



# Recommendations to the German Presidency of the Council of the European Union

July - December 2020



# AmCham EU speaks for

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American companies **committed to Europe** on trade, investment and competitiveness issues. It aims to ensure a **growth-orientated business** and **investment climate** in Europe. AmCham EU facilitates the **resolution of transatlantic issues** that impact business and plays a role in creating **better understanding** of EU and U.S. positions on business matters. Aggregate U.S. investment in Europe totalled more than **€3 trillion in 2019**, directly supports more than **4.8 million jobs** in Europe, and **generates billions of euros** annually in income, trade and research and development.

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**Secretariat point of contact:**

Roger Coelho

*Senior Policy Director*

[RCO@amchameu.eu](mailto:RCO@amchameu.eu)

# Message to the German Presidency of the Council of the European Union



**Susan Danger**  
CEO  
AmCham EU

The German Presidency of the Council of the European Union comes at an unprecedented moment in the history of the European Union. Europe, like the world, has been rocked by the COVID-19 pandemic. In this context of an uncertain international environment impacted by a global health crisis, the case for strong transatlantic cooperation embedded in a rules-based multilateral system has never been as compelling. The EU and the US are the biggest economies in the world. We must be united in the fight against COVID-19 and pull together as drivers of the global economic recovery.

We are pleased to present the American Chamber of Commerce to the EU's (AmCham EU's) recommendations to the German Presidency. However, we do so with the caveat that the document was conceived before the extent of the COVID-19 crisis was fully understood. The recommendations therefore refer to the files open and ongoing in the European Commission's original 2020 work programme as it was published on 29 January.

We believe that many of the issues raised by AmCham EU in this report are still pertinent to ensuring the EU's economic recovery. Nonetheless, we recognise that the Presidency's focus has necessarily shifted to mitigating the crisis and formulating the recovery. We are developing a 'road to economic recovery' paper, offering our perspectives on how to ensure a return to full economic health. We will share this paper with the Presidency as soon as the work is completed.

We look forward to working closely with Germany during its Presidency to ensure we reach our common objectives of a stronger and more competitive EU. AmCham EU stands ready to support Germany in this crucial role and wishes the Presidency every success. We are confident that the EU's economy is in the safest of hands.



AmCham EU has developed a public portal to share information and resources on the COVID-19 pandemic. It brings together updates from the EU institutions and Member States, as well as insights into the business response to the crisis.

The global health crisis we face today is an unprecedented challenge for our society. Our member companies have taken immediate action to protect employees, but also to ensure, wherever possible, business continuity. American companies are committed to Europe and stand ready to help policy-makers as they steer the region through the crisis.

Our member companies are also doing what they can to help local communities in Europe and around the world. They contribute their skills, capacities and infrastructure to provide resources to respond to the crisis and support health workers.

**Visit the portal: [amchameu.eu/covid-19](https://amchameu.eu/covid-19)**

# Committed to Europe: Agenda for Action 2019-2024

The last few years have tested European unity and the post-war world order. From the Brexit vote to the rise of populism, the EU had to demonstrate its ability to take the lead and deliver for European citizens. As the effects of digitalisation and globalisation continue to transform our economies, societies around the world are pressured to become more resilient. Tackling global challenges such as rising inequalities, climate change and migration requires collective leadership and bold policy action.

As American companies committed to Europe, the competitiveness of the region in the global economy is of utmost importance to us. With sustained focus, Europe can remain one of the most attractive regions in the world to do business, but also one of the best places to live, study, work and raise a family.

Our *Agenda for Action* outlines the four priority areas we believe should drive the political agenda:



## Empowering people

- Education
- Skills
- Inclusion



## Leading global cooperation

- Transatlantic partnership
- Trade and investment
- Sustainability



## Boosting the Single Market

- Smart regulation
- Better harmonisation and implementation
- Capital, digital, energy and transport



## Investing in the future

- Human capital
- Research and innovation
- Infrastructure and best-in-class public procurement

Learn more: [www.amchameu.eu/Agenda4Action](http://www.amchameu.eu/Agenda4Action)

# Policy recommendations by Council configuration

## Agriculture and Fisheries

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### ISSUE

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### RECOMMENDATIONS

#### **Common Agricultural Policy (CAP)**

It is imperative for the EU to establish a balanced and competitive agricultural policy that respects the urgency to protect our planet and to ensure a future for European farmers. The CAP should offer the support that European farmers need in order to meet the European Green Deal and Farm to Fork (F2F) Strategy ambitions and objectives. It should therefore enable farmers to achieve more sustainable and efficient farming practices while providing sufficient safeguards. This includes the promotion of a system based on 'prevention first and always', bringing old practices of farming in line with the latest digital technologies. AmCham EU wants fair and non-discriminatory treatment of local versus imported raw materials to supply the European market. Moreover, further support in R&D initiatives in agriculture including digital and precision farming is critical to support farmers and to help improve food safety and public health.

Any changes brought forward by the F2F strategy, need to link clearly with the new CAP framework, including additional budget and incentives in order to help strengthen the environment and climate change aspects of the CAP. In this context, the CAP should also reiterate the need for funding of comprehensive disease prevention programmes, including vaccination, in the CAP-funded National Strategic Plans and more precisely the CAP eco-schemes as an effective means of tackling antimicrobial resistance (AMR).

#### **Farm to Fork Strategy (F2F)**

A swift transition towards more sustainable food systems is essential and should be made in a holistic, fair and coordinated approach.

The transition will require engagement and co-operation from all actors throughout the food supply chain.

The Farm to Fork strategy should be a tool to ensure protection of the environment, promote sustainable production and consumption, facilitate sustainable trade and encourage increased research and innovation. In particular, AmCham EU would like to emphasise: the need for alignment from the outset between F2F and other policy initiatives, in particular with the various parts of the European Green Deal dealing with food, the fact that food safety continuous to be paramount and that the F2F strategy should be guided by the latest available reliable science.

Additionally, the F2F should support the development of greener veterinary medicines. Among the measures taken to reduce the use of antibiotics in farmed animals, and thus AMR, the Commission needs to encourage industry to further develop medicines for animals with a reduced impact on the environment, such as biopharmaceuticals and vaccines.

