



Regulation and R&I Policies

Comparing Europe and the USA

Written by Andrea Renda, CEPS and Duke University
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1 INTRODUCTION

Regulation has for a long time been considered mainly as an obstacle to innovation, especially with respect to rules that create so-called “red tape”, or administrative burdens. However, academics have demonstrated that regulation can greatly facilitate innovation, by creating markets for existing ideas and stimulating entrepreneurship and inventions that contribute to social welfare (Ashford et al. 1985; Porter 1999). Pelkmans and Renda (2014) observe that regulation and the overall legal environment affect both research and innovation, in many ways, and that the relationship between regulation and innovation is complex and ambiguous, which creates challenges for those that wish to use regulation as a pro-innovation tool.

The European Commission has emphasised the role of regulation, and more broadly of the EU better regulation agenda, as tools that can lead to more innovation. This implies *i.a.* that existing rules are reviewed with peculiar attention to their potential impact on innovation. In a recent Staff Working Document on “Better Regulation for Innovation-driven Investment”, the European Commission made the case for the use of more flexible and pragmatic regulatory instruments, which would be able to bridge the gap between the needs of innovators and investors, and existing rule at the national or EU level¹. The deployment and use of “Innovation deals”, anticipated in the document and now officially launched with a first call for expressions of interest, is presented as a step in that direction. In addition, the document advocates use of the REFIT programme of the European Commission to remove existing barriers to existing products and services (...) and facilitate the emergence of new technologies and business models by addressing existing collective actions problems; or facilitating diffusion through targeted action”.

Against this background, some scholars have argued that the “innovation emergency” often denounced in Europe (which is probably more correctly defined as a “diffusion deficit”, see Ashford and Renda 2016) is heavily affected by policies that do not belong to the traditional domain of innovation, such as single market policies, competition policy, intellectual property policy and sector-specific policies. From this perspective, *the role of better regulation for innovation would thus have to expand to all those policies that affect incentives to innovate, rather than on the rather more limited toolkit of innovation policymakers.* This is why REFIT (which so far has mostly used stakeholder consultation, and has focused on the removal of administrative burdens) would probably have to be gradually re-oriented towards a new overarching goal (that of ensuring the alignment between legislation, innovation and overall societal welfare).

To further complicate this issue, *the overall context in which innovation takes place is very rapidly changing, and this change affects an increasing number of economic sectors.* In particular, the emergence of the data-driven economy and the ongoing “platformization” of many economic sectors is leading new, disruptive business models to enter existing markets in a way that creates enormous challenges for incumbent players. This has a number of consequences: (i) the role of data, and their seamless flow, becomes essential to power innovation and entrepreneurship, in a growing portion of the economy; (ii) the virtualization of production, which from software and services is now encompassing also part of hardware, is lowering barriers to entry related to fixed costs of production, and possibly creating new barriers (e.g. user attention, data availability, etc.); (iii) innovation is becoming more multi-dimensional and systemic than in the past, now encompassing not only product and service innovation, but also organizational innovation and user innovation and this in turn calls for policies that do not focus only on traditional (linear) innovation models; (iv) all better regulation tools based on negotiation, cooperation or exchange of information with incumbent players (including REFIT, and possibly innovation deals) are not necessarily fit for the purpose of eliminating incumbency problems (OECD, 2015).

Finally, *the literature on innovation is increasingly realizing and acknowledging that innovation is a means, not an end.* Policies that support innovation should thus be designed by considering that not all innovation contributes to grand societal challenges in the same way and to the same extent; and that innovation should possibly lead to sustainable development, in terms of long-term economic, social and environmental goals (for example, decarbonisation and high quality employment). In this respect, the REFIT program (if adequately adjusted) provides an ideal framework for linking innovation to the ultimate goals of EU policy: these goals, spelled out originally in the Europe 2020 strategy and incorporated *i.a.* in Horizon 2020, are today in need of a revision, which unfortunately does not seem likely to occur in the coming months. Meanwhile, some (but not all) of these goals have been subsumed under Juncker’s “Ten Priorities”²; and Commissioner Moedas has launched a new “Open Science, Open Innovation and Open to the world”

¹ See https://ec.europa.eu/research/innovation-union/pdf/innovrefit_staff_working_document.pdf.

² https://ec.europa.eu/priorities/index_en

strategy, which incorporates ways to create a more inclusive process for research and innovation in the EU. But overall, it is fair to state that Europe has lost momentum in pursuing its strategy for long-term sustainable development.

An important source of inspiration in this challenging task is provided by international experience, and in particular at the past and present experience of the United States. This study looks at the ways in which U.S. regulatory policy contributes to innovation, and focuses in particular on the new U.S. innovation policy strategy, on negotiated rulemaking, implementation and compliance, and on the US better regulation system more broadly.

As a preliminary *caveat*, it is important to recall that the U.S. and EU regulatory frameworks and better regulation agendas are remarkably different, in a number of respects. First, *the multi-level governance and level of integration of the two jurisdictions is remarkably different*. This implies that the possibility, for the U.S. administration, to develop innovation policies for the whole 50 US states is generally greater than the corresponding power of the EU institutions. In other words, the EU28 still enjoy a significant degree of autonomy in their decisions about innovation policy, and indeed the EU budget dedicated to R&I is only a tiny fraction of public expenditure in R&I in the EU (and more generally, the EU budget in and of itself is much smaller than the U.S. federal budget)³.

Second, *the scope of better regulation tools used in the US and in the EU is also very different*. While the United States use Regulatory Impact Analysis and retrospective review with exclusive reference to secondary legislation, in the European Union the better regulation agenda encompasses all major initiatives included in the European Commission's annual work program, and the use of impact assessments and stakeholder consultation was recently expanded to cover also implementing and delegated acts (Renda 2015). This, in turn implies that the extent to which the two jurisdictions can use better regulation to promote innovation is different; and that the relevance of a possible "innovation principle" in the US would likely be less significant than in Europe.

Third, and relatedly, *the U.S. experience with "negotiated rulemaking" (the closest analogy one could find to the proposed "innovation deals") has been confined to administrative rules*, which again entails that negotiated rulemaking is likely to be less able to inspire a more pro-innovation agenda from the outset, compared to a more flexible instrument such as the innovation deals. That said, innovation deals are being designed mostly as a tool that would operate *rebus sic stantibus*, i.e. with no change envisaged in existing regulation, and thus leading only to better implementation, clarification and interpretation of rules to the benefit of regulatory certainty, innovation and entrepreneurship: this, too, limits the extent to which innovation deals can be used to pave the way for systemic innovation of the type needed in many areas to bring about change (Ashford and Renda 2016).

Fourth, drawing comparisons between the two legal systems can be a tricky exercise also due to the fact that *in the United States, litigation plays a very different, and most likely stronger, role in shaping the incentives of private players, as well as the enforcement of existing rules*. The prospect of litigation and the pervasive nature of settlements and collective redress schemes such as opt-out class actions, especially if coupled with contingency fees for lawyers, exerts a significant impact on the way regulations are shaped *ex ante*, and such difference has to be factored into the analysis in order to understand how legal rules will end up affecting innovation and market incentives.

With these caveats in mind, the next sections discuss the current evolution in U.S. innovation policy, as well as the way in which regulation takes into account possible impacts on innovation. Section 1 discusses more in depth why the US system does not provide a good reference for Europe on how to mainstream innovation in the better regulation agenda. Section 2 then illustrates the main aspects of the recently re-launched strategy for American Innovation, for what concerns the introduction of an innovation-oriented mindset in federal agencies. Section 3 looks at horizontal policies such as competition law, copyright law, data protection and risk regulation. Section 4 ventures in the analysis of flexible regulatory approaches adopted by a number of agencies in the U.S. and the EU. Finally, Section 5 summarizes the lessons that can be drawn from an analysis of the U.S. policy and legal system for EU's future innovation agenda.

³ Total gov budget in the US is approx 6.4 trillion (two thirds is federal level); total budget in the Eu is approx. 8 trillion, but the overwhelming majority is member states. The overall EU budget is about 1% of the EU's and GDP. That compares with national budgets of between 35% and 58% of GDP.

2 BETTER REGULATION: WHY THE U.S. SYSTEM IS NOT A “PERFECT MATCH” FOR EUROPE

The better regulation agenda in the United States has traditionally focused on a specific tool, i.e. the ex-ante regulatory impact analysis (RIA) that federal agencies (and to some extent, independent agencies) draft when preparing most economically significant regulations. Since the 1990s, and even more after 2011, the U.S. system has tried to promote also the use, within government, of ex post evaluations, also termed lookbacks or retrospective reviews. However, the current state of development of retrospective reviews seems to lag behind that of ex ante RIA, and most agencies do not feature a systematic, formalized, well-planned ex post evaluation agenda.

In addition, as already mentioned in the introductory section, it must be recalled that the use of better regulation tools in the U.S. is mostly confined to secondary legislation. This, of course, does not mean that no economic analysis (or any analysis on innovation) is carried out on proposed primary legislation. But such analysis is performed in many different ways, for example within the Congressional Budget Office, the Congressional Research Service or by the Council of Economic Advisors, to name a few, in a way that does not follow a very structured and systematic procedure. In addition, the Office of Technology Assessment, created in 1972 and by many regarded as a contributor of high quality studies, was dismantled in 1995.

That said, for secondary legislation the need to focus on impacts on innovation has been stressed more vibrantly in the U.S. by Executive Order 13,563, which observes that the U.S. regulatory system “must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation”; and that “each agency shall also seek to identify, as appropriate, means to achieve regulatory goals that are designed to promote innovation”⁴. This laudable intent, however, has not been translated into specific methodologies applied to assess the impact of specific regulation on innovation. Accordingly, innovation impacts are normally accounted for within the more general framework of cost-benefit analysis, and through other means such as the general encouragement of flexible regulatory mechanisms and management-based regulatory solutions where appropriate.

Another important factor that limits the applicability of the U.S. experience to the EU better regulation agenda is the fact that, as observed by authoritative commentators (Rai and Benjamin 2008), some of the agencies that have the largest impact on innovation act, in the United States more through adjudication than through rulemaking. This is the case, i.a. of the FTC, the Patent Office, and the Antitrust Division of the Department of Justice⁵.

As a result, the way in which the U.S. uses better regulation tools is very difficult to compare with the EU one, and certainly the indirect way in which innovation has been mainstreamed in the rulemaking practice of US agencies is too impalpable to represent a real reference for EU policymakers. That said, recent measures adopted as part of the Strategy for American Innovation, aimed at increasing attention towards innovation inside individual agencies, and more generally the individual regulatory approaches adopted in the U.S. on a number of policy issues provide very important lessons for the EU, and this is why in the remainder of this paper we will focus on these two issues.

3 MAINSTREAMING INNOVATION IN THE DAILY WORK OF AGENCIES: AN ANALYSIS OF THE 2015 STRATEGY FOR AMERICAN INNOVATION

In October 2015, the U.S. administration unveiled an updated Strategy for American Innovation (hereinafter “the Strategy”)⁶. The Strategy, first issued in 2009, provides an overview of Administration efforts to ensure America continues to lead as the world’s most innovative economy, to develop the industries of the future, and to harness innovation to help address most important societal challenges. The Strategy also makes the case for the key innovation investment in a number of selected emerging technologies, presented as critical for ensuring that the United States remains an innovative nation. The Strategy, released in October 2015, features three core components:

- The importance of investing in research and development (R&D) and the other building blocks of long-term economic growth.

⁴ See <https://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf>.

⁵ http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=2729&context=faculty_scholarship, footnote 21.

⁶ See https://www.whitehouse.gov/sites/default/files/strategy_for_american_innovation_october_2015.pdf.

- A focus on nine Strategic areas where focused effort can advance national priorities and help create shared prosperity⁷.
- New efforts to make the Federal government more innovative to improve performance and create a better environment for innovation by the private sector and civil society.

While a full description of the 2015 strategy would fall outside the scope of this report, a number of interesting features can be highlighted for the purposes of this Study.

