Recommendations to the French Presidency of the Council of the European Union

January - June 2022
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Foreword

The French Presidency of the Council of the European Union (EU) will have a key role to play in shaping the EU’s future trajectory. Despite impressive efforts to get vaccines into the arms of a majority of Europeans, Europe now finds itself in the midst of a fresh wave, which is further complicated by the emergence of the new Omicron variant of the virus. Following the progressive disbursement to Member States of the historic NextGenerationEU recovery instrument, the French Presidency will take on a critical task in overseeing the substantive rebuild of Europe’s economy around the twin transitions of environmental protection and digitalisation.

Furthermore, the transatlantic partners have demonstrated renewed cooperative spirit. The EU and the US are drivers of global growth: the transatlantic economic partnership is the largest and wealthiest market in the world. Aggregate US investment in Europe totalled more than €3 trillion in 2020, and directly supports more than 4.8 million jobs in Europe. However, with new challenges emerging, we need strong transatlantic cooperation to defend our collective interests and values now more than ever. The recently inaugurated Trade and Technology Council – a culmination of the first EU-US summit in seven years – further highlighted that the EU and the US are ready to rekindle their leadership on the global stage.

In this context, I am pleased to present our recommendations to the French Presidency on behalf of the American Chamber of Commerce to the EU (AmCham EU) and its member companies. We hope they can provide concrete input and direction to the Presidency’s work programme over the coming six months. We believe that many of the issues raised in this report are vital to shaping a strong and competitive Europe.

AmCham EU stands ready to support France in this crucial role and wishes the Presidency every success.
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 require 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
2022 policy priorities

In the wake of the COVID-19 pandemic, the European Commission and Member States agreed to a historic and ambitious €750 billion recovery and resilience facility, linked to a strengthened long-term EU budget. The EU budget can act as a powerful multiplier. It can help pool cross-border resources, trigger private investment and fill financing gaps for innovative projects. In order to compete globally, the EU should increase funding in key areas such as human capital, research and innovation, environmental sustainability, the deployment of digital and health technologies, modern infrastructure and best-in-class public procurement. The EU should also create the enabling conditions and regulatory framework to help communities and business recover.

As the EU recovers from the pandemic, regulatory initiatives should continue to focus on areas aiming to address COVID-19 challenges and manage the recovery from the pandemic rather than adding additional regulatory burden which would offset economic revival. Any new EU proposals should continue to rely on rigorous science and fact-based impact assessments.

The ‘twin transitions’ towards a greener and more sustainable economic model, as well as the digital transformation of our economy and society will define Europe’s continued competitiveness on the global stage. The transitions should be coupled with smart investment into strengthening the resilience of healthcare systems, preparedness for any future pandemics or healthcare threats, and the wellbeing of Europe’s ageing population.
What our planet looks like tomorrow will depend on how we balance economic recovery and environmental protection today. With clearly defined targets, and a path for achieving them, AmCham EU companies will continue to be constructive partners in the definition and implementation of climate policies. The following eight key action areas within the green deal will be essential to the green transition:

- **Fit for 55**: The climate and energy policy framework developed for emissions reduction should be all-encompassing to balance sustainability, competitiveness and innovation.
- **COP26**: International cooperation has been and will be key to work towards an ambitious and attainable multilateral framework to address climate change.
- **Circular economy**: Maintaining the value of products, materials and waste for as long as possible, while supporting recycling infrastructure and technologies, protecting human health and preserving Europe’s competitiveness can create a truly circular economy.
- **Energy**: Further development of an integrated European energy market and uptake of technology-neutral and cost-efficient innovations will accelerate the transition to a low-carbon economy.
- **Environment**: Cutting-edge innovation to find alternatives to harmful substances can protect human health and safeguard the natural environment.
- **Finance**: Integrated European capital markets to attract and activate new pools of investment can drive sustainable innovation.
- **Food systems**: A holistic, fair and coordinated agri-food supply chain will make food systems more sustainable.
- **Mobility and transport**: A balanced approach to low-emission mobility and heightened use of digital technologies can contribute to a more competitive and clean transport sector.

The digitisation of industries and public services will be vital as we build a more resilient and sustainable economy. Investments in the digital sector will enhance the broader business community’s ability to contribute to future growth. Investments should ensure that all Europeans benefit from an increase in digital services and innovations. There are six key areas to ensuring the digital transformation:

- **Connectivity**: The roll-out of 5G, coupled with fibre and enhanced Wi-Fi capacity will give consumers access to more information faster than ever before and will make business more efficient.
- **Data**: Investment in European data spaces and federated cloud infrastructures could have the transformative effect of making Europe one of the most attractive markets for the storage, processing and profitable use of free data flows.
- **Digital capacities**: Europe should accelerate investment, innovation and entrepreneurship to foster the uptake and scale-up of new technologies which have tremendous economic and social potential.
- **Digital skills**: Significant investments in education, life-long learning, upskilling and reskilling are essential to ensure the workforce is ready for the jobs of tomorrow.
- **E-customs**: The EU should accelerate the transition to a fully electronic customs environment and take advantage of new technologies, such as blockchain, to create a world-leading robust customs framework that genuinely facilitates trade and supports the respect of the rule of law, including intellectual property rights.
- **Intellectual property rights**: Efficient, well-designed and balanced intellectual property (IP) rights enforcement will be key to promote investment, research, innovation, growth and the global business activities of companies. It will also allow Europe to increase its global competitiveness in innovative sectors.
Agriculture and Fisheries
Common Agricultural Policy (CAP)

EU agricultural policy must remain aligned with the objectives and targets of all EU Green Deal initiatives and respect the urgency to protect our planet and to ensure a future for European farmers. This can create a predictable regulatory environment that encourages the innovation needed to develop sustainable food systems. The CAP should enable farmers to achieve more sustainable, efficient and safe farming practices.

Recommendations:

• Ensure fair and non-discriminatory treatment of local versus imported raw materials to supply the European market, including removal of non-tariff barriers to trade and recognition of different agronomic needs around the world.
• Support R&D initiatives in agriculture including digital and precision farming to support farmers and help improve food safety and public health.
• Invest additional budget to meet the strengthened environmental ambitions of the CAP reform.
• Ensure a well-functioning international agri-food supply chain that supports the economic recovery.

Farm to Fork Strategy (F2F)

The Farm to Fork strategy should be a tool to ensure the protection of the environment, promote sustainable production and consumption, create healthier food and more sustainable food environments, facilitate sustainable trade and encourage increased research and innovation while preserving Single Market principles.

