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EU Policy Update for December 2015

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Digital Single Market Policy

On November 4, 2015, the UK Home Secretary, Theresa May, published her draft Investigatory Powers Bill in the House of Commons. Following the draft, the government announced the formation of a joint parliamentary committee designed to scrutinize the new surveillance bill. However, the committee will only have two weeks to hear witnesses, and NGOs fear that this legislation is being fast-tracked. Under the new surveillance proposal, internet firms must store details of every website visited by UK citizens in the past 12 months. Any intercept warrants will need ministerial authorization and will then be reviewed by a panel of judges, who will be given veto power. This panel will be overseen by a single senior judge, the newly created Investigatory Powers Commissioner. The detailed communications data collected under the bill would be available to a wide range of public agencies, including law enforcement and other agencies, such as the Food Standards Agency.

On November 6, 2015, the European Commission issued guidance on transfers of personal data from the EU to the U.S. following the October 6 judgment of the EU Court of Justice in the *Schrems* case. The Commission guidance largely follows the statement issued mid-October by the Article 29 Data Protection Working Party ("WP29"), namely in that alternative tools (standard or *ad-hoc* contractual clauses, Binding Corporate Rules or derogations) authorizing data flows can still be used by companies for lawful data transfers to the U.S. But the Commission, like the WP29, emphasized the responsibility of data controllers to take additional safeguards where necessary. Moreover, although the Commission aims at finalizing the renewed Safe Harbor negotiations within three months, in practice (mainly due to procedural reasons), a new Commission decision on Safe Harbor will likely take longer before entering into force.

On November 19, 2015, the European Data Protection Supervisor ("EDPS") issued an Opinion regarding the challenges of Big Data. The opinion calls for more effective data protection through four essential elements: (i) greater transparency, (ii) more user control (iii) user-friendly data protection, and (iv) more accountability. These principles are also enshrined in the draft General Data Protection Regulation.

The Commission's public consultations for various initiatives under the Digital Single Market, such as consumer rules for online sales, online platforms, telecoms reforms, copyright and geo-blocking issues and

standardization, are nearing their deadline of mid/late December 2015.

Energy and Climate Change Policy

On November 18, 2015, the Commission presented its first annual State of the Energy Union. The Energy Union is a comprehensive approach to decarbonize the EU's energy supply, promote energy efficiency, complete the internal energy market, guarantee the EU's energy security, and encourage research and innovation on energy and climate technologies. According to the Commission, the EU is on track to meet its target to reduce greenhouse emissions by 20% below the 1990 level and achieve its 20% energy efficiency target by 2020.

However, the Commission indicated that more efforts are needed to achieve the Union's climate and energy objectives for 2030. It therefore announced that it will propose the following legislative initiatives in 2016: a proposal on the implementation of the non-ETS target (Effort Sharing Decision); a legislative proposal on Land Use, Land Use Change and Forestry (LULUCF); a review of the Energy Efficiency Directive; a legislative proposal on the new electricity market design; and a revision of the Security of Gas Supply Regulation.

Along with the State of the Energy Union, the Commission published a second list of **Projects of Common Interest** ("**PCIs**"). They are specific energy infrastructure projects that are necessary to implement the 9 priority corridors and the 3 thematic areas laid down in the TEN-E Regulation. From the first PCI list, 13 have already been commissioned and some 60 projects are expected to be completed by the end of 2017. As an example, one project underway is the electricity transmission interconnector at the Spanish-French border. The second list is composed of 195 PCIs, including 108 electricity projects, 77 gas projects, 7 oil projects and 3 smart grids projects.

The European Commission also published a <u>first guidance document</u> on the national energy plans as part of the **Energy Union governance between 2020 and 2030**. The document launched a gradual process that stipulates the main tasks and roles of both the Member States and Commission in the drafting and adoption of national energy plans by 2018. In this context, in 2016 the Commission will make a legislative proposal to streamline the planning and reporting requirements of the Member States and present a template for the structure of national energy plans. The Commission gives particular focus to regional cooperation to coordinate national energy plans across borders. At the latest Energy Council, the EU ministers for Energy included in the conclusions that the first national plans will be finalized by the end of 2019 (rather than 2018).

In November, the Commission launched two **public consultations** on: (i) the future **revision of the Renewable Energy Directive**, which runs until February 10, 2016 – see here; and (ii) the review of Directive 2012/27/EU on **Energy Efficiency**.

