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September 2015 - EU Policy Update re: Digital Single Market, Energy, Climate Change and more

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Digital Single Market Policy

In recent weeks the ***European Commission*** has launched a number of **public consultations related to its Digital Single Market strategy**. The Commission is currently soliciting stakeholder views on a wide variety of issues, including: (i) Telecoms Regulation, (ii) Online Platforms, (iii) Geo-blocking and Copyright Reform, (iv) Internet Connectivity, Interoperability - Cybersecurity reforms, (v) ICT Standards, and (vi) Online Consumer Rules and VAT. The responses to these consultations will feed into legislative and policy proposals through 2016.

On October 6, the Court of Justice of the European Union (CJEU) invalidated the European Commission's Decision on the EU-U.S. Safe Harbor arrangement. The Court responded to pre-judicial questions put forward by the Irish High Court in the so-called Schrems case. More specifically, the High Court had enquired about the powers of European *data protection authorities* (DPAs) to suspend transfers of personal data that take place under the existing Safe Habor arrangement. The CJEU ruled both on the DPAs' powers and the validity of the Safe Harbor, finding that national data protection authorities do have the power to investigate in these circumstances, and further, that the Commission decision finding Safe Harbor adequate is invalid. This decision affects all companies that rely on Safe Harbor. They now need to consider alternative data transfer mechanisms. Read further here.

Energy and Climate Change Policy

On September 23, the Dutch Government appealed against the verdict of the Hague District Court **ordering the Dutch State** to increase its efforts **to reduce the Netherlands' greenhouse gas emissions (GHG emissions) by a minimum of 25% by 2020** (compared to 1990 levels). The verdict follows a complaint filed by the Urgenda Foundation, a civil platform representing 866 citizens, which holds the Dutch Government responsible for taking insufficient measures to reduce its GHG emissions and to prevent its dangerous consequences. This decision underlines a trend in Europe whereby NGOs use litigation in order to influence climate change and environmental policies.

The European Union only imposes a target of 21% reduction in GHG emissions by 2020 for those sectors that are part of the European Emissions Trading Scheme (ETS) and a minimum reduction of 16% for the non-ETS sectors (all compared to 2005 levels). For the Netherlands, this would result in a 17% reduction in GHG emissions by 2020 compared with 1990 levels.

Despite this, Urgenda argued that the Netherlands should reduce its GHG emissions by between 25% and 40% by 2020 compared to 1990 levels, in order to keep global warming within a margin of 2°C. The target of 2°C is an internationally accepted threshold to limit the consequences of climate change and is based on several reports of the Intergovernmental Panel on Climate Change (IPCC).

The decision of the Hague District Court is based on a "duty of care" established in Dutch tort law doctrine. The Court held that an application of the duty of care in light of the reports of the IPCC and international law necessarily means that the Dutch State has a duty to mitigate the emission of greenhouse gases as quickly and as much as possible in order to protect its citizens from climate change. The Court did not consider as sufficiently relevant that the contribution of Dutch emissions to climate change is minimal and that increasing the emission cuts in the Netherlands would go beyond the EU targets and even allow carbon leakage.

However, the Court also recognized that the Government has discretion when it decides on how to pursue its policy objectives. It therefore "only" imposed the minimum obligation to limit emissions to at least 25% GHG emissions by 2020 (compared with 1990 levels) in order to restrict climate change to 2°C.

In a letter to the Dutch Parliament, the Dutch Minister of Infrastructure and Environment elaborated on the grounds of the appeal – see here. The Dutch government questions the scope of judicial review; the invocation of the duty of care; the interpretation of the duty of care; and the spillover of international law in national law.

The appeal has no suspensory effect and thus the government has started executing the judgment. The concrete measures will be presented towards the end of 2015 and the start of 2016. For a more complete analysis – see here.

On September 18, 2015, the US Environmental Protection Agency (EPA) announced that **German carmaker Volkswagen (VW)** had rigged its diesel cars to cheat on emissions tests and that the vehicles on the road emit 10-40 times more pollution than US emission standards allow. VW admitted that 11 million cars worldwide are equipped with this "defeat device" software. The issue involves Type EA 189 diesel engines, which exist in cars manufactured from 2009 to 2015, including the VW models Jetta, Beetle, Golf and Passat. The issue also affects other VW-owned brands such as Audi, SEAT and Škoda.