Recommendations:

• Carry out a comprehensive cumulative impact assessment on all Green Deal initiatives affecting farming.
• Use the F2F to drive sustainable change in the supply chain, which reflects customer choices and online sales of food as well as the need for a framework that encourages innovation and choice.
• Base the F2F-related initiatives on scientific evidence.
• Support the development of greener veterinary medicines and biological pesticides through the F2F and incentivise a reduction in environmental impact.
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Farm to Fork Strategy (F2F) (cont.)

- Consider antimicrobial resistance (AMR)-neutral vaccines as ‘green pharmaceuticals’.
- Encourage the digitalisation of agriculture through the F2F and support farmers in making the transition.

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

The VMP regulation should not hamper international trade by imposing on third countries EU technical measures that are not compatible with World Trade Organization (WTO) rules.

Recommendations:
- Base the implementation of the VMP Regulation on a sound benefit-risk assessment, not hazard-based approaches.
- Ensure that the use of a list of critically important antimicrobials (CIAs) does not hamper transatlantic trade.
- Invest in research and bring to market innovative treatments, new technologies and care options.

Risk assessment, management and communication in the agri-food sector

A balance between risk assessment, perception, management and communication is of paramount importance for the integrity of the food chain and to promote innovation and sustainable growth in the agri-food sector.

Recommendations:
- Communicate risk management decisions in a clear, timely and transparent way to encourage consumer acceptance of technological developments.
- Prioritise rigorous scientific and risk-based decision-making in all discussions.

Sustainable nutrition

The triple burden of malnutrition – overnutrition, undernutrition and insufficient consumption of essential nutrients – is a problem in Western countries. Many consumers lack the essential knowledge to make informed choices for a varied and balanced diet.

Recommendations:
- Make essential information about nutrition part of education curricula and campaigns across Europe.
**ISSUE**

**Sustainable nutrition (cont.)**

- Provide EU citizens with easily accessible, affordable, nutritionally adequate and safe food choices. A coordinated effort throughout the food chain is necessary to achieve a healthier and more sustainable food environment.
- Promote innovation in the food space, support the use of sustainable food technologies and guarantee easier access to a variety of food products across the EU.

**Trade and sustainable food systems**

Global food systems account for nearly one-third of global greenhouse gas emissions and result in severe biodiversity losses; they need to be redesigned. Transitioning towards more sustainable food systems should be made in a holistic, fair and coordinated way, in cooperation with all actors at all levels of the food and feed supply chain.

**Recommendations:**

- Consider the global dimension of trade and sustainable development - including collaboration with the EU’s trading partners - when dealing with the F2F and EU food and agriculture policy (eg, CAP).
- Account for production conditions in third countries when creating regulatory barriers. They should be science and risk-based, linked explicitly to sustainability objectives and implemented in a manner consistent with the equivalent obligation established at the WTO level.
Competitiveness
**ISSUE**

**Digital Markets Act (DMA)**

The DMA seeks to introduce new rules complementing EU competition law and reflecting the prominence of digital platforms. The co-legislators should ensure that it brings stability and predictability.

**Recommendations:**

- Promote unambiguous criteria and thresholds for the designation of gatekeepers.
- Establish clear guidance on the applicability of obligations to all gatekeepers and those obligations which only apply to certain core services while ensuring that measures are proportional.
- Guarantee that the scope of the DMA is clearly defined in terms of its interaction with EU competition law and also with Member State legislation and other EU laws.
- Ensure alignment and interaction with the US in the context of the Trade and Technology Council to avoid irritants to a rule-based trading system.

**EU competition law for the digital age**

EU competition law forms the bedrock of investment in the Single Market, ensuring an open and free market system for all.

**Recommendations:**

- Avoid unreasonable inversions of the burden of proof which could weaken the market and call into question the reliability of existing case law.
- Guard against ‘mission creep’ which could see competition instruments misused to achieve goals that are beyond the scope of EU competences.

**Electronic Data Interchange (EDI) standards**

AmCham EU is in favour of a proposal to align Value Added Tax (VAT) and customs legislations to provide certainty for relevant authorities and eliminate confusion for operators over liability. An Import One-Shop Stop (IOSS) model that works by including an end-to-end green lane status would simplify the registration process for all operators.

**Recommendations:**

- Centralise procedures through a single European Customs Agency where economic operators can file their customs declarations in order to streamline free movement of goods.
- Implement the VAT e-commerce package in a harmonised and effective manner.
Industry is a critical driver of economic growth, innovation and prosperity. The EU has recently made ‘open strategic autonomy’ the cornerstone of its approach to trade policy. The EU industrial strategy must have both a strong internal and external dimension that makes the EU’s domestic market more attractive to foreign investment and ensures equal opportunity for market players – this is key for companies to remain competitive globally and achieve their digital and decarbonisation goals.

Recommendations:

- Support the European Commission’s proposal for a renewed EU industrial strategy.
- Pursue free and rules-based trade.
- Aim for the effective implementation of the Better Regulation agenda.
- Enhance international cooperation to facilitate the adoption of globally coherent rules, standards and regulations.
- Define more concretely the criteria that would apply to the terms of ‘open’, ‘strategic’ and ‘autonomy’, and how they will translate into practical policy choices in internal and external contexts.
- Strengthen the development of future technologies in Europe while ensuring that they do not harm EU-based American companies.

The EU and the US have an opportunity to reframe the aim and structure of foreign subsidies through regulatory toolkits that can ensure balanced and proportionate regulation.

Recommendations:

- Ensure balanced and proportionate future legislative proposals on non-EU subsidies, acquisitions of EU assets by companies in receipt of non-EU government funding and public procurement bids from third-country entities.
- Define, succinctly, ‘foreign subsidies’ and ‘distortion’ and establish guidelines outlining how indicators of distortion will be applied. This should also align with state aid rules and outline which subsidies are considered most distortive for the Single Market.
- Provide indicators of what may trigger a review through the Ex Officio Tool (tool 1), including clear thresholds and timelines.
- Reduce to one the ten-year look-back period.
- Avoid duplication between tool 2 (Concentrations) and EU Merger Regulation.
**ISSUE**

**Foreign subsidies**
(cont.)

**RECOMMENDATIONS**

- Reduce the administrative challenge of gathering and validating subsidy information from subcontractors and suppliers in tool 3 (Procurement).
- Grant the European Commission sole competence to review cases of general distortions and acquisitions.
- Counter unfair foreign financial support of IP where there is a real risk of stifling innovation due to an increase in state-backed litigations.

**Single Market**

The Single Market is the basis of Europe’s economic success and a key determinant of US investment in Europe. Despite increased pressure, the will of EU policymakers to complete the Single Market is clear.

