



FLEISHMANHILLARD

Europe's Back to School

September 2016



EU Policy and Politics Highlights Q3-Q4 2016

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Political Reassessment: An Overview of Brussels in the coming months

As we head into a crucial 12 months for the future of Europe, the commercial environment for organisations will continue to be impacted by significant macro-political trends – affecting the policy agenda and the economic backdrop. Important political questions remain to be answered on the issues of Brexit, migration, sluggish growth, terror, Russia, Turkey and indeed on the transatlantic economic relationship, which has been clouded by stalling trade negotiations. We wanted to bring into sharp relief how this could impact the areas of manufacturing & industrials, financial services, food & agriculture, healthcare, technology, and energy.

Europe is challenged by political instability, with upcoming elections in Austria, the Netherlands, France and Germany. With this in mind, governments will be less willing to make significant decisions regarding the critical issues above. A referendum in Italy will be essential to continuing political and economic stability, while in Hungary a referendum on the migrant resettlement plan could spur a new wave of dissent from already wary countries such as Slovakia. Within EU institutions a degree of uncertainty remains over European Parliament President Schulz stepping down in January, as both he and Commission President Juncker support his continuation in the face of protests from certain MEPs.

In times of great uncertainty there is an important role for trusted interlocutors to play. Businesses which can provide advice and information while facilitating public discourse will surely be listened to by policymakers assessing the solutions to Europe's crises. However, there is also a new wave of scrutiny on business practices which can undermine the influence of corporate citizens in the broader policy sphere. Issues such as tax and trade have proved thorny for companies deemed to be shirking their responsibilities, and the EU in particular has shown little hesitation in sanctioning those it feels are not meeting expectations.

With a range of issues on the horizon, the last part of 2016 is unlikely to be quieter than the year so far. A populist surge across Europe, and indeed the US, has left policymakers reassessing the role of governments and the EU. It is now more important than ever that businesses actively participate in the public discourse, providing concrete insights and sound arguments on how the new EU takes shape.

Caroline Wunnerlich
Managing Director, FleishmanHillard Brussels

Three drivers for the Chemicals, Transport & Environment sectors

Circular Economy

Make no mistake about it: the Circular Economy package will affect you. Some companies will find opportunities while others will see new rules that severely impact their cost base, supply chain or market. Regardless, now is the time to engage!

The package relies on two pillars: a revision of the waste legislative framework and a broader action plan. With a view to stimulating Europe's transition towards a circular economy, various legislative and non-legislative actions are proposed that address all stages of a product's life cycle; product design, use, waste management and the secondary raw materials market. Discussions on the legislative proposals on waste have already started in the European Parliament and Council and will gain further momentum from September onwards. Meanwhile on the action plan front, the Commission services will be working on some of the landmark initiatives that are expected to come out in 2017, such as the plastics strategy and the analysis of the interface between waste, products and chemicals legislation. The European Parliament will most likely pay close attention to progress made by the Commission's services. Vice President Katainen is expected to report on such progress every six months.

Decarbonisation of transport

The EU has not given up its mantle as the most ambitious emissions reducer. Indeed its communication from this July seeks to accelerate the phasing out of fossil-fuelled transport. Manufacturers of cars, trucks, boats and planes face a legislative challenge to their current products – one that may not recognise the immediate realities of our transportation demands in light of current technology.

On 20 July, the European Commission published its most recent strategy for European Low-Emission Mobility, which describes how the EU will continue its path of reducing emissions from the transport sector. The greatest impact may be to truck manufacturers who, for the first time, will have to take into account CO₂ emission targets.

In the skies, the International Civil Aviation Organisation (ICAO) is scheduled to decide by 7 October on a Global Market-Based mechanism to curb emissions from aviation. Should an agreement not be found, the EU will have to decide on whether to re-introduce its Emission Trading Scheme for the aviation sector.

Chemicals REFIT

The Commission is rolling out its REFIT Programme on EU chemicals legislation. The REACH Evaluation will combine the reports on the implementation of REACH, the assessment of the outcome of the 2012 REACH review, and the results of a number of quantitative and qualitative studies. In September, stakeholders will be invited to provide feedback on whether and how REACH impacts their operations. The final report is due for 2017. In parallel, the Commission will work on its fitness check of the most relevant chemicals legislation (excluding REACH), which will notably cover legislation on hazard identification and classification, and legislation on risk management measures (i.e. environmental protection or chemicals control legislation). Both REFITs aim to support jobs and growth by lightening regulatory barriers and ensuring the highest level of protection of health, workers and the environment.

Brexit and Manufacturing

The UK EU referendum result has ushered in a sustained period of uncertainty for EU and UK manufacturing.

The initial “bounce-back” to UK manufacturing after the vote, stimulated by the weakened pound and cheaper UK exports, does not mask what a weaker UK, in terms of longer-term GDP, will mean for both UK and EU27 manufacturing. Uncertainty around the future conditions for UK-EU trade, in particular a possible return of import tariffs, and the future status of conformity certifications for manufactured goods, could hit mutual investment hard in sectors such as chemicals and automotive, which from a UK perspective rely heavily on EU-related exports, and have well-established pan-European supply chains.

From a policy-making perspective, the decreased UK influence across the policy dossiers listed here, amongst others, could result in the absence of a pragmatic influence across the EU institutions. This will mean that interest groups will need to carefully reconsider engagement at EU level on these issues.

What's in store for Financial Services?

A new Commissioner in a post-Brexit world

Legislative activity in the coming months will be the **highest seen since the current Commission took office in November 2014**, despite Brexit raising new questions over the future shape of the EU's financial sector. Jonathan Hill's resignation as Commissioner left the financial services portfolio in the hands of **Valdis Dombrovskis**. The Latvian will inherit a legacy agenda, but will also develop his own priorities and style in a post-Brexit environment.

