

SEPTEMBER  
2017



# Europe's Back to School

2<sup>nd</sup> ANNUAL EDITION



FLEISHMANHILLARD

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# New dynamics: Brussels and Europe in a changing world

As we look back at our first 'Back to School' briefing last year, the dust from the British vote to leave the European Union was at that point still far from settling. In the last twelve months, the EU27 has shown remarkable resilience, resisting populist surges in France and maintaining unity with the launch of Brexit negotiations. At this important moment the EU has also launched a debate on its own future as well as on its relationship with the outside world.

Challenges both internal and external nevertheless remain, with concerns regarding the strength of commitment to the European project in some Member States, and as a consequence, a possible crack in the strong unity among the EU 27. These concerns are compounded by upcoming national elections where the outcome in Italy will be particularly crucial. It has become clear that the EU can no longer address these challenges separately. As such, it is not enough for stakeholders to focus only on the developments in their respective sectors, the wider political climate must be equally considered.

Over the past year, elections in France symbolically reversed the tide of populism, and gave Europe a renewed sense of spirit. In turn, the German elections look likely to return Angela Merkel to the Chancellorship. However, she is likely to be accompanied by coalition partners, and the make-up of the German government will have significant effects on policies at the European level. Furthermore, the Franco-German relationship is central to how the future of Europe will evolve, but will be impacted by the success of President Macron's domestic reform agenda.

Restoring confidence in the European project will also likely trigger initial steps towards reforming the Eurozone. If the outcome of the election is close to what polls suggest today, Germany looks set to support reforms in line with the thinking of Macron. The idea of forming a Eurozone Monetary Fund and a Eurozone Finance Minister will certainly be on the table. However, this is a balancing act: any reform will remain incremental, and will likely fall short of expectations of proponents for rapid integration.

Externally, Europe faces a new EU-US relationship, which has emerged since the election of President Trump. A symptom of this is the uncertainty facing the EU-US Privacy Shield program, the arrangement which streamlines data sharing across the Atlantic. Relying fundamentally on trust between governments, the program will face a tumultuous review when both sides meet in September. Nonetheless, the EU has been quick to capitalise on the US' stepping back from the world stage. New momentum on trade is driving deals with Mercosur, Japan, Singapore and Vietnam while the Commission seeks to open talks with further nations such as New Zealand and Australia.

However, the Commission's new approach to the screening of foreign investments this autumn will reflect the new changing attitudes towards globalisation, with particular focus on investments from China in critical areas. All of these initiatives reflect a Europe which sees itself as a central player in international affairs in the coming years, but also a Europe which wants to protect and keep some of its critical industries in European hands. While the EU has strengthened relations with China, conflicts are therefore unavoidable. It is also noteworthy that the EU has redoubled its commitment to the Paris Agreement in the face of the US' withdrawal. There are however challenges closer to home. With issues such as migration causing political divergence, and without the carrot of EU accession to dangle, Europe needs to deploy all of its soft power to foster stability in its neighbourhood.

Across the spectrum, the EU is more than ever addressing the interlinkages between sectors and showing that wider politics can never be forgotten. How to strengthen inter-institutional cooperation and the outcome of the debate around Europe's future are both questions that need to be addressed in the coming year. Businesses should therefore try to look outside of their immediate sphere, find partners and build coalitions on the macro-political trends which affect all sectors. It is in every business interest to help shape a Europe that is moving forward, and this is the year to do so before institutional changes in 2019 start to dominate the agenda.

In last year's edition of our 'Back to School' paper, we called on businesses to take on the role of trusted interlocutors. The past year has proven the vital nature of this role, as well as the benefits of playing it.

The FleishmanHillard Brussels Team



# What's in store for Financial Services?

The next 12 months will see a plethora of policy initiatives and discussions in the EU financial sector. While work has started addressing the unfinished financial stability agenda (e.g. the “banking package” and the new framework for resolving CCPs in crisis), the European Commission is set to also tackle emerging trends for the sector (e.g. fintech and sustainable finance). In the background, the ‘shadow’ of Brexit will have a growing influence on these and other initiatives (e.g. Capital Markets Union or other upcoming legislative reviews).

## A new approach to how Europe allows access to its market in financial services

The consequences of the UK's Brexit decision are trickling down to financial services legislation. The next six months will see further elaboration of Europe's new approach to 3rd country market access in financial services.