**Recommendations:**

- Complete the Single Market to increase productivity, investment, trade and job creation and ensure Europe’s position as a global leader.
- Deliver greater action at Member State level to ensure the integrity of the internal market in the long term in order to promote investment and innovation.
- Foster the right environment to conduct business and ensure a solid infrastructure to encourage skills, talent, innovation and labour flexibility.
- Develop the Digital Single Market where online services, goods and data can move freely to allow industry and people to reap the full benefits of the digital transformation.

**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 results in different customs obligations in each Member State, using local languages and complying with varied rules.

**Recommendations:**

- Harmonise further national rules related to the movement of goods and customs in the EU and enhance cooperation among customs authorities. This should be done to safeguard the competitiveness of the internal market as well as EU-level research and development efforts.
- Expedite the mandatory introduction of the Single Window in order to ensure a truly frictionless EU Single Market.
**ISSUE**

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

Europe has one of the strongest frameworks for IPR protection, which is key to incentivise investment in innovation, scientific and technological research as well as creativity. Given that IP infringements of all kinds such as piracy, patent infringement and counterfeiting have continued to grow in size and scope. New proposals would be important to modernise and strengthen the existing framework.

**Recommendations:**

- Strengthen enforcement of IPR to protect European consumers and IP-owning businesses.
- Continue collaboration with IP enforcement agencies in third countries to enhance information sharing on IP infringements and key players (relevant for anti-counterfeiting and piracy operations) as well as share best practices for IP protection and enforcement.
- Improve visibility of the EU Counterfeit and Piracy Watch List so that IP brand owners and consumers can better understand what are the benefits of this list.

**Intellectual Property (IP) Action Plan**

IP is a key pillar that will support the economic recovery and pave the way towards EU leadership on the global stage. A robust European IP system based on strong IPR and appropriate enforcement drives research, manufacturing, employment and innovation, and attracts capital for pioneering and creative enterprises. In addition, IP-intensive industries create high-value long-term jobs.

**Recommendations:**

- Complete the Unitary Patents System.
- Maintain a strong and competitive framework of IP incentives to stimulate R&D, eg in innovative medicines.
Intellectual Property (IP) Action Plan (cont.)

- Strengthen the enforcement of IPR, specifically through funding and prioritisation of law enforcement agencies.
- Adapt the EU framework to an increasingly digital ecosystem while refocusing on approaches to tackle the volumes in physical trade.
- Modernise the EU design legislation.

The current legislative revisions stemming from the Pharmaceutical Strategy for Europe can be an outstanding opportunity to maintain a competitive IP-incentive framework for pharmaceuticals.

Recommendations:

- Collaborate with industry to address areas of high unmet medical need such as rare paediatric diseases and AMR.
- Maintain and further encourage global competitiveness of the EU’s life science sector by ensuring the highest standards of IP and regulatory incentives and protections.
- Implement new pull incentives to the current market failures in antimicrobial R&D and the fight against AMR.

Tourism and hospitality recovery

Europe’s tourism and hospitality sectors have been severely impacted by the COVID-19 crisis. Supportive policy, fiscal and financial measures – including from the EU’s recovery fund – will be essential to help the sectors build back better with more resilient, sustainable and digital business models.

Recommendations:

- Ensure that national recovery plans detail specific measures to support tourism and hospitality, as well as what funding will be available.
- Establish a dedicated EU task force to support the resilience, reopening and recovery of Europe’s hospitality sector.
- Develop a long-term European vision for both sectors focusing on issues such as upskilling and reskilling, crisis management capacities as well as the green and digital transformations.
Economic and Financial Affairs
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.

Recommendations:

- Complete the Banking Union.
- Ensure a globally consistent implementation of international banking standards (eg, Basel framework).
- Avoid fragmentation and localised ring-fencing requirements.

The second CMU action plan outlines a comprehensive strategy to further unlock the potential of capital markets across Europe. This renewed effort is crucial to address the continued fragmented state of Europe’s capital markets which represent an obstacle to cross-border investments and efficient allocation of capital.

Recommendations:

- Encourage the establishment of formal consultative mechanisms between regulators and supervisors to support inter-jurisdictional deference.
- Continue to underline increased international coherence and alignment as well as consistency throughout the EU, coupled with cross-border regulatory and supervisory cooperation as the foundation for openness.

Any new European regulation or supervisory approach should encourage and facilitate the adoption of digital business models by financial institutions and foster Europe’s global competitiveness. Simultaneously, it should address potential new risks for customers or the financial system arising from the speed or scale of adoption of new technologies.

Recommendations:

- Enable the financial services sector to test and develop new applications.
- Foster improvements within customer engagement, processes and service delivery, risk management, fraud detection, anti-money laundering, anti-terrorism financing and compliance with regulation.
- Apply the principle of ‘same activity, same risk, same regulation’. New rules should be proportionate to the risks associated with the specific activities.
The speed of innovation and the use of innovative technologies in the financial services sector have not only seen an increase in the use of information and communications technology (ICT) but have also led to a greater demand for the security and resilience of firms. The DORA represents a valuable step towards a harmonised and robust framework for digital resilience in financial operations.

Recommendations:

- Build on existing international practices and remain open to incorporating international best practices into the implementation of the DORA.
- Ensure that the DORA or any other regional framework does not lead to any conflicting or overlapping requirements for financial services and technology companies operating globally, e.g., Network and Information Systems (NIS) Directive or General Data Protection Regulation (GDPR).

The recent uncertainty of Brexit may lead to 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.

Recommendations:

- Prioritise increased transparency and predictability around the equivalence process in order to provide greater certainty.
- Take an approach of mutual deference to partners’ regulatory and supervisory regimes in tandem with adequate cooperation and exchange of information agreements that can foster trust.

To achieve the EU’s 2030 targets agreed in Paris, including a 55% cut in greenhouse gas emissions from 1990 levels, 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. International partnerships and cooperation in the field of sustainable finance are key to ensure sustainable policies and finance that can combat climate change and other environmental risks.
Recommendations:

- Ensure investors 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.
- Avoid constructing inflexible and complex regulatory frameworks around sustainable finance which limit investors’ choices and remove their investment tools.
- Ensure a proportionate approach to balance the demand for ESG data in the context of the Corporate Sustainability Reporting Directive (CSRD).
- Make progress on building a Capital Markets Union (CMU).
- Minimise the bias towards short-termism in fiscal, prudential and supervisory policies.

The OECD Inclusive Framework reached consensus from over 130 countries to reform the global corporate tax framework. AmCham EU commends the Inclusive Framework’s work to stabilise the international tax system and welcomes the agreement. Nonetheless, proceeding with a separate EU-wide digital levy risks inflaming trade tensions and destabilising the OECD agreement.

