Cooley

Brexit Readiness: Key Impacts of the UK-EU Brexit Deal

February 11, 2021

Since our <u>last update in December</u>, the UK and the EU have officially agreed on a Brexit deal. The agreement has brought with it a multitude of legislative changes across various areas of UK law. In support of understanding those changes, please find below a summary of key changes across these six discrete areas.

- Antitrust & competition
- Cyber/data/privacy
- Ecommerce & marketplace
- International trade
- Life sciences
- Product liability & compliance

We'd be happy to discuss your Brexit transition across these areas. Please reach out to your Cooley contact if you have any questions.

Antitrust & competition

1. What changes can be expected for UK competition law?

The EU-UK Trade and Cooperation Agreement does not bring major changes to UK competition law. Whilst the agreement presents a slightly different terminology to what we are familiar with, the common principles appear largely the same as under the existing regime. In terms of jurisdiction, the European Commission continues to be the competent authority for UK antitrust cases initiated before 31 December 2020. The only exception to this rule is where the anticompetitive conduct is still ongoing at the end of the transition period and may have an effect on trade in the UK. In those circumstances, the UK Competition and Markets Authority may investigate facts from 1 January 2021 onwards. For all other cases that have not been formally initiated by the EC before 31 December 2020, the EC will cease to have jurisdiction over the UK aspects of the investigation, which will pass to the CMA.

2. How will merger control be affected?

With regards to merger control, since 1 January 2021, the UK is now outside the EU's one-stop-shop principle, meaning that the EC's review of a merger will no longer cover the UK. As a consequence, parties may find that their transaction is subject to review by both the CMA and the EC, creating additional burdens and uncertainties for businesses, which will need to be reflected in deal documentation. While the UK will continue to operate a voluntary regime, merging parties should bear in mind that the CMA is increasingly becoming one of the most interventionist merger authorities in the world.

3. Will the European Commission's jurisdiction change on State aid?

The EC will continue to have jurisdiction over existing State aid cases, including State aid cases initiated before 31 December 2020. In addition, the EC will be competent to launch new State aid investigations concerning the UK for aid granted before such date until 31 December 2024.

4. How will State aid rules be affected?

From 1 January 2021 until 31 December 2024, Northern Ireland will be subject to EU State aid rules. Under the Protocol on Ireland and Northern Ireland contained in the 2019 EU-UK Withdrawal Agreement, State aid rules will continue to apply to the UK for measures that impact trade between Northern Ireland and the EU. The EC and the UK government already appear to have diverging views on the scope of the application of such regime. These differing positions will undoubtedly create some uncertainty for businesses.

5. Which body will regulate UK competition law?

Under the terms of the agreement, each party must have in place and maintain "an effective system of subsidy control," and it is up to each regime to determine how this will be implemented into domestic law. This means that, while the UK must adopt a subsidy regime, it is free to set up its own rules without being bound to EU law and to the European Court of Justice. Nonetheless, the agreement provides a legal framework for both sides to follow, including the obligation to establish an independent authority, "with an appropriate role in its subsidy control regime." For the UK, this may be the CMA, but that has yet to be determined.

On 3 February 2021, the <u>UK government launched a consultation</u> on the best way to design a bespoke subsidy control regime in the UK, seeking views, in particular, on the way to manage the most distortive type of subsidies as well as on the role and powers of the independent body that will oversee the regime. The consultation is due to end on 31 March 2021.

For more details, please see our Cooley alerts "Brexit Readiness: Possible Key Impacts of the Conclusion of the Transition Period on 31 December 2020" and "The EU-UK Trade and Cooperation Agreement – the 'Level Playing Field"

If you have questions related to the above, please contact Ben Shribman, Christine Graham or your usual Cooley contact.

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Cyber/data/privacy

1. What is the key data protection takeaway from the EU-UK Trade and Cooperation Agreement?

The <u>agreement states that</u> transfers of personal data to the UK from EU member states will not be treated as "restricted transfers" for an interim period of up to six months from 1 January 2021. (See more on timing below.) This also applies to transfers to the UK from European Free Trade Association states (being Iceland, Liechtenstein and Norway), each of which have notified the UK and the EU of their express acceptance to accede to the relevant provision of the trade deal.

