *GT Alert*, "[Brexit: 100 Day Update](#)", the UK Prime Minister Theresa May recently announced plans for a "Great Repeal Bill" for the repeal of the 1972 European Communities Act (ECA). Under the ECA, European Union (EU) law was established as part of the UK's legal order and was given supremacy over the UK's domestic laws.

It is intended that the Great Repeal Bill will enter into force on the date of Brexit (which appears to be March/April 2019 at the earliest). It is expected that the Great Repeal Bill will preserve the majority of existing EU law in domestic UK legislation until the UK Government has had an opportunity to assess individual EU-derived domestic laws and decide whether to retain, amend, or remove them. This process is likely to take many years, depending on the resources devoted to it. New, post-Brexit EU law, including the decisions of the European Court of Justice, will not form part of UK domestic law.

The UK Secretary of State for Exiting the European Union, David Davis, has stated that the Great Repeal Bill will "*provide for a calm and orderly exit and give as much certainty as possible to employers, investors, consumers and workers*". Importantly, however, Mr Davis also stated that EU law would be converted into UK domestic law through the Great Repeal Bill only "*wherever practical*".

This significant qualifier indicates that the scope and effect of the Great Repeal Bill may not be as wide as many people assume. As a result, although the Great Repeal Bill should, as Mr Davis stated, provide some legal certainty and continuity in the short to medium term, it is important to be aware of its likely limitations.

These limitations may be of particular interest to businesses currently subject to the EU's chemicals, emissions, and medicines regimes, all of which operate at a pan-European level and may not be capable of being easily preserved in UK domestic law through the Great Repeal Bill.

Chemicals

In the chemicals arena, a key piece of EU law is the REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Regulation pursuant to which the European Chemicals Agency (ECHA) was established. One of the ECHA's key tasks is in relation to determining, via the REACH registration process, whether an applicant may or may not start or continue manufacturing in, or importing a substance into, the EU.

Emissions Trading

Under the EU's Emissions Trading Scheme (ETS), companies receive or buy emission allowances which they can trade as needed. At the end of each year, companies must surrender enough allowances to cover all of their emissions, otherwise fines are imposed. If a company reduces its emissions, it can keep the spare allowances to cover its future needs or else it can sell them to another company that is short of allowances. The ETS is a pan-European regime, allowing companies to trade emissions allowances across national borders.

Medicines

In addition to national medicines approval systems run by each EU Member State, the EU currently operates a centralised pan-European approval system, run by the European Medicines Agency (EMA) for pharmaceutical products. The current EU approval system allows companies to provide their pharmaceutical products across the EU on the basis of a single marketing-authorisation application process. Each EU Member State can also authorise pharmaceutical products at the national level for pharmaceutical products outside the scope of the centralised approval procedure. Such national approvals can, through the EU's "mutual recognition procedure", be recognised in other EU Member States.

Conclusions

Unless agreement is reached with the EU that the UK can participate in the existing pan-European regimes with effect from Brexit in the same manner as it does now, the UK may find itself having to implement its own independent replacement regulatory regimes if it wishes to continue to regulate the same underlying activities. This is irrespective of what the Great Repeal Bill purports to do with regard to preserving existing EU law in the UK.

Therefore, businesses could, depending on the scope of their pan-European operations and the scope of any future agreement regulating the UK's relationship with the EU post-Brexit, find themselves subject to multiple regulatory frameworks: the existing EU regimes in respect of their EU operations and new UK regimes in respect of their UK operations. Businesses with global operations that already deal with multiple regulatory frameworks (*e.g.*, in the United States, China, Korea, etc.) may be better positioned to address any additional complexity caused by these developments. Further, there is no guarantee of any future inter-relationship between the existing EU and the potential independent UK regimes permitting, for example, the "passporting" of approvals (in the cases of chemicals and medicines) or the transfer of allowances (in the case of emissions trading) between the UK and the EU.

While the UK could potentially seek to unilaterally accept or recognise the EU's chemicals and medicines approvals, there is no certainty that the UK's own, post-Brexit, national chemicals or medicines approvals would be so accepted or recognised in the EU. For its part, the exchange of emissions allowances between the UK and EU regimes would necessarily require formal cooperation between the relevant UK and EU regulatory authorities.

If the UK decides to design and implement its own independent regimes then, due to their inevitable complexity, the UK may not be able to get them off the ground in time for Brexit. However, the alternative is that the current EU regimes cease to operate in the UK without replacement regimes being put in place, something which can be regarded as being implausible. If no regime is put in place in respect of chemicals, this could be controversial given the activities currently regulated under the REACH regime (although this could also be attractive to many businesses that have complained that complying with REACH is unduly onerous). In the case of emissions, if no replacement regime is put into place, the UK could find itself struggling to meet its climate change obligations under, for example, the Climate Change Act 2008, if UK businesses are unable to participate in a sufficiently large carbon-trading market. Finally, in the case of medicines, it is very unlikely that their approval and use would be left unregulated.

Implications

The Great Repeal Bill should provide some legal certainty and continuity in the short to medium term until the individual EU laws that form part of the UK's legal systems at the time of exit can be properly assessed. However, significant uncertainty remains in relation to the terms the UK will ultimately negotiate for its future relationship with the EU. As a result, the scope of the Great Repeal Bill and what it is capable of achieving is currently unclear.

It is therefore important that businesses continue to closely monitor developments and seek to identify those areas that are likely to be affected by new or amended legislation and arrangements in order to consider how impacts in affected areas can be mitigated.

Further information from Greenberg Traurig about issues relating to Brexit can be found [here](#).

This *GT Alert* was prepared by **Aonghus Heatley** and **Cate Sharp** in Greenberg Traurig's London office. Questions about this Alert can be directed to:

- > [Aonghus Heatley](#) | +44 (0) 203 349 8759 | heatleya@gtlaw.com
- > [Cate Sharp](#) | +44 (0) 203 349 8777 | sharpc@gtlaw.com
- > The GT London Brexit team:
 - > [Gillian Sproul](#) | +44 (0) 203 349 8861 | sproulg@gtlaw.com
 - > [Lisa Navarro](#) | +44 (0) 203 349 8757 | navarro@gtlaw.com
 - > [Simon Harms](#) | +44 (0) 203 349 8767 | harmss@gtlaw.com
- > Or, your [Greenberg Traurig](#) attorney

For more information:

Greenberg Traurig, LLP
The Shard, Level 8
32 London Bridge Street
London SE1 9SG

T +44 (0) 20 3349 8700

F +44 (0) 20 7900 3632

www.gtlaw.com

Amsterdam + 31 20 301 7300	Denver +1 303.572.6500	Northern Virginia +1 703.749.1300	Tallahassee +1 850.222.6891
Atlanta +1 678.553.2100	Fort Lauderdale +1 954.765.0500	Orange County +1 949.732.6500	Tampa +1 813.318.5700
Austin +1 512.320.7200	Houston +1 713.374.3500	Orlando +1 407.420.1000	Tel Aviv[^] +03.636.6000
Berlin⁻ +49 (0) 30 700 171 100	Las Vegas +1 702.792.3773	Philadelphia +1 215.988.7800	Tokyo[⌘] +81 (0)3 4510 2200
Berlin-GT Restructuring⁻ +49 (0) 30 700 171 100	London[*] +44 (0)203 349 8700	Phoenix +1 602.445.8000	Warsaw[~] +48 22 690 6100
Boca Raton +1 561.955.7600	Los Angeles +1 310.586.7700	Sacramento +1 916.442.1111	Washington, D.C. +1 202.331.3100
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