Recommendations:

- Finalise technical details for Pillars 1 and 2 to ensure that they are easy to administer and provide certainty to tax authorities and taxpayers alike. The final policies should avoid double taxation and promote cross-border trade, investment and economic growth.
- Adopt a simplified compliance mechanism to lower the administrative burden of implementing the global agreement.
- Allow sufficient time to ensure a complete and consistent implementation of global rules. Legislation must be in line with the international agreement and jurisdictions should not seek to go beyond the global arrangement.
- Withdraw digital services taxes in countries that have already enacted them. Jurisdictions should not seek to circumvent the global agreement by adopting new digital taxes in the future.
- Design future policy developments to promote cross-border trade, investment and economic growth.
- Follow the Ottawa principles regarding the taxation of e-commerce.
Education, Youth, Culture and Sport
As demonstrated by the COVID-19 emergency, digital technologies are crucial in providing opportunities for education and learning.

Recommendations:

- Devote resources to digital infrastructure to ensure that everyone can reap the benefits of digital learning.
- Ensure EU-wide systems of micro credentials to encourage the free circulation of talent.
- Train teachers and provide them with the necessary tools to make use of digital technologies and enable remote learning where necessary.

Europe faces a major skills shortage in the workforce as the digital transformation takes hold. Training opportunities are best seized through effective public-private partnerships.

Recommendations:

- Encourage company investment schemes in reskilling and upskilling.
- Raise awareness about the existing training schemes offered by business.
- 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.
- Incentivise lifelong learning in training and apprenticeship programmes using EU investment funds, such as the European Fund for Strategic Investment (EFSI).
- Increase horizontal coordination to focus national curricula on adopting more digital tools as well as broader Science, Technology, Engineering and Mathematics (STEM) and non-cognitive skills, such as adaptability and creativity.
**Antimicrobial resistance**

AMR is responsible for 33,000 deaths per year in the EU. If left unchecked, it could overtake cancer as the leading cause of death in the bloc by 2050. Tackling this threat should be a top priority.

**Recommendations:**

- Increase broad stakeholder collaboration for prevention and early detection.
- Increase best practice sharing across Member States, including behavioural studies in healthcare facilities of surgical site infections (SSI) and aftercare, including wound care.
- Create new pull incentives to increase innovation in AMR R&D.
- Promote antibiotic stewardship to preserve the effectiveness of existing treatments and secure the next generation of antibiotics.
- Leverage broader and more effective use of vaccines by Member States in order to reduce reliance on antibiotics.
- Develop new economic models and a robust package of incentives to expand R&D.

**Beating cancer action plan**

Cancer is among the leading causes of premature death in the EU. The social and economic cost of non-communicable diseases is significant.

**Recommendations:**

- Encourage preventive actions in the fight against cancer and all noncommunicable diseases with a focus on early detection, diagnosis and increased access to vaccinations and treatment programmes.
- Stimulate product innovations to find new ways to tackle cancer, particularly the use of personalised cell therapies – such as advanced therapy medicinal products (ATMPs) – and one-time treatments with potential long-term benefits that can change lives and create efficiencies for healthcare systems.
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Digitisation of health

European approaches to data must foster a life sciences ecosystem that can capitalise on innovative health technologies. The European Health Data Space provides an opportunity to leverage the European digitalisation of healthcare.

- Support actions to build a digital service infrastructure that ensures adequate data privacy standards.
- Promote adoption of digital health solutions which have the potential to empower patients (e.g., remote monitoring, ePrescriptions).
- Mobilise health data collection to address evidence gaps and provide greater access to innovative treatments.
- Encourage cross-border data sharing (i.e., standardised health records) to ensure adequate standards for data privacy and custodianship.
- Develop a broadly focused healthcare AI strategy for Europe to capitalise on advancements in personalised treatments, acceleration of product approvals and more.

Health Emergency and Preparedness Response Authority (HERA)

HERA is necessary to ensure coordinated responses by the EU to tackle cross-border health threats.

Recommendations:

- Support HERA with a sufficient financial basis to undertake targeted tasks that add value and not duplicate or depend on other research programmes or health related initiatives.
- Set priorities in collaboration with relevant authorities (e.g., European Centre for Disease Control [ECDC]) and industry stakeholders to identify the next generation of medical countermeasures and pitfalls in current preparedness strategies, including those issues related to supply and demand (e.g., of personal protective equipment).

Health technology assessment (HTA)

In the light of the compromise reached on the HTA Regulation, Member State should retain the autonomy 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. The development of the Regulation’s implementing acts can provide an opportunity to define clear clinical assessment criteria that adequately capture the specificities of each of the therapies under evaluation.
**RECOMMENDATIONS**

**Health technology assessment (HTA) (cont.)**

Recommendations:

- Develop specific methodological guidelines for ATMPs.
- Ensure coordination and dialogue between the coordination group and Member States to define a solid joint clinical assessment framework and limit possible duplications at national level.
- Maintain a constructive open dialogue with manufacturers throughout the development of the implementing acts.

**Integrated approach to life sciences**

A holistic approach bringing together patient organisations, healthcare professionals, industry and policymakers will provide patients with the maximum benefits.

Recommendations:

- Increase synergies in the European life science R&D in terms of funding (EU4Health, Horizon Europe, Innovative Medicines Initiative, Recovery and Resilience Facility) and across agencies (EMA, ECDC, Health and Digital Executive Agency, etc).
- Tailor approaches to value assessment across different technologies.
- Adapt to new healthcare business models.

**Gender balance**

Equality between men and women can 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.

Recommendations:

- Incentivise female representation in leadership positions across the public and private sectors, creating a race to the top around diversity and inclusion worldwide.
- Encourage young women to pursue careers in critical sectors, such as STEM, ICT and cybersecurity.
- Mirror the horizontal nature of gender equality in institutional governance, considering its impact on all industry sectors and society as a whole.
Modernisation of EU consumer law

Awareness of consumer rights needs to be higher among traders and consumers to avoid insufficient compliance and high fines. The ongoing transposition of the Omnibus Directive/REFIT in the Member States and forthcoming guidance from the European Commission should set the tone for the harmonisation of consumer rights for all goods and services.

Recommendations:

• Modernise rules on consumer protection to strike the right balance between consumers and traders.
• Apply and enforce rules online and offline (e.g., product safety).
• Harmonise and synchronise consumer rules throughout the EU.
• Cooperate between consumer protection and enforcement authorities.

Workforce size expansion

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.

Recommendations:

• Work to overcome biases throughout the hiring process and support both school-to-work and work-to-work transitions. This must entail creating opportunities for success.
Environment
The Regulation seeks to improve the environmental footprint (especially carbon dioxide emissions) of the EU’s battery value chain by tackling each stage of batteries’ lifecycle. In doing so, new provisions should acknowledge that the battery value chain is extremely diverse, and rules must enable best-in-class batteries for all applications.