The Commission released the State of the Energy Union in the context of the <u>COP 21</u> of the United Nations Framework Convention on Climate Change ("UNFCCC"), currently underway in Paris. It is yet to be seen whether the parties will approve a new legally binding and universal agreement to mitigate and adapt to climate change. The summit will last until December 11. As noted above, the Covington Brussels office will be hosting an event on the main results of COP 21 on Monday, December 14.

On December 2, **the Commission adopted a new Circular Economy Package**. It consists of a framework Communication and various legislative and non-legislative initiatives, including: a revised waste proposal with binding waste recycling targets; promotion of Green Public Procurement; a proposal to amend the fertilizers regulation; and an Ecodesign working plan for 2015-2017.

Internal Market and Financial Services Policies

On November 24, 2015, the European Commission proposed a new regulation on the European Deposit Insurance Scheme ("EDIS"). The proposal foresees the creation of a European Deposit Insurance Fund and offers guarantees up to €100,000 to European depositors. The objective of the EDIS is to ensure that European depositors enjoy the same level of protection, irrespective of the bank's home state, and overcome the vulnerability of national deposit guarantee schemes to larger local shocks. The EDIS will be mandatory for all Euro area Member States and open to non-Euro area Member States.

In order to smooth over political opposition by the Member States on the mutualization of costs related to bank resolutions or pay-outs, the EDIS would be implemented gradually and only be fully operational in 2024. In the first stage (until 2020), the National Deposit Guarantee Schemes ("DGS") would absorb losses in the first instance, while the EDIS would only cover losses after national funds have been fully depleted, and in limited amounts under strict conditions. In the second stage, the EDIS would absorb a progressively larger share of any losses over the 4-year period in the event of a pay-out or resolution procedure. In the third and final stage, the EDIS would fully insure deposits and would cover all liquidity needs in case of a pay-out or bank resolution procedure.

Currently, the EU has 38 different DGSs of various sizes and levels of funding. The European Deposit Insurance Fund will be financed by bank contributions originally designated for national DGSs. The contributions will be paid by banks directly to the managing board of the EDIS and calculated on invoices by participating DGSs. The proposal also foresees the possibility for the managing board of the EDIS to disqualify a participating DGS from EDIS, if the DGS fails to comply with obligations under the Regulation or Directive 2014/49/EU on deposit guarantee schemes.

On November 25, 2015, the European Parliament adopted a report prepared by the special TAXE Committee on tax rulings and other measures similar in nature – see here. The TAXE Committee was established after the revelations of the International Consortium of Investigative Journalists on tax rulings in Luxembourg. In the report, the European Parliament calls on the Member States to end harmful tax competition and to respect the principle that profits should be taxed in the place where they are generated. To that end, the report endorses the automatic exchange of tax information between national authorities, the adoption of a mandatory common consolidated corporate tax base in the EU, and extensive country-by-country reporting. Moreover, the report questions the role of financial institutions and tax advisers in harmful tax practices. The report and the work of the TAXE Committee will be continued by a new temporary Committee at the European Parliament, for which the specific mandate will be adopted in December.

On November 27, 2015, the European Parliament's MiFID II team informed the European Commission that it is ready to accept a one-year wholesale delay to the implementation of MiFID II – both the Directive and the Regulation, MiFIR. This means that MiFID II and MiFIR will now apply by January 3, 2018, rather than the set date of January 3, 2017. The Parliament says that it is only prepared to accept this delay provided that the Commission finalizes the implementing legislation without further delay and urges the Commission and ESMA to produce a "roadmap" on the implementation work and the setting up of the IT systems required.

In a letter dated November 27 to the Commission, the MiFID II negotiating team of the Parliament expressed its disappointment over ESMA not adequately addressing the Parliament's concerns relating to Position Limits (RTS 21), non-equity transparency (RTS 2) and the ancillary activity exemption (RTS 20). The Parliament urged the Commission to take these issues very seriously and to "swiftly make the appropriate and necessary changes to the draft RTS". Given the Parliament's agreement to a year's delay, this now seems to be the likely outcome; however, the extent to which the Commission will make the changes to the RTS required by the Parliament remains uncertain.

Life Sciences and Healthcare Policies

On November 16, 2015, **the Council adopted a new Regulation on novel foods**, after the Parliament voted on the compromise text on October 28 – see here. Novel foods are defined as any food not used for human consumption to a significant degree within the EU before May 1997 (the entry into force of the existing Regulation). These include foods such as newly-developed foodstuff, or food that has been produced using new technologies or production processes. The agreement is significant since a previous revision of the rules in 2008 failed because the Council and the Parliament could not reach an agreement.