# Agriculture and Fisheries (cont.)

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## ISSUE

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## RECOMMENDATIONS

### **Farm to Fork Strategy (F2F) (cont.)**

Vaccines have an AMR neutral effect and should be considered as ‘green pharmaceuticals’ allowing a more sustainable food production in the EU.

F2F should also promote digitalisation in the agricultural sector. It should support farmers to make the transition, allowing them to benefit from the full range of technological capabilities. To ensure a smooth transition, the Commission should invite and involve all parties of the food supply chain, from the production to consumption in a dialogue on the digitalisation of the food chain.

### **Implementation of the legal framework for veterinary medicinal products (VMP)**

The implementation of the VMP Regulation should reflect a sound benefit-risk assessment, not hazard-based approaches. It should not hamper international trade by imposing EU technical measures on third-countries that are not compatible with World Trade Organization (WTO) rules. This relates to the setting up of a list of critically important antimicrobials (CIAs) and prohibiting the import of animals and animal products treated with these CIAs in third countries. Furthermore, investment in research is paramount to ensure that innovative treatments, new technologies and care options become available.

### **Risk assessment, management and communication in the agro-food sector**

A balance between risk assessment, management and communication is of paramount importance for the integrity of the food chain and to promote innovation and sustainable growth in the agro-food sector. Risk management decisions should be communicated in a clear, timely and transparent way to foster and encourage consumer acceptance of technological developments and rigorous scientific and risk-based decision-making should be at the front and centre of all discussions.

### **Sustainable nutrition**

The triple burden of malnutrition – overnutrition, undernutrition and insufficient consumption of essential nutrients – is a problem in developed countries. Many consumers lack the essential knowledge to make informed choices for a varied and balanced diet. This essential information should be part of education curricula and campaigns across Europe. Achieving a healthy and sustainable diet pattern is a complex challenge, but it is important in contributing to the health and well-being of European citizens. AmCham EU promotes efforts to provide EU citizens with easily accessible, economically affordable, nutritionally adequate, safe and healthy food choices. The German Presidency should promote innovation in the food space, support the use of sustainable food technologies as well as guarantee an easier access to a variety of food products across the EU. This will enable better health and economic outcomes for all Europeans and it would be in line with the Sustainable Development Goals (SDGs) and the UN Decade of Action on Nutrition 2016-2025 to which the EU is committed.

# Competitiveness

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## ISSUE

### EU competition law for the digital age

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## RECOMMENDATIONS

The German Presidency should build on the expertise of the private sector to find solutions to the challenges posed by digitisation. As the Directorate-General for Competition (DG COMP) moves to update EU competition law and policy for the digital age, AmCham EU encourages stability and predictability in the field of competition. The latter forms the bedrock of investment in the Single Market and ensures an open and free-market system for all. In particular, Member States should ensure that unreasonable inversions of burden of proof or other definitions do not weaken the market. Such actions would in fact widen the discretion of competition authorities and could call into question the reliability of decades of case law built on the current rules.

It is also critical to ensure that competition instruments are not misused to achieve goals that are not within the competences of the Union or the Commission (eg, state aid cases aimed at influencing the tax policies of Member States).

### Industrial competitiveness

Industry is a critical driver of economic growth, innovation and prosperity. Boosting manufacturing must be embedded in all areas of EU policy and regulatory competence, in order to make the EU more attractive to foreign investment and to avoid the risk of undermining industrial competitiveness. In addition, the EU industrial strategy must also have a strong external dimension, ensuring equal opportunity for market players – this is key for companies to remain competitive globally. To tackle the downward trend of investment in manufacturing, the German Presidency should support the European Commission’s proposal for a renewed EU industrial strategy.

AmCham EU wants to create the right environment to conduct business and ensure a solid infrastructure, to foster skills, talent, innovation and labour flexibility while strengthening the Single Market. This includes encouraging free and rules-based trade and the effective implementation of the Better Regulation agenda. Moreover, the Digital Single Market should ensure that online services, goods and data can move freely to allow industry and people to reap the full benefits. Finally, the EU should encourage the adoption of globally harmonised standards and regulations by enhancing international cooperation and fostering its leadership role.

### Single Market

The Single Market is the basis of the economic success of Europe and a key determinant of US investment in Europe. Completing the Single Market would increase productivity, investment, trade and job creation, helping to ensure Europe maintains its position as a global economic leader.

Despite increased pressure, the will of EU policy-makers to complete the Single Market is clear – as demonstrated by the Commission’s Single Market Strategy. Now is the time for greater action at Member State level to ensure the integrity of the internal market in the long term and to promote investment and innovation in Europe.

# Competitiveness (cont.)

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## ISSUE

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## RECOMMENDATIONS

### **Electronic Data Interchange (EDI) standards**

In order to streamline the free movement of goods, AmCham EU recommends centralising procedures through, a single European Customs Agency where economic operators can file their customs declarations. In the same spirit, the German Presidency should be a strong advocate for an effective and smooth implementation of the VAT e-commerce package. To that end, the German Presidency should propose to align VAT and customs legislations to provide certainty for relevant authorities and eliminate confusion for operators over liability and ensure that the Import One Stop System (IOSS) model works effortlessly by including an end-to-end green lane status and simplifying the registration process for all operators.

### **Streamlining customs procedures across the EU**

Although the EU operates in a Customs Union and constitutes a Single Market, the free movement of goods continues to face considerable obstacles. Currently, importing into the EU requires the submission of different customs declarations in each Member State, using local languages and complying with varied rules. AmCham EU recommends that the German Presidency should further push to harmonise national rules related to the movement of goods in the EU and customs. In this context, we request the German Presidency to expedite the mandatory introduction of the Single Window. These are critical for ensuring a truly frictionless Single Market across the EU.

### **Enforcement of intellectual property rights (IPR) offline and online**

Europe has one of the strongest frameworks for the protection of IPR, which is key to incentivising investment in innovation and creativity. As IP infringements such as piracy and counterfeiting have continued to grow both in size and scope, we look forward to the Commission's intention to modernise and strengthen the existing framework. In particular, as the German Presidency will hopefully coincide with the adoption of post-Covid-19 recovery measures, it will be critical to ensure that the focus is on authentic goods and content and to eliminate the unfair competition coming from rogue actors.