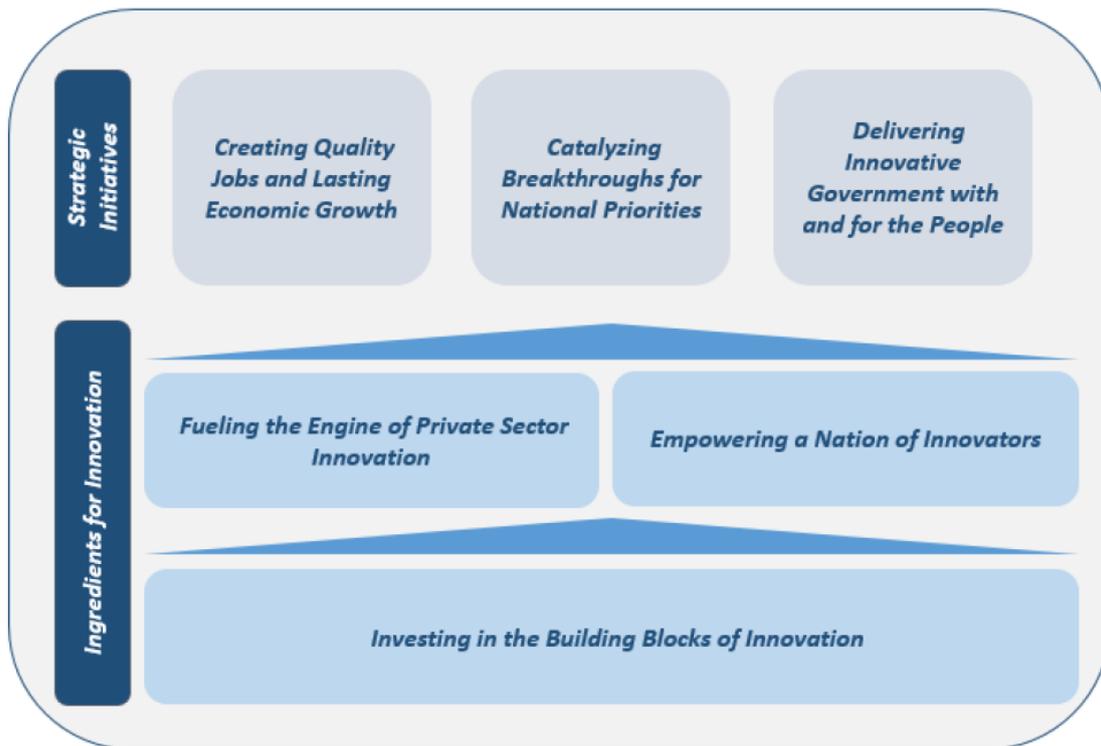
First, *there is an explicit recognition of the importance of creating the right policy and regulatory environment to stimulate private-sector investment*. Interestingly, part of this “right environment” includes, besides more straightforward instances such as IPR protection, effective competition law and access to finance for startups, also a renewed commitment to a trade policy that promotes sustainable innovation⁸. The Strategy document observes that “although the government’s role of creating the right ‘rules of the road’ and investing in continued long-term economic growth is less visible than that of the entrepreneur, it is critical to America’s economic future”.

Second, *the governance of the strategy appears at once simpler and more comprehensive compared to that of the EU research and innovation policy*. As shown in Figure 1 below, the strategy is based on a first, foundational set of policies aimed at the so-called building blocks of innovation policy (Making World-Leading Investments in Fundamental Research, Boosting Access to High-Quality STEM Education, Clearing a Path for Immigrants to Help Propel the Innovation Economy, Building a Leading 21st Century Physical Infrastructure, and Building a Next-Generation Digital Infrastructure). On top of these foundations the strategy identifies two broad initiatives: fueling the engine of private sector innovation (through R&E Tax Credits, support for Innovative Entrepreneurs and Ensuring the Right Framework Conditions for Innovation; Empowering Innovators with Open Federal Data; boosting the Commercialization of Federally-Funded Research; supporting the Development of Regional Innovation Ecosystems and helping Innovative American Businesses Compete Abroad); and Empowering a nation of innovators (through Incentive Prizes, Making, Crowdsourcing, and Citizen Science). These two pillars create the preconditions for more challenge-led initiatives, grouped under three areas: creating jobs (especially in manufacturing and in the industries of the future); catalyzing breakthroughs for national priorities (which includes concerted actions on grand societal challenges, from precision medicine to neuro-technologies, smart cities, clean energy, education, space, computing, and the eradication of poverty); and delivering innovative government to citizens.

⁷ Note that the expression “shared prosperity”, besides recalling a strategy launched in 2014 by the World Bank, echoes the importance of promoting accessibility to innovation for society as a whole, and as such incorporates distributional impacts in the assessment of the possible effects of innovation.

⁸ This issue is fundamental to trigger innovation that fosters long-term decarbonization. See Ashford and Renda 2016.

Figure 1 – Strategy for American Innovation: an overview



Source: A New Strategy For American Innovation, October 2015

The sections below focus on a selected number of areas, which seem to be more directly relevant for the purpose of this Study. In particular, the “Smarter government” area includes:

- The identification of societal grand challenges and the governance arrangements selected to pursue them.
- The adoption of an Innovation Toolkit for Public-Sector Problem-Solving.
- The creation or re-launch of Innovation Labs at Federal Agencies.
- More Effective Digital Service Delivery through the creation of U.S. Digital Service teams across government.
- Building and Using Evidence to Drive Social Innovation, including through “Pay-For-Success” approaches to pay for outcomes as opposed to inputs.

3.1 A Spotlight on Nine Areas of Strategic Opportunity

As part of the Strategy, the U.S. Administration is highlighting new areas of strategic opportunity where focused effort can advance national priorities and help create shared prosperity, including the following nine highlights:

- **Advanced Manufacturing:** American manufacturing, which supplies nearly three-quarters of all U.S. private-sector R&D, is central to American innovation, both to discoveries being made today and our ability to drive productivity and job growth in the future. The President and his Administration have put forward a comprehensive agenda to strengthen U.S. manufacturing, including restoring the nation’s lead at the cutting-edge of manufacturing innovation by launching a National Network for Manufacturing Innovation, reinvesting in supply chain innovation, supporting the scale-up of technology-intensive manufacturing startups, and more.
- **Precision Medicine:** Most medical treatments have been designed for the “average patient.” As a result of this “one-size-fits-all” approach, treatments can be very successful for some

patients but not for others. Precision medicine gives clinicians tools to better understand the complex mechanisms underlying a patient's health, disease, or condition, and to better predict which treatments will be most effective – but the potential for precision medicine to improve care and speed the development of new treatments has only just begun to be tapped. The 2016 U.S. Budget earmarked \$215 million for a new Precision Medicine Initiative, which will leverage advances in genomics, emerging methods for managing and analyzing large data sets, and health information technology, while seeking a high level of privacy protection.

- **BRAIN Initiative:** the Strategy reports that the social and economic burden of neurological disorders and diseases is overwhelming, and developing new treatments is critical to addressing these burdens. For example, the current cost of caring for the five million Americans with Alzheimer's disease is over \$200 billion per year, including \$150 billion from Medicare and Medicaid. The BRAIN Initiative has the potential to do for neuroscience what the Human Genome Project did for genomics by enabling a dynamic understanding of brain function. A deepened knowledge of how brains work will help scientists and doctors diagnose and treat diseases more incisively, educate children more effectively, and develop novel technologies and devices to help alleviate the burdens of illness and injury. The U.S. 2016 Budget allocates over \$300 million to the BRAIN Initiative.
- **Advanced Vehicles:** Breakthrough developments in sensing, computing, and data science have brought vehicle-to-vehicle communication and cutting-edge autonomous technology safety features into commercial deployment, while vehicles approaching full autonomy – self-driving cars – are already being tested on public roads. Accelerating the development and deployment of these advanced vehicle technologies could save thousands of lives annually by applying the split-second reaction times and precision decision-making of machine intelligence to the more than 90 percent of crashes involving human error. The President's 2016 Budget calls for doubling Federal investments in autonomous vehicle technology research to develop performance and safety standards for autonomous, connected, and self-driving vehicles on public roads and to comprehensively pilot these technologies in cities, on highways, and in commercial environments.
- **Smart Cities:** An emerging community of civic leaders, data scientists, technologists, and companies are joining forces to build "Smart Cities"—communities that are building an infrastructure to continuously improve the collection, aggregation, and use of data to improve the life of their residents—by harnessing the growing data revolution, low-cost sensors, and research collaborations, and doing so securely to protect safety and privacy. For example, by coordinating adjacent traffic signals to decrease local traffic, a pilot project in Pittsburgh has reduced commuting travel times by nearly 25 percent on average. The U.S. Administration's new Smart Cities Initiative invests over \$160 million in Federal research and leverages more than 20 cities participating in new multi-city collaborations to help local communities tackle key challenges such as reducing traffic congestion, fighting crime, fostering economic growth, managing the effects of a changing climate, and improving the delivery of city services. The President's 2016 Budget calls for over \$30 million in new research and deployment investments for smart cities.
- **Clean Energy and Energy Efficient Technologies:** Over the past six years, the amount of electricity generated from wind power has tripled and from solar power has increased by more than 20-fold. The U.S. Administration is determined to sustain this momentum through continuing to build on its progress in developing and deploying clean electricity technologies, catalyzing independent commitments by major foundations, institutional investors, and other long-term investors to fund climate-change solutions, make energy go further through improved energy efficiency, and work to reduce carbon pollution while helping to improve energy security.
- **Educational Technology:** Currently, a large gap remains between the relatively modest impact that technology has had on education, particularly in grades K-12, and the transformative impact that technology has had on other parts of our lives. The President's Council of Advisors on Science and Technology estimates that less than a mere 0.2% of overall education spending goes to R&D, unlike knowledge-intensive sectors like biotechnology which allocate 15-20 percent of revenue to R&D. But that is poised to change. The technological conditions are ripe for the development of advanced educational technologies that can transform teaching and learning. In just the past five years, DARPA has showed that Navy IT students trained with a DARPA-developed digital tutor can outperform 98% of the students trained with a traditional instructor. Through the President's ConnectED Initiative, the United States is now on the path to give 99% of students access to high-speed broadband by 2018. And the 2016 Budget includes \$50 million for the creation of an Advanced Research Projects Agency for Education (ARPA-ED) to pursue breakthroughs in learning technology.

- **Space:** President Obama has emphasized the importance of investing in space technology and a long-term goal in space of venturing “out into the solar system, not just to visit but to stay,” as he articulated in the 2015 State of the Union Address. In addition to core investments to develop a U.S. commercial crew space transportation capability by 2017, NASA is increasing its support for longer-term research projects with ambitious goals, such as protecting astronauts from radiation in space, developing advanced propulsion systems, and allowing humans to “live off the land” by producing fuel, oxygen, and water on other planets. These investments will create the foundations for a space-faring civilization and a future human mission to Mars. The 2016 Budget proposes \$1.2 billion for NASA’s Commercial Spaceflight program, and \$725 million for NASA’s Space Technology Mission Directorate.
- **New Frontiers in Computing:** Advances in high-performance computing (HPC) have the ability to improve public services, grow the economy, improve the health and safety of our community, and promote scientific discovery. Coordinated new investments are needed to overcome key challenges, including: the end of Moore’s Law as a predictor of increases in system performance, the rise of extremely large data sets and attendant computational challenges, and the coming end of a two-decade period of stability in HPC architecture. In July 2015, the President created a National Strategic Computing Initiative (NSCI) by Executive Order to meet these challenges and create a cohesive, multi-agency strategic vision and Federal investment strategy for HPC. This strategy will spur the creation and deployment of computing technology at the leading edge, helping to advance Administration priorities for economic competitiveness, scientific discovery, and national security.

In addition to these nine priority areas, the U.S. Administration also continues to encourage investment in a pipeline of emerging “general-purpose technologies” that will serve as a source of future strategic initiatives. These technologies are innovations that have a pervasive impact on our economy and our society. Past examples include the steam engine, electricity, interchangeable parts, the transistor, and the Internet. The Administration is committed to spurring the development of the next generation of general-purpose technologies, such as nanotechnology, robotics and autonomous systems, advanced materials, and engineering biology.