This new approach is already materialising in the recently launched review of EU rules on oversight over central clearing houses (CCPs), a crucial node in financial markets' infrastructure. Legislative negotiations will gain momentum in the autumn.

One of the key initiatives to watch is the planned reform of the ESAs, expected this autumn, which will likely hard-code aspects of the new EU approach on 3rd country issues into law. Beyond that, this review has the potential to significantly strengthen pan-EU supervision bodies and strengthen their roles in cross-border issues.

In some cases, we expect that Brexit may also lead to delays in progressing existing initiatives (e.g. a European financial transaction tax).

## The legacy building phase will start, driving new ambitious initiatives

Fueled by Brexit, a recovering economy, and reinvigorated confidence in the EU project, momentum is gathering to press ahead with concrete policy reforms. The EU's financial services chief, Valdis Dombrovskis, will use this momentum to build a legacy for his term, particularly on positive agendas, such as financial innovation. This is part of broader efforts started by former Commissioner Jonathan Hill to turn the lens of financial services policy onto citizens and growth, after the past two years of legislation have focused on financial stability.

As FinTech is growing, its interaction with existing regulation is increasingly being scrutinised, assessing how new technology interacts with cyber risk, data protection, and financial stability. At the same time, the development of sustainable capital markets has become a priority for the Commission in

order to further the EU's climate goals. A dedicated expert group set-up by the European Commission will feed concrete policy recommendations that can materialise as early as Q1 2018. The standardisation of green bonds is one of the main ideas the Commission wants to take forward.

The persistent presence of bad loans on bank balance sheets in some EU countries is also expected to be tackled more decisively, with a number of regulatory and non-legislative initiatives planned in the coming months. This is important as non-performing loans (NPLs) are widely seen as the “ball and chain” holding back a stronger economic recovery in Europe.

## “Business as usual” continues

At the same time, a bucket of legislative files will remain important. On the banking side, Parliament and Member States will move forward on accounting standards for capital calculations and a clarification to the creditor waterfall when a bank goes bust. A final agreement on these elements is expected by the end of this year.

However, the rest of the November 2016 legislative proposals on risk reduction are still at a very initial stage. This comes in a context where international bank capital discussions at the Basel Committee remain deadlocked. Negotiations will also continue on a common bank deposit guarantee for the Eurozone (EDIS).

To further the Capital Markets Union, negotiations on harmonising business insolvency rules across the EU will continue, while the Commission will start preparing for a legislative proposal to harmonise rules on covered bonds, a key instrument in many mortgage markets, early next year.

Before the end of the year, the Commission will propose new proportional capital, liquidity and remuneration rules for investment firms, while asset managers face the prospect of proposals to facilitate cross-border distribution of investment funds (AIFMD/UCITS). Negotiations on separate proposals on the creation of an EU-wide personal pension product (PEPP), a limited review of the EU's derivatives rulebook, and the set-up of a crisis management framework for troubled CCPs (CCP R&R) will continue.

Other outstanding issues are expected to be concluded shortly after the summer recess including negotiations on strengthening anti-money laundering rules in light of terrorist financing and the Panama Papers revelations, and renewing the Juncker Investment fund (“EFSI 2.0”).

# Road Transport agenda finally into full swing

The three things to expect on road transport before the end of 2017? Here we go:

**1. Negotiations on the Mobility Package** – including eight proposals tackling road charging, social aspects and competition issues. The road charging part is likely to have a big focus in the coming months. The Estonian Presidency is expected to handle tolling digitalisation as a matter of priority by aiming for a general approach on the revised European Electronic Toll Service Directive, and also seeks to advance the Eurovignette Directive.

**2. Release of Mobility Package in November or December** – which will include the proposal for post-2020 CO2 standards for cars and vans. One of the options under consideration is a 2030 target in the range of 68-78g CO2/km (NEDC) as proposed by the European Parliament in 2013. The Commission will have to make a few critical decisions: Should there be absolute or percentage-based reduction targets? Should the 2030 target have a 2025 interim target or even annual targets? Should a sales mandate for zero- or low-emission vehicles be introduced, and if so, how should such vehicles be defined? Should the weight-based utility parameter be phased out? Is there a future for super credits? We'll know more towards the end of the year.