### **Review of the pharmaceutical incentives framework**

In the current review of the incentive framework for pharmaceutical innovation, the EU must maintain its robust intellectual property rights (IPR) and incentive framework that has been proven to deliver hundreds of novel therapeutics for EU citizens. IPR are fundamental to a knowledge-based economy. AmCham EU urges caution when considering whether to reopen EU legislation on orphan, paediatric medicines or in considering a review of other key incentives for the pharmaceutical sector. It needs to be mindful of any unintended consequences that may result from a dilution of IPR.

In order to maintain the EU's global competitiveness of the life science sector and to protect the health and wealth of the EU, it should maintain the current incentives and protections. In parallel, we call on the German Presidency to advance discussions on new incentives to address areas where there is market failure such as AMR.

## Competitiveness (cont.)

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### ISSUE

#### Unitary patent (UP)

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### RECOMMENDATIONS

A fully functioning UP system would signal that intellectual property is a driver of innovation, competitiveness and growth for Europe in the global economy. We call on the German Presidency to resume the debate on ways to move forward towards ratification of the Unitary Patent Court (UPC) and the UP system across all Member States.

## Economic and Financial Affairs

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### ISSUE

#### Banking Union

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### RECOMMENDATIONS

AmCham EU is a long-standing supporter of European rules aimed at strengthening financial stability via improvements to prudential requirements, as well as to recovery and resolution mechanisms. The overarching priorities in the field of prudential regulation should be to complete the Banking Union, to ensure a globally consistent implementation of international banking standards (eg, Basel framework) and to avoid fragmentation and localised ring-fencing requirements.

#### Capital Markets Union (CMU)

AmCham EU supports efforts to complete the Single Market for financial services, including the project to build a CMU. The CMU needs to remain a priority, with renewed focus on the creation of open, innovative and inter-connected financial markets. The CMU agenda is important both to increase the resilience of EU economies to external shocks and to create the pre-conditions for the sustainable finance agenda. The CMU agenda will also help mitigate the Brexit-related risks of additional market fragmentation and of increased obstacles to cross-border investments and efficient capital allocation.

#### International tax cooperation

The Organisation for Economic Co-operation and Development (OECD) is the best forum for a coordinated and coherent approach to the taxation of multinational companies across the EU. The OECD's Base Erosion and Profit Shifting (BEPS) recommendations must be consistently adopted across the EU. Going beyond the recommendations would negatively impact the EU's attractiveness for investment from EU and third-country companies. A unilateral EU approach to the direct taxation of multinational companies could create double taxation problems and reaffirm concerns about protectionism. This is especially true if potential actions are not coordinated with the ongoing multilateral tax discussion at the OECD level.

For example, the taxation of the digital economy needs to strike the right balance between taxing value where it is created and fostering growth. A serious, structured conversation about how to tax new business models should take place in a multilateral context in order to ensure widespread agreement.

## Economic and Financial Affairs (cont.)

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### ISSUE

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### RECOMMENDATIONS

#### Market openness

Open, well-functioning and appropriately regulated transatlantic capital markets have been a crucial driver of long-term economic growth and competitiveness in Europe and the US. The recent uncertainty of Brexit may mean an inevitable fragmentation of financial markets, bringing risks to financial stability and increased costs for investors and issuers. Open markets are inextricably linked to Europe's ambition of becoming more globally competitive. As the German Presidency further considers the future supervisory and regulatory framework for third-country market access, increased transparency and predictability around the equivalence process should be prioritised. This should also include greater certainty over the determination and withdrawal of equivalence. In addition, mutual deference to one another's regulatory and supervisory regime should become the preferred approach, supplemented by adequate cooperation and exchange of information agreements that can foster trust.

#### Sustainable finance

To achieve the EU's 2030 targets agreed in Paris, including a 40% cut in greenhouse gas emissions, Europeans have to fill an investment gap estimated at €180 billion per year. In order to close this gap, it will be critical to leverage the capabilities of the private sector to support the transition to a sustainable economy.

The best way to engage the private sector in this field is to empower investors. This can be done by ensuring they have options that are in line with their environmental, social and governance (ESG) objectives and risk appetite, as well as the tools they need to pursue these goals. By contrast, constructing inflexible and complex regulatory frameworks around sustainable finance which limit investors' choice and remove their investment tools will limit the reorientation of investment towards more sustainable solutions.

The sustainable finance agenda is heavily dependent both on progress in building a Capital Markets Union (CMU), and on steps taken to minimise the bias towards short-termism in fiscal, prudential and supervisory policies.

## Education, Youth, Culture and Sport

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### ISSUE

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### RECOMMENDATIONS

#### Reskilling and upskilling

The German Presidency should endeavour to set up schemes encouraging companies to invest in reskilling and upskilling, while raising awareness about the existing training schemes offered by business. Training opportunities are best seized through effective public-private partnerships. In addition, legislators should make use of the Multiannual Financial Framework (MFF) to provide ambitious funding for educational institutions and private operators to collaborate and help the active workforce adapt their skillsets to new demands.

## Education, Youth, Culture and Sport (cont.)

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### ISSUE

#### Skills of the general population

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### RECOMMENDATIONS

EU institutions should increase horizontal coordination to encourage national curricula to focus on adopting more digital tools as well as broader Science, Technology, Engineering and Mathematics (STEM) and non-cognitive skills, such as critical thinking, adaptability and creativity. Investment in training and apprenticeships for young students should foster adequate incentives to provide workforce exposure to education and lifelong learning, for instance through the European Fund for Strategic Investment (EFSI).

## Employment, Social Policy, Health and Consumer Affairs

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### ISSUE

#### Workforce size expansion

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### RECOMMENDATIONS

Gender, age, origin, social background, sexual orientation or health condition should never become barriers to success and well-being. The participation of all individuals in the workforce will lead to considerable social and economic gains. Beyond simply facilitating entry into the workforce, we need to create opportunities for success, for example by overcoming biases throughout the hiring process and supporting both school-to-work and work-to-work transitions.

#### Gender balance

Progress on equality between men and women should be fostered by using evidence to underline the need for gender-friendly policies and demonstrating that female leadership in the public and private sector leads to concrete economic benefits. The German Presidency should push for incentives to increase female representation in leadership positions across the public and private sectors, creating a race to the top around diversity and inclusion worldwide. It should also take initiatives to encourage young women to pursue careers in critical sectors, such as STEM, ICT and cybersecurity. Finally, institutional governance around gender equality should mirror the horizontal nature of this topic, considering its impact on all industry sectors and society as a whole.