Boosting investment in Europe

The newly appointed EU financial services chief will continue to pursue the investment and capital markets union ("CMU") agenda as a key priority, with a renewal of the **Juncker Investment fund** ("EFSI 2.0") expected. As part of this agenda, the Commission will also propose to harmonise aspects of **business insolvency** rules across the EU, while negotiations on the rules to promote venture capital will start and those to stimulate the **EU's securitisation market** and **improve the prospectus regime** will crawl closer to conclusion. Changes to bank capital rules to make **infrastructure and SMEs** more appealing are in the pipeline too. The fragmented market for **retail investment funds** will remain under scrutiny, with particular attention to the way investment products are distributed, while the Commission may launch a framework for **EU-wide personal pension products**. The details, however, are still on the drawing board.

As EU policy-makers want the EU economy to tap into market-based finance, drivers of **market liquidity** (including regulation, monetary policy and rise in electronic trading) will remain under close watch given potential implications for market stability. While not aligned with the CMU objectives, 10 Eurozone countries will continue to discuss introducing a financial transaction tax ("FTT"), even if slow progress is expected.

Strengthening the sector's resilience

Despite all this focus on growth, 8 years after the collapse of Lehman, efforts to strengthen the financial sector's resilience proceed apace. Top priority is transposing international rules agreed in the Basel Committee and the G20, with **EU legislative proposals expected around November**. As part of a broader overhaul of bank capital rules,

the Commission will introduce rules to prevent banks building up excessive leverage ("**Leverage Ratio**") and over-relying on financial markets to stay liquid ("**NSFR**"). The Commission will also bring the existing requirement for banks to issue a "wall of convertible debt" in line with international rules ("**TLAC implementation**"), which are meant to keep investors on the hook when banks fail and avoid future tax-payer bailouts. **Central clearing houses** ("CCPs"), a key component of financial markets' plumbing, will come under scrutiny as rules will be put forward to manage the risk of these crucial cog-wheels failing, whilst EU rules on derivatives imposed after the crisis will see a targeted review ("**EMIR**"). All these initiatives are intended to reinforce the sector. On the downside, **it may challenge banks' ability to fund the economy**, meaning a key political question will be: **will Europe deviate from these international rules?**

Discussions on deepening the **Banking Union** will linger on. The two main sticking points, the proposal to **mutualise national deposit insurance** and the idea that banks should price in risky **EU government bonds**, are both linked to de-coupling a country's financial fate from its banking sector, and vice versa. The controversial proposal to force large banks to **separate their trading and retail activities** remains on the table, too. However, no short-term breakthroughs are expected.

Stepping away from the banks, **insurers and fund managers** will see increased attention as international regulators are looking into potential risks associated with those actors.

Increased overlap between financial services and other sectors

As blockchain matures and technology reaches areas touching on personal financial data, **fintech** is revolutionising the sector. The interaction with existing regulation and potential for economic growth are closely monitored. So is Cybersecurity. Elsewhere, last year's COP21 deal elevated the financial sector to a crucial ally achieving the EU's climate goals, as '**climate finance**' increasingly becomes part of the financial sector's jargon. **Terrorist financing** and **anti-money laundering rules** will be revised in light of Europe's terrorists threat and Panama revelations.

The Agenda for Food and Agriculture

Agricultural Markets Crisis

A major priority for Commissioner Phil Hogan between now and the end of the year is the ongoing crisis in agricultural markets – particularly the milk and pig meat markets. EU dairy farmers are suffering with prices currently significantly lower than the cost of production for many, as the milk market continues to get to grips with oversupply following last year's abolition of national quotas. Added to this, the Russian ban on EU imports continues to hurt European farmers. July was a busy month, with the Commission establishing a Meat Market Observatory to give a boost to the pigmeat and beef & veal sectors by providing greater transparency through issuing market data and short-term analysis. Later that month the Commission presented a €500 million aid package for struggling farmers, €150 million of which was ring-fenced for a scheme to incentivise voluntary reductions in milk production. The next moves in this area will most likely depend on how successful or otherwise this aid package proves to be.

Brexit and Food & Agri

As it stands, the UK will lose access to all 53 of the EU's trade agreements once it leaves the Union. The UK can of course renegotiate each of these agreements themselves, but this will take years, possibly even decades. Meanwhile, the UK and its citizens will be subject to higher rates for importing and exporting food where it previously enjoyed tariff-free movement of goods.

Food industry players are also set to lose a precious ally at the Council level. Traditionally industry-friendly, the UK was known for taking science-based approaches, as seen in the recent glyphosate debate.

As for farmers, the likely longer term impact of the loss of access to CAP subsidies is a rise in domestic food prices as already struggling farmers look to make up for that lost income, with new British agricultural subsidies expected to be lower than those provided through CAP.

Trade

Trade is another hot topic in Food and Agri coming into September. Having already visited Columbia, Mexico, China and Japan this year, Commissioner Hogan will lead a delegation to Vietnam, Singapore and Indonesia in November with a view to winning new export partners for EU farmers. Meanwhile,

the Slovak Council Presidency has flagged the ratification of the EU trade deal with Canada (CETA) as its own number one trade priority for the second half of 2016, with Bratislava hoping that the deal can be signed at the EU-Canada summit on 27 October. Much focus will be placed on this process, as it is seen as a taster of what may be further down the line with TTIP.

Audiovisual Media Services Directive

Food and Agri operators should keep an eye on the progress report on the Audiovisual Media Services Directive (AVMSD), due in November. Proposed reforms for an updated AVMSD alter rules relating to product placement and encourage the development of EU codes of conduct for the advertisement of foods high in fat, salt and sugar.