This means that personal data can continue to flow from the EU and EFTA (together, the EEA) to the UK without the need for additional safeguards (i.e., entering into EC-approved standard contractual clauses).

The intention behind the establishment of this interim period is to give the EC more time in which to conclude its adequacy assessment in respect of the UK.

2. How long will the interim period last?

The interim period is initially for a period of four months from 1 January 2021, but will automatically be extended for a further period of two months unless either the UK or the EU objects to that extension.

However, the period will come to an end if and when:

- The EC adopts an adequacy decision in respect of the UK
- Or the UK amends the so-called UK GDPR or exercises certain "designated powers" regarding data transfers under the UK GDPR/UK Data Protection Act 2018 without the consent of the EU (unless those powers are exercised for the sole purpose of aligning UK laws with EU data protection laws)

3. What happens next?

This depends on the conclusion of the EC's adequacy assessment in respect of the UK:

- If the EC does not adopt an adequacy decision in respect of the UK before the expiry of the interim period, any transfer of
 personal data from the EEA to the UK will then need to be effected subject to EU GDPR-compliant additional safeguards
 (i.e., entry into EC-approved standard contractual clauses)
- If the EC does adopt an adequacy decision in respect of the UK before the expiry of the interim period, personal data can continue to flow from the EEA to the UK on the basis of that decision, without the need for additional safeguards

If you have questions related to the above, please contact Ann Bevitt, Leo Spicer-Phelps or your usual Cooley contact.

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Ecommerce & marketplace

1. What is the consequence of the disapplication of the Ecommerce Directive?

The Ecommerce Directive allows EEA-based information society service providers to operate in any EEA member state, while only following relevant rules in the country in which they are established. This is the so-called country of origin principle.

However, with effect from the end of the Brexit transition period, the Ecommerce Directive ceased to apply in the UK – meaning that relevant providers established in the UK and providing services in the EEA will need to comply with the national rules applicable to their services in each such EEA member state. Likewise, providers established in the EEA and providing services to customers in the UK will need to comply with UK laws applicable to those services.

2. What is an information society service provider?

The Ecommerce Directive applies to information society services, being services that are normally provided:

- For payment, including indirect payment (i.e., advertising revenue)
- At a distance (i.e., where the service is provided without the customer and provider being simultaneously present)
- By electronic means
- At the individual request of a recipient of the service

This captures the vast majority of online service providers, including online retailers, social media platforms, cloud service providers (including SaaS providers) and internet service providers.

3. What does "established" mean for this purpose?

The Ecommerce Directive refers to the "place of establishment" of the service provider. This means the fixed establishment where the provider pursues its economic activity for an indefinite period of time. Recitals to the directive clarify that in respect of companies providing services via the internet, the place of establishment is not the place at which the technology supporting its website is located or the place at which its website is accessible. Rather, it is the place where it pursues its economic activity.

Where a provider has several places of establishment, the relevant place of establishment for the service concerned is the place where the provider has the centre of its activities relating to the particular service.

4. What is the substantive scope of the change?

The country of origin principle applies to rules falling within the directive's so-called coordinated field.

This includes rules relating to:

- Online information
- Online advertising
- Online shopping
- Online contracting

This means that information society service providers established in the UK will need to review and comply with national legal requirements in each of the coordinated fields of the directive in each EEA member state in which they operate, in order to be sure that they are compliant. Alternatively, they may seek to retain the benefit of the country of origin principle by moving their place of establishment to an EEA country.

If you have any questions related to the above, please contact Chris Coulter, Amy Collins, or your usual Cooley contact.

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International trade

1. What are the key aspects of the EU-UK Trade and Cooperation Agreement for companies trading goods?

Reintroduction of customs and custom formalities: With the end of the transition period, customs between the UK and the EU have been fully reintroduced. Importers and exporters alike will have to fill in custom declarations and comply with all customs' formalities.