Besides the clarity and focus of the nine strategic areas selected by the U.S. government, it is important to highlight that the effectiveness of these initiatives is pursued through specific governance arrangements, which take the form of smart, challenge-led agencies such as ARPA-E and ARPA-ED; and the creation of public-private partnerships that leverage public support to incorporate private funding and capabilities (e.g. the Cancer Moonshot). The strategy was enthusiastically received by most stakeholders, in particular by higher education institutions, industry associations and think tanks. Some commentators wait to see its implementation before drawing a final judgment, especially looking at the promise of openness, which has not fully materialized to date, especially for what concerns open access to data held by government.

Box: ARPA-E: an example of challenge-led smart institution

Modeled after the Department of Defense’s Defense Advanced Research Projects Agency (DARPA), ARPA-E’s mission is to catalyze and accelerate the creation of transformational energy technologies by making high impact investments in their early stages of development. ARPA-E’s Program Directors are experts in their respective fields and have a passion for innovation. Each Program Director is encouraged to challenge the status quo and find new ways of looking at America’s energy issues, bringing together collaborators across varied technical and professional disciplines to solve complex problems.

ARPA-E also focuses on moving innovative technologies out of the lab and into the market. Dedicated ARPA-E Technology-to-Market Advisors provide awardees with practical training and critical business information to equip project teams with a clear understanding of market needs to guide early stage technical development and help projects succeed. To date, ARPA-E has invested approximately \$1.3 billion across more than 475 projects through 30 focused programs and three open funding solicitations.

In a recent contribution, Mariana Mazzucato (2016) convincingly argued that while private sector efforts such as Elon Musk’s Tesla have marked important steps towards the production of “an existing, pretty powerful battery technology”, ARPA-E has been pursuing technological innovation in the purest sense, by “creating new ways of doing” things, which “have the potential to be

significantly better.” Bill Gates himself acknowledged that only the state, in the form of public institutions like ARPA-E, can lead the way to an energy breakthrough⁹.

At the same time, however, other commentators have observed that very few of the projects funded by ARPA-E have had a significant commercial impact in the seven years in which the agency has been in operation. While this is in the nature of ARPA-E’s work (high risk, early stage investment), there are margins for improvement, and the U.S. government has earmarked a 21% increase in the 2017 for clean-energy R&D funding, most of which goes to ARPA-E. Obama also proposed a so-called “ARPA-E Trust” for developing “larger-scale investment-ready outcomes,” which would begin with \$150 million in funding in fiscal 2017 and provide \$1.85 billion over five years to ARPA-E.

The Cancer Moonshot: public-private cooperation or competition?

Another important example of mission-led initiative that focused on a specific type of scientific challenge is the Cancer Moonshot, officially launched by President Obama during his 2016 State of the Union, and led by Vice President Joe Biden. The Moonshot initiative will begin immediately with \$195 million in new cancer activities at the National Institutes of Health (NIH) in Fiscal Year 2016, whereas Fiscal Year 2017 additional \$755 million should be earmarked in mandatory funds for new cancer-related research activities at both NIH and the Food and Drug Administration. Moreover, The Departments of Defense and the Veterans Affairs are increasing their investments in cancer research, including through funding Centers of Excellence focused on specific cancers, and conducting large longitudinal studies to help determine risk factors and enhance treatment.

Within the Department of Health and Human Services (HHS), these investments will support cutting edge research opportunities such as: Prevention and Cancer Vaccine Development; Early Cancer Detection; Cancer Immunotherapy and Combination Therapy; Genomic Analysis of Tumor and Surrounding Cells; Enhanced Data Sharing; a virtual Oncology Center of Excellence developed by the Food and Drugs Administration; Pediatric Cancer.

Like the ARPA-E, the proposed new fund will be focused on high-risk, high-return research identified by the collaborative work and new ideas stimulated by the research community as part of this work. Interestingly, the White House announced that the National Cancer Moonshot requires a whole-of-government approach, marshalling resources from across the Federal government to address this singular goal.

But here too, not all agree on the governance of this ambitious new initiative, also since a number of similarly named, but privately-led, projects have been launched since the beginning of 2016. More in detail, three privately funded immuno-therapy research projects are being announced: the \$250-million Parker Institute for Cancer Immunotherapy, funded by Sean Parker, co-founder of the music-file-sharing company Napster, and announced on 13 April; a \$125-million Immunotherapy Center at Johns Hopkins University in Baltimore, Maryland, unveiled in March; and the Cancer MoonShot 2020 Program, announced in January by biotechnology billionaire Patrick Soon-Shiong. These announcements have raised an alarm in the U.S., as the projects, rather than cooperating, might end up cannibalizing themselves: part of the governance challenge will be to ensure adequate data sharing and coordination of efforts, in order to maximise the effectiveness of the publicly funded research without incurring in undesirable circumstances such as free riding, insufficient scale, etc.

3.2 Mainstreaming innovation within government: the new Innovation Toolkit for Public-Sector Problem-Solving

Now that innovation has been recognized as a whole of government effort, the administration decided to create a toolkit for innovation, mostly referring to success stories and examples that many civil servants are unaware of, and would want to follow. Accordingly, the Toolkit appears to be more an awareness-raising tool, rather than a real methodological guidance; and will consist of online resources that explain how and why certain approaches can yield important results. The Toolkit is also accompanied by a number of “communities of practice” that allow Federal employees to address common challenges that many agencies face and to share expertise.

The Innovation Toolkit will include resources that help Federal employees deploy new approaches in areas such as the following:

⁹ See, i.a. <http://www.theatlantic.com/magazine/archive/2015/11/we-need-an-energy-miracle/407881/>.

- **Rapidly hiring top talent** using flexible hiring authorities and accelerated hiring practices, particularly for areas where there is a significant gap between world-class performance and current public-sector practices.
- **Developing high-impact innovation labs** like the HHS IDEA Lab that support employee efforts to experiment with new approaches to meeting agency missions.
- **Making open and machine readable the default for government data**, and encouraging entrepreneurs and developers to create compelling applications that take advantage of it.
- **Designing incentive prizes** that serve as magnets for good ideas from startups and citizen inventors.
- **Identifying and pursuing the "Grand Challenges"** of the 21st century.
- **Paying for outcomes through Pay for Success** and innovative approaches to contracting that only pay for what works.
- **Enabling government to serve as an early customer** for new firms with breakthrough technologies.
- **Funding what works by building and using evidence** – e.g. the "tiered evidence" framework used by the Department of Education's Investing in Innovation program.
- **Using human-centered design** and the Lean Startup methodology to improve delivery of government services.
- **Launching high-impact multi-sector collaborations** involving companies, foundations, nonprofits, researchers, regional initiatives, and skilled volunteers.
- **Designing Federal policies and programs in ways that are informed by what people really need** and how they actually make decisions by, for example, partnering with the Social and Behavioral Sciences Team or the Innovation Lab at the Office of Personnel Management.

3.3 The creation or re-launch of Innovation Labs at Federal Agencies

To increase Federal capacity for innovation, the U.S. Administration announced that it is supporting the development of Innovation Labs at Federal agencies. Such labs provide the resources and support for employees and members of the public to develop, test, and scale new approaches to meeting agency goals, resulting in significant improvements to the effectiveness and efficiency of the Federal Government. The Strategy mentions that already several U.S. agencies have made significant strides in developing their internal innovation capacity through Innovation Lab models. These include the HHS IDEA Lab, the USAID Global Development Lab, the OPM Innovation Lab, the VA Center for Innovation, and the National Security Agency (NSA) Incubation Cell.

A good example is the **IDEA Lab**, launched by the Secretary of the Department of Health and Human Services (HHS) in early 2014. The Lab aims at fostering innovation on specific solutions to problems in government and health care, mostly by empowering entrepreneurs and intra-preneurs (especially inside the HHS). The Lab develops resources to help HHS Operating Divisions/Staff Divisions advance their modernization and problem solving abilities with the goal of streamlining processes, improving services, and refining the way the HHS meets its mission. The Lab follows a three pronged approach:

- **Encouraging internal entrepreneurship by investing in HHS employees.** This pillar includes the HHS Ignite Accelerator, an internal program providing selected teams methodological coaching and technical guidance within a startup framework for the testing of new products, services, and processes that could lead to dramatic improvements in service delivery or treatment; the HHS Ventures Fund, which provides growth-stage funding and support to HHS employees with proven concepts for how to dramatically improve their Office, Agency, or the Department's ability to carry out its mission; and the HHS Innovates Awards, which recognizes every year HHS employees who have taken innovative approaches to solving some of the biggest problems in government and in delivering health and human services.

- **Bringing in external talent.** This pillar encompasses an Entrepreneurs-In-Residence Program, in which employees hire outside talent to come to HHS and work with an embedded team on high-risk, high-reward projects over a 1 year time period; and an Innovator-In-Residence Program, in which HHS organizations partner with a private sector not-for-profit organization to hire outside expertise and work on a common problem over a 1-2 year time frame.
- **Building collaborative communities.** This stream of activities includes the HHS Buyers Club, which aims at leveraging under-utilized language in the Federal Acquisition Regulation (FAR) to improve the purchase decision-making pathways; the HHS Competes, which supports the development and deployment of open innovation contests and challenges as a means of addressing some of the biggest challenges faced by HHS; the "Health Data Initiative: Liberating Data", which aims at leveraging access to health data to spur the development of new applications and a data-driven health care environment, including through the organization of yearly "Datapaloozas"; and the Invent Health Initiative, aimed at empowering inventors both inside and outside government to create tools for better living and better clinical care.

Building on the success of the HHS Idea Lab, the 2016 Budget includes funding for several other agencies – including the Department of Commerce, Department of Education, Department of the Treasury, and the Small Business Administration – to create their own versions of an IDEA Lab, tailored to their specific missions and operations.

3.4 A whole of government effort: the creation of U.S. Digital Service teams across government

The U.S. administration observes that the success rate of government digital services is improved when agencies have digital service experts on staff who are experienced with the modern design, software engineering, and product-management techniques that have powered the growth in America's technology sector for the past decade. To ensure agencies can effectively build and deliver important digital services, the **2016 U.S. Budget includes funding for several Federal agencies for staffing costs to build Digital Service teams.** These teams will be composed of experts who will focus on transforming some of the country's most important citizen- and business-facing services so they are easier to use and more cost-effective to build and maintain.

These digital service experts will bring private-sector best practices in the disciplines of design, software engineering, and product management to bear on the agency's most important services. The positions will be term-limited, to encourage a continuous influx of up-to-date design and technology skills into the agency. The digital service experts will be recruited from among America's leading technology enterprises and startups, and will join with the agency's top technical and policy leaders to deliver meaningful and lasting improvements to the services the agency provides to citizens and businesses.

This effort builds on the success of the Administration's U.S. Digital Service and the General Service Administration's digital service team known as "18F," both created in 2014. Since their creation, these small teams have worked in collaboration with Federal agencies to implement cutting-edge digital and technology solutions to best serve the American people. Projects have included improvements to the Veterans Benefits Management System, green card replacements and renewals, the creation of the College Scorecard, and more. In addition to their work on these high-priority projects, these small teams of tech experts have worked to establish best practices, to develop government-wide design standards, and to recruit more highly-skilled digital service experts and engineers into government.

BOX – The "18F" group: from problems to solutions

A very interesting experience from within the U.S. government is the creation of Digital Service Teams such as the 18F group, which makes digital products for government organizations and uses lean startup methods, open source code, and contemporary programming languages. Its name refers to its office location in northwest Washington, D.C., on 18th and F Streets. 18F is within the Office of Citizen Services and Innovative Technologies (OSCIT) and runs in parallel with the Digital Government Strategy's Digital Services Innovation (DSI) Center.

The group was started following multiple problems in the rollout of the HealthCare.gov health insurance marketplace, which began an effort to reform citizen-facing government technology. A similar group was created also in the UK (the Government Digital Service). Interestingly, 18F runs on a cost recovery model where client agencies reimburse the digital agency for its work. Their

operation is closer to a traditional business than government organizations like the DSI Center. The agency started with 15 employees, including 11 former Presidential Innovation Fellows from both the private and public sectors. The staff previously worked in front and backend development, design and usability, and product management.

Upon its opening, 18F began to host the Presidential Innovation Fellows program that started in May 2012 in the Digital Government Strategy. The 18F group launched several projects such as analytics.usa.gov, the College Scorecard, myRA, Every Kid in a Park and MyUSA.