To catch up with Asian and US battery production expertise, the Commission is also expected to publish a battery action plan. Actions to boost the implementation of the Alternative Fuels Infrastructure Directive are also expected, in the wake of the launch of infringement procedures by the Commission against 8 Member States last May that did not submit their national plans.

**3. Trilogues on the revision of the EU's type-approval and market surveillance framework** – co-legislators will face the daunting task of sealing an agreement on thorny questions such as independent Commission tests and inspections, as well as fines in the event of non-compliance. Four trilogues have been scheduled during the Estonian Presidency, but it looks likely that its Bulgarian successor will have to wrap up an agreement in the first weeks of 2018.

Earlier this month, two new frameworks entered into force for all new type-approved vehicles: the Worldwide harmonised Light vehicles Test Procedure (WLTP), and the Real Driving Emissions 2nd Package (RDE), both of which should reduce the gap between laboratory and real-driving CO2 and pollutant emissions respectively. Starting from next year, they will apply to all new vehicles.

Finally, in 2018 we expect to see the introduction of CO2 standards for heavy duty vehicles for the first time.

## Emission reductions and fair competition: the priorities on aviation

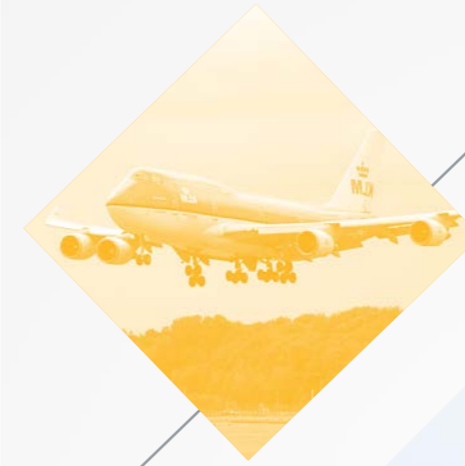
The Parliament and Council are expected to start trilogues on the recast of the Emissions Trading Scheme for aviation. Whether to indefinitely extend the derogation of the ETS on flights to and from the EU until the first phase of ICAO's global market-based mechanism, CORSIA, is implemented in 2021 will be the main bone of contention. Meanwhile, ICAO is expected to adopt the CORSIA Package in May or June 2018, paving the way for emission monitoring by operators in 2019 and 2020. The Commission has also just published the proposal to revise Regulation 868/2004 to tackle unfair practices in aviation. It will be up to the Estonian Presidency to address Member States concerns over how a revised '868' might interfere with existing and future bilateral aviation agreements and relations with third-countries.

## Digitalisation of transport will be in the spotlight

With tech-savvy Estonia at the Council's helm, digitalisation will receive high attention until year-end. The Digital Transport Days in November will address the challenges and opportunities of digital technologies in passenger and freight transport, including expected Council conclusions in December on the free flow of data, paperless freight and Mobility as a Service. The Commission is also currently carrying out an evaluation of the Intelligent Transport Systems (ITS) Directive, which is expected to be finalised by March 2018. Meanwhile, the Parliament, in an own-initiative report, is setting out its views on the 2016 strategy enabling the roll-out of connected vehicles.

## Maritime transport

No major new initiatives are expected for the maritime sector, but we can expect a proposal for the revised Port Reception Facilities Directive in autumn, seeking to improve harmonisation and enforcement, align with international conventions and to ensure facilities can cover new types of waste. Simultaneously, the Commission is currently conducting a public consultation on the Reporting Formalities Directive to see how the European maritime single window can be made a reality.



# What to expect on Taxation?

The fight against corporate tax evasion remains one of the Commission's key priorities in the coming year. A number of legislative proposals are on the table aimed at increasing corporate transparency and ensuring effective taxation. EU-level decision-making in the area of taxation can be difficult at times, but public and political pressure has already resulted in agreements in a number of cases. A renewed Franco-German cooperation might give further impetus.

## A new Franco-German push post-Brexit?

After the election of French President Macron, both countries have renewed efforts to drive the corporate tax reform agenda forward, following the UK's decision to leave the bloc. More than anything, what has brought the pair together is their agreement that some degree of tax harmonisation at EU level is required. A concrete example of this cooperation is the new joint working group aimed at agreeing on common rules on how to calculate corporate tax liabilities.