Recommendations:

• Grant producers and users with adequate grace periods for the implementation of new requirements, especially technical ones, to best adapt to these legislative changes without hindering innovative capacity. The current 12-month proposal for implementation is insufficient.
• Ensure that recycling remains ‘open loop’ and that recycled content requirements which reflect market reality are set to avoid any production bottlenecks. Targets for recycling materials should be technically, economically and environmentally achievable.
• Guarantee that information-sharing in battery passports does not raise concerns for IP.
• Ensure consistency with other pieces of legislation, such as chemicals management and supply chain due diligence.
• Clarify the term ‘transfer of responsibility’ under extended producer responsibility as well as end-of-waste status for electric vehicle batteries.

AmCham EU supports in principle the introduction of the CBAM as an effective tool to combat carbon leakage and drive global efforts towards net zero. But it has the potential to inadvertently disrupt highly integrated supply chains and lead to trade conflicts. The primary objective of the CBAM should be to address climate change and avoid carbon leakage.

Recommendations:

• Ensure a market-based emissions trading system (ETS) when designing the mechanism, as it allows the market to determine the most efficient and effective price level to drive emissions reduction.
• Incentivise companies to reduce the emission intensity of their products, provide a level playing field for domestic industry and encourage governments globally to increase their climate ambitions.
Carbon border adjustment mechanism (CBAM) (cont.)

- Assess the impact of measures against the potential impact on supply chains and manufacturing production, including for SMEs.
- Provide CBAM exemptions to avoid double taxation of imports for countries that have their own carbon pricing mechanisms.
- Minimise impact on the flow of legitimate trade by moving its administrative processes away from the border, where possible.

Circular Economy Action Plan (CEAP)

The circular economy goals aim to create products with lower environmental impact and greenhouse emissions while maintaining economic benefits through cutting-edge technologies, processes and business models.

Recommendations:

- Make a supportive regulatory ecosystem for industry the driving force behind the circular economy transition.
- Promote an EU-wide approach to circular economy legislation, limiting national initiatives that could inhibit Single Market rules.
- Review the current regulatory framework for waste to facilitate the transition to a circular economy and see waste as a resource.
- Create a framework for product sustainability that is consistent with existing legislation and creates the right conditions for innovation to flourish.
- Evaluate the total impact of new fiscal initiatives while accounting for schemes such as the ‘extended producer responsibility’.

Chemicals Strategy for Sustainability

The Chemicals Strategy for Sustainability seeks to reform the existing EU chemicals policy framework to achieve sustainability and competitiveness.

Recommendations:

- Ground the EU chemicals management system in a risk-based approach. Hazard-based regulatory instruments would fail to consider key socio-economic factors and would hinder innovation.
- Base new measures on science and clear definitions. Risk management should be based on socio-economic factors and availability of alternatives.
Chemicals for Sustainability Strategy (cont.)

• Avoid extending the ‘Classification, Labelling and Packaging’ (CLP) regulation to new hazard classes, which would lead to inconsistencies that aren’t scientifically justified and to a departure from the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).
• Simplify risk-assessment processes to strengthen regulatory predictability.
• Justify the proposed perfluoroalkyl chemicals (PFAS) restrictions with appropriate EU-based evidence. PFAS are a diverse group of chemical compounds that should not be regulated as one group, but rather distinctively and based on physicochemical properties and exposure considerations.
• Clearly define what constitutes as ‘essential’ in terms of emission reduction targets, technological developments or pandemic response. This definition should be enshrined into the existing REACH assessment framework.
• Regulate fluorinated gases under Regulation (EU) No 517/2014, not under the PFAS restriction, to avoid overlapping requirements and regulatory uncertainty.

The EU must balance sustainability, competitiveness, reliability and innovation if it is to achieve its ambitious objectives on climate change.

Recommendations:

• Support existing technologies and cutting-edge innovation by taking a technology-neutral approach and working to reduce emissions.
• Create a common regulatory framework that fosters an EU-wide market for greener products and services.
• Anticipate the potential displacement effects of the climate transition on the workforce.
• Pay greater attention to Member States’ enforcement of relevant EU legislation.
• Ensure enforceability at national level in order to determine the Fit for 55 proposal’s credibility and attractiveness for the private investment needed.
• Encourage ‘nature-based solutions’ through initiatives like watershed restoration and good water stewardship.
• Ensure policy coherence across all elements of the Fit for 55 package and other legislation related to emission reduction.

Recommendations to the French Presidency of the Council of the European Union

AmCham EU
Guidelines on state aid for environmental protection and energy (EEAG)

The EEAG has raised questions of legal certainty and regulatory stability for renewable energy investors in the EU. The revised EEAG will aim to reflect and align recent regulatory and technological developments.

Recommendations:

• Ensure that the EEAG supports new technologies needing help to reach scale and mature technologies that are best suited to ensure a cost-effective energy transition.
• Avoid questioning the legality of capacity remuneration mechanisms (CRMs) approved under the current EEAG, or making the assessment conditions of CRMs so complex that Member States are dissuaded from introducing them.
• Cultivate an improved investment climate that can stabilise the security of supply, promote faster technology development and create a more competitive market.
• Develop a clear framework for assessing compatibilities and highlight that corporate power purchase agreements can be compatible with the EU internal market.

Packaging and Packaging Waste Directive (PPWD)

As part of the CEAP, the Commission will review the PPWD to reinforce the mandatory requirements for packaging allowed in the EU market and to consider other measures. The review expands beyond essential requirements and includes measures to reduce (over-) packaging and packaging waste. Additionally, it will involve measures to improve packaging design for reuse and recycling and to drive the uptake of recycled content. However, the complexity of the measures requires a thorough and evidence-based impact assessment.

Recommendations:

• Promote an EU-wide approach to the review of the PPWD, limiting national initiatives that could inhibit Single Market rules.
• Supervise Member States’ enforcement of relevant EU legislation.
• Ensure enforceability at the national level to legitimise and appeal to the needed private investment.
• Consider packaging as a resource for materials circularity as done with the other extended producer responsibility schemes.
• Avoid limiting substances without having carried out prior impact assessments in regard to the PPWD’s ‘substances of concern’ clause as defined by the Strategy for Sustainability Towards a Toxic Free Environment.
RoHS has been a highly effective market access law valued by industry for the clear regulatory signals it sends. The directive is due for review in 2022.

Recommendations:

- Reflect on the strengths of the regulation and look to build on successes by pursuing existing opportunities.
- Provide clearer exemption timelines that are more aligned with product design realities.

This initiative, which will revise the Eco-design Directive and propose additional legislative measures, aims to make products in the EU market more sustainable.