The scope of the Regulation remains, in principle, the same as the scope of the existing Regulation from 1997. However, the novel food categories have been updated in light of new technological and scientific developments and now include, among others, insects and their parts, new or intentionally modified molecular structure, food from cell or tissue culture, and food derived from microorganisms, fungi or algae. Moreover, the recitals state that food from animal clones falls under the scope of the Regulation until specific legislation is adopted.

The revised legislation foresees a single authorization procedure for the EU. The Commission will manage the application, while the European Food Safety Authority ("EFSA") will be in charge of conducting a scientific risk assessment. The novel food will be evaluated on:

?	whether it is as safe as food from
	a comparable food category
	already placed on the EU market;
?	whether it poses a safety risk to
	human health; and
?	whether the normal consumption
	of the novel food would not be
	nutritionally disadvantageous
	from the food which it intends to
	replace.

The new regulation also intends to facilitate the entry of traditional foods from third countries into the EU market. Foods that have been consumed in a third country for at least 25 years as part of a customary diet of a significant number of people will be allowed to be placed on the market following a notification from the food business operator.

Finally, in order to stimulate research and development within the European food sector, the Regulation allows for an overall five-year period of data protection in support of an application for a novel food. The data will therefore not be used to the benefit of a subsequent applicant without the agreement of the initial applicant. The new Regulation will likely come into force on January 1, 2018.

On November 16, 2015, **the European Commission opened a public consultation** on aspects of the application of Articles 3 (criteria for designation), 5 (procedure for designation and removal from the register) and 7 (Union marketing authorization) of Regulation 141/2000 **on orphan medicinal products**. The consultation is part of a review of Communication 2003/C 178/02 in light of technical progress. In particular, the Commission is collecting views and information on:

?	the definition of "significant
	benefit";
?	the development of orphan medicinal

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	products for communicable diseases
	(e.g. Ebola);
?	the reassessment of orphan criteria
	when two authorization application
	procedures are pending in parallel;
?	the reassessment of the orphan
	criteria when a sponsor extends the
	use of its products after marketing
	authorization; and
?	the transfer of orphan designations
	between sponsors.

The public consultation is joined by a <u>draft notice</u> from the Commission intended to replace the Commission's Communication.

Trade Policy and Sanctions

In October 2015, China made a formal application for membership to the European Bank for Reconstruction and Development ("EBRD"). The EBRD was founded in 1991 and currently has 64 member nations. It was designed to aid Eastern and Central European states emerging from Communist rule in making the transition towards a market economy. The bank now oversees development projects in 36 countries, including Central Asia and as far as Mongolia, and focuses mainly on infrastructure and transport projects. The EBRD is very active in Central Asia, the Caucasus, and south-eastern Europe, which are all areas in which Chinese investors and Chinese financing have become very important in recent years. Some of the countries where EBRD operates are included in what China calls the "Silk Road economic belt" where Beijing is developing trade and investment links. The board of the EBRD will review the request and will seek shareholders' views. The EBRD is expected to respond by mid-December.

On November 15-16, 2015, the **G20 held a summit in Antalya, Turkey**. It was Turkish president Erdogan's ninth G20 summit and the first over which he presided. Because of the recent deadly terrorist attacks in Paris and Antalya, and the downing of the Russian airliner in Egypt on October 31, the media attention of the G20 was strongly focused on terrorism and the Syrian refugees. In a separate statement, the leaders condemned terrorism strongly - see here. The G20 leaders also made important commitments on boosting global economic growth, strengthening the resilience of the international financial systems, and promoting sustainable growth. The next meeting will be held under the Chinese Presidency in Hangzhou in September 2016.

On November 27, the European Ministers for Foreign Affairs met for a **Council meeting on the ongoing trade issues**. Among others, the Council discussed the EU's strategy for the 10th World Trade Organisation ministerial conference to be held in Nairobi from December 15 to 18, 2015 and the prospects to reinvigorate the stalling EU-Mercosur Free Trade Negotiations. The Council also confirmed their support to the Commission for negotiation of an ambitious and comprehensive agreement with Japan. The intention is to conclude the talks in early 2016. The full outcome on the Council meeting can be found here.

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