#### Digitisation of health

EU policies need to keep pace with technological advancements to enable the development and wide-scale deployment of digital health solutions. The German Presidency should promote the wide-scale deployment of digital health solutions, which have the potential to empower patients (eg, remote monitoring). The German Presidency should support the Commission's actions to build a digital service infrastructure (eg, ePrescriptions, patient summaries). It should also enable secure access and data sharing across borders (ie, through electronic health record (her) standards) to ensure adequate standards for data privacy and custodianship. Moreover, the standardisation of electronic health records, core outcome sets and registries can contribute to improving the collection of real-world data (RWD). This is a critical contribution to better inform HTA/payers' decisions about the use of highly innovative technologies, such as cell and gene therapies, thereby addressing the evidence gaps linked to their innovative nature and resulting in greater access for patients.

# Employment, Social Policy, Health and Consumer Affairs (cont.)

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## ISSUE

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## RECOMMENDATIONS

### **Digitisation of health**

*(cont.)*

Artificial intelligence (AI) policies should take into account the specificities and opportunities in the healthcare sector. AI technologies allow the development of innovative and personalised approaches to cancer treatments by simulating physiological and biochemical processes, such as immune system responses. They also enable the monitoring of real-time clinical trials conducted globally, thereby helping to reduce costs and accelerating product approvals. Given the relevant role of AI technologies can play in the healthcare sector, AmCham EU recommends the development of a Healthcare AI Strategy for Europe.

### **Fighting Antimicrobial Resistance (AMR)**

AmCham EU urges the German Presidency to continue focusing on the growing cross-border public health threat posed by AMR. We recognise and welcome the continued prioritisation of AMR by the Commission, noting that the EU can and should serve as a leader in the fight against AMR.

The German Presidency should work together with Member States and the European Commission to promote antibiotic stewardship and preserve the effectiveness of existing treatments, and secure the next generation of antibiotics. In addition, Member States should work with the European Commission to expand and better coordinate surveillance tools.

Vaccination is an important tool in tackling AMR: the broader and more effective use of vaccines by Member States can help to decrease infections and thus reduce the need to use antibiotics.

AmCham EU stresses the urgent need to secure sustainable R&D investment into new antibiotics, vaccines and rapid diagnostics through new economic models and a robust package of 'push' and 'pull' incentives to address the current market failure in this area. AmCham EU calls on the German Presidency to advance these discussions, and we look forward to collaborate in the design of a robust 'pull' incentive at EU level via sui generis EU legislation.

### **Health Technology Assessment (HTA)**

AmCham EU welcomes the ongoing efforts to reduce duplication of clinical assessments across Member States. Any new regulation should accelerate patient access to medicines. This is of particular importance to the testing and implementation phase in the development of a joint process. In this phase the system should allow flexibility to all parties involved in testing. It should also follow a step-wise approach, covering all centrally approved medicinal products. Finally, it should include provisions to extend any periods of transition, in order to avoid any possible delays in implementation.

It should ensure joint clinical assessments are of the highest possible quality such that it will command the full confidence of all interested stakeholders and the wider public; and it should clarify and streamline data requirements for manufacturers.

# Employment, Social Policy, Health and Consumer Affairs (cont.)

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## ISSUE

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## RECOMMENDATIONS

### Health Technology Assessment (HTA) (cont.)

AmCham EU encourages an approach that reflects the specificities of each healthcare sector and prevents any duplication of assessments and access delays. AmCham EU supports retaining Member State autonomy to perform country-specific socio-economic appraisals and to make decisions regarding pricing and reimbursements (P&R) as well as to limit the scope of the regulation to joint clinical assessments for pharmaceutical products.

### An integrated approach to life sciences

In order to build safe, accessible and more integrated health systems, AmCham EU recommends a holistic approach to healthcare policy accounting for a mix of services and products needed for treatment as part of an integrated life sciences strategy. As part of this strategy, European policy-makers need to safeguard innovation by implementing dynamic policies that adequately balance concerns in the short-term with the longer-term (eg, R&D investment and innovation in healthcare). To address unequal access to medicines across EU, a more strategic partnership approach should be encouraged, bringing together industry, patient organisations, healthcare professionals and policy-makers to co-create ideas and solutions. To boost biopharmaceutical R&D, arbitrary cost-containment should be avoided while intellectual property should be strengthened and innovative public-private partnership should be encouraged, including in healthcare delivery.

The EU needs an integrated life sciences strategy to ensure the sector continues to innovate, to respond to today's policy challenges in order to ensure patients are able to access tomorrow's treatments and cures. AmCham EU encourages the German Presidency to support the realisation of these recommendations through the appropriate legislative acts with a view to encourage innovation while balancing future healthcare systems' sustainability. To support the European institutions, AmCham EU has set out several novel policy solutions to these challenges in its 2019 report . These include:

- Overcoming limited funding and budgeting issues;
- Tailored approaches to value assessment across different technologies;
- Introducing robust data protection and security; and
- Adapting to new healthcare business models.

### EU's beating cancer action plan

Non-communicable diseases – such as cancer, cardiovascular or respiratory diseases – represent the leading cause of premature death in the EU and contribute to considerable social and economic costs. In light of the European Commission's new Europe's Beating Cancer Plan to reduce cancer across the EU, the German Presidency should play a leading role in encouraging preventive actions in the fight against cancer and other non-communicable diseases including measures fostering healthy lifestyles. This includes policies related to vaccination (in the instance of HPV) or access to effective HCV treatments (preventing hepatocellular carcinoma), as well as smoking cessation programmes. Early detection and diagnosis should be key pillars to consider in tackling cancer.

# Employment, Social Policy, Health and Consumer Affairs (cont.)

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## ISSUE

### **EU's beating cancer action plan** (cont.)

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## RECOMMENDATIONS

Finally, stimulating product innovation is key to ensure scientific progress can result in new ways to tackle cancer. In this respect, highly personalised cell therapies have already demonstrated promising results in patients suffering from a range of blood cancers, and the ability to induce 'complete response' (no detectable cancer) in patients with few or no other treatment options available. Such breakthrough innovation holds the potential to pave the way for an exciting journey for future scientific developments. The possibility for a one-time treatment which cures diseases could not only dramatically change the lives of cancer patients but also significantly enhance the efficiency of healthcare systems.