In the European Union, Regulation No. 715/2007 (harmonisation of technical emission requirements on manufacturers and national authorities) generally prohibits the use of defeat devices, with exceptions. It mandates that Member States lay down the provisions on penalties for an infringement of this prohibition.

The European Commission has released a Statement urging all Member States "to carry out the necessary investigations at national level and report back." Member States have also announced road testing to establish whether vehicles in Europe with the defeat devices release more emissions than current standards allow. Some jurisdictions around the world, e.g. the U.S. and several EU Member States, have confirmed a halt in VW diesel sales.

The VW controversy may expose a much broader problem on the credibility of the EU harmonised system to "certify" the compliance of vehicles, as well as many other products. NGOs, such as those in the Clean Air Project, warn that the VW scandal may just be the tip of the iceberg in terms of manipulated tests in Europe.

Internal Market and Financial Services Policies

On September 30, the European Commission published its action plan on a **Capital Markets Union**. According to the Commission, the European capital market is currently too fragmented and underdeveloped in comparison to the U.S.. In order to address this issue and to facilitate funding for businesses, the plan outlines the following six goals:

1.	**Improve financing for innovation, start-ups and non-listed companies.** The Commission proposes to promote the development of alternative funding channels for small and medium-sized enterprises (SMEs). It therefore intends to adopt a series of measures that will increase non-bank finance options for SMEs. Among others, the Commission will monitor and support evolutions in the crowdfunding sector and amend the Regulation on European Venture Capital Funds (EuVECA) as well as the Regulation on European Social Entrepreneurship Funds (EuSEF) to unlock more venture capital, streamline information requirements on credit data for SMEs, and promote direct loans from large institutional investors to mid-sized firms.
2.	**Make it easier for companies to enter and raise capital on public markets.** The Commission proposes to modernize the Prospectus Directive with the aim of simplifying the regulatory regime for SMEs to draw up a prospectus and access capital markets. Further, the Commission will review all other regulatory barriers to public markets for SMEs in order to limit the administrative burden. In addition, the Commission will monitor the liquidity of the secondary corporate bond markets and propose measures, if necessary, to prevent the higher borrowing costs associated with illiquidity.
3.	**Stimulate the environment for long term infrastructure and sustainable investment.** The Commission would like to anticipate the coming into force of the European Long Term Investment Fund Regulation (ELTIF) on December 9, 2015, by agreeing on a definition for infrastructure investment. This definition would prescribe the regulatory capital required to be held against an infrastructure investment, creating a new predictable asset class that is easy for investors to trade and invest in. To this end, the Commission will review the Capital Requirements Regulation (CRR) and the Directive on the business of Insurance and Reinsurance (“Solvency II”) to

	calibrate the regulatory capital required for infrastructure investment. Further, the Commission will review the cumulative impact of the legislation adopted in response to the financial crisis. The review aims to address the overall coherence of existing EU financial legislation.
4.	**Foster retail and institutional investment.** According to the Commission, the markets for retail financial services and for institutional investments are too fragmented along national boundaries. Consequently, it will assess the potential of further policy initiatives in the near future. A particular concern is the market for personal pensions, where currently a patchwork of European and national rules apply. As a result, the Commission is considering a regulatory template for pension products that providers could choose to use when offering pension products.
5.	**Leverage banking capacity to support the wider economy.** In order to improve the lending of banks to the real economy, the Commission envisages three important measures. First, it proposes a new EU framework for simple, transparent and standardized (STS) securitization, which shall kick-start the securitization market in Europe. Second, the Commission launched a consultation on the development of a pan-European framework for covered bonds—a more integrated market for covered bonds has the potential to reduce the cost of funding for banks and liberate capital for investments in the wider economy. Third, the Commission is considering allowing credit unions to operate outside the EU's capital requirements framework for banks.
6.	**Facilitate cross-border investing.** Finally, the Commission proposes tackling long-standing barriers to cross-border investment in the EU. Among others, the Commission would like to eliminate legal uncertainty regarding the ownership of securities and the applicability of national laws to third party effects caused by the transfer of claims. Further, the Commission intends to promote convergence on tax legislation, insolvency procedures and financial supervision among Member States with a mix of recommendations, guidelines, best practices and codes of conduct.