Recommendations:

- Maintain the principles of the eco-design legislative framework which are achieving excellent results.
- Align future legislation with existing regulations in a coherent manner that addresses products in different life phases. Ensure consistency with legislation on sustainable chemicals, RoHS, to provide clarity for all supply chain operators.
- Increase transparency and communication across the value chain through the Digital Product Passport in order to improve circularity without imposing excessive costs on industry. Sensitive data should be protected and only accessible by the market operators that need it for circularity purposes.
Foreign Affairs and General Affairs
Enforcement of IP rights in third countries

IP violations, including piracy, counterfeiting and other infringements, are global and growing issues which harm investments and consumers.

Recommendations:

- Secure a better IP environment in third countries and engage with third-country governments and policymakers on technical programmes.
- Strengthen EU-US cooperation to prevent IP violations throughout the global supply chain.
- Cooperate with like-minded global partners to tackle IP infringements in third countries that might jeopardise EU competitiveness.

Constructive dialogue with major trading partners, including the US, is key to enhance mutual understanding, economic growth and prosperity in the Single Market.

Recommendations:

- Support the early conclusion of free trade agreements (FTAs).
- Build EU trade policy based on openness and interdependence in order to avoid trade disputes that would threaten jobs and growth on both sides of the Atlantic.
- Advocate for strong enforcement of all European FTAs.
- Foster Member States’ support for ambitious intellectual property and digital trade provisions.
- Promote the free flow of data across borders and prohibit unjustified data localisation requirements.

EU bilateral trade relations

Recent developments have shown the essential functions and benefits of an open and free trading system. Unfortunately, they have also shown the downsides of go-it-alone trade policies.

Recommendations:

- Avoid inward-looking trade policies that are detrimental to the interests of businesses in Europe.
- Maintain and emphasise the EU’s open economic nature.
- Focus on cooperation with trading partners and corporations that have strong commitments to Europe, no matter where they are headquartered.
EU Trade Strategy (cont.)

• Place digital trade at the heart of the new strategy to promote open digital markets, innovation and prosperity.

EU-UK trade and investment relationship

The EU and UK’s close political and economic ties make maintaining a good relationship and a comprehensive economic partnership a vital necessity.

Recommendations:

• Implement the agreement thoroughly alongside the Northern Irish protocol so as to provide business with certainty.
• Continue close communications between the EU and the UK to manage the interface between their respective regulatory environments and minimise disruption.
• Broaden the scope of the relationship over time, including to topics currently excluded from the deal.

EU-US relations

Ever closer transatlantic cooperation would bring substantial economic benefits, promote global standards and retain technological leadership.

Recommendations:

• Deepen regulatory cooperation across the Atlantic.
• Engage constructively in the Trade and Technology Council (TTC) to ensure the initiative remains ambitious in its objectives and delivers tangible results.
• Promote R&D&I cooperation across the Atlantic by ensuring business input and collaboration in the TTC.
• Develop and strengthen the TTC’s capacity to address barriers to trade and investment - including tariffs - and work towards long-term solutions that avoid new barriers.
• Seek appropriate reforms at international level and make use of transatlantic leadership to resolve long-running disputes at the WTO.
• Put small and medium-sized enterprises (SMEs) at the heart of EU-US initiatives, as they stand to gain most from greater transatlantic cooperation.
• Foster Member State endorsement of EU-US trade discussions in order to normalise and expand the transatlantic trade and investment relationship.
• Allow EU-based American companies to have access to Horizon Europe projects and funding.
ISSUE

Role of the World Trade Organization (WTO)

A renewed EU-US relationship must provide leadership to secure the necessary WTO reforms that can make the organisation fit for the twenty-first century.

Recommendations:

• Ensure that the WTO maintains its role as a negotiation body and an arbitration mechanism for the global economy.
• Continue strengthening the principles of a rules-based multilateral trading system with the WTO at its core.
• Pioneer transatlantic leadership on WTO reforms and the broader multilateral agenda.
• Work constructively with like-minded partners in the pursuit of sensible reforms.
• Ensure that all major WTO players are involved in the modernisation efforts.
• Push for the successful conclusion of multilateral and plurilateral negotiations in the WTO – including the ongoing e-commerce negotiations – to provide tangible outcomes for business and enhance the WTO’s credibility.
• Encourage WTO solutions that alleviate the COVID-19 crisis and enhance multilateral coordination.

Review of EU-Mexico FTA

Provisional application of the revised EU-Mexico FTA will be instrumental in increasing export opportunities for European businesses and a return to post-COVID-19 sustainable growth, including the job creation.

Recommendations:

• Push for swift ratification and provisional application of the modernised agreement enabling EU businesses to build on already existing trade flows and generate new economic opportunities.

Standard Contractual Clauses (SCCs) and EU-US Privacy Shield Agreement

The European Court of Justice decision on SCCs and Privacy Shield has left thousands of data-dependent businesses in a legal limbo. Businesses and economies rely on the free flow of data to provide valued services to European consumers. While SCCs have been the most accessible and stable means to transfer data outside of the EU for many businesses, over 5,000 small and large companies have relied on Privacy Shield to transfer personal data across the Atlantic.
Recommendations:

- Engage with and encourage regulators to set up clear and realistic guidance to enable valid use and reliance on SCCs for global data transfers.
- Ensure new SCCs are quickly adopted, future-proof and robust enough to provide legal certainty for businesses.
- Support the adoption of a successor agreement for transatlantic data transfers.
- Prioritise citizen protection and integrity of privacy rules to ensure trust in the digital economy.
- Achieve legal certainty in transatlantic data flows to ensure technological advancements, reduced costs and improved productivity and scale.

Strong and prosperous Transatlantic Defence Technological and Industrial Cooperation (TADIC) is instrumental to maintain the transatlantic relationship, ensure sustainable growth and achieve collective security.

Recommendations:

- Encourage programmes that include both EU and US stakeholders to enhance cost-effective innovation, standardisation, interoperability and technological leadership on both sides.
- Establish open defence markets based on reciprocity to guarantee similar regulatory conditions on both sides of the Atlantic.

The exclusion of third-country entities from major EU and Member States’ R&D and procurement funding programmes could lead to the exclusion of vital economic contributors for the EU from like-minded countries such as the US, Canada and the UK. This could cause market distortions and ultimately weaken the transatlantic and the EU-UK relationship.

Recommendations:

- Promote the participation of EU-based American companies in Member State funded R&D and procurement programmes based on their added value, locally developed IP and overall contribution to the EU’s technological and industrial base (ie, employees, infrastructure, know-how).
Access to EU-funded R&D and procurement programmes
(cont.)

Export control of dual-use goods

ISSUE

RECOMMENDATIONS

• Monitor a fair implementation of the final European Defence Fund (EDF) Regulation, European Space Programme (ESP) Regulation and Horizon Europe Regulation which should all take into account the global nature of the defence and space industries and preserve open markets and fair competition.