AmCham EU encourages the German Presidency to act to stimulate and foster scientific innovation in the field of non-communicable diseases.

### **Modernisation of EU consumer law**

AmCham EU wants to promote the importance of enforcement and cooperation between consumer protection authorities. The Commission's proposal to modernise existing rules and enhance consumer protection should aim to strike the right balance between consumers and traders while maintaining the existing level of harmonisation. Legislation should not stigmatise specific distribution methods corresponding to consumer demand and creating job opportunities. There should be an increased level of awareness of consumer rights for traders, consumers and consumer associations to avoid insufficient compliance and high fines that can jeopardise business operations in a disproportionate manner if non-compliance is due to a lack of knowledge.

## Environment

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## ISSUE

### **Regulation establishing the framework for achieving climate neutrality** (Climate Law)

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## RECOMMENDATIONS

AmCham EU members are already researching, investing in and developing a wide range of low-carbon technologies in Europe.

To achieve the EU's ambitious objectives, a framework that balances the objectives of sustainability, competitiveness, reliability, and promotes innovation is required.

To drive innovation and investment, the German Presidency should endorse a technology-neutral approach, supporting both cutting-edge innovations and technologies already on the market that incrementally reduce emissions, fostering the development of an EU-wide market for greener products and services through a harmonised and cost-effective regulatory framework, while measuring potential emission reduction policies in common units, such as Euros-per-ton, to enable transparency and comparisons between programs to drive the most cost-effective emission reductions. Future policy strategy should also anticipate the impacts of the transition on the workforce by supporting employee lifelong

# Environment (cont.)

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## ISSUE

**Regulation establishing the framework for achieving climate neutrality (Climate Law)**  
(cont.)

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## RECOMMENDATIONS

learning and re-education in partnership with industry. Greater attention must be dedicated to enforcement by the Member States of the relevant EU legislation e.g. the Fluorinated Greenhouse Gas Regulation.

Finally, we must stress that ambition is about more than targets alone. We hope legislators will ensure during their debates that the climate law as adopted will be enforceable and implementable effectively at national level. This focus is essential for the Green Deal policy agenda's credibility and its success in attracting the vast private investment needed for the energy transition.

**Carbon border adjustment mechanism**

AmCham EU recognises the challenge of maintaining the competitiveness of manufacturing production in jurisdictions with strong climate ambitions in the face of competing jurisdictions in the global economy with more lax climate ambitions. We are concerned about the potential of any Border Adjustment Mechanism (BAM) to disrupt highly integrated supply chains and lead to trade conflicts.

Any mechanism to promote carbon-neutral domestic production must be WTO compatible and consider the broader ramifications of impact to supply chains and highly integrated manufacturing production.

**EU plastic tax and current MFF discussions**

In the current uncertainty around EU funding caused by Brexit, the EU Commission and member States have rushed discussions around using a 'Plastic Tax' to increase EU own resources. Such a tax was not impact assessed, and raises significant doubts for industry.

The new proposed 'own resource', which is set to impact non-recycled plastic packaging waste, risks diverting significant resources away from where they need to be invested, to enable circularity. The revenue will not be earmarked, and will therefore not serve environmental policy objectives.

AmCham EU is concerned about the discriminatory effects resulting from the measure, as the 'own resource' is likely to have proportionally greater impact on countries less equipped with necessary recycling infrastructure, undermining EU solidarity principles.

**Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH) and sustainable chemicals**

The Commission's Circular Economy action plan refers to enhancing circularity in a 'toxic free environment.' Although the objective is laudable, without clear definitions of what 'toxic free' or 'sustainable chemistry' means the politics of existing chemicals legislation can be unjustifiably hard to navigate for industry.

A highly efficient REACH that protects human health and the environment should not come at the cost of innovation and competitiveness. Policy-makers should promote greater clarity in the different REACH processes for industry, limit possible overlaps with sectoral policies and facilitate the equal treatment of cases by assessing Member State authorities. REACH would further benefit from streamlining the authorisation process and giving the Risk Management Option Analysis (RMOA) a more formal standing.

## Environment (cont.)

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### ISSUE

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### RECOMMENDATIONS

#### EU circular economy action plan

The circular economy promises products with lower environmental impacts and significant economic benefits through the development of cutting-edge technologies, processes and business models. Policy-makers will need to ensure a supportive regulatory ecosystem that ensures industry is able to successfully assume its role as the primary driving force behind the implementation of a circular economy in the EU.

We note that the current regulatory framework for waste may require a fundamental review to facilitate the transition to a circular economy.

#### Restriction of Hazardous Substances (RoHS)

RoHS has been a highly effective market access law that has been copied in over 40 jurisdictions globally. It is valued by industry for the clear regulatory signals it sends. As the directive comes up for review in 2021, certain things should be considered in order to build upon previous strengths and benefit from existing opportunities. For example, the RoHS exemption process should be improved, with clearer exemption timelines, which are aligned with business' product design realities.

## Foreign Affairs and General Affairs

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### ISSUE

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### RECOMMENDATIONS

#### Brexit and EU-UK trade and investment relationship

Member States should push for an ambitious and forward-looking future relationship that builds on the deep and comprehensive ties between the EU and the UK. To the extent feasible given the decision to pursue an FTA, the agreement should seek to mitigate supply chain disruption, and seek to limit longer-term uncertainty, and preserve the integrity of the Single Market. Ensuring citizens' rights and unhindered cross-border data flows are key elements of the future relationship.

#### Enforcement of IPR in third countries

IP violations, including piracy, counterfeiting and other infringements, are global and growing issues which harm investments and jeopardise consumer safety. The EU should focus on securing a better IP environment in third countries. This should be done through engagement with third-country governments and other stakeholders on technical programmes and in EU FTAs. In order to prevent IP violations throughout the global supply chain, the EU and the US need to maintain and strengthen their cooperation.