3.5 Building and Using Evidence to Drive Social Innovation, including through “Pay-For-Success” approaches to pay for outcomes as opposed to inputs

As announced in the Strategy for American Innovation, the U.S. Administration has ushered in a new era of data-driven social innovation by piloting creative approaches to seemingly intractable problems. Highlights of agency efforts to promote evidence since 2011 include the following:

- *The Corporation for National and Community Service’s Social Innovation Fund (SIF)*, which provides grants to grow and further test community-based social interventions at several organizations. Recently the SIF added a Pay for Success (PFS) grant program, selecting eight grantees to help communities study using this approach to tackle social problems ranging from childhood asthma to chronic homelessness. PFS strategies tie funding for an intervention to its impact in the community. Instead of paying for services regardless of their effects, government or other entities only pay if programs actually achieve positive outcomes for the people they are designed to benefit. As of mid-2015, the SIF was funding 34 PFS feasibility studies and providing support for transaction structuring for five PFS projects, with more to come.
- *Investing in Innovation (i3) Program* tiered-evidence grants are granted by the Department of Education. These grants fund the development, validation, and scale-up of promising or proven interventions to dramatically improve student outcomes.
- *The Department of Labor* in 2013 established and formalized a policy that requires rigorous, independent and transparent evaluations in all of its discretionary grant programs. For example, the Workforce Innovation Fund’s performance is measured in terms of outcomes for job seekers and employers, and in terms of cost effectiveness. Newer programs backed by less evidence are eligible for less funding, whereas more sizable grants to proven programs make possible the wider-scale expansion of these models. This is a very interesting experience in terms of program evaluation, which could be followed by the European Commission.
- *Administration-wide evidence and innovation process*. Through this process, all agencies will take concrete and meaningful steps to better build and use evidence to increase government effectiveness and social program impact.

In addition, the U.S. Administration is deepening its investment in evidence and social innovation. Among its priorities, the 2016 budget allocates funding to initiatives aimed at better use of existing data while protecting privacy to learn more about what works, and to the creation of an incentive fund for Pay for Success approaches¹⁰.

¹⁰ These initiatives have already seen a first implementation in the EU: in particular, the EIF’s Social Impact Accelerator was set up in 2013 as a “fund of funds”, seeking to mobilize an initial amount of EUR 60m of capital for investment in social impact funds. In addition to enhancing the availability of finance for social enterprises, SIA aims to build up the existing market infrastructure for social impact investing in such a way that this emerging asset class is placed on a path to long-term sustainability. The first investment of the accelerator, in late 2013, was in the Social Venture Fund, a German social venture capital fund, which was awarded more than €16 million in funding.

3.6 Is all that glitters gold? Remaining challenges in U.S. innovation policy

The two Obama administrations have certainly marked a shift of gear in U.S. policies to promote innovation. The U.S. government is now more aware of the importance of proactive policy to stimulate innovation, as well as the government's role in boosting the results of research. At the same time, it is clear that, even if probably in lower measures compared to the EU, also in the U.S. there is no problem of innovation deficit, and there is rather a diffusion deficit problem.

A recent report by the MIT, rather explicitly titled "future postponed", collects a number of cases of technologies that are not finding enough space in the market to reach the minimum scale and start creating their positive effects on society¹¹. For example, in the domain of low-carbon energies technologies have achieved, also thanks to publicly funded research, dramatic drops in prices: however, the deployment of these technologies requires smart government (Romm 2016). This, in turn, suggests that the U.S. government could do even more to promote the uptake of existing technologies, a theme that lies at the core of the current commitment of the Administration. Leveraging entrepreneurial and intrapreneurial skills in support of existing societal challenges is certainly a very promising avenue, but the U.S. administration seems to be at the beginning of this process, and accomplishments are not numerous to date.

Similarly, the declared commitment towards open data in the U.S. administration has so far produced less than it has promised, and a lot still remains to be done in terms of liberating data to generate data-driven social innovation. Certainly, initiatives such as hackathons and datapaloozas are important references also for the EU, and the same goes for the various cross-governmental initiatives launched to promote an innovation-oriented mindset in the administration, including Labs, toolkits, Presidential Innovation Fellows and communities of practice. All these are ideas that EU institutions have started to test (for example, the European Food Safety Authority organizes hackatons¹², and the European Commission already hosts a number of communities of practice), but should be probably tested further across DGs, in recognition of the fact that innovation is a whole of government exercise, and needs to be adequately mainstream in the daily activity of the administration in order to produce long-lasting results. That said, it is also important to observe that the U.S. administration is composed of federal agencies that have a more direct regulatory power compared to the European Commission DGs, and this in turn places them in a position that is closer to the public, and to the core of problems to be addressed and solved. Not surprisingly, at the EU level the best experience with adaptive, flexible policymaking comes from an agency, the European Medicines Agency; and that hackatons have been launched by the European Food Safety Authority. Whether this can be seen as an argument in favor of a further "agencification" of EU institutions, is a theme that would deserve further investigation in the future, and cannot be kept separate from the role of agencies in the overall regulatory process. In the United States, federal (government and independent) agencies perform their own evaluations of policy initiatives, and are bound by the Administrative Procedure Act and by a number of White House Executive Orders to rely on better regulation tools such as ex ante regulatory impact analysis, retrospective review and notice and comment (i.e. stakeholder consultation). This puts them in direct contact with their stakeholders, in turn enhancing their accountability and the overall transparency of the regulatory process.

¹¹ See MIT, <http://www.technologyreview.com/news/543351/at-a-time-of-plenty-some-technologies-are-shut-out/>

¹² <https://www.efsa.europa.eu/en/prizes/hackathon>

4 IS THE U.S. REGULATORY FRAMEWORK MORE INNOVATION-FRIENDLY THAN THE EUROPEAN ONE?

Apart from the specifics of innovation policy, and besides differences in the better regulation agendas, the extent to which the overall legal and regulatory framework is conducive to entrepreneurship and innovation in the United States and Europe has been increasingly under the spotlight over the past decade. The factors to be taken into account in order to perform a meaningful comparison are numerous. While regulation is still considered by many authors as a barrier to innovation in all or most circumstances, evidence suggests that the relationship is way more ambiguous, and that in many cases regulation, if well-drafted and designed, acts as a stimulus for the type of innovation that society needs (Ashford and Renda 2016). The key elements to be taken into account in order to determine whether regulation will have a positive or a negative impact on innovation include stringency, time, flexibility and certainty (Pelkmans and Renda 2014). *Stringency* relates to how difficult and costly it is for firms to comply with new regulatory requirements using existing ideas, technologies, processes and business models. The amount of *time* that a regulation gives to the targeted stakeholders for compliance with the regulatory requirements is essential to stimulate innovation, but timing is a double-edged sword: too little time might discourage innovation and determine an unsustainable increase of compliance burdens, too much time might crystallize innovation efforts due to the lack of pressure to meet the requirements¹³. Flexible, performance- or outcome-based regulation stimulates innovation more than purely prescriptive regulation, provided that it is coupled with adequate monitoring and enforcement (see *i.a.* Coglianese 2015). And also uncertainty has been found to act as a driver and also as an inhibitor of innovation depending on the circumstances¹⁴.

That said, for so-called “horizontal policies” such as *i.a.* competition law, public procurement, standardization, and increasingly copyright and data protection regulations, it is possible to draw a comparison of U.S. and EU policies. The same could be done also, with some caveats, for sectorial policies, where (as will be explained below) the regulatory approaches adopted in the U.S. have not always been more stringent and precautionary than in the EU: a fact that should be subject to further research in the future¹⁵. In addition, the debate on the use of flexible approaches to regulation in order to stimulate more innovation and overcome legacy problems has been very lively in the United States over the past few years, and led to sparse initiatives adopted by different regulatory authorities, or proposed by institutions such as presidential commissions. These include the FTC’s case-by-case approach to new technologies (recently dubbed “regulatory humility” by one of the FTC Commissioners)¹⁶; the “prudent vigilance” or “regulatory parsimony” approach proposed by the Presidential Commission on Bioethics, which requires prudent vigilance and a proportionate, cautious approach to rulemaking and oversight¹⁷; adaptive licensing or planned adaptation approaches proposed by academics on both sides of the Atlantic¹⁸; and cases of

¹³ BERR (2008) and Centre for International Economics (2006) discuss specifically the timing of standardization: here too, the message is that standardization should not occur too early, and also not too late to stimulate and encourage innovation. An early standard can kill alternatives (e.g. the GSM standard for mobile communications), creating more intra-standard competition. If the standard is imposed too early, this can generate an undesirable lock-in effect, which leaves society trapped into a suboptimal standard. Similarly, the selection of a rigid, non-scalable standard can inhibit both incremental and disruptive innovation, and as such is highly damaging to social welfare and progress.

¹⁴ Ashford et al. (1985) claim that “although excessive regulatory uncertainty may cause industry inaction on the part of the industry too much certainty will stimulate only minimum compliance technology. Similarly too frequent change of regulatory requirements may frustrate technological development.” More generally, it is fair to state that whenever innovation requires large investment in R&D, the absence of reasonable stability or certainty in the regulatory framework can significantly hinder innovation. Our case study of competition rules applied in the e-communications sector below can contribute to shedding some light on this aspect of uncertainty.

¹⁵ See J.B. Wiener, M.D. Rogers, J.K. Hammitt and P.H. Sand (eds.) (2011), *The Reality of Precaution: Comparing Risk Regulation in the US and Europe*, RFF/Earthscan/Routledge.

¹⁶ See Ohlhausen, M. (2015), *Regulatory Humility in Practice*, at https://www.ftc.gov/system/files/documents/public_statements/635811/150401aeihumilitypractice.pdf

¹⁷ See Presidential Commission for the Study of Bioethical Issues (2011), *Moral Science: Protecting Participants in Human Subjects Research*, Washington D.C., December 2011, at <http://bioethics.gov/sites/default/files/Moral%20Science%20June%202012.pdf>

¹⁸ See e.g. McCray, L.E., K.A. Oye and A.C. Petersen (2010), *Planned adaptation in risk regulation: An initial survey of US environmental, health, and safety regulation*, *Technological Forecasting & Social Change* 77 (2010) 951–959. And more recently, IRGC (2015), *A short introduction to “planned adaptive regulation”*, at https://www.irgc.org/wp-content/uploads/2015/12/A_short_introduction_to_Planned_Adaptive_Risk_Regulation-19Nov15.pdf.

negotiated rulemaking that ended up stimulating innovation, such as the “Innovation Waivers” initiative and the “Common Sense Initiatives” launched by the EPA¹⁹.

Below, these areas of analysis are illustrated and discussed. Section 2.1 discusses horizontal policies, whereas Section 2.2 illustrates some of the regulatory flexibility and negotiated rulemaking initiatives U.S. agencies have experimented with over the past decades, their performance and possible lessons to be drawn for the EU. Section 2.3 discusses possible take-aways for the EU.

4.1 Competition policy

Nowhere like in antitrust law have the United States and Europe shown signs of convergence in the past century. As a matter of fact, the introduction of rules on competition in the Treaty of Rome in 1957 is seen as largely inspired by the U.S. tradition, starting with the 1890 Sherman Act and the 194 Clayton Act. And indeed, broadly speaking the rules contained in the antitrust legislation of the two blocs are close to identical. However, when it comes to antitrust the devil is the details, and the details are numerous. Without pretending to provide an exhaustive explanation, this section explores existing differences with a specific focus on digital markets and the Internet ecosystem.

First, even if the wording of Sections 1 and 2 of the Sherman Act and Articles 101 and 102 TFEU is broadly comparable, the overall approach to anticompetitive conduct, and specifically single-firm conduct has always been described as divergent in the literature. This is particularly the case for single-firm conduct (abuse of dominance in the EU jargon), due to the prevalence of the Chicago School of economics in the United States, and the influence of the more structuralist Ordoliberal school in Europe, starting from the early days of the debate on the Treaty of Rome²⁰. This is not only a matter for historians or a subject matter for academic writings: the different approach has resulted in starkly divergent positions being adopted in merger control (e.g. on the *GE/Honeywell* merger cleared in the U.S. and rejected in the EU in 2001), and also most notably in the area of single-firm conduct (e.g. in the U.S. and EU *Microsoft* cases) (Renda and Yoo 2015).