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

Recommendations:

• Align export control regimes between Member States and with the US via regulatory exchanges and joint actions, notably in the context of the EU-US Trade and Technology Council and the provisional political agreement on the revised regulation.
• Align guidelines between the Commission and the US Advisory Opinion on Cloud Computing and Deemed Exports to address the miscommunication regarding intangible technology transfers.
Justice and Home Affairs
New Consumer Agenda

The European New Consumer Agenda has a strong focus on online enforcement which risks creating gaps in the offline world and increasing risks for consumers. Enforcement gaps in the EU can lead to consumer harm and mistrust, as well as commercial detriment for the EU industry.

Recommendations:

- Streamline the information available to consumers regarding the sustainability performance and safety of products.
- Ensure that consumers stay protected and aware of their consumer rights in the new Consumer Agenda.
- Ensure harmonisation and strong enforcement of the existing legal framework of European consumer rules.
- Highlight the importance of general product safety and sustainability in future legislation and a good coordination and information exchange between authorities and private actors (quality of notifications can be improved).
- Provide for accessible and transparent information on rights in any new consumer legislation.
- Focus on enforcement against the bad actors: without enforcement commitments action by private actors is far less powerful - bad actors can be removed from the online world but they will keep coming back.

Representative actions for the protection of collective interests of consumers

With the adoption of the proposal on representative actions, Member States should ensure coherent enforcement and harmonisation. Forum shopping prevention 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.

Recommendations:

- Create stronger safeguards, including through swift and adequate regulation of third-party litigation funding, in order to harmonise the practice in the EU and grant transparency and high protection to all parties.
- Establish strong criteria for the types of entities that can represent consumers in the EU, such as public bodies and consumer organisations, and require consumers’ consent before actions are launched on their behalf.
AmCham EU member companies act as custodians of their users’ and customers’ electronic data and invest heavily to protect their security and confidentiality. The European Commission proposals and the adoption of a negotiation mandate for an EU-US agreement are a step in the right direction to increase legal certainty.

Recommendations:

- Safeguard data subjects’ fundamental rights with transparent and balanced rules, while allowing for effective policing of cross-border access to data in criminal investigations.
- Work towards a balanced and harmonised framework, a pre-condition for concluding any international agreement.

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.

Recommendations:

- Promote a uniform and balanced application of the GDPR across Europe.
- Ensure that any additional regulation on privacy is fully consistent with the GDPR (see issue: ‘ePrivacy’).
- Ensure transfers of personal data can happen across the Atlantic and globally, as they are essential for the competitiveness of many sectors (see issue: ‘SCCs and Privacy Shield’).
- Ensure that Data Protection Authorities (DPAs) interpret the GDPR in a harmonised way and that cooperation and enforcement are taking place in accordance with the mechanisms described in the GDPR.
Sustainable corporate governance

The European Commission aims to establish new rules regarding mandatory due diligence and directors’ duty of care, building on existing human rights due diligence obligations.

Recommendations:

- Ensure a proportionate legal framework that is complementary to existing international principles.
- Minimise administrative burden with consistent rules, harmonisation and industry standards that effectively identify risks and adverse impact.
- Address directors’ duty of care through recommendations and guidance for companies, rather than binding legislation.
Transport, Telecommunications and Energy

Recommendations:

• Implement a public sector target of 3% for annual renovation of publicly owned buildings.
• Promote comprehensive and integrated renovation interventions for smart buildings and the use of smart ICT technologies, including building automation.
• Encourage increased financing for required energy renovations in Member States and cultivate financial incentives to increase energy efficiency that can drive economic recovery.
• Provide the needed levels of indoor air quality in response to changing indoor and outdoor conditions, while also managing energy consumption and operating costs.
• Encourage a comprehensive approach towards the operation of heating and cooling systems to support decarbonisation efforts.
• Increase levels of ambition in the EPBD revision for electric vehicles charging infrastructure in private buildings. This will be important to support the deployment of e-mobility.

Future infrastructure investment needs to focus on infrastructure investments that create growth and jobs in Europe and support the EU economic recovery. International cooperation and third-country participants in the MFF 2021-2027 add value by enabling the EU to act as a world leader in global talent and research.

Recommendations:

• Use European funding to promote technological neutrality and co-modality as well as to avoid market distortion.
• Support funding at EU level with ambitious commitments from Member States.
• Prioritise the completion of the Trans-European Transport Network (TEN-T).
• Use the completed TEN-T network 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.
Infrastructure investment
(cont.)

ReFuel EU Aviation

Alternative Fuels Infrastructure Regulation proposal (AFIR)

Sustainable aviation fuels (SAF) are vital for the transition of aviation to a net zero future. Increased supply and demand of SAF is required to help reach the EU’s climate ambitions.

Recommendations:

- Develop regulatory and financial incentives for the research, development and deployment of SAFs.
- Complement the blending mandate with measures to invest in SAF supply chain.
- Support market-based mechanisms and industrial alliances that can support SAF uptake.
- Promote increased coordination with EU institutions and airlines, airports and fuel producers to implement a book and claim system to enable airlines to refuel their aircraft with SAF across European airports.

AFIR seeks to ensure proper deployment of an alternative fuels infrastructure. This could ensure that EU-wide infrastructures for liquid natural gas (LNG), compressed natural gas (CNG), hydrogen and electric charging points are available at the latest by 2025 and significantly increase in numbers by 2030. AFIR will be instrumental in supporting low-carbon road transport in Europe and therefore reaching the decarbonisation target for this sector.

Recommendations:

- Ensure EU-wide infrastructure is available when and where needed and that administrative burdens are minimised.
- Ensure interoperability for a seamless user experience. This relies on proper market rules that ensure transparency for the user and avoid unnecessary costs.
- Coordinate energy, digital and transport policies in order to leverage the flexible energy demand potential of e-mobility and ultimately support the integration of more renewables into the grid.
- Support strong funding programmes for stations and hydrogen generation as part of national policy frameworks.
The transport sector is facing enormous challenges to further reduce emissions in all modes of transport. Deployment of cooperated, connected and automated mobility (CCAM) and Intelligent Transport Systems (ITS) in Europe has the potential to increase road efficiency and improve the safety and the environmental performance of vehicles.

Recommendations:

- Clearly define ‘sustainable’ mobility in terms of quantitative emissions reduction targets.
- Adapt to the requirements for various types of transport while taking into account the complexity of technical data use in the mobility sector and ensuring harmonisation across Europe.
- Incentivise the aviation sector to continue to increase the uptake of sustainable fuels and reduce emissions.
- Encourage investment in CCAM systems to ensure interoperability, user safety, trust and liability.
- Adapt road infrastructure ahead of the deployment of autonomous vehicles.
- Foster flexible and technology-neutral rules for data processing.