Unfair Trading Practices

The Commission and the Slovak Presidency have both outlined their intention to tackle Unfair Trading Practices (UTPs). The Commission's Agricultural Markets Task Force has been meeting since January to examine how the position of farmers in the food chain might be improved and is due to deliver its final report in Autumn 2016. A key component of the Task Force's work has been to examine UTPs in the food supply chain, with farmers regarded as particularly vulnerable. While any EU-wide UTP legislation is unlikely to be proposed by the Commission at this point in time, further emphasis may well be placed on the voluntary Supply Chain Initiative, and Member States without any regulatory framework for UTPs are likely to be encouraged to ensure they have legislation or at least voluntary initiatives in place covering the entire B2B food supply chain.

Public Health

The European Commission and Member States will maintain a focus on public health, and more specifically on food reformulation as a way to combat non-communicable diseases. The Slovak Presidency will continue to address food product improvement, and most likely in a less industry-friendly way than seen during the Dutch Presidency. Meanwhile, the European Commission will keep putting pressure on operators to review product composition with a view to cutting the sugar, salt and fat content in everyday food offerings. With recent stats showing obesity rising in Europe, and Malta stating that diet-related diseases will be a priority issue for its Council Presidency in the first half of 2017, this is an issue which won't be going away any time soon.

Healthcare Horizons

Access to Medicines

Drug prices and drug consumption has risen and the concern is that prices have become disconnected from drug value, often inhibiting access. There has been a call from the Council to ensure that Member States have access to essential medicines at affordable prices. The Dutch Council Conclusions on strengthening the balance in pharmaceutical systems, which had a significant focus on affordability and access to medicines, were seen as significant progress by many who have been calling for action to be taken on the topic.

Before the summer break, MEP Soledad Cabezón Ruiz (S&D) and MEP José Inácio Faria (ALDE), as Rapporteur and Shadow Rapporteur of ENVI Committee INI on *EU Options for Improving Access to Medicines*, gathered a dynamic mix of EU health stakeholders from NGOs, Patient Groups, Industry and the Commission to discuss access to medicines in the European Parliament. The discussion was tough on industry and we expect Ms Ruiz's draft resolution to reflect that - prior to the Workshop in the Parliament, she was recorded as speaking in favour of compulsory licencing. The indicative plenary sitting date for the first reading is forecast for 12 December 2016. We'll be watching how the debate unfolds until then.

Brexit and Health – what will be the big issues in the coming months?

Until Article 50 is triggered, we're looking at business as usual in health. However the debate will continue on where the European Medicines Agency, headquartered in London, will relocate to. Officials in Denmark, Ireland, Italy and Sweden have all expressed interest in taking over as host country.

We're also watching how research projects being conducted within the UK will continue to liaise with IMI and Horizon 2020. When Article 50 is triggered, companies will likely lose the mandate to continue to lobby DG RTD for funding for existing projects or new projects within the UK.

European Health Forum Gastein, Austria 2016 (28-30 September)

This year's European Health Forum in Gastein will look at healthy ageing and migration and health. As usual, the list of high-level speakers is extensive, including Commissioner Andriukaitis

himself, Martin Seychell (Deputy Director-General for Health and Food Safety) and Zsuzsanna Jakab (Regional Director, WHO Europe). We look to EHFG each year to get a better understanding of DG SANTE's upcoming focus and priorities.

Consultations on Key Pieces of EU Health Legislation

Orphan medicinal products

There is an ongoing Public Consultation on the concept of 'similar medicinal product' in the context of the orphan legislation. The aim is to improve the implementation of the regulatory framework and to adapt the text to scientific developments. The Consultation will close on November 4.

There will be a new notice to make orphan designation a more effective tool, to further encourage R&D for orphan medicines, and to support that the best treatments receive a designation.

Paediatric Regulation

The European Commission will open a public consultation on Paediatric Regulation in December. Since its introduction in 2007 it has been an integral part of the overall development of medicinal products in the EU. All stakeholders are expected to play an active role.

In 2017, it is expected that the Commission will publish a report on the Paediatric Medicines Regulation that analyses the cost and value of the regulation from the perspective of national health systems.

eHealth

The final text for the mHealth Code of Conduct from the industry-led drafting committee has now gone to the Article 29 Working Party. It is difficult to predict when we will hear back from them as they are not obliged to deliver feedback within a fixed period. In addition to the GDPR implementation, the upcoming FABLAB, and activity around the Privacy Shield they won't produce anything before October/November. The Commission has announced that it wants to ensure a high level of health, safety and protection for consumers in relation to apps. On 9 June, the Commission opened a public consultation (PC) on the safety of 'apps and other non-embedded software'.

Three Tech Initiatives to Watch

Telecoms Review & Content Package

First out the gate in September will be the Telecoms Review. This tackles broadband speeds, 5G coverage, and the extension of regulation to new Over-the-top (OTT) communication services (i.e. WhatsApp, Skype). This could force OTT providers to provide free access to public services, like the emergency number 112.

Following shortly after is the Content Package which opens the Pandora's Box of copyright. This includes the Satellite and Cable ([SatCab](#)) Directive which pits platforms against broadcasters as the Commission moves to tackle the licensing of copyrighted material and expanding access to it. The key word you'll become familiar with is the '**country of origin**' principle and whether it should be extended to online transmissions. As it stands, this principle allows broadcasters to acquire one **license** and then broadcast a service throughout the EU. Maria Martin-Prat, Head of the Copyright Unit in DG Connect, already commented that there was a "colourful reply to the SatCab consultation". Expect 'colourful' debates from broadcasters and platforms once the proposal sees the light of day in September. Moreover, new proposals will address the **safe harbor** status of online intermediaries (i.e. YouTube, Daily Motion). This limits the liability of platforms when users upload or generate content to websites, something musicians are not pleased about.