Second, notable differences between the two legal systems on the treatment of single-firm conduct are highly relevant for the ICT sector, which is considered as a key enabler of innovation in many markets. For example, EU antitrust rules (and consequently, also the EU regulatory framework for electronic communications) heavily reflect reliance on the so-called “essential facilities” doctrine, whereas the US Supreme Court has never endorsed that doctrine (Renda 2010; Renda and Yoo 2015). This, in practice, means that the set of circumstances in which EU authorities might end up imposing asset sharing or compulsory licensing in refusal to deal cases is, in all likelihood, broader than what occurs in the U.S. Cases like *Trinko* and *Linkline* in the United States have been easily compared with the interoperability stance taken by the European Commission and the Court of First Instance (now General Tribunal) in their decisions on *Microsoft* in 2004 and 2007, respectively. Moreover, the rulings of the Court of Justice of the European Union on issues of predation and margin squeeze (especially the *Telia Sonera* case) and on loyalty rebates (*Intel*) have confirmed that EU antitrust dances “on a different drummer” compared to the U.S. one: in particular, in Europe large companies are explicitly attributed a “special responsibility” vis à vis their market which has recently led the Court to theorize that large firms should ensure, besides the survival, also the profitability of their smaller rivals.

Third, the different antitrust economics applied in the two jurisdictions becomes even more relevant when it comes to high tech markets, and in particular on the Internet, due to the prevalence of network externalities and multi-sided platforms. Many of these settings, as a matter of fact, tend to be characterized by competition “for”, rather than “in”, the market, as firms compete in a high risk, high reward game that selects the one and only product that will spread to all or almost all consumers. The structuralist view of competition prevailing in the European Union

¹⁹ Innovation waivers have been made available by Congress in certain environmental statutes. When the Environmental Protection Agency grants such a waiver, the firm is given additional time to comply with the standard so that it may perfect a promising innovative compliance technology. Similarly, the Occupational Safety and Health Act (“OSHAct”) authorizes OSHA to grant waivers to selected firms that need additional time to perfect new and improved technologies to protect worker health or safety. The EPA’s Common Sense Initiative assembled groups of interested parties to focus on regulatory issues concerning a particular industry sector (e.g., automobile manufacturing), with the goal of developing “cleaner, cheaper, smarter” ways of reducing or preventing pollution.

²⁰ See Gerber, D. (1994), “Constitutionalizing the Economy: German Neo-liberalism, Competition Law and the ‘New’ Europe”, *American Journal of Comparative Law*, Vol. 42, pp. 25-84; and Akman, P., (2009), “Searching for the Long-Lost Soul of Article 82”, *Oxford Journal of Legal Studies*, Vol. 29, No. 2, pp. 267-303.

reverberates on the authorities' understanding of this dynamic form of competition (as a "sequence of monopolies", rather than a static situation of pluralism), despite the fact that in Europe, just as in the U.S., market power is not equated with market share, but in principle requires a finding of independence of behavior. The consequence is that the European Commission can end up defining as dominant companies that have a high chance of being fagocitated by market competitors in subsequent generations of their product, in what is an ever-changing competitive landscape.

The continental drift in antitrust, exacerbated by the peculiar economics of high tech markets, is at the roots of many differences between regulatory practice in the two legal systems, including the ones on infrastructure regulation and network neutrality. It is, also, at the origin of the U.S. relatively "hands-free" approach to both merger regulation and single-firm conduct in cyberspace, which lies in stark contrast with the EU "interventionist" approach. And while the numerous antitrust investigations against Microsoft in both jurisdictions over the past fifteen years are probably the clearest example of the existing divergence, the current European Commission's case against Google is a good example of a case dismissed by the FTC in the United States, and currently being re-proposed, with remarkable emphasis, in the European Union²¹.

These signs of divergence have been interpreted by the literature as evidence that the U.S. privileges dynamic competition and allows, where possible, also more concentrated market structures compared to the EU, which focuses more on static efficiency and a pluralist market structure when enforcing competition rules. That said, the EU's relatively stricter approach to antitrust law must also be seen in light of the weaker enforcement existing in Europe, where private antitrust damages actions and criminal sanctions for antitrust violations are, respectively, under-developed and non-existent (Renda et al. 2007). In other words, a holistic look at the effectiveness of antitrust requires that both the scope of the law and the strength and credibility of enforcement are duly taken into account: the relatively more lenient approach in the U.S., especially on single-firm conduct, could be also framed as an "equilibrating tendency" that results from awareness of the existence of a very strong litigation system²².

Finally, it is important to stress that competition policy is not limited to antitrust and not even to the regulation of network industries: most regulation can have an impact on competition, and such impacts have to be adequately taken into account when crafting legal rules. Importantly, in the United States the better regulation agenda has not explicitly contemplated the assessment of impacts on competition, which end up being considered within the cost-benefit analysis performed by federal agencies (and a number of independent agencies) when drafting Regulatory Impact Analyses in support of new regulation. However, in April 2016 a new Executive Order was adopted by the White House, which mandates that all federal agencies assess the impact of their rules on competition²³. This new Executive Order has not been accompanied, to date, by guidelines on how to assess competition impacts: such guidance, developed i.a. by the OECD and also in the EU Impact Assessment Guidelines, would promote better awareness of the possible impacts of regulatory options on levels of competition. Based on the description of the diverging competition regimes offered above, such guidance would anyway be different for the U.S compared to the EU, and possibly more oriented towards dynamic efficiency and impacts on long-term innovation incentives.

4.2 Copyright law in the age of big data

With the rise of the data-driven economy, copyright legislation is becoming increasingly important for innovation, and at the same time increasingly unfit for purpose both for what concerns its overall design, and even more importantly its enforcement. This is particularly important for ICT-enabled innovation. Renda et al. (2015) and Renda (2016b, for JRC) highlight that digital technologies make it extremely easy to combine existing content in order to develop new artistic

²¹ The new EU Commissioner for Competition Margarethe Vestager announced on April 15, 2015 that the Commission had sent a Statement of Objections to Google, arguing that the giant IT company abused its dominant position in the "general Internet search" market and also in the market for mobile operating systems, apps and services. Most importantly, Ms Vestager is accusing Google of having awarded preferential treatment to its own online comparison shopping service, to the detriment of competing services. By exploiting its very large share of the general search market, Google has thus allegedly leveraged its market power into a neighbouring market, thus foreclosing competitors from such market and thwarting competition on the merits. In April 2016 the Commission took additional action against Google for possible abuses in the field of smartphone operating systems, where Google is accused of having illegally tied the license for Android to the pre-installation of a suite of Google applications.

²² See Kovacic 2004; Calkins 1982; and Renda et al. 2007.

²³ <https://www.whitehouse.gov/the-press-office/2016/04/15/executive-order-steps-increase-competition-and-better-inform-consumers>

works and services, and that in Europe it is still uncertain whether the unauthorised scanning and digitisation of literary works which are not displayed to users but are merely used for purposes of data²⁴ and text mining²⁵ infringe copyright or not.²⁶ Considering that text and data mining entails a temporary reproduction of copyright works, as a technical necessity, the issue is whether or not such a reproduction should be regarded as transient or incidental under the mandatory exception of Article 5(1) of the InfoSoc Directive²⁷. The issue is so urgent that the UK started developing a comprehensive reform plan that resulted, in 2014, in the enactment of new copyright exceptions that included an exception covering text and data mining for non-commercial research, which was not contemplated in the list of exceptions originally included in the 2001 Information Society Directive.²⁸ UK law now allows researchers to make copies of any copyright works for the purpose of computational analysis if they already have lawful access to the copyright work, without having to obtain additional permission from the copyright-holder to make the necessary copies.

The OECD recently observed that “the potential for productivity gains in the creation of scientific knowledge are ... huge. However, questions have emerged about whether current copyright regimes are appropriately calibrated with regard to ‘automatic’ scientific knowledge creation”. The OECD quotes the JISC (2012) analysis of the value and benefits of text mining, which concluded that “the barriers limiting uptake of text mining appeared sufficiently significant to restrict seriously current and future text mining in UKFHE [UK further and higher education], irrespective of the degree of potential economic and innovation gains for society.” Copyright has been identified as one of these barriers, which has led to debates between the scientific community and the publishers of scientific journals.

Research on TDM techniques has advanced considerably in recent years. The OECD reports that the number of academic articles published on the subject of TDM since the beginning of the 1990s reveals that the United States has so far produced 46.6% of the publications dealing with TDM, followed by the United Kingdom (11.1%), Taiwan (8.8%), Canada (5.7%) and China (4.6%). The OECD argues that “Whether current copyright regimes are promoting or hindering TDM is an open question”. According to a recent JISC report on the value and benefit of text mining (JISC, 2012), licensing agreements represent a key barrier to the use of text mining techniques in the higher education and research communities in the UK. Recent OECD analysis has highlighted how the context in which IP frameworks operate has been changing substantially. In this evolving context, the way copyright laws address TDM is not always clear in all jurisdictions (OECD, 2015). According to the same report, there is some (disputed) evidence that researchers in certain jurisdictions (such as the European Union and Brazil) are inhibited from engaging in TDM due to fears of infringing copyright in the process.

One step further, the blossoming data analytics sector seems to be increasingly reliant on open source software rather than on traditional copyright protection, possibly as a consequence of the difficulties connected with the copyright regime²⁹. Many data processing and analytic tools that are now spreading across the economy as enablers of new data-driven goods and services were initially

²⁴ ‘Data mining’ is normally referred to as the extraction of implicit, previously unknown, and potentially useful information from data. Data mining is in many ways conceptually similar to ‘reading’ and ‘research’. It is a way for software to perform tasks such as reading, comparing and analysing large quantities of data in order to draw conclusions. It has become a ‘copyright suspect’ since the above-mentioned tasks are achieved through technology.

²⁵ ‘Text mining’ indicates finding structural patterns in texts, extracting information out of these patterns and combining them with data on the use of works such as data on searching and accessing works.

²⁶ On automated text processing and data mining Borghi & Karapapa point out that automated data processing can pursue commercially valuable objectives such as data analysis, sophisticated text analysis (e.g. the content of a book or the whole production of a specific author), analysis of metadata on patterns of use of digital copies (e.g. to create databases of user profiles) and computational analysis (which includes image analysis and text extraction, linguistic analysis and automatic translation and indexing and search) (Borghi & Karapapa, 2013).

²⁷ See the so-called “Hargreaves Report” to the European Commission, “Standardisation in the area of innovation and technological development, notably in the field of Text and Data Mining, at http://ec.europa.eu/research/innovation-union/pdf/TDM-report_from_the_expert_group-042014.pdf

²⁸ See UK Intellectual Property Office (2012), *Modernising Copyright: A modern, robust and flexible framework*, 20 December, p. 16. Other areas in which the document announced legislative intervention are educational uses, quotation, parody, research and private study, disabilities, preservation, public administration and reporting.

²⁹ Clark, J. (2013), *Text Mining and Scholarly Publishing*, Publishing Research Consortium; European Commission (2014), “Standardisation in the area of innovation and technological development, notably in the field of text and data mining”, Report from the Expert Group; Filippov, S. (2014), “Mapping tech and data mining in academic and research communities in Europe”, Lisbon Council, 16/2014; OECD (2015a), *Inquiries into Intellectual Property’s Economic Impact*, OECD Publishing, Paris; JISC (2012), *The Value and Benefits of Text Mining*, JISC, www.jisc.ac.uk/sites/default/files/value-text-mining.pdf.

developed by Internet firms. Apart from the already-mentioned Hadoop, a well-known example is R, a GPL-licensed open source environment for statistical analysis, which is increasingly used as an alternative to commercial packages such as SPSS and SAS. Today R is also an important part of the product portfolio of many traditional providers of commercial database and enterprise servers such as IBM, Oracle, Microsoft and SAP, which have started integrating R together with Hadoop into their product lines. The OECD report also mentions a study by Muenchen (2014), which suggests that the most popular statistics software (SPSS, SAS) is declining in popularity, while R is becoming more and more popular; and a survey by the data mining website KDnuggets (2013) confirms the trend that a large number of data analysts are using open source or free software for data analysis³⁰. More specifically, RapidAnalytics (free edition), R, Excel, Weka/Pentaho, and Python were the top five data analytics tools used in 2013. All but Excel are free or open source tools.