Zero tariffs: Goods imported into the EU and the UK will pay zero tariffs as long as they are originating goods. For example, a good that has been imported from a third country to the EU and re-exported (with no transformation) to the UK market will not be originating.

Rules of origin: Goods will only pay zero tariffs if they comply with the Free Trade Agreement's <u>rules of origin</u>, which determine what goods originate from either the EU or the UK. A product will be considered as originating if: (i) it is "wholly obtained" in the UK or the EU; (ii) it is produced in the UK and the EU exclusively from originating materials, or (iii) the non-originating materials incorporated into the good satisfy certain rules that set out in the agreement's annexes.

Temporary easements: Traders importing goods into the UK from the EU will have time until 30 June 2021 to submit a full customs declaration and pay any tariffs due if the goods are not originating. Additionally, traders importing goods from the EU to the UK and from the UK to the EU will not need to file suppliers' declarations at the time the goods are exported. This easement will expire by 31 December 2021 and traders might need to provide suppliers' declarations retroactively to cover all of their imports for 2021.

Trade remedies: Trade remedies are measures that states can take to protect their domestic industries against unfairly

imported goods. There are three types of trade remedies:

- Anti-dumping remedies target imported goods being sold within the UK at prices which are below the normal value in the country they are being exported from
- · Counter-veiling remedies are aimed at imported goods which are being subsidised by foreign governments
- · Safeguard remedies protect domestic industries against an unforeseen surge of imports

From 1 January 2021 onwards, the UK will undertake its own trade remedies investigations through its newly created Trade Remedies Investigations Directorate (TRID).

All current anti-dumping, anti-subsidy and safeguard measures in place by the EU are being reviewed by the TRID. The TRID will then determine if the measure in question needs to be maintained, varied or terminated. It is very important that companies wishing to maintain any trade remedy contact the TRID.

2. How will service providers be affected?

End of the free movement of persons, free provision of services and freedom of establishment: UK and EU service providers will no longer be able to automatically offer services in the other bloc's market. UK companies will need to establish themselves in the EU territory to continue operating in the EU market and vice versa. A UK company establishing itself in the territory of one EU member state will need to comply not only with the EU rules but also with the rules of the host country. Country of origin and passporting rules, which were applicable up to the end of the transition period, will no longer be valid.

Conditions for service providers to operate under the EU-UK Free Trade Agreement: The trade agreement incorporates a non-discrimination obligation ensuring that the EU grants the same treatment to UK service providers established in the EU than the one given to EU service providers and vice versa.

Market access: The level of market access of service providers from one bloc operating in the territory of the other bloc will depend on the way the service is supplied. There are four modes of supplying services:

- Mode 1: Cross-border provision of services from the supplier's home state (i.e., over the internet)
- Mode 2: Supplied to the consumer in the country of the supplier (i.e., a tourist buying services while traveling)
- Mode 3: Services that are supplied by means of a locally established enterprise owned by a foreign service supplier
- Mode 4: Providing services via temporary presence in a foreign territory by a service provider who is a natural person

The EU-UK Trade and Cooperation Agreement also includes a most-favoured nation clause which entitles either party to claim more favourable treatment granted by the UK or the EU to other third-party countries. This most-favoured nation provision excludes treatment granted in the area of financial services.

Professionals and travel: As of 1 January 2021, there is no longer free movement of EU citizens to the UK and vice versa. However, the EU and the UK have agreed on some reciprocal commitments for temporary movement of persons for business purposes.

- Recognition of professional qualifications: UK nationals and EU nationals will be required to have their qualifications
 recognised in the relevant member state based on each country's rules. The EU-UK Trade and Cooperation Agreement
 foresees the possibility of future bilateral agreements for the mutual recognition of specific professions
- Equivalence of financial services: The EU-UK Trade and Cooperation Agreement does not cover equivalence frameworks for financial services. Whether to grant such equivalence will depend on unilateral decisions by each of the parties

If you have questions related to the above, please contact James Maton, Juan Nascimbene or your usual Cooley contact.