# Foreign Affairs and General Affairs (cont.)

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## ISSUE

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## RECOMMENDATIONS

### EU bilateral trade relations

Constructive dialogue with major trading partners, including the US, is key to enhancing mutual understanding, economic growth and prosperity in the Single Market. The German Presidency should support the early conclusion of free trade agreements (FTAs) and promote a de-escalation in the current transatlantic trade disputes, which could threaten jobs and growth on both sides of the Atlantic. Additionally, the German Presidency should advocate for a strong enforcement of all European FTAs.

Member States should support ambitious intellectual property provisions and robust digital trade provisions, with the latter promoting the free flow of data across borders and prohibiting unjustified data localisation requirements.

### EU-US relations

The transatlantic economic relationship is the largest and most integrated of its kind in the world. It has guaranteed the prosperity and security of successive generations of Europeans and Americans. Fostering a closer transatlantic cooperation would allow the EU and the US to bring substantial economic benefits, set global standards and retain their technological leadership.

The German Presidency should support efforts to deepen regulatory cooperation across the Atlantic and to remove barriers to trade and investment, including tariffs. Small and medium-sized enterprises (SMEs) should be put at the heart of EU-US initiatives as they stand to gain most from greater transatlantic cooperation. Member States should endorse EU-US trade negotiations as it would normalise and expand the transatlantic trade and investment relationship.

### EU-US Privacy Shield Agreement

The Privacy Shield agreement is an indispensable mechanism to ensure robust privacy protection and continued data flows between the EU and the US. Despite differing approaches to privacy policy, in 2015 the US and the EU agreed on a mechanism which could meet commercial needs and protect personal data. Today more than 5,000 companies of all sizes from both sides of the Atlantic are certified under this mechanism, demonstrating their commitment to strong privacy safeguards. The Privacy Shield agreement has now undergone three successful annual reviews. The German Presidency should support the implementation of the Privacy Shield and the need for strong and credible enforcement of privacy rules to protect citizens and ensure trust in the digital economy.

### Role of the World Trade Organization (WTO)

The current gridlock at the WTO is cause for significant concern. The multilateral trading system, underpinned by the WTO, has helped to open up international markets, raise standards globally and continues to act as a crucial guarantee for governments, companies and societies in global markets. The EU needs to continue strengthening the principles of a rules-based multilateral trading system with the WTO at its core. The German Presidency should be a vocal supporter of the WTO. Additionally, the German Presidency should keep working constructively with like-minded partners in the pursuit of sensible reforms and should aim to ensure that all major WTO members are involved in these modernisation efforts.

## Foreign Affairs and General Affairs (cont.)

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### ISSUE

#### Third-country participation in EU funded programmes

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### RECOMMENDATIONS

The exclusion of third-country entities with considerable European footprints from major EU and Member States R&D and Procurement funding schemes could lead to the exclusion of vital economic contributors from major R&D and procurement programmes and undermine the EU's objective to strengthen the EDTIB (European Defence Technological and Industrial Base). This could cause market distortions and ultimately weaken the transatlantic relationship. Participation of third-country entities in EU and Member State funded R&D and Procurement programmes should be based on their overall contribution to the EU's technological and industrial base. These entities contribute significantly to the EU, often creating local IP without any export restrictions and involving European employees, infrastructure and know-how. We therefore call on the German Presidency to secure a final EDF Regulation which takes into account the global nature of the defence industry and preserves open defence markets.

#### Common Security and Defence Policy (CSDP) and the European Defence Action Plan (EDAP)

Strong and prosperous Transatlantic Defence Technological and Industrial Cooperation (TADIC) is instrumental in maintaining the transatlantic relationship, sustainable growth and achieving collective security. This can be further encouraged through programmes that include both EU and US stakeholders to enhance cost-effective innovation, interoperability and technological leadership on both sides. These programmes should be based on reciprocity. By establishing open defence markets, they will guarantee similar regulatory conditions on both sides of the Atlantic and best of industry to Government customers.

#### Export control of dual-use goods

A heavy-handed review of the dual-use goods export regime could stifle innovation and how industry responds to new cyber threats. AmCham EU supports the approach that has been adopted in the Council as this will maintain alignment with multilateral regimes, such as the Wassenaar Arrangement, and ensure that companies are not disproportionately burdened and put at an unfair disadvantage. This will support international cooperation in this area and overall preserve the competitiveness of the EU.

## Justice and Home Affairs

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### ISSUE

#### Future Consumer Agenda

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### RECOMMENDATIONS

The new Consumer Agenda should ensure that consumers stay protected and aware of their consumer rights amid the green and digital transformation. AmCham EU advocates for the enforcement of strong and existing legal framework of European consumer rules.

# Justice and Home Affairs (cont.)

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## ISSUE

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## RECOMMENDATIONS

### **Future Consumer Agenda** (cont.)

Future consumer legislation should highlight the importance of general product safety and sustainability as it is related to consumer consumption and protection. Any new consumer legislation should also ensure that consumers to be well informed about consumer rights through accessible and transparent information.

### **Representative actions for the protection of collective interests of consumers**

AmCham EU is committed to supporting the EU's efforts to facilitate access to justice and ensure a high level of protection for consumers. However, there should be a stronger application of common minimum standards and harmonisation of domestic and cross-border actions to facilitate an effective collective redress system and avoid forum shopping. Prevention of forum shopping should remain a key pillar of any collective redress mechanism and promote a narrower definition of a domestic action when evaluating national vs. cross border cases.

AmCham EU also calls for stronger safeguards including a ban on third-party litigation funding and contingency fees for both legal practitioners and funders, an opt-in/register system, the introduction of a claim certification mechanism, the 'loser pays' principle and a specific requirement on who is allowed to be designated as a qualified entity. They protect consumers from exploitative and profit-driven litigation. The EU also needs strong criteria for the types of entities that can represent consumers, such as public bodies and consumer organisations, and a requirement for consumers' consent before actions are launched on their behalf.

### **Cross-border access to electronic evidence (e-evidence)**

AmCham EU member companies act as custodians of their users' and customers' electronic data and invest heavily to protect security and confidentiality of user data. Given the increasing demand for cross-border access to data in the context of criminal investigations, transparent and balanced rules are needed to safeguard data subjects' fundamental rights while allowing for effective policing. The proposals presented by the European Commission and the adoption of a negotiation mandate for an EU-US agreement are a step in the right direction to increase legal certainty in this space. The co-legislators should work towards a balanced and harmonised framework, which is a pre-condition for concluding any international agreement.