4.3 Data protection in the age of big data

Besides copyright, legislation on data protection is of course an essential driver of innovation incentives. Too rigid regulatory frameworks on data protection can inhibit data-driven innovation; but at the same time, insufficient protection of citizens' privacy can reduce demand for innovative, data-based solutions, and create regulatory uncertainty for entrepreneurs. Striking a dynamic, comprehensive balance between the needs of data-driven innovation and the protection of personally identifiable data is thus a challenge that all governments are facing, and the U.S. – still considered by the CJEU as providing for "inadequate protection" of individuals' privacy – provides no specific best practice in this field. Still, it is worth mentioning a number of developments, which make the U.S. potentially more open to data-driven innovation than the EU.

First, the U.S. legal system considers privacy as a property right, whereas the EU legal system holds privacy as a fundamental right (Renda 2015). Following authoritative literature, this dichotomy has been often presented as a chasm between approaching privacy as an aspect of liberty, and privacy as an aspect of dignity³¹. This, in turn, implies that agreements between private companies and end users based on the possibility to use personal data in exchange for more customized, welfare-enhancing services is in principle more possible in the U.S. than in the EU.

Second, and relatedly, the focus of US legislation on privacy mostly falls on government intrusion into the private sphere (as derived from the Fourth Amendment), whereas in the EU most legislation focuses on the use of personal data by private players. This provides for a more flexible regulatory approach to privacy in the U.S., where the Federal Trade Commission is mostly empowered to enforce legislation that affects the interplay between private parties with respect to privacy, under various statutory legislation and also based on Section 5 of the FTC Act on unfair trade practices and commercial conduct.

Third, the FTC itself has decided to adopt a case-by-case approach to enforcing privacy, which has resulted in no slowdown in enforcement, but thus at the same time created a more open regime for new business models. The trade-off to be struck, here, is very challenging: on the one hand, the EU legal system exhibits a much more comprehensive, coherent and incisive legislation on data protection, even more now that the General Data Protection Regulation has been signed into law. On the other hand, the FTC's case-by-case approach, now reinforced with new rules on email privacy (adopted in April 2016), appears more potential prone to innovative business models, provided that the FTC is able to signal consistency and regulatory quality to regulated stakeholders.

The rigidity of the EU framework has been extensively discussed in the literature. Already in the early days of discussions on the reform of EU data protection rules, Berkeley Professor Paul Schwartz (2013) observed that the new rules would significantly affect U.S. companies' daily practice of authorizing the sharing of personal information through simple "notice and consent." More specifically, Internet companies would not be able to justify processing by a party's consent if they offer take-it-or-leave-it terms for the processing of personal data or provide services for employees or other parties that lack effective bargaining power. As a consequence, Schwartz concludes that U.S. IT companies will not be able to rely on one-sided click-through agreements. The new rules are also far-reaching also in terms of jurisdiction, since the proposed Regulation

³⁰ OECD (2015), Data-Driven Innovation: Big Data for Growth and Well-Being, OECD Publishing, Paris. DOI: <http://dx.doi.org/10.1787/9789264229358-en>

³¹ See Whitman (2004), at 161, quoting Post (2001), and arguing that "Continental privacy protections are, at their core, a form of protection of a right to respect and personal dignity ...By contrast, America, in this as in so many things, is much more oriented toward values of liberty, and especially liberty against the state".

potentially subjects all cloud services to EU privacy law³². The same concerns have recently been expressed also on the new proposed German law on data retention, which would require the government to delete certain statistical data it collects about firms after 10 years: such a change is thought to potentially harm important economic research that depends on longitudinal data (Castro and MacDonnell 2016)³³.

Importantly, the U.S. have recently started a thorough re-appraisal of the balance to be struck between security, privacy and big data. Following the U.S. President's speech on reform of the National Security Agency's bulk metadata collection program under Section 215 of the USA Patriot Act, White House counsellor John Podesta announced "a comprehensive review of the way that 'big data will affect the way we live and work; the relationship between government and citizens; and how public and private sectors can spur innovation and maximize the opportunities and free flow of this information while minimizing the risks to privacy.'" This was the first major privacy initiative announced by the White House since the release of the Consumer Privacy Bill of Rights in 2012. The undertaking involved key officials across the federal government, including the President's Science Advisor and the President's Council of Advisors on Science and Technology.

On May 1, 2014, the White House released the Big Data Privacy Report. The report noted that "[b]ig data technologies will be transformative in every sphere of life" and that they raise "considerable questions about how our framework for privacy protection applies in a big data ecosystem."; but also that "data analytics have the potential to eclipse longstanding civil rights protections in how personal information is used in housing, credit, employment, health, education, and the marketplace". On the same day, the President's Council of Advisors on Science and Technology ("PCAST") released a report on the same day, entitled, "Big Data and Privacy: A Technological Perspective." PCAST wrote that "[t]he challenges to privacy arise because technologies collect so much data (e.g., from sensors in everything from phones to parking lots) and analyze them so efficiently (e.g., through data mining and other kinds of analytics) that it is possible to learn far more than most people had anticipated or can anticipate given continuing progress. These challenges are compounded by limitations on traditional technologies used to protect privacy (such as de-identification). PCAST concludes that technology alone cannot protect privacy, and policy intended to protect privacy needs to reflect what is (and is not) technologically feasible."

In February 2015, the White House released an interim progress report on its big data initiative. The administration wrote that "[p]olicy development remains actively underway on complex recommendations [from the report], including extending more privacy protections to non-U.S. persons and scaling best practices in data management across government agencies." Later during the year, in November 2015, the National Science Foundation announced four awards, totalling more than \$5 million, with the aim to establish four Big Data Regional Innovation Hubs (BD Hubs) across the nation. These will be followed by Big Data Spokes, each focused on a specific Hub priority area and addressing one or more of three selected key issues: improving access to data, automating the data lifecycle, and applying data science techniques to solve domain science problems or demonstrate societal impact.

4.4 Precaution and risk: comparing the U.S. and the EU

One of the most often quoted differences evoked in the debate the innovation-friendliness of the U.S. and EU legal systems is the alleged existence of a more precautionary approach to regulation in Europe, which would act as a constraint to innovation by inhibiting risk-loving behaviour that is typical of entrepreneurs, and shutting the door to innovative products for fear that they would cause harm. This approach has been extensively quoted in areas such as environmental standards, health and safety, chemicals, etc. One authoritative scholar, David Vogel, has concluded in a widely read book that the EU has gradually come to overtake the US in the area of risk regulation over the past three decades, mostly by bringing in a more precautionary approach to regulation. The issue of the precautionary approach is so heavily felt in Europe that a broad debate has emerged on the need to incorporate an "innovation principle" in EU policymaking.

The innovation principle was proposed in 2013 by a group of industry representations, think tanks and large companies' CEOs, and was vibrantly advocated as a necessary change in the EU policy

³² Schwartz, Paul M. (2013), EU Privacy and the Cloud: Consent and Jurisdiction under the Proposed Regulation. BNA Privacy and Security Law Report 12: 1-3.

³³ <https://www.datainnovation.org/2016/04/germanys-proposed-data-retention-law-for-government-statistics-would-harm-economic-research/>

process³⁴. Its aim is to ensure that “whenever policy or regulatory decisions are under consideration the impact on innovation as a driver for jobs and growth should be assessed and addressed”³⁵. One of the key concerns voiced by the signatories is the negative effect that increasingly risk-averse legislation is having on European innovation; that said, the innovation principle is said to be complementary to the precautionary principle. The innovation principle is also said to be open to “anyone who is interested in promoting an ‘innovation friendly’ and environmentally responsible regulatory environment in Europe”, which potentially makes it consistent with long-term decarbonization objectives, which appear to be the only responsible way to tackle environmental issues today. The innovation principle was certainly received with a degree of sympathy in some parts of the European Commission, and its proponents articulated the proposal in a more comprehensive way over the past year, as exemplified in a recent monograph³⁶. That said, the methodology behind the innovation principle is still not very detailed, whereas methodological quality would be a decisive factor for the usefulness of adding yet another test to the already quite complex ex ante impact assessment process. The current description of the innovation principle does not add much to the already existing guidance available as “Tool 18” in the European Commission guidelines on impact assessment, now part of the integrated Better Regulation Guidelines³⁷. The Council conclusions of 27 May 2016 have specifically called on the European Commission to further develop the concept, also with respect to the precautionary principle³⁸.

Against this background, it is useful to reflect on a number of open questions, which too often received standardized, not carefully pondered answers.

First, the statement according to which the EU legal system follows a more precautionary (some would say, anti-innovation) approach does not appear to be fully substantiated in practice. While Vogel (2010) and others have reported this trend based on a limited number of specific, selected cases, a ten-year-long research effort culminated in the publication of a thorough report (Wiener et al., 2011) found that reality is way more complex, and there are important cases in which U.S. regulation is way more precautionary than the EU one. Examples include the U.S. standards on particulate matter (so-called PM2.5), which are way more stringent than in Europe, and are also more strictly enforced. More generally, the authors have expanded the number and diversity of qualitative case studies to risk connected to food safety (genetically modified foods, beef hormones, mad cow disease), air pollution, climate change, nuclear power, tobacco, chemicals, marine and terrestrial biodiversity, medical safety, terrorism and precaution embodied in risk information disclosure and risk assessment systems. In addition to detailed case studies, they also presented a broad quantitative analysis of specific precaution based on a sample of 100 risks drawn from a dataset of nearly 3000 risks from the 1970s up to 2004 in both the United States and the EU. The the results suggest that the degree of precaution exhibited in European and American risk regulation is very similar: averaging across the 100 risks sample in a 35 year period, there are 36 risks that show greater US precaution and 31 risks that show greater EU precaution. In the quantitative analysis the authors find no difference between the relative levels of precaution.

Second, there is not strong evidence in the literature confirming that the precautionary principle can harm innovation. Ashford and Renda (2016) survey existing wisdom in this field and argue that in many cases, precaution coupled with adequate stringency, appropriate timing and overall quality or the legal rules is a very important stimulus for innovation, and especially of the type of innovation that more directly contribute to addressing specific societal grand challenges.

Third, the overall effect on innovation of legislation in the field of risk regulation must be appraised in a more comprehensive way, in particular accounting for the enforcement and compliance phases. Simply comparing the text of the rules makes very little sense, if one does not account for the incentives that follow: perhaps the clearest example is the existence of completely different litigation and enforcement systems in the U.S. and the EU: a rule that is apparently more flexible and lenient in terms of ex ante controls (e.g. U.S. legislation on chemicals, as opposed to REACH) might end up being more effective thanks for the threat of opt-out class-actions fuelled by lawyers paid through contingency fees, and seeking punitive damages with the help of relatively favorable access to evidence rules – of course the opposite could also occur and outcomes would have to be judged on a case by case basis. In Europe, the absence of a strong litigation system (no opt-out and in many countries not even opt-in collective litigation; no contingency fees; no punitive damages; high cost of access to evidence in court) implies that, once ex ante regulation were

³⁴ Initially 13 CEPS in 2013, then became 22. The 22 CEOs sent a letter to Juncker upon his election.

³⁵ ERF

³⁶ http://www.riskforum.eu/uploads/2/5/7/1/25710097/monograph_innovation_principle.pdf

³⁷ http://ec.europa.eu/smart-regulation/guidelines/tool_18_en.htm

³⁸ See <http://data.consilium.europa.eu/doc/document/ST-8675-2016-INIT/en/pdf>.

relaxed, very little means would remain to incentivise virtuous conduct on the side of regulated businesses.

Accordingly, it is fair to state that there is insufficient evidence in support of revisiting the precautionary approach as an obstacle to innovation. In a recent speech, Commissioner Moedas announced the introduction of the innovation principle but contended that “this does not mean that there is anything wrong with the precautionary principle. Quite the opposite. If the precautionary principle is understood correctly, it should support innovation”³⁹. The judgment must thus be made on a case-by-case basis: existing literature only confirms that it is bad regulation (including badly enforced regulation), not the precautionary approach, that can stifle innovation. Once this myth is dispelled, of course it remains to be seen if certain regulatory practices in the U.S. foster innovation more than the homologous EU ones.