## CC(C)TB: round two continues

Following the Commission's unsuccessful attempt in 2011 at establishing a Common Consolidated Corporate Tax Base (CCCTB), the proposal is back on the agenda but this time in a two-step approach: agreeing on common tax rules across the EU in the form of a Common Corporate Tax Base (CCTB) first, followed by consolidating taxable corporate income at EU level (CCCTB). Like the original version, the new proposals are being met with some scepticism. In particular, smaller Member States are afraid that they could lose out on tax revenues, as the formula apportionment might reallocate revenues to larger economies. That could also impact companies' tax burden, as the larger countries tend to have higher corporate tax rates.

A specific attention of policy makers to taxing the digital economy is building up, fuelled by State aid investigations into tax deals and following recent revelations over the amount of taxes digital companies paid in France.

## Debate on public CBCR set to continue

An important pillar of the Commission's tax transparency work is the proposal for public Country-by-Country Reporting (CBCR) that requires companies to publish business and taxation data. Member States have yet to find agreement on the text, but the Parliament, following two very tight votes, put down its position before the summer.

Attention will thus be on the Council this autumn where questions remain over a clause to permit companies to not disclose commercially sensitive information in limited circumstances. A debate over the correct legal basis remains unsolved and may reignite after the German elections, as some Member States are opposed to the Parliament being co-legislator on this mainly taxation related proposal. Withstanding any legal objections, future negotiations between the two institutions are likely to focus on precise wording and scope of this safety clause for companies to not have to publish certain data – with some Member States keen to ensure that any transparency measures do not impact the EU's attractiveness as an investment destination.

## Companies' tax plans to come under scrutiny

Following recent tax scandals such as the Panama Paper leaks, the Commission has decided to clamp down on aggressive tax planning by requiring intermediaries as well as companies to disclose potentially aggressive cross-border tax arrangements. As categories for identifying potentially aggressive tax planning are rather broad, the proposal could potentially require many companies, or their tax advisors, to notify their tax strategies to competent authorities. Discussions between Member States are expected to begin this autumn, with the criteria to determine what are aggressive tax plans likely to be at the centre of debates.

## Definitive EU VAT regime to be introduced

The Commission is set to propose a "definitive EU cross border VAT regime" in September. Perceived as too complex, the current transitional system was also set up before the rise of digital economy, and an update is overdue. The definitive regime is expected to anchor the EU's cross border VAT on the destination principle (taxing products where they are sold), a step supported by Council and Parliament.

## Brexit and Trump to influence future EU taxation agenda

Since the UK voted to leave the EU and the election of Donald Trump as US President, EU leaders have begun to examine the impact on taxation, specifically on how to ensure the UK does not adopt a low-tax model post-Brexit and the potential consequences of a US border adjustment tax on the EU economy. Both could trigger further action by the Commission on the taxation front in the years to come.

# What's coming on Environment and Chemicals?

Before the end of the year, we can expect some key dossiers to move forward:

## Finding compromises on waste

Early in 2017, the Parliament and Council agreed their positions on the legislative proposals on waste and held their first trilogues before the summer. In the coming months there will be an intense programme of further technical trilogues. Given the number of challenging issues, an agreement on the text before the end of 2017 is far from certain.

While it is relatively late in the process, there are certainly still good opportunities to continue engagement with the three institutions and industry should continue to share examples of what is/should be done at EU and national level, explaining the very practical implications for companies involved in waste management and product design.

At this stage in the process, in order to have a voice that can be heard, it is critical to be as concrete as possible and help institutions find compromises.

## Contributing to Circular Economy landmark initiatives

In addition to the waste package, implementation of the other 50+ initiatives from the Circular Economy Action Plan continues steadily. By the end of this year, we can expect two of the Action Plan's landmark initiatives: a European Strategy on Plastics as well as a Communication on the interface between chemicals, product and waste legislation.

Although plastics are indispensable materials in our economy, their use and therefore release in the environment have raised concerns the European Commission aims to address. The question of micro plastics in particular has received a lot of attention. With the strategy, the Commission intends to make plastics "more sustainable", for instance by diversifying the feedstock and improving the recycling and reuse rates.

Meanwhile, the analysis of the interface between chemical, product and waste legislation is crucial for delivering a circular economy where materials can be used efficiently, reused and recycled, therefore turning waste into valuable resources. The

Communication will look into the current legislative barriers but will also identify options to facilitate recycling and improve the uptake of secondary raw materials.