Technological improvements and sustainable fuels are key to reaching the EU’s climate ambitions in the aviation sector. However, today’s uptake is only marginal due to a lack of price-competitiveness in the available sustainable options. Air Traffic Management (ATM) performance is also key to optimise flight route efficiency, increase airspace capacity, reduce delays, reduce costs and minimise aviation’s environmental footprint.

Recommendations:

- Incentivise technological improvements as key enablers of fuel efficiency to reduce carbon emissions in the mid to long term.
- Develop regulatory and financial incentives for the research, development and deployment of sustainable aviation fuels.
- Implement the Single European Sky (SES) via a full integration of EU ATM networks.
5G

5G will be one of the most critical building blocks of our future digital economy and society.

Recommendations:

• Adopt and implement Member States’ 5G roadmaps and 2030 digital decade targets swiftly.
• Release both licensed and unlicensed spectrum in a timely and coordinated fashion.
• Finalise the implementation of the Electronic Communications Code in Member States quickly and consistently.
• Ensure the freedom to develop new business models, as 5G will be crucial for business digitisation.
• Consult and coordinate among stakeholders to ensure Europe and consumers reap the full potential of 5G.
• Continue to ensure a shared European approach to trustworthy, resilient, diverse and competitive supply chain for ICT, especially as the rollout of 5G accelerates.

Artificial intelligence (AI) Act

The AI Act is the first attempt to lay out a comprehensive legislative framework for the development and use of artificial intelligence. The proposal has room for clarification and improvement.

Recommendations:

• Develop a more precise definition of AI, as the current one is excessively broad and could encompass techniques and software that do not perform functions normally associated with AI.
• Tighten up the list of high-risk AI systems which may include in scope systems that are not inherently high-risk.
• Reconsider the horizontal product safety framework adopted for the proposal.
• Redefine some of the overly prescriptive and unrealistic requirements for high-risk AI systems. All the demands should be flexible and attainable.
• Allow providers and users of AI systems to contractually allocate their responsibilities.
• Safeguard innovation by ensuring that requirements are manageable and realistic.
• Commit to achieving concrete EU-US advancements in the AI sphere in the context of the TTC.
It is essential for strong public-private partnerships to maintain a voluntary and market-driven approach to tackle IoT security, given the complexity of value chains, diversity of business models and fast-developing digital environment. Companies need to retain the ability to develop the security features for their unique risk situation.

Recommendations:

- Base any requirements on secure networks and information regarding the application’s risk profile.
- Ensure consistency between IoT security solutions and existing international practices and standards.
- Raise awareness of IoT security amongst vendors, service providers, industry, employees and consumers.
- Build and improve cybersecurity skills.

The European Cybersecurity Competence Centre and Network initiative has the potential, if implemented appropriately, to reduce fragmentation and create synergies across the EU in research and investment on cybersecurity.

Recommendations:

- Keep the European Cybersecurity Competence Centre and Network open to all companies.
- Base participation on relevance and excellence, rather than establishment.

The European Strategy for Data has enormous transformative potential, but data must be high-quality, credible, timely and available in machine-readable formats, while cloud infrastructures must be trustworthy, secure and energy efficient. Collaboration is key, along with ensuring access to the widest range and choice of technologies and partners.

Recommendations:

- Provide significant investment to deliver on the strategy and achieve the EU’s aims in competitive storage, processing and profitable use of data.
AmCham EU shares the European Commission’s ambition to make the 2020s Europe’s ‘digital decade’ and expresses the following suggestions to achieve the EU’s digital ambitions for 2030.

**Recommendations:**

- Accelerate and facilitate investment, innovation in broadband networks and entrepreneurship in order to create financial incentives and foster uptake of new technologies with high economic and social potential for the digital transformation of EU businesses and the public sector.
- Enhance digital skills and inclusion to build and preserve trust between society and technology. Skills and inclusion must be central tenets of any public and private digital transformation strategies.
- Ensure a common approach toward the digital decade, including measures such as the pooling of resources across the Member States and the alignment of all actors.
- Define the perimeter of digital sovereignty, oppose protectionist measures and allow American companies to be trusted digital enablers and business partners in Europe.
The DGA seeks to capitalise Europe’s ambition to develop a better culture of data sharing and to enable the data economy to boost economic growth, competitiveness, innovation, job creation and societal progress.

**Recommendations:**

- Contribute to the free flow of data by more narrowly defining what falls under the ‘highly sensitive’ definition.
- Clarify concept of ‘data altruism’ and ensure consistency with legal bases provided in GDPR.
- Limit verification and prohibition of data processing by re-users in case of potential threats to national security or disclosure of commercially confidential data.
- Avoid burdensome, Member State specific compliance requirements and notification processes.
- Ensure the leadership of the European Data Innovation Board (EDIB) in the implementation of the DGA by using international standards as a point of reference.

The Regulation seeks to build trust in services for consumers and businesses. Since the proposal was presented, the importance of metadata and electronic communications has been reinforced, especially for new technologies like IoT.

**Recommendations:**

- Ensure clarity on the scope and guarantee alignment with the GDPR – including on data processing legal basis – whilst adopting a risk-based approach to the text.
- Encourage additional permitted data processing for software updates, security, compatible processing and statistics.
- Include additional lawful bases in privacy settings to allow the use of storage capabilities on-device for limited processing activities.
The revised Directive aims at establishing a more secure cyber-environment by defining legal obligations of entities tangent to cyber risks. Nonetheless, it should implement a risk-based approach and seek alignment with existing and draft legislation.

**Recommendations:**

- Limit the scope of entities falling under the legislation by applying a risk-based approach with targeted and proportionate requirements.
- Set the reporting requirements at 72 hours to ensure consistency with GDPR and allow companies to provide regulators with more detailed and valuable information.
- Maintain voluntary certification mechanism and ensure these certifications are based on relevant and international cybersecurity standards.
- Maintain and enhance the possibility to involve industry in the computer security incident response teams (CSIRTs) Network and Cooperation Group and further incentivise voluntary private-public information sharing.

The comprehensive strategy can unlock the potential of data and digital technologies.

**Recommendations:**

- Deliver the investment on skills, infrastructure and emerging technologies needed to deliver on this strategy.
- Build citizens’ trust in innovative digital technologies.
- Prioritise data integrity and security to fulfil the realisation of the digital economy.
AmCham EU leadership

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AmCham EU speaks for 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 US positions on business matters. Aggregate US investment in Europe totalled more than €3 trillion in 2020, 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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List accurate as of December 2021

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