4.5 Is the EU stifling innovation through regulation?

The previous sections have analyzed specific cases of horizontal policies, such as competition, data protection, intellectual property, and risk regulation, with the overall aim to reach a conclusion on the possible anti-innovation features of EU policy as opposed to the U.S. Based on the findings from these sections, the claim that the “innovation emergency” denounced in the EU is a result of specific policy choices such as the precautionary principle appears unsubstantiated. That said, there are a number of features in existing horizontal policies, which deserve careful scrutiny in the near future, as they potentially hamper the overall environment in which innovation can occur. These are listed below, and then again described in Section 3 of this report, which draws overall conclusions from this study.

First, competition rules (and all regulation that heavily depends on them) should be carefully re-appraised to match the specific economics of emerging new sectors, in which innovation is bringing into the market entirely new business models, often challenging incumbent ones. Evident cases include FinTech and the collaborative economy, which breaks barriers between sectors and leads to disruptive entry in markets such as public transportation or hotels and accommodation. Importantly, it is not the actual principles behind competition rules that are at stake: rather, it is the proxies and instruments that are used to implement those principles in practice that appear to have gone into trouble in many sectors starting with ICT and now extending into the many sectors that are being disrupted by ICT-enabled innovation.

Second, copyright law must not be exclusively focused on the right of original copyright holders, but rather on a multitude of objectives, which include the right for end users to produce user-generated content, to access as much information and data as possible, and to process these data through mining techniques and big data analytics. IN this respect, copyright law appears as fundamental as data protection law as a possible driver of data-driven innovation: as such, the reform of the EU copyright law, and in particular of the Information Society Directive, should be inspired by the need to create easy access to non-personal data in aggregated form, and to allow for analysis of longitudinal data, which can create new avenues for both research and innovative business models, let alone smarter government.

Third, data protection rules can and should be stringent to avoid the cannibalization of the personal sphere in the name of data-driven progress: at the same time, imposing too burdensome requirements on data controllers can result in an important hurdle to innovation, and can scare the most innovative entrepreneurs away. It can also hamper basic research, including citizen science. If one considers that the overwhelming majority (some say 98%) of data available for processing have been created in the past two years, then it become clear that creating the right setting for data science and innovation is a promising, and urgent, priority for all governments. Without emulating the U.S. piecemeal (or case-by-case) approach to data protection, the EU could do something to lift the burdens on smaller companies and create a more flexible setting for data protection for entrepreneurs.

Fourth, there is no solid evidence that the EU adopts a more precautionary approach to risk regulation than the U.S. From beef hormones to climate change, from automotive emissions (NOx and CO2), from nuclear power to fisheries or toy safety, cases in which the U.S. has used more precaution than the EU abound. And even where the EU has adopted a more precautionary approach, this does not automatically translate into an anti-innovation stance: to the contrary, the

³⁹ See Commissioner Moedas’ speech, “Better Regulation for Innovation”, 26 May 2016, at https://ec.europa.eu/commission/2014-2019/moedas/announcements/better-regulation-innovation_en.

stringency, appropriate timing and overall quality of regulation can only be a stimulus to innovation, as increasingly recognized also by the European Commission.

Box – Planned adaptive regulation: where Europe leads on smart regulation

There is widespread consensus among scholars that regulation in a number of fields must become more adaptive and flexible, often to remain in tune with breath-taking technological development. Nowhere is adaptive regulation more explicitly invoked than in the field of drug development and testing, where the cost of developing new drugs is increasing, and policymakers have to solve a number of trade-offs such as that between the need for a timely introduction of drugs into the market, and the need for reasonable certainty about the effects of the drug on patients. Over the past few years, several countries have experimented with prospectively planned adaptive approaches to drug licensing by using various labels, including staggered approval, managed entry, adaptive approval, and progressive authorization. Recently, a paper co-authored by several representatives of institutions and academia proposed a working definition of “adaptive licensing”, as “a prospectively planned, flexible approach to regulation of drugs and biologics. Through iterative phases of evidence gathering to reduce uncertainties followed by regulatory evaluation and license adaptation, [adaptive licensing] seeks to maximize the positive impact of new drugs on public health by balancing timely access for patients with the need to assess and to provide adequate evolving information on benefits and harms so that better-informed patient-care decisions can be made.”

Adaptive licensing seems to feature a number of very important prospective benefits in the form of earlier access to treatment, and better monitoring of risks (Eichler et al. 2015). In this field, the proactive and enlightened approach of the European Medicines Agency and its authoritative Senior Medical Officer have placed Europe in the driving seat when it comes to the development of adaptive pathways, which build upon the experience of Conditional Marketing Authorizations in the EU (and Accelerated Approvals in the US). The introduction of an observational phase between the experimental pre-licensing phase and the post-approval phase is expected to improve accuracy of approval and time-to-market for proposed treatments. In all this, data collection and sharing is absolutely of the essence, and authorities both in the U.S. and in the EU still have not defined a viable way to enable sharing of clinical trial data without compromising privacy and confidentiality of information. Possible future improvements in this respect could consist in the creation of a shared, distributed platform (of the types used by the blockchain) shared by pharmaceutical companies and coordinated by regulators, in which access to clinical data could be granted selectively to market players and not to other third parties.

Against this background, the example of adaptive licensing is not only a possible precedent for many other fields of policy (and indeed, the UK “regulatory sandbox” approach in FinTech resembles this approach); but it is also a good example of regulatory flexibility and data-driven regulatory innovation that are made possible, in Europe, by the innovation-oriented mindset of the EMA and its senior staff. A reassuring testimony that adaptive regulation is possible also in Europe; and possibly a sign that open data in the U.S. is still not a reality in many policy fields.

5 NEGOTIATED REGULATION IN THE UNITED STATES, AND ITS RELEVANCE FOR EU INNOVATION DEALS

Since the mid-1970s, many commentators in the United States have advocated the use of negotiated rulemaking as a more efficient, sensible alternative to the traditional “notice and comment” procedure typically followed by federal agencies in the development of regulations. Occasionally in the 1970s, and more often in the 1980s, EPA, OSHA, and other federal agencies used the negotiation process as an aid to the development of certain regulations. During the 1990s and the early 2000s, the U.S. Environmental Protection Agency has been very active in experimenting with flexible regulatory solutions to offer incentives for the private sector to invest in environmentally innovative solutions. The underlying idea, as summarized by Caldart and Ashford (1999; 2007), is that negotiation is more efficient than more adversarial regulatory approaches since it saves resources and allows a more effective management of incentives. This idea, which seems to come close to the underlying approach of the Dutch “Green Deals”, has however produced mixed results in the U.S., and was later superseded by different approaches to regulation.

5.1 The anatomy of "Reg neg"

In 1990, Congress formally endorsed negotiated rulemaking with the passage of the federal Negotiated Rulemaking Act, and both the Clinton Administration and the current administration have been among negotiated rulemaking's strong supporters. Those who advocate negotiated rulemaking – including Congress – tend to identify two primary benefits that are expected to flow from its use: reduced rulemaking time, and decreased litigation over the final rule. In practice, however, it is not at all clear that negotiated rulemaking delivers on either of these promises. Of all the federal agencies in the United States, EPA has used negotiated rulemaking the most often. A study by Penn's Cary Coglianese (1997) concluded that: (a) on average, the promulgation of EPA rules through negotiated rulemaking took no less time than did the promulgation of a "control" group of similar EPA rules through traditional notice and comment rulemaking; and (b) 50% of EPA's twelve finalised negotiated rulemakings were the subject of legal challenge, compared with a litigation rate of 26% for all EPA rules issued during the period from 1987 through 1991.

Caldart and Ashford (1999; 2007) observe that there are three major instances in which negotiation has been used to make or effectuate policy within the federal administrative system of the United States: (i) negotiated rulemaking, wherein negotiation is used to help set regulatory standards; (ii) *negotiated implementation*, where negotiation is used to determine how a regulatory standard, once set, is to be applied to a particular firm (or other member of the regulated community); and (iii) *negotiated compliance*, where negotiation is used to determine the terms by which regulatory standards will be enforced against a particular firm (or other regulated entity) that is out of compliance with a particular regulatory standard.

Cases of negotiated rulemaking in the early years included (Caldart and Ashford, 1999):

- The *woodstoves rule*, aimed at regulating woodstoves—one of the primary contributors of polycyclic organic matter – as "stationary sources" of air pollution under Section 111 of the Clean Air Act⁴⁰. To devise such a national emission standard, EPA convened an advisory committee consisting of representatives from industry, environmentalists, certain states, a consumer group, and the agency itself. Agreement on a single national standard was complicated, however, by the fact that there were two major categories of woodstoves on the market— those that utilised catalytic combusters and those that did not. It was clear that, at least in the short term, the stoves with catalytic combusters were capable of meeting a lower (more protective) emission standard than those without catalytic combusters. Because catalytic combusters require a higher degree of maintenance, however, there was some question as to whether they would continue to deliver this greater level of emission reduction over the long term. Rather than resolve this technical issue, the negotiating committee agreed rather early on to adopt the industry position on the matter, and to propose two standards – one for stoves with catalytic combusters and the other for those without. Thus, the opportunity to diffuse what may well be a superior emission-reduction technology throughout the woodstove industry was lost (as was an opportunity for innovation through the development of new woodstove technology).
- *The coke oven emissions rule*. In 1992, EPA estimated that some 3.5 million pounds of toxic chemicals, including benzene, phenol, toluene, and polyaromatic hydrocarbons, were emitted to the air annually from coke ovens operating in the US. Based on this estimate, EPA put the cancer risk to exposed individuals at 1 in 100. Many of the materials emitted by coke ovens are subject to regulation as hazardous air pollutants under Section 112 of the Clean Air Act, and the 1990 amendments to the Act specifically required that Section 112 standards for coke oven emissions be promulgated by December 31, 1992. In early 1992, after meeting with representatives of the steel industry, relevant labour unions, states, and environmental groups "to discuss available data to be used as the basis of [a Section 112 regulation]," EPA convened a negotiated rulemaking committee that drew from all of these constituencies. After several negotiating sessions, the committee agreed on a draft rule that was proposed by the agency in December 1992, and was published as a final rule in October 1993⁴¹. At the conclusion of the negotiated rulemaking process, participants from environmental groups, labour, industry, and state

⁴⁰ Section 111 of the Clean Air Act requires that a New Source Performance Standard (NSPS) reflect the level of emission limitation achievable through the application of the "best system of emission reduction...[that] has been adequately demonstrated."

⁴¹ In general, Section 112 of the Clean Air Act takes a two-tiered approach to the regulation of hazardous air pollutants. EPA is first to set technology-based emission standards, on an industry-category by industry-category basis. These are commonly known as the "MACT" standards, because they are to be set with reference to the application of the maximum achievable control technology that the industry category can currently achieve.

governments all expressed their satisfaction with the negotiated rule⁴². Caldart and Ashford (1999) argued that the chief contribution of *negotiation* to the rulemaking process appears to have been to afford the industry the opportunity to negotiate a standard that actually is *less* stringent than that which was mandated by Congress.