The range of initiatives that the Commission envisages will be accompanied by the necessary stakeholder consultations and impact assessments. The implementation for most measures will start

in 2016.

The **European Securities and Markets Authority (ESMA)** has now published the long-awaited **Final Report on its draft Implementing Technical Standards** (ITS) and **draft Regulatory Technical Standards** (RTS) under the **MiFID II Directive** and the **Markets in Financial Instruments Regulation** (MiFIR) – see here. Published on September 28, 2015, the Final Report follows ESMA's consultation on the draft technical standards in December 2014 and February 2015. The Final Report details ESMA's final proposals in relation to 28 draft Technical Standards and attaches those draft Technical Standards in an Annex. The Final Report also discusses the feedback received by ESMA and ESMA's rationale in making the final proposals, and includes a cost-benefit analysis.

The Final Report and draft RTS and ITS contain ESMA's proposals on the following areas:

- Transparency
- Microstructural Issues
- Data publication and access
- Requirements applying to trading venues
- Commodity derivatives
- Market data reporting
- Post-trading issues
- Best execution

Alongside the publication on September 28, 2015 of the ITS and RTS on MiFID II, **ESMA** has published a **Final Report containing draft technical standards** (i.e. regulatory technical standards (RTS) and implementing technical standards (ITS)) on the Market Abuse Regulation (MAR) – see here. The final report covers the nine areas on which the European Commission gave mandates to ESMA to develop RTS and ITS. These include requirements on market participants conducting market soundings, requirements to report suspicious orders and transactions, rules for public disclosure of insider information and the delay of such publication, specific arrangements on how to present investment recommendations and specific formats for establishing insider lists, and the notification and disclosure of managers' transactions. ESMA has now sent the final report to the European Commission, which has three months in which to decide whether or not to endorse the draft RTS and ITS. Assuming that the European Commission endorses ESMA's draft recommendations, the Council of the European Union and the European Parliament then have a period of time in which they can raise any objections.

Life Sciences and Healthcare Policies

At the start of September, the European pharmaceutical industry issued a complaint with the European Commission against a French law that allows **the reimbursement for the off-label use of medicines**. The issue relates to *Avastin*, an anti-cancer product of Roche, reimbursed as of September 1 even though two other more expensive drugs are approved. The European Federation of Pharmaceutical Industries and Associations (EFPIA), the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), and the European Association for Bioindustries (EuropaBio) are concerned that the off-label use of medicines on economic grounds will harm patient safety and undermine the EU authorization process for medicinal products. In January, the industry protested against an Italian off-label law adopted in 2014. The statement of EFPIA can be found here.

In September, two publications below suggest that the European Commission is preparing for computer simulated ("*in-silico*") clinical trials of medicines and medical devices. ***In-silico* trials** are clinical trials where a computer model of a treatment is applied to simulate pathophysiological reactions of patients to the administration of medical products. The technique is considered promising because it could shorten the cost and the development time of new medicines.

On September 11, the European Commission published the draft Work Programme for 2016-2017 in the area of "Health, demographic change and well-being". The Work Programme includes two requests for proposals on the research and development of *in-silico* trials and computer models. The budget is anticipated to be at least €50 million a year. In addition, a roadmap is developed by a consortium of international experts financial with aid from the Commission, which will map the benefits, the barriers and the way ahead to introduce *in-silico* trials into the preclinical and clinical assessment of medical products. The roadmap is available here.

Trade Policy and Sanctions

On September 16, the European Commission proposed a **new Investment Court System** for the Transatlantic Trade and Investment Partnership ("TTIP") and other EU trade and investment negotiations – see here. Under the proposal, a court system is envisaged with a first instance tribunal and an appeal body, publicly appointed judges, limited and clear grounds for investors to present cases, provisions explicitly guaranteeing the governments' right to regulate and transparent proceedings allowing for parties with an interest to intervene. It is the aim of the Commission to replace the existing investment dispute resolution mechanisms with the new system in EU trade agreements and to promote the adoption of the Court system in trade agreements between non-EU countries.

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