Life sciences

1. How will supplementary protection certificates change in length?

Supplementary protection certificates compensate patent owners for time lost between filing a patent and gaining a marketing authorisation. Under the terms of the EU-UK Trade and Cooperation Agreement, both the UK and the EU are to provide extended periods of protection but can each decide the terms and conditions, including the duration, of such extension. While the position is, for the time being, largely unchanged, there may therefore be divergence in the future between the UK and the EU.

2. What is the new position regarding exhaustion of rights?

The position regarding exhaustion of rights is asymmetric. Notably any product put on the market in the EEA will be viewed by the UK as having its rights exhausted, and therefore capable of being sold freely in the UK. However, products put on the market in the UK will be viewed as **not** having their rights exhausted in the EEA, and therefore parallel imports from the UK to the EEA will be able to be blocked by the holders of the relevant rights.

3. Where does the UK stand regarding Horizon Europe?

The EU-UK Trade and Cooperation Agreement provides that the UK will be able to participate in Horizon Europe, and it has been clear that the UK intends to do so. One weakness of the deal for UK based entities is that they will no longer have access to the European Innovation Council Fund.

4. Will there be a mutual recognition of EEA batch testing between the UK and the EU?

The EU-UK Trade and Cooperation Agreement fails to provide for the mutual recognition of batch testing and release. The UK will, until 1 January 2023, continue to accept EEA batch testing but this is not reciprocated by the EU. Therefore, UK-based manufacturers of medicinal products will have to duplicate batch testing and release, adding cost and administrative burden.

5. How will medicines treating orphan conditions be treated differently?

Medicines that treat orphan conditions benefit from longer periods of market exclusivity and refunds of marketing authorisation application fees compared to medicines that are used in the treatment of more common conditions. The periods have not changed, but orphan designation will now be granted based on the prevalence of the targeted condition in Great Britain, as opposed to in the EU as a whole, which may mean that different conditions are eligible for orphan designation (i.e., if they have higher prevalence in GB than the EU).

If you have questions related to the above, please contact John Wilkinson, Nicola Maguire or your usual Cooley contact.

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Product liability and compliance

1. What are the new limitations to the regulation of goods between the EU and the UK?

The EU and UK have the right to regulate goods independently within their own territories, subject to limited restrictions which

aim to ensure technical regulations, standards and conformity assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade. This means:

- The UK has the freedom to diverge from EU product compliance laws, though currently it will only be able to do so for Great Britain (England, Scotland and Wales), as products sold in Northern Ireland must comply with EU laws under the Northern Ireland Protocol. In practice, there are also questions about to what extent divergence from such a big neighbouring market is desirable
- For most products, companies will now have to comply with two separate regulatory regimes for the EU (and Northern Ireland) and for Great Britain

2. How does the new deal immediately impact manufacturers, importers and distributors?

The EU-UK Trade and Cooperation Agreement changes little of the immediate impact of Brexit for manufacturers, importers and distributors who may have new product compliance obligations. These include using the UK Conformity Assessed mark, updating declarations of conformity and providing new traceability information. Read more here.

3. What can be expected for the development of future technical requirements?

The agreement contains commitments from the EU and UK to take a common approach when it comes to the development of future technical requirements for products (i.e., standards, conformity assessments and the marking and labelling of products). In the longer term, these commitments may help to limit the practical impact of divergence in some areas.

4. What changes can be expected regarding EU and UK market surveillance and enforcement of products sold?

The EU and UK have agreed to cooperate on market surveillance and enforcement of products sold in both markets. They have committed to exchange of information on corrective actions notified in the EU's rapid alert system and the new UK Product Safety Database.

5. Will any specific products benefit from facilitated cooperation?

There are some simplified measures to facilitate cooperation and trade for certain products including motor vehicles, medicinal products and chemicals.

If you have questions related to the above, please contact Claire Temple, Ed Turtle, or your usual Cooley contact.

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