## Objecting or not objecting to endocrine disrupters criteria, that is the question

The endocrine disrupters saga continues. Criteria proposed by the European Commission in July are now on the European Parliament's and Council's desk for scrutiny. While the Council will most likely not oppose the proposal, all eyes are on the Parliament. A majority of MEPs in the ENVI committee could be in favour of objecting (based on legal reasons), leaving the plenary with the difficult task to decide what to do.

Should the Parliament object, the European Commission is left with 3 options: Do nothing (interim criteria apply), bring the proposal back to the expert committee or draft a legislative proposal.

## Learning more from REACH

In October, the Commission is expected to publish its report on the experience acquired from the implementation of REACH. The report, foreseen by the legal text, also relies on a comprehensive REFIT exercise which has been an opportunity for all interested stakeholders to share their experience with REACH and recommendations as to how its implementation should evolve in coming years. Some – governmental and non-governmental – had openly expressed views in that matter; in some case suggesting changes that would require a legislative revision of REACH.

We understand the Commission is not planning to take such direction. Recommendations will be made; however a reopening of the text is likely to take a few more years.



# Scaling up the Digital Single Market

With at least 14 of the already published Digital Single Market (DSM) legislative initiatives still to be adopted, the EU institutions will certainly be thrown into the deep end of the tech landscape when they arrive back to school. A swift agreement on the removal of certain online regional sales restrictions through the Geo-Blocking Regulation could pave the way for advances on other prominent files in fields such as copyright, audiovisual media services, telecoms, data protection, and digital content.

September will also see what Commissioner Jourova has termed 'the moment of truth' for Privacy Shield, namely the joint EU-US review of the famous data transfer agreement. However, amidst these potential accomplishments, the EU institutions are also adjusting to a revamped tech political landscape, and the publication of even more legislative and policy initiatives.

## Settling into a new political landscape

The dust has yet to settle on recent political shifts in the EU tech landscape. The portfolio of Digital Economy and Society has been reinvigorated under the newly appointed Bulgarian Commissioner, Mariya Gabriel. Gabriel's declaration that being a Commissioner is 'primarily a political job, not a technical one', could mean that she redefines the working dynamics with Vice-President Andrus Ansip, Commissioner Věra Jourová, and the DG for Communications Networks, Content & Technology (CONNECT).

Meanwhile, the Council is now under the most digital-savvy EU Member State, Estonia. Estonia has evangelised tech in Brussels, with Commission President Juncker preaching that 'digital is the most important performance Estonia could give as a gift'. With a calendar of events containing no fewer than 24 high-level tech events, the Estonian Presidency needs to advance on the Digital Single Market (DSM) so as to keep their digital reputation intact.

Finally, in the European Parliament, Anneleen Van Bossuyt (ECR, BE) will power ahead in her recent promotion to Chair of the key digital Committee on the Internal Market and Consumer Protection (IMCO). At the working level, the influential Copyright Directive is now under the tutelage of Axel Voss (EPP, DE), following Therese Comodini Cachia's (EPP, MT) return to the Maltese Parliament. Meanwhile, the allure of national politics could mean that the highly contested ePrivacy Regulation is set to be passed from current Rapporteur

Marju Lauristin (S&D, EE) to Birgit Sippel (S&D, DE). With this revitalised political landscape, all three institutions are searching for fast, influential, and easy wins. While the decisions are bound to be influential, it remains to be seen how fast and easy they can be.

## Pushing forward with more tech proposals

If a new political landscape weren't enough of a hurdle, the next six months will also see several new legislative and policy initiatives. After electoral hacks and the WannaCry ransomware scandal, the Commission is looking to tackle standards, certification, and potential IoT labelling schemes when it announces its September review of the 2013 EU Cybersecurity strategy.

Also in September, and after intense political and industrial pressure, we'll be treated to the long-awaited proposal on the Free Flow of Data. The Estonian Presidency and Vice-President Ansip hope that this will remove unjustified data localisation measures.

Looking further ahead, by the end of 2017, the Commission has promised to act on platforms by tackling unfair contractual clauses and trading practices identified in B2B platform relationships, as well as the removal of illegal content. This is likely to bring about guidance on notice-and-takedown procedures and may further encroach on the EU's (in)famous platform liability exemptions.

One also cannot forget the everlasting saga about measures to protect intellectual property (IP) under a Communication on Standardisation and an updated IP Enforcement Directive (IPRED). While these topics have besotted lobbyists and officials for years, the next six months could ultimately bring about their tumultuous publications.