### **General Data Protection Regulation (GDPR)**

The GDPR has introduced important benefits for American companies in Europe: increased legal certainty, harmonisation and flexibility. However, there remains a long journey ahead in the area of privacy and data protection. First, we need to promote a uniform and balanced application of the GDPR across Europe. Second, just as consistent implementation of the GDPR is vital to the success of the Digital Single Market, we must ensure that any additional regulation on privacy is fully consistent with the GDPR (see issue: 'ePrivacy'). Third, the ability to transfer personal data across the Atlantic and globally is essential for the competitiveness of many sectors (see issue: 'Privacy Shield'). In terms of unintended consequences, we would welcome a concrete solution or encouraging guidance on Access to the WHOIS registry, used by companies for security and IP infringements.

## Justice and Home Affairs (cont.)

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### ISSUE

#### Preventing the dissemination of terrorist content online

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### RECOMMENDATIONS

The misuse of the internet for illegal activities, including for the dissemination of terrorist content, is a serious threat to our societies which needs to be tackled. In view of the ongoing trilogues, AmCham EU encourages co-legislators to work towards targeting the scope and clarifying the definitions in the Commission proposal, in line with the position adopted in April 2019 by the European Parliament. In particular, the one-hour delay needs to be reconsidered, as it does not take into account technical problems and resources restraints of the variety of companies involved in the fight against terrorism online. Furthermore, co-legislators need to clarify the role and nature of the competent authorities able to issue removal orders, as well as the consultation procedure between authorities. The scope of the proposals should target service providers that make information available to the public only, in order to avoid imposing a burden on business-to-business (B2B) services which are not a natural vector of dissemination for terrorist content. Finally, legal clarity is required around the obligation for proactive measures.

## Transport, Telecommunications and Energy

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### ISSUE

#### Deployment of connected mobility

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### RECOMMENDATIONS

A stable policy framework will be critical for the deployment of cooperated, connected and automated mobility (CCAM) and Intelligent Transport Systems (ITS) in Europe. These innovations have the potential to increase the efficiency of road use and improve both the safety and the environmental performance of vehicles. AmCham EU encourages the enhancement of a regulatory framework that allows the digital ecosystem to thrive allowing for market penetration of new systems reliant on mutual investment in physical and digital infrastructure. Additionally, policy-makers should be careful when developing rules in the mobility sector due to the complexity of scenarios involving technical data.

Moreover roads should meet the expectations and the performances of the system that is embedded in automated vehicles: for this reason it is essential that Europe's road infrastructure (including road signs and markings) be adapted ahead of the deployment of autonomous vehicles. This should happen only on a pan-European basis to avoid discrepancies between the Member States' rules and roads that will prevent effective cross-border use of automated vehicles.

Member States should prioritise consumers' needs, privacy, security, competitiveness, interoperability, trust and liability. They should also aim to foster flexible and technology-neutral rules for data processing, such as the swift deployment of required digital communications infrastructure (V2X) to complement existing transport and rapid infrastructure.

# Transport, Telecommunications and Energy (cont.)

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## ISSUE

### Infrastructure investment

The next MFF needs to focus on infrastructure investments that create growth and jobs in Europe. AmCham EU recognises the value of international cooperation and third-country participants in the MFF 2021-2027, and for funds to enable the EU to act as a world leader in bringing together global talent and research. Therefore, European funding should remain focused on promoting technology neutrality, co-modality and avoiding market distortion. Funding at EU level can be further supported and complemented by ambitious commitments from Member States.

In this sense, the completion of the Trans-European Transport Network (TEN-T) should be a priority. Once completed, the network should help to connect European regions, alleviate congestion, improve interoperability and facilitate the use of different transport modes, as well as helping to achieve the EU's climate objectives.

### Sustainable Aviation

AmCham EU supports the EU's increased ambitions in reducing carbon emissions and encouraging a more sustainable European aviation industry. Our members across the entire aviation value chain, from jet fuel providers and engine manufacturers to airframers and aircraft end-users, are investing sizable amounts in innovating for environmental improvement.

Technological improvements are a key enabler to achieving greater fuel efficiency and decreasing emissions of the sector. Improvements ranging from weight reductions, innovative materials and manufacturing processes, increased engine efficiency have made every new generation of aircraft approximately 20% more efficient than the previous and will continue to demonstrate emission reduction opportunities of similar magnitudes in the future. Technological innovation and improvements will play an important role in achieving carbon emission reductions in the mid- to long term. The development of sustainable aviation fuels (SAF) and the improvement of airspace air traffic management (ATM) are actions that could lead to reductions in carbon emissions immediately.

SAF is the most direct way to make substantial reductions in net carbon emissions for aviation. Policy-makers should consider developing regulatory and financial incentives for the research, development and deployment of sustainable aviation fuels. An incentive-based approach would create stable market demand and therefore stable production as the industry continues to innovate.

The upcoming Multiannual Financial Framework and upcoming regulatory reviews should be leveraged towards this goal.

Improving EU's ATM performance is also key to optimise flight routes' efficiency, increase airspace capacity, reduce delays, increase safety standards, reduce costs related to service provision and minimise the environmental footprint of aviation with less fuel burn and fewer emissions.

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## RECOMMENDATIONS

# Transport, Telecommunications and Energy (cont.)

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## ISSUE

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## RECOMMENDATIONS

### Revision of the Alternative Fuels Infrastructure Directive (AFID)

Alternative Fuels Infrastructure Directive (AFID) to set binding targets for Member States on the deployment of alternative fuels infrastructure.

This could ensure EU-wide infrastructures for LNG, CNG, Hydrogen and electric charging points are available at the latest by 2025 and significantly increase in numbers by 2030.

Especially, transport operators should be incentivised to invest early in private and semi-publicly accessible depot charging stations. In addition, the EU should require a robust implementation of the 27 national policy frameworks also by supporting strong funding programs for stations and hydrogen generation.