Free Flow of Data initiative

Next on the chopping block will be the Free Flow of Data initiative. The European Commission wants to ensure that data can flow cross-border within the EU and is not restricted by national legislation. The initiative is rumoured to contain a legislative proposal and non-legislative policy communication.

On the legislative front, the proposal aims to remove the legal barriers and restrictions to the **free movement of data** in the EU. However, the legislative proposal is likely to include a list of possible justifications for **data localisation** e.g. national security. Secondly, the non-legislative communication will aim to clarify issues such as **data ownership, access to data, and liability**. This is of interest to a wide range of sectors as current questions include who is responsible for data created by autonomous systems in case of malfunctioning or damage (e.g. driverless cars), what third parties can access data held by a

Brexit and Technology

Tech companies were one of the loudest voices warning that a leave vote would hurt the UK's tech scene.

With the UK outside the EU, an approved legal framework will be required so as to transfer data. A Commission 'adequacy decision' will have to assess if the UK can deliver the same level of protection an EU citizen can expect through the General Data Protection Regulation. This may prove challenging as the UK's proposed Investigatory Powers Bill includes elements of mass surveillance.

Politically, the Council of the EU loses a strong voice that did not want to 'over-regulate' the digital market. The consequent shift in power, to France and Germany, may prove tricky as both countries have made clear that they favour copyright levies, data localisation, and platform regulation. Companies that understand these dynamics will be better placed to assess the outcomes of upcoming votes and better gauge where new threats may appear.

commercial entity, and does data have an economic value? Answers should be coming your way in November.

Ongoing legislation

With close to two-thirds of Digital Single Market legislation already announced, all institutions will press ahead with their discussions, positions, agreements, and of course disagreements. In the Council, the [Slovak Presidency](#) wants to conclude trilogues on [Spectrum](#), and will begin trilogues on the proposals for [Digital Content](#) and the [Online Sale of Goods](#). Furthermore, Slovakia wants a general approach for the proposals on [unjustified geo-blocking](#), and the Audiovisual and Media Services Directive ([AVMSD](#)) will be subject to a 'progress report' and presentation at the November meeting of the European Youth, Culture and Sport Council. Turning to Parliament, a swathe of Committees continue their quest for digital literacy, as the aforementioned proposals near the end of first reading. Moreover, IMCO and ITRE will have joint custody over non-legislative reports on the [e-government action plan](#), [digitising European industry](#), [collaborative economy](#), [European standards](#), and [online platforms](#).

Coming Your Way on Energy & Climate Policy

Emissions Trading Scheme reform

Followers of the EU ETS file were able to go on holidays reassured by the fact that MEP Ian Duncan (UK, ECR) would after all remain in charge on the European Parliament's side and a new rapporteur wouldn't have to be found – along with the delays this could have led to. How much influence he will still have after the UK EU Referendum remains to be seen. The amendments to Mr. Duncan's report in the ENVI Committee were released over the summer and will now be the main thing to keep an eye on in view of the Committee vote scheduled for December. In parallel, the ITRE Committee (which shares competence with ENVI on the file) will deliver its opinion report in October. In Council, the Slovak Presidency is hoping to secure a general approach by December, before it hands the keys of the Justus Lipsius to Malta. Main things to watch out for will be the overall ambition of the reform (Linear Reduction Factor), the criteria for carbon leakage and benchmarks for industry, as well as the number of allowances found in the Modernization and Innovation Funds.

Energy Efficiency, Ecodesign and Labelling

Later this year the European Commission will release a package comprised of a review of the Energy Efficiency Directive (EED), the Energy Performance of Buildings Directive (EPBD), an overarching Communication setting out the Commission strategy, and an initiative on 'Smart Finance for Smart Buildings'. The EED dossier has been historically sensitive and the Commission is therefore not expected to conduct a major shake-up and in-depth review of the Directive but rather to focus on adjusting specific aspects of it. The main issues to keep an eye on are the overall energy efficiency target for 2030 (will the Commission propose a 30% target instead of the

agreed 27%? Will it be binding?) and the continuation and parameters of Article 7 of the EED which currently imposes annual energy saving obligations on power suppliers. The Commission will also be reviewing the Ecodesign Directive.

Power Market Design & Renewables

In December the Commission will table new rules for the electricity market market design to reshape the way they function. The Package is expected to be unusually technical, covering issues such as market access rules and price zone formations. A review proposal for the Renewable Energy Directive will also be tabled; the question of governance – how to make sure we actually reach the 27% EU level target and what happens if we don't – will be on everyone's mind, as well as measures to raise advanced biofuels' share in transport.

Security of Supply

On the Security of Supply side of things, the Slovak Presidency of the Council of the EU aims to broker an agreement between Parliament and Council on the Security of Gas Supply Regulation proposal, a high priority for Slovakia which happens to be a key transit country for imports of Russian gas across Ukraine. For this to happen, the Council will first have to reach an agreement internally on the issue of regional groupings – so far, the Commission's proposal has been criticized by some of the more 'secure' (read Western European) Member States who want more flexibility in the formation of these groupings and are trying to impose alternative proposals. A blocking minority of these EU capitals could complicate the Slovakian Presidency's plans. At the same time the Commission is working on a new list of Projects of Common Interest.

The Impact of Brexit

The Energy Union strategy will continue but the content and shape of its policies could change. On energy security for example, a strong voice in favour of a tough stance towards Russia will be gone. Likewise, EU climate policy will continue to move in the same direction, though without the UK, the Commission, France and Germany lost a strong ally in the push for further long-term ambition in the context of the Paris Agreement, but will have an easier time pushing for binding measures to reach the renewable energy target.