Recent consultations on the review of the EU Database Directive, collective redress, access to e-evidence, digital healthcare, data centres, and the consumer law REFIT could herald even more initiatives with sector wide implications. Needless to say, the abundance of political and legislative activity means we must all be prepared to hit the ground running now that the EU policy school is back in session.



# Completing the Energy Union

Energy policy is currently dominated by the European institutions' negotiations on the Clean Energy Package (CEP), consisting of eight legislative proposals. Published in November 2016, progress has been steady so far, with the Council agreeing on its General Approaches in the field of energy efficiency in June. Simultaneously, the Parliament is moving rapidly towards finding consolidated positions. However, there remain challenging unanswered questions, with large divergences dominating debate between and within institutions.

## Ambition

Since 2014, when the European Council agreed to climate and energy targets for 2030, the European Parliament has been calling for a more ambitious trajectory. These calls have continued as the Parliament assesses the proposals, with more ambitious targets almost certain to be included in the final positions. How much to raise ambitions by remains contentious, with divisions across the political groups. The EPP in particular has struggled to find consensus among its members on what level of targets should be set.

The Council, on the other hand, is sticking to its original position. Concerned that overly rigid targets, deadlines and obligations will obstruct cost-effective decarbonisation, some Member States continue to call for more flexible legislation. Discussions within the Council have been challenging, and agreement difficult to find. The General Approach reached on the revised Energy Efficiency Directive was found by vote rather than consensus, and did not address some contentious provisions.

## Unanswered questions

Alongside the Clean Energy Package, EU institutions are currently negotiating the reform of the EU Emissions Trading Scheme, which will drive industrial decarbonisation toward 2030. Trilogue negotiations are proving politically difficult and technically challenging, as co-legislators struggle to strike the right balance between safeguarding EU industries an equal playing field, global competitiveness and incentivising

innovation in low carbon technologies. The EU is also searching for agreement on decarbonising for non-ETS sectors, under the Effort Sharing Regulation.

Within the CEP, the debate on the proposed reforms of the EU electricity market is progressing though still in early stages. The Council is still discussing contentious topics such as an effective end to capacity payments for old fossil fuel power stations with an emissions performance standard, and the role of national grid operators vs new European level entities. With regards to the latter, Member States are particularly concerned with repercussions for their national security of supply.

Last but not least is the proposed regulation on the Governance of the Energy Union, which will set the overall framework for Member States' planning and reporting obligations on their objectives and contributions to the EU 2030 climate and energy targets. The proposal has opened a lively and wide debate in Parliament and discussions with the Council promise to be extremely challenging. Whether the proposed Governance framework will streamline overlapping existing requirements (as specifically requested by the Council in 2014) or increase the administrative burden remains to be assessed.

The Clean Energy Package is likely to dominate energy policymaking until the end of this Parliamentary term in 2019. The complex interaction between the Governance Regulation and each individual directive could lead to a "nothing is agreed until everything is agreed" scenario. For EU negotiators, the agreement on the Clean Energy Package will be an enormous political challenge which will require a comprehensive and a balanced approach from all sides.



# The agenda for Food and Agriculture

## Reforming the CAP in a post-Brexit EU

The number one priority for Commissioner Hogan by the end of 2017 will be to share progress on the simplification and modernisation of the Common Agriculture Policy (CAP). Following a three-month public consultation and 323 000 responses, findings will be at the core of the Commission's Communication expected by the end of the year.

An impact assessment is also planned for autumn 2017 and the future of the CAP will be on the agenda at the informal meeting of the Agriculture and Fisheries Council in Tallinn in September. One of the core issues will be the CAP's budget in view of a financial gap of around 15% due to Brexit and the end of the UK contribution.

At the same time, looking at the future of European farming post-2020, the EU is gradually entering new fields for the sector, including advances in new plant breeding techniques, precision and smart farming.

## A fragmented EU food market

Despite DG SANTE's efforts towards a pan-European approach to food labelling, several Member States have announced national schemes that regulate front-of-pack (FOP) and Country of Origin Labelling (COOL). While the Commission's infringement procedure against the UK's traffic light labelling is still pending, the EU is evaluating France's Nutri-Score system, a voluntary labelling scheme to guide consumers on the nutritional value of products. Six multi-national companies, followed by objections by six Member States, criticised the French FOP labelling, urging the French Minister to work towards a European Reference Intake approach.