### A strategy for Sustainable and Smart mobility

The transport sector is facing enormous challenges to further reduce emissions in all modes of transport. The EU should continue to develop a comprehensive strategy for the transition to low- and zero-emission mobility and put the principle of 'co-modality' at the heart of the future EU Transport Policy. Additionally, the EU should consider all low and zero emissions technologies (renewable gas, hydrogen and electric) that can help to further reduce emissions in Member States through financial and non-financial incentives, while promoting adequate and favourable market conditions that meet the diverse mobility and transport needs of all Europeans. AmCham EU supports the adoption of new rules that encourage freedom of mobility for all EU citizens regardless of their financial status and recognises that decarbonisation can only happen at a pace that is supported by society as a whole.

### 5G

The fifth generation of telecommunication systems, 5G, will be one of the most critical building blocks of our digital economy and society over the next decade. Several factors will determine the successful roll-out of ultra-fast 5G services in Europe. Member States must adopt and implement their 5G roadmaps - including the timely release of both licensed and unlicensed spectrum. The Electronic Communications Code must be implemented swiftly and consistently by all Member States. Furthermore, freedom to develop new business models in light of 5G services will be crucial to the digitisation of business. More consumer focused telco regulation may therefore not always be appropriate. Regular consultation and coordination among all relevant stakeholders will be key to ensuring Europe will reap full potential of 5G.

# Transport, Telecommunications and Energy (cont.)

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## ISSUE

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## RECOMMENDATIONS

### Confidentiality of electronic communications (ePrivacy)

The ePrivacy Regulation proposal (EPR) continues to create confusion and raise concerns across all industry sectors. While discussions in Council have introduced some potential improvements, recent discussions under the Croatian Presidency have seemed to roll back previous progress and create greater confusion with GDPR overlaps. AmCham EU believes any new rules should be fully aligned with GDPR in order to allow for the functioning and innovation of the vast range and new scope of different devices, services and features that rely on processing of communication data. Greater flexibility should be introduced into the EPR for the processing of both communication content and metadata in order to better reflect the realities of the wide variety of services which would fall into scope, particularly machine-to-machine communications and ancillary messaging services. Legislators should consider the impact of the suggested restrictions beyond simply cookies and browsers and more discussions, and answers, are needed on areas which overlap legislation elsewhere, particular e-evidence and law enforcement access to communications data.

### Cybersecurity of Internet of Things (IoT)

When addressing security in the IoT space, it is essential to maintain a voluntary and market-driven approach. The complexity of value chains, the diversity of business models and fast-developing digital environment requires strong public-private partnerships to tackle IoT security. Companies need to retain the ability to develop the security system features for their unique risk situation. In addition, any requirement to secure networks and information should be based on the risk profile of the application. In doing so, it is essential that IoT security solutions, including any future European certification scheme, are consistent with existing international practices and standards. The challenge security brings is not just technical, but also deeply human. IoT security requires raising awareness amongst the entire community – vendors, service providers, industry, employees and consumers. Building and improving cybersecurity skills is critical and is the responsibility of industry and governments alike.

### Shaping Europe's digital future

In its 'shaping Europe's digital future' communication, the European Commission outlined a comprehensive strategy to unlock the potential of data and digital technologies. AmCham EU supports this approach which aims to piece together the many building blocks needed for a successful digitisation of the European economy. Significant investment will be needed to deliver on this strategy – in skills, infrastructure, emerging technologies, and more. This must go hand in hand with building trust from citizens. Data integrity and security are crucial to the full realisation of the digital economy.

### Artificial Intelligence (AI)

Industry has a crucial role in promoting the responsible development of AI. Hence, AmCham EU was pleased to see the approach taken by the Commission in their white paper proposing a risk-based, sector-specific approach where high-risk AI applications and those with significant risk to individual rights would need to comply with mandatory obligations. While clarity for a definition of high-risk and the impacted sector requirements, ex-ante conformity assessments, and a harmonized approach for regulatory oversight are needed, we believe Europe has a unique opportunity to become a global leader in AI. The potential benefits of AI development are enormous, whether a start-up, SME, or larger tech company,

# Transport, Telecommunications and Energy (cont.)

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## ISSUE

### **Artificial Intelligence (AI)** *(cont.)*

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## RECOMMENDATIONS

AI developments will and can help to solve some of society's most pressing challenges. It is why it is important we advance innovation while simultaneously building trust in technological advancements to work for the people. The ambition in forthcoming legislature should be to facilitate the uptake of AI development and to increase research funds, public-private partnerships, skills, education, and more, to leverage technological innovations that make positive changes and accelerate global capabilities.

### **European Cybersecurity Competence Centre and Network**

The future European Cybersecurity Competence Centre and Network should be based on excellence and openness. This initiative has the potential, if implemented appropriately, to reduce fragmentation and create synergies across the EU in research and investment as well as enhance industrial capacity building between Member States. The co-legislators should make sure that the European Cybersecurity Competence Centre and Network does not exclude non-European headquartered companies from partnership and funding without duly justified national security grounds. Participation should be based on relevance and excellence, rather than establishment. Otherwise, the EU risks harming its attractiveness to foreign investment and ultimately its competitiveness at a global level.

### **European Data Strategy**

AmCham EU welcomes the Commission's Data strategy which has enormous transformative potential. Significant investment will be needed to deliver on this strategy if Europe is to become the most attractive market for the storage, processing and profitable use of data. The creation of European data spaces and federated cloud infrastructures requires instilling confidence that data protection rules will be adhered, but also that data is of a high-quality, credible, timely and available in machine-readable formats, as well as that cloud infrastructures are trustworthy, secure and energy efficient. Industry will be a crucial partner to realising the great opportunity, but also to help bring the skills and data literacy needed to fulfil this vision. Any new regulatory initiatives should also be carefully assessed against existing regulations (including but not limited to personal data protection or liability for defective products) to avoid creating conflicting obligations and therefore confusion for companies. AmCham EU is pleased to contribute to supporting fair and clear rules on data access and use that comply with European values and competitiveness and that will recognise data-driven innovation as key to the success of a data-agile economy for Europe.

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**American Chamber of Commerce to the European Union (AmCham EU)**  
Avenue des Arts/Kunstlaan 53, B-1000 Brussels, Belgium • [amchameu.eu](http://amchameu.eu)  
T +32 (0)2 513 68 92 • F +32 (0)2 513 79 28 • [info@amchameu.eu](mailto:info@amchameu.eu)