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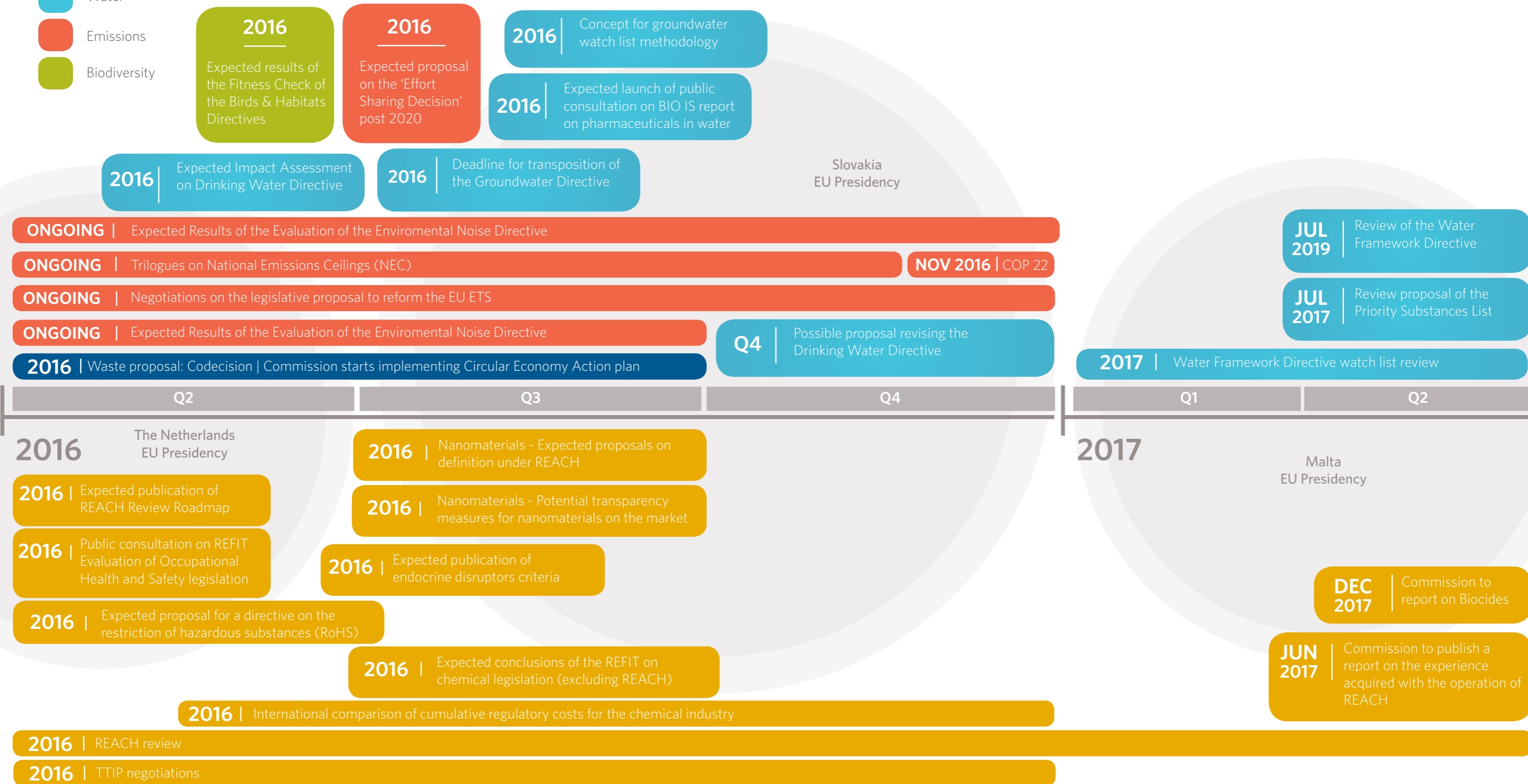
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Chemicals and Environment legislation: EU Agenda 2016/ 2017