In parallel, Italy decided in July to demand that all pasta and rice sold in the country show where the produce was grown, treated and packaged. While the country may be subject to infringement proceeding for breaching EU law, it is clear that, in view of new trade agreements and increasing consumer pressure, Member States are taking the lead in protecting their own products, fragmenting the internal market.

President Juncker himself got involved in the 'dual foods' debate, whereby food sold in identical or similar packaging is of inferior quality in Eastern Europe, promising new guidelines for national authorities in September.

## Alcohol policy tops the Estonian agenda

Quantifying yearly societal costs of EU alcohol consumption at up to €372 billion, the Estonian Presidency intends to focus on tackling harmful alcohol use, particularly on cross-border issues, including marketing, labelling, trade and taxation. The

Presidency has criticised the 'soft' approach taken by the Commission through its initiative to invite producers of alcoholic beverages to develop a self-regulatory proposal. While Estonia will drive its agenda, aiming at proposing Council Conclusions on cross-border aspects in alcohol policy, it looks improbable that stakeholders will reach an agreement over alcohol labelling by the March 2018 deadline.

In parallel, the Presidency and Member States will continue examining the Commission's proposal for the spirit drinks regulation with the aim of agreeing on the Council's general approach by end of 2017.

## Agricultural products at the centre of trade deals

In face of concerns over US protectionism, the EU has moved ahead in prioritising its promotion of free trade, with a number of agreements due for conclusion by the end of the year. Following the free trade political agreement reached with Japan in July, Trade Commissioner Cecilia Malmström hopes to announce a political agreement between the EU and Mercosur at the WTO Ministerial Meetings in Buenos Aires in December 2017. However, an agreement before the end of the year will only be possible if both blocs are willing to make timely offers on the access to their markets, in particular of 'sensitive' agricultural products, which include beef, sugar and ethanol. Concessions over agricultural products will also be key for the EU negotiations with Mexico.

In parallel, EU-China trade relations are moving forward as 100 European and 100 Chinese geographical indications were published as part of a bilateral agreement expected to be concluded by December 2017.

## Comitology reform: shifting accountability

In an effort to increase transparency and accountability, the Commission put forward a proposal in February to reform comitology rules, in particular those on voting in the Appeal Committee, where the Commission has found itself on the frontline when having to make decisions on sensitive topics. Although the proposal is horizontal across sectors, it principally aims to address decisions on GMOs, Plan Protection Products, pharmaceutical products and food safety.

A comitology reform would need approval of both the Parliament and the Council and the timeline is yet to be finalised. In the meantime, under current comitology rules, the Commission restarted discussions with Member States on glyphosate, with the objective of a final vote for a 10 year renewal of the substance in October.

# Hot topics in Healthcare

## E-health takes centre stage

In line with the Presidency's focus on the development of digital technologies, e-health features as a top priority in the Estonian Programme. The Presidency will be hosting, in a combined effort with ECHAlliance, the eHealth Tallinn 2017 Conference on 16-17 October 2017. The Estonian's Digital Health Society Declaration, calling for the digital transformation of healthcare systems, will be presented and signed there. In view of May 2018, when the General Data Protection Regulation will enter into force, Estonia aims to reach Council conclusions by the end of 2017 on EU political guidelines for the establishment of e-health policies and initiatives in coming years, as well as to agree on 7-9 large impact digital project commitments co-funded by Member States and the Commission.

## The review of Intellectual Property Incentives for the Pharmaceutical Industry

The EPSCO Council Conclusions of June 2016 invited the European Commission to prepare an evidence-based analysis of the impact of pharmaceutical incentives and rewards on innovation, availability and accessibility of medicinal products in the EU. To respond to this quickly, the Commission extended the scope of its planned economic study of Supplementary Protection Certificates (SPCs), 'Bolar' and research patent exemptions in the EU. There is also an ongoing study by Copenhagen Economics on the impact of pharmaceutical incentives and rewards on innovation, as well as on the availability and accessibility of medicinal products in the EU. The publication of this study could lead to the opening of multiple pieces of pharmaceutical legislation, which would bring damaging legal uncertainty to the industry and have a negative impact on the appetite for research and innovation in the EU.