- Chemicals
- Circular Economy
- Water
- Emissions
- Biodiversity

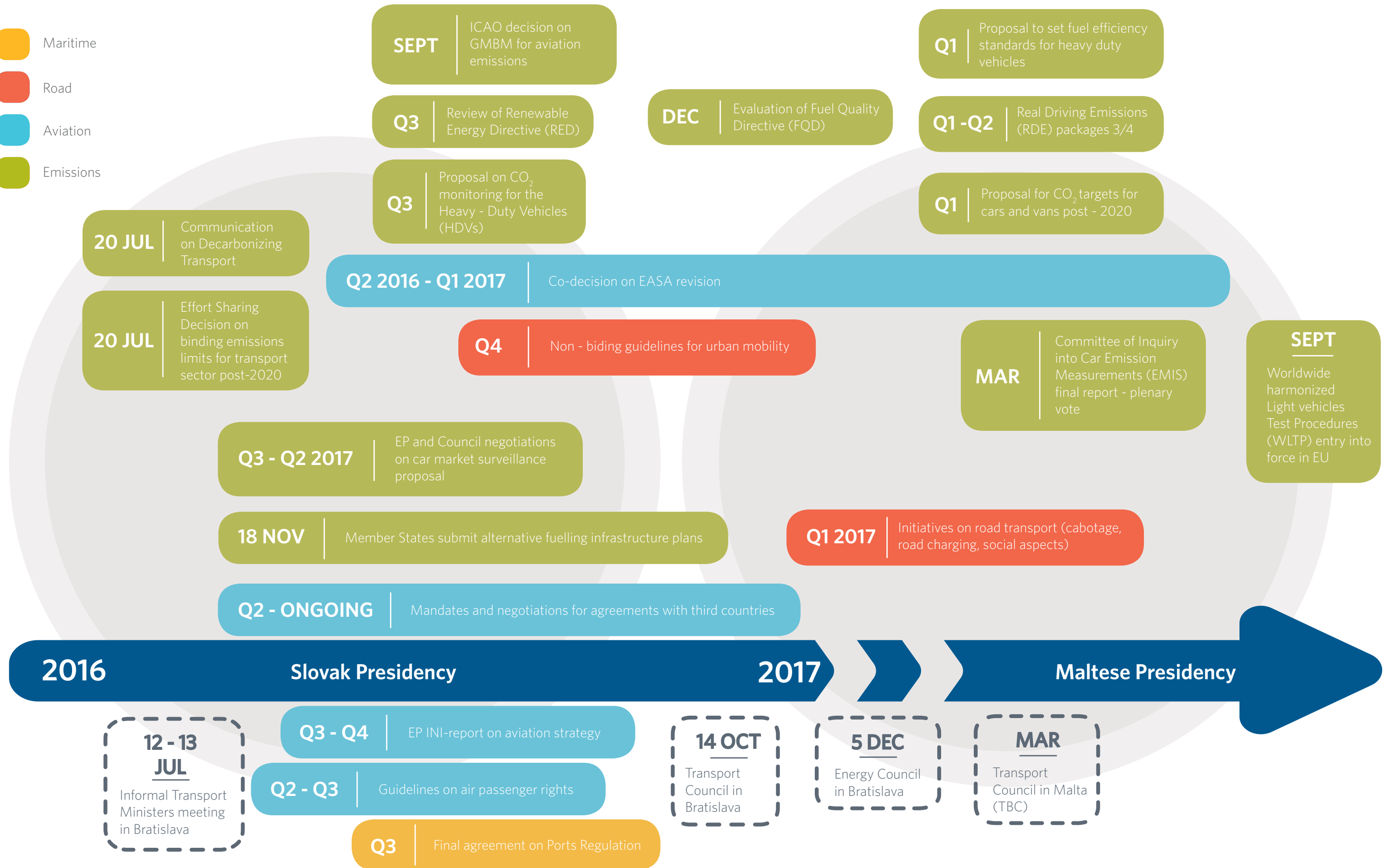


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Timings are indicative

Transport: EU Agenda 2016/ 2017

- Maritime
- Road
- Aviation
- Emissions

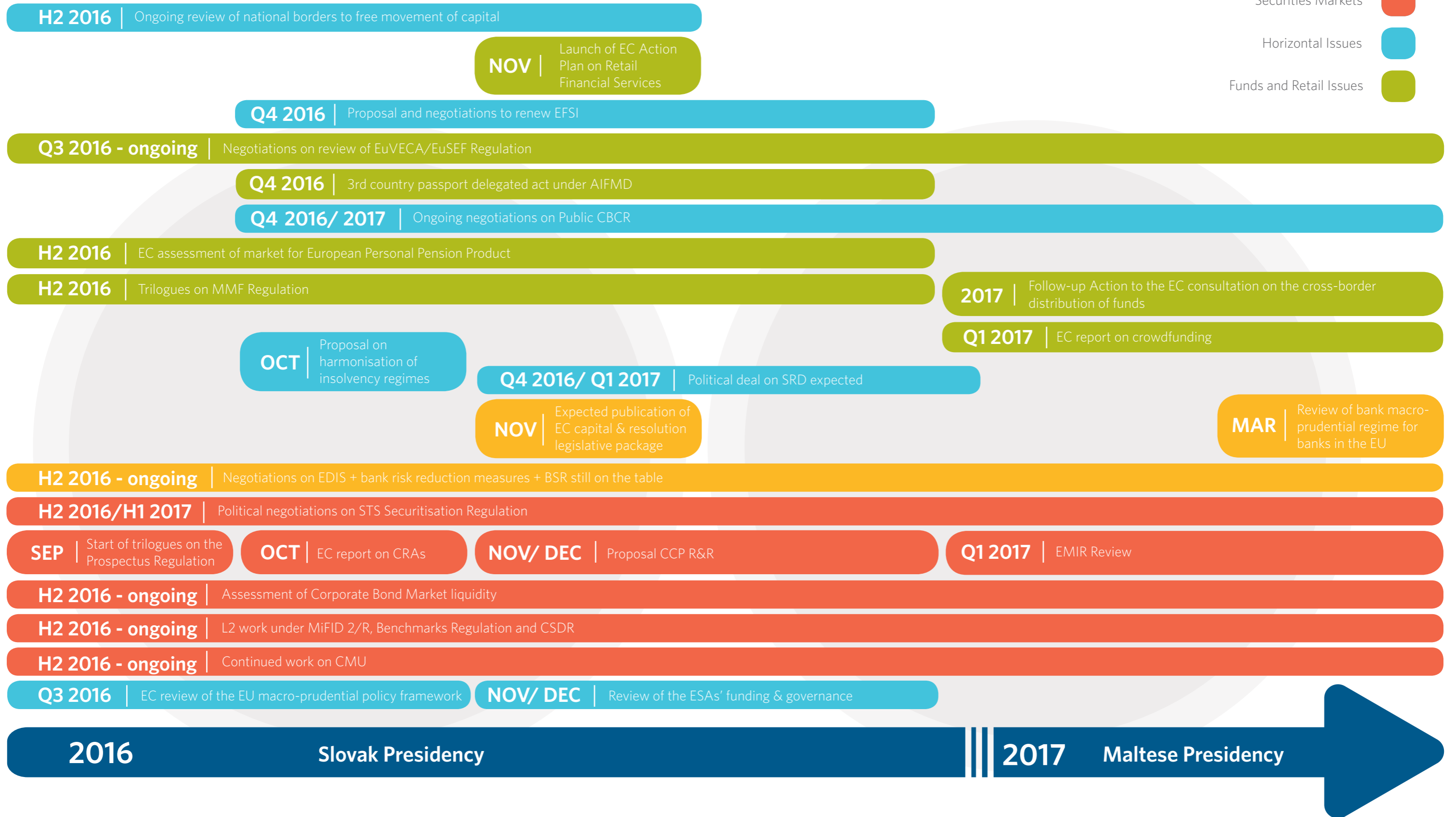


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Timings are indicative

Financial Services: EU Agenda 2016/ 2017

- Prudential Issues ●
- Securities Markets ●
- Horizontal Issues ●
- Funds and Retail Issues ●



Corporate Taxation: EU Agenda 2016/ 2017

■ EU initiatives on tax avoidance
 ■ EC State aid investigations
 ■ OECD/G20 anti-BEPS initiatives
 ■ European Parliament



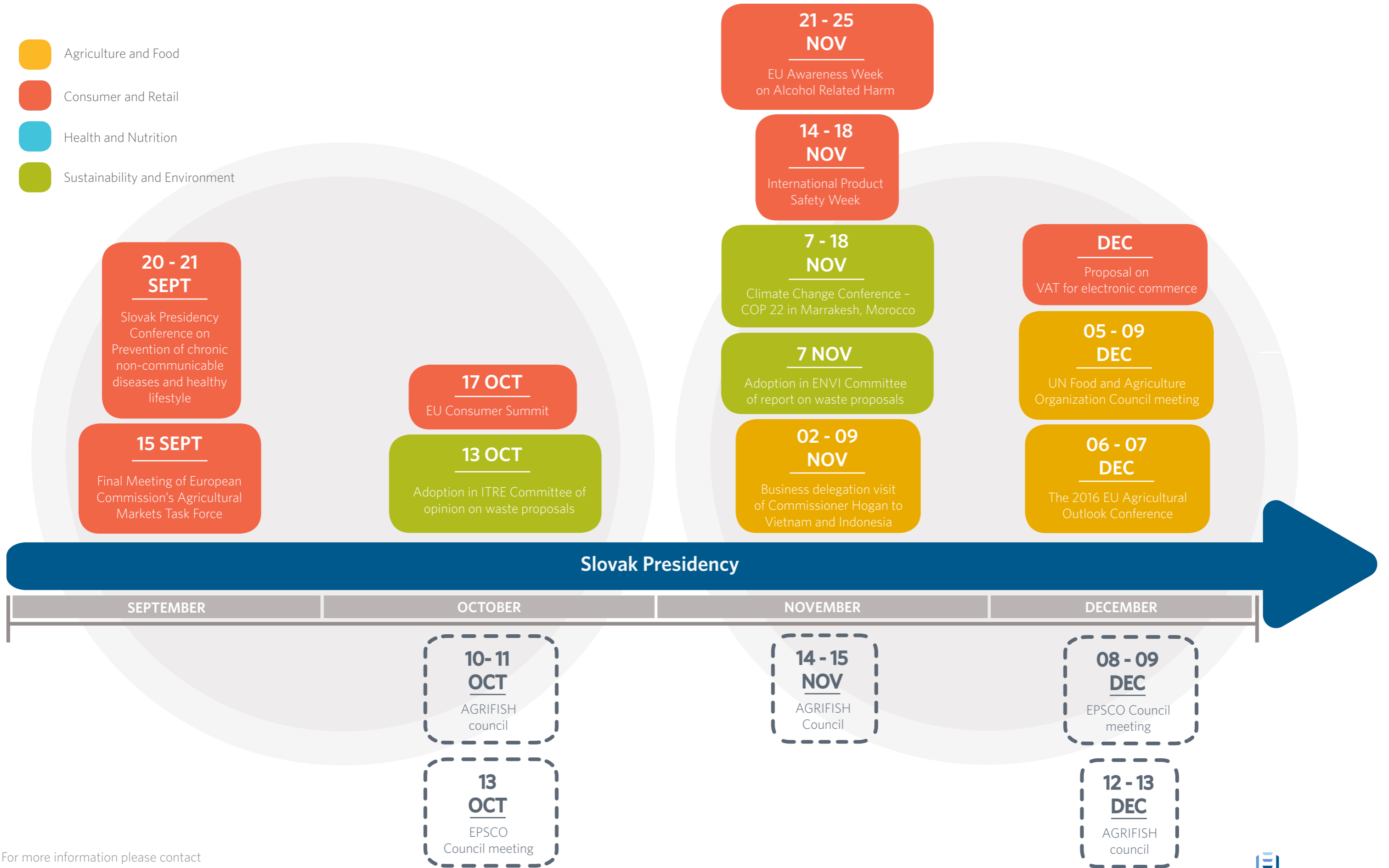
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Timings are indicative

OECD list of non-cooperative jurisdictions and work towards defensive measures – July 2017

Food and Agriculture: EU Agenda 2016

- Agriculture and Food
- Consumer and Retail
- Health and Nutrition
- Sustainability and Environment



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Timings are indicative

Health: EU Agenda 2016

- Health Policy Initiatives
- Research and Innovation
- Antimicrobial Resistance
- Slovakian Presidency

28 - 30 SEPT | European Health Forum Gastein

29 SEPT | ENVI Committee to discuss a resolution on access to medicines

28 - 29 SEPT | Innovative Medicines Initiative Stakeholder Forum

21 SEPT | UN high-level meeting on antimicrobial resistance

20 - 21 SEPT | Conference: Prevention of chronic non-communicable diseases and healthy lifestyle.

16 SEPT | First European Medicines Agency-European Federation of Pharmaceutical Industries and Associations annual bilateral meeting - **EMA**

8 SEPT | EPHA 7th annual conference

6 - 7 SEPT | Head of Medicines Agencies I. meeting (HMA I.)