## Antimicrobial resistance

Singled out as "one of the biggest threats to global health" by WHO, antimicrobial resistance (AMR) will continue to be at the forefront of health policy for the current Presidency. On 29 June 2017 the EU Commission published the new EU One Health Action Plan to combat AMR, which was met with mixed reviews. As part of its plan to define inter-sectoral indicators for assessing the AMR Action plans through expert-level

discussions, the Presidency will be hosting a high-level meeting on the topic on 23 November in Brussels.

Additionally, in the next four months, the Estonians will prioritise progress on the Regulation on Veterinary Medicinal Products, which promotes effective antimicrobial veterinary medicines to protect animal health and welfare, with the objective to reach an agreement between Member States and kick-off trilogues as soon as possible.

## Health Technology Assessment

Once the Regulatory Scrutiny Board reviews DG Sante's impact assessment (predicted to be sometime in November 2017) the Commission will begin drafting a legislative or non-legislative proposal regarding Health Technology Assessment (HTA).

Vytenis Andriukaitis, Commissioner for Health and Food Safety is keen to have the proposal finalized before the end of the year. The proposal addresses the future of EU cooperation on HTA. 87% of the 250 respondents to the public consultation were in favor of EU cooperation beyond 2020.

## European Medicines Agency relocation

The European Medicines Agency (EMA), currently located in London and employing nearly 900 staff, must be relocated as result of Brexit. The European Commission will review the 19 bids submitted by cities across the EU to host the agency by 30 September. The bidding cities must meet six criteria, including a guarantee that operations can continue immediately following the move. Following political discussion in October, the EU27 ministers will vote at the General Affairs Council in November 2017.

The agency's relocation will likely result in a number of pharmaceutical companies' following the agency outside of the UK. The pharmaceutical industry and consumer organisations are calling to avoid divergence and duplication of practices and standards between the EU and the UK after the move is finalised.



## What's at stake for the EU's trade agenda?

More than ever, the EU's trade agenda is in the spotlight. Fears over globalization, insurgent populist movements and looming protectionism have thrown trade liberalisation into question. The Commission has embarked on a twin strategy: on the one hand, buoyed by the election results in Austria, the Netherlands and France, it has defied calls for protectionism by putting renewed energy in ongoing and future negotiation tracks.

On the other hand, it has sought to address popular concerns over transparency in negotiations, national sovereignty, investor courts and food and product standards by overhauling its trade strategy under the banner 'Trade for All'. It is currently also negotiating with third countries to set up a permanent Investment Court System to replace existing investor-state dispute settlement mechanisms in ongoing and future investment negotiations.

The European Court of Justice delivered the landmark Opinion 2/15 on the EU-Singapore Free Trade Agreement, ruling that the EU cannot pass comprehensive trade agreements, including chapters on investor protection, without involving national parliaments. All eyes are now on the Commission, which will have to determine whether it will seek to pass future trade agreements with chapters solely dealing with matters of exclusive EU competence, with a separate agreement on investment, or continue to combine them in single negotiating mandates.

As a result, the UK government will likely need to curry favour with national parliaments in order to reach the desired deep, comprehensive, post-Brexit trade relationship with the EU.

In September, the Commission will seek to introduce a mechanism for screening of foreign direct investment into strategic sectors of the EU economy. This comes as a reaction to a recent wave of state-subsidised takeovers of EU

tech companies, notably by Chinese investors, and as a response to increasing public concerns over the effects of globalization. The idea has already received strong backing from the highest political level, including from France, Italy and Germany, and most recently, Commission President Juncker. The specifics are to be determined, but an EU-wide mechanism leaving the final decision to block an investment in the hands of the affected member state is emerging as the most likely option.

Meanwhile, Council and Parliament have entered into trilogues in order to reach an agreement on shoring up the EU's anti-dumping and subsidized imports instruments. While an agreement in September is still on the cards, both parties will need to hammer out an agreement on the burden of proof, the main sticking point in the negotiations.

In his upcoming State of the Union address in September, President Jean-Claude Juncker is furthermore expected to announce that the Commission will seek a mandate to start negotiations with New Zealand and Australia. It is also pushing for the conclusion of the negotiations with Mercosur, as well as the modernization of the existing agreement with Mexico.

Following a political agreement with Japan last July, negotiators are now working out the technical chapters, though a final text is not expected before mid-2018.





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