29 OCT - 2 NOV

ISPOR 19th Annual European Congress, Vienna

19 - 20 OCT | National Drug Coordinators Meeting

13 - 14 OCT | 15th meeting of the National Microbiology Focal Points

17 - 19 OCT | Competent Authorities for Medical Devices Meeting (CAMD)

13 OCT | Employment, Social Policy, Health and Consumer Affairs Council

3 - 4 OCT | Informal Meeting of Health Ministers (Informal EPSCO - Health)

29 NOV

Conference: Alzheimer's Disease - the epidemic of the third milenium. Are we ready to face it?

4 NOV

Public Consultation on the concept of 'similar medicinal product' in the context of the orphan legislation closes

3 - 4 NOV

Joint meeting of Chief medical, nursing and dental officers

3 - 4 NOV

Committee for Orphan Medicinal Products - **EMA**

8 - 9 DEC

Employment, Social Policy, Health and Consumer Affairs Council

6 - 8 DEC

Committee for Orphan Medicinal Products - **EMA**

12 DEC

Forecast indicative plenary sitting date for the first reading of ENVI Committee (INI) EU Options for Improving Access to Medicines

SEPTEMBER

OCTOBER

NOVEMBER

DECEMBER

SEPT | Open Public Consultation - Adaptation to technical progress of orphan legislations

SEPT | Public Consultation on 3rd EU Health Programme + results of its mid-term evaluations

SEPT | Open Public Consultation Regulation of General Manufacturing Practices for IMPs

OCT | Public Consultation on Implementing Directive on General Manufacturing Practices for medicinal products for human use opens

21 - 24 NOV

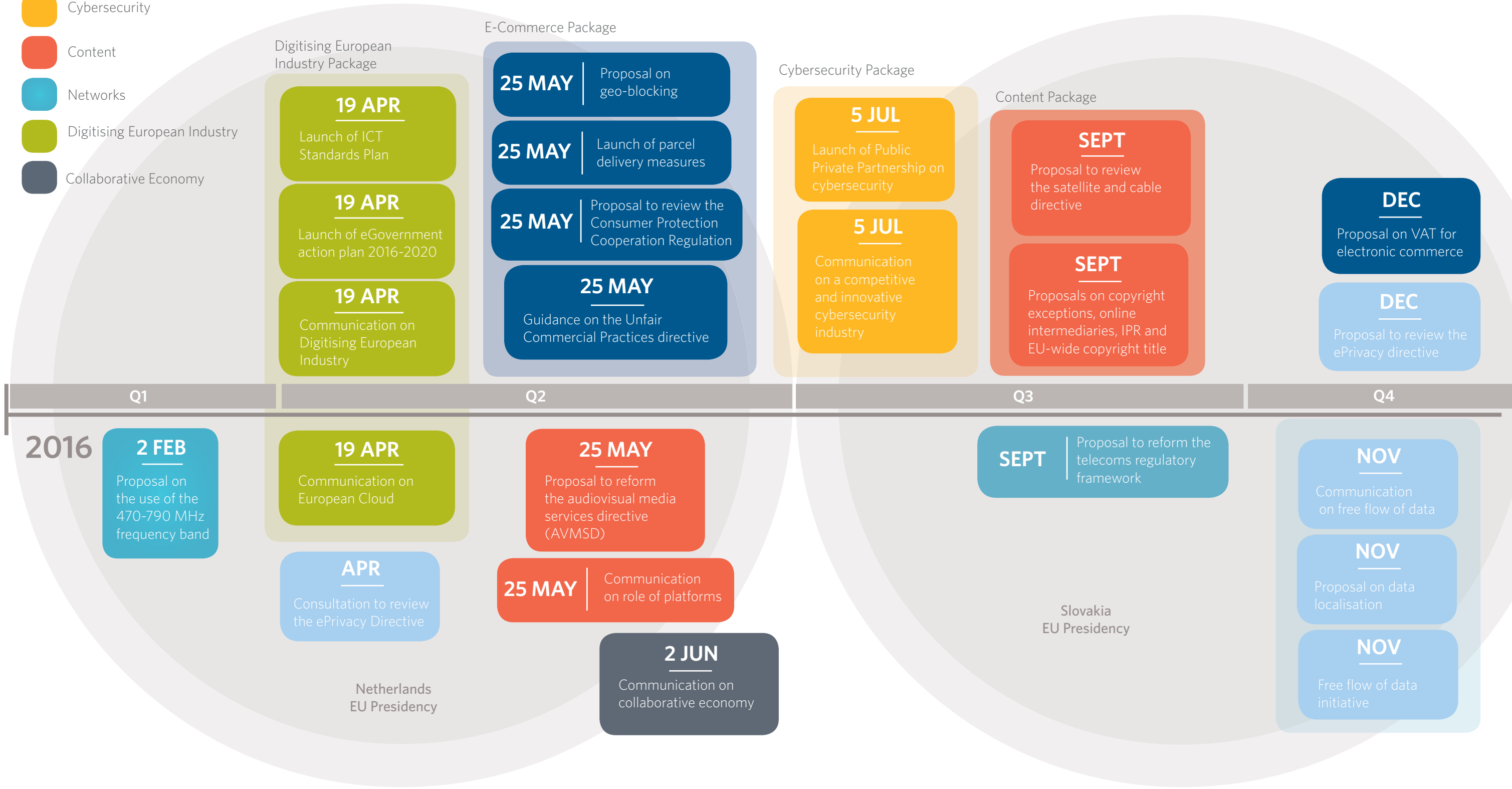
9th Global Conference on Health Promotion - **WHO**

DEC

Public Consultation on Pediatric Regulation Report opens

Digital Single Market: EU Agenda 2016

- E-commerce
- Data Protection
- Cybersecurity
- Content
- Networks
- Digitising European Industry
- Collaborative Economy



Energy: EU Agenda 2016/ 2017

- Security of supply
- Internal energy market
- Decarbonisation of economy
- Energy efficiency
- Research & innovation