- *The wood furniture coatings rule*, another Section 112 regulation that was drafted, in large part, through negotiated rulemaking. After a series of public meetings with representatives from industry, environmental groups, and state government in late 1992 and early 1993, EPA convened a negotiated rulemaking committee to attempt to formulate a rule governing wood furniture (surface coatings) nation-wide. The final rule - virtually unchanged from the proposed rule - was promulgated on December 7, 1995, although portions of the rule were challenged in court by the chemical industry. Based on the committee's work, EPA determined that wood furniture manufacturers performed four basic operations in producing a finished product - finishing, gluing, cleaning and washoff - and the proposed rule contained standards for each. All but the gluing operation standards were drafted by the committee. The standards for the gluing operations were developed "outside of the regulatory negotiation process, because adhesive suppliers were not represented on the Committee." The wood furniture rule might well be viewed as a compromise of the stringency of emission levels in exchange for a clear focus on pollution prevention (as opposed to simply "end-of-pipe" emission control). Concerns were expressed as, despite a number of technical concerns, EPA simply accepted the proposed rule as written by the negotiated rulemaking committee (Caldart and Ashford 1999). Nonetheless, it does appear that the use of negotiated rulemaking facilitated the agency's focus on pollution prevention in the development of the rule. It seems likely that the active participation of industry representatives (who are in the best position to identify productive opportunities for pollution prevention) helped to both deepen and legitimise the committee's efforts to build pollution prevention into the rule. Moreover, the committee negotiations produced an agreement, *outside of the parameters of the rule*, under which the industry will prepare a semi-annual "trends report," beginning in 1994, which is to contain "a brief discussion of technologies being used by the industry to reduce emissions, and a discussion of evolving technologies including new finishing materials, adhesives, and improved application equipment." This agreement reflects the belief - apparently shared by many committee members - that "new, lower emitting (both VOC [volatile organic compounds] and HAP) technologies...- are...on the threshold of demonstration." In addition, to help determine whether the rule actually results in the targeted reductions in hazardous air pollutant emissions, and to determine whether those emission reductions are being met through the substitution of other hazardous chemicals that are *not* regulated as hazardous air pollutants, the trends report is to include a chemical use and emission survey from a representative sample of the industry.

Caldart and Ashford (1999) provide a comparison table of these three negotiated regulations, shown below, and argue that:

- The woodstoves rulemaking did not seek to push the envelope of woodstove technology, and focused instead on the diffusion of existing control technology: the mixed rating stems from the fact that it set a different emission standard for each of the two types of woodstove technology on the market, rather than seeking to devise a standard that would diffuse the superior technology throughout the industry. This resulted in short-term environmental gain, but did not create a strong, consistent signal designed to encourage the kind of innovation in woodstove technology that might produce greater environmental gain in the long-term.
- Similarly, the coke oven rule focused on the use of readily-available control techniques to improve the performance of the dominant existing (byproduct recovery) technology, and has resulted in short-term environmental gain. Further, by setting a standard for new facilities that is not tied to the performance of the cleaner existing technology, and by setting a 2010 standard for existing facilities that many firms were meeting easily in 1993, the negotiated rule provides clear incentives for keeping the dirtier technology in operation longer, thus actually reducing long-term environmental gain.

⁴² Eight years later, the agency is to set a more stringent, health-based standard if further emission reductions are deemed necessary to provide "an ample margin of safety to protect public health." A health-based standard for carcinogens *must* be set if the technology-based standard fails to "reduce lifetime excess cancer risks to the individual most exposed to [the] emissions...to less than one in one million." For coke oven emissions in particular, however, Section 112 offers an alternative whereby a source may delay compliance with the health-based standard until 2020 if it meets a different, more stringent technology-based standard in the interim. The committee followed this framework in drafting its proposed rule, and steel industry representatives said afterwards that, because they viewed any likely health-based standard as "essentially a shut-down standard," they expected all plants except those that planned to go out of business in the near future to choose this "extended compliance" option.

- The wood furniture coatings rule, in contrast, had both a focus on pollution prevention - denoted as "+(PP)" - and a focus on innovation. It can thus be expected to diffuse existing pollution prevention technologies and, especially given industry's agreement to prepare the semi-annual trends report, has a real potential to produce innovation (and, concomitantly, to produce long-term environmental gain).

Table 1. Technological and environmental impact of three negotiated air emission standards

	Diffusion	Innovation	Short-term environment gain	Long-term environment gain
Woodstoves	+/-	-	+	-
Coke ovens	+/-	-	+	-
Wood furniture	+(PP)	+(PP)	+	+

Source: Caldart and Ashford (1999)

5.2 Negotiated implementation

A different type of negotiated rulemaking is so-called "negotiated implementation". Cases in point are the so-called "innovation waivers" and EPA's *Project XL* initiative. More specifically:

- Various US environmental statutes have had provisions allowing EPA to issue *innovation waivers* to qualifying firms, thus allowing them additional time to develop innovative approaches to compliance. The Clean Air Act and Clean Water Act both contain provisions authorising EPA to grant innovation waivers in certain circumstances. Under these provisions, EPA is authorised to extend the deadline by which a firm must meet emission or effluent limitations, so long as the agency is persuaded that the firm is actively pursuing an innovative approach to compliance that shows real promise of coming to fruition. Innovation waivers are meant to focus squarely on the innovation of new technology, and are not designed to promote diffusion of an existing technology. Basically, the innovation waiver exempts the firm from such penalties during a designated trial period, and offers it the prospect of the cost savings that may be derived from the development of a superior technology. Although it may be unrealistic to expect EPA to use innovation waivers to promote radical process innovation, because of the long time generally needed to develop the innovation, the agency might well use such waivers to encourage both incremental process innovation and the acceleration of radical innovation already underway.
- A similar approach was adopted by EPA through the Excellence in Leadership Project, popularly known as *Project XL*. The Clinton White House announced this program, with considerable fanfare, in a 1995 policy statement, and EPA published a set of guidelines for approving Project XL proposals in 1996. The basic idea of Project XL was to allow regulatory flexibility, in return for superior environmental performance, at selected facilities, on a facility-by-facility basis. As conceived, the cornerstone on which Project XL was to rest is negotiation among the regulators, the facility owners, and the affected community, resulting in a Final Project Agreement ("FPA") governing environmental performance at the facility. The underlying rationale for Project XL was the belief that, for appropriately selected (new and existing) facilities, such negotiations could produce a plan for limiting pollutant discharge from the facility that will both cost *less*, and reduce environmental and public health risks *more*, than would have been the case under existing regulations⁴³. The program was far from a clear success, and no new applications were taken after January 2003. Few FPAs have been negotiated, and some of those that have are the subject of considerable debate and opposition. A fundamental problem with Project XL was that it envisioned a kind of regulatory flexibility

⁴³ Negotiation between the agency and the facility owner (sometimes also involving environmental groups and/or local community groups) is commonplace in the permitting process. Project XL negotiations were different, however, in that they purported to *replace* current standards with an alternative approach, while traditional permit negotiations generally are over the proper way to *apply* current standards to the facility in question. Thus, XL purported to be the negotiation of environmental *policy*, albeit on a facility-by-facility basis.

that has not been authorised by Congress; in addition XL fell short of defining the relevant "community" and its composition, and thus to trigger a real multi-stakeholder process⁴⁴.

5.3 Negotiated compliance

A third approach to regulatory flexibility was *negotiated compliance*, where negotiation was used to determine the terms by which regulatory standards was enforced against a particular firm (or other regulated entity) that was out of compliance with a particular regulatory standard. By its nature, of course, almost all enforcement involves some amount of negotiation between the enforcing agency (or, in the case of citizen enforcement suits, the enforcing citizen) and the alleged violator. Of interest here are those compliance negotiations that result in compliance through the use of innovative technology, and/or environmental gains *beyond* compliance. Since the early 1990's, EPA has pioneered the use of what it terms "Supplemental Environmental Projects" in an attempt to meet these goals within the compliance context. The key to the SEP policy is the trade-off between penalties and SEPs. The EPA 2015 Updated SEP Policy revises and supersedes the February 1991 Policy on the Use of SEPs in EPA Settlements, the May 1995 Interim Revised SEP Policy, and the May 1998 EPA SEP Policy. It also reflects and incorporates by reference all the policy and guidance documents listed on this site (which may contain more detailed discussions of certain issues). Where there may be inconsistencies between these documents and the Update, the Update shall supersede the memoranda and guidance documents.

5.4 Regulatory reinvention

Finally, a fourth type of policy-relevant negotiation – *regulatory reinvention* – was launched during the Clinton administration, and continues today in evolving forms. The most prominent early example was EPA's *Common Sense Initiative* (CSI), wherein the agency assembled groups of interested parties to focus on regulatory issues concerning a particular industry sector (e.g., automobile manufacturing), with an eye toward developing "cleaner, cheaper, smarter" ways of reducing or preventing pollution. Started in July 1994, the CSI was perhaps the most similar scheme to the "green deals" applied in the Netherlands. As a matter of fact, contrary to the Project XL this scheme had an industry-wide focus, and was governed with the help of six advisory committees, one for each of six industrial sectors: automobile manufacturing, computers and electronics, iron and steel, metal finishing, petroleum refining, and printing. Each advisory committee consisted of representatives from EPA, the relevant industry sector, state and local regulatory agencies, national and local environmental groups, labour, and community organisations. The work of these committees was overseen by a separate Council, the membership of which was drawn from the same sources. The Council was chaired by the EPA Administrator, and each of the six sector committees was chaired by an EPA official. The work of the Council and the committees was assisted by EPA staff.

In December 1998, arguing that the CSI approach had been proven a success, EPA announced that CSI itself would be phased out, but that the lessons learned from the initiative would be expanded to other industry segments in a future action plan. However, as reported by Caldart and Ashford (1999), the results of the CSI experiment were mixed. While the initiative brought together six groups of people representing a diverse set of interests, and encouraged an ongoing dialogue on issues that are important to the future development of environmental policy, CSI has been criticised for its lack of substantive results. A series of reviews of CSI have raised this issue, including a 1997 report issued by the U.S. Government Accountability Office⁴⁵. The most important problems experienced were:

⁴⁴ Probably the best-known Project XL agreement to date, for example, pertains to Intel Corporation's newest semiconductor production site in Chandler, Arizona. The five-year project agreement, which covered operations at a 720-acre site, was negotiated among the company, federal and state regulators, and five Chandler residents. Although the participants apparently were satisfied with the FPA negotiated through this process, many non-participants were not. Two vociferous critics were the Silicon Valley Toxics Coalition, a California-based group that addresses pollution problems in the semiconductor industry, and the Natural Resources Defense Council, a national environmental group. These two groups, who were concerned about the national and industry-wide implications of this agreement as much as, if not more than, its local environmental impacts, mounted a high-profile campaign against the Intel agreement, and against Project XL itself. This level of opposition clearly indicates that the negotiating committee that devised the regulatory plan for the Intel facility was *not* representative of the "relevant" community.

⁴⁵ <http://www.gao.gov/products/RCED-97-155>

- *Slow progress in negotiations and results.* The reasons for CSI's slow pace, GAO found, were multifold: the time necessary to collect and analyse data; the variations in the participants' understanding of the technical issues involved; the time taken by the participants "in reaching consensus on the approaches needed to address large, complex issues or policies;" the time taken by participants "discussing how they would carry out their work and developing their own operating standards;" and the difficulties experienced by some participants in making the necessary time commitment. None of this should be particularly surprising. Indeed, when one adds to this list the overall need to establish a degree of trust among the participants in each sector group sufficient to permit a meaningful discussion on substantive issues, it is not particularly difficult to understand why substantive progress was slow in coming.
- *No formal legal context.* Contrary to cases of negotiated rulemaking (see above), the CSI was lacking a formal legal context and a legal backstop. Moreover, it proved difficult to reconcile the industry's interest in cutting red tape and reducing compliance costs with the environmental groups' interest in high levels of environmental protection. Thus, it should not be surprising that the petroleum and automobile industries decided to abandon their participation in the CSI Initiative. Effective participation in negotiations of this nature takes a considerable commitment of resources. As noted by the American Petroleum Institute in a letter to EPA explaining the withdrawal of its member companies from the CSI negotiations, the companies "believe the refining industry's resources...can be more productively directed toward other approaches."
- *Information asymmetries and lack of trust.* Another problem was informational asymmetries, fuelled by the participants' unequal access to relevant data. If effective strategies to encourage pollution prevention are to be crafted by consensus, reliable technical information - especially information relating to the technological potential for pollution prevention - is likely to be important. Much of the relevant data, of course, will be in the hands of industry. Without a clear incentive to make these data available to the other participants, industry is likely to prefer to pick and choose what it will share, thus making meaningful negotiations all the more difficult. This reportedly has been a major issue, for example, in the computer and electronics work group. Firms reportedly have been reluctant to divulge information because "they feared that regulators would use data to extract further concessions," and because they believed that environmental groups would "use any information divulged during CSI meetings to mount lawsuits." This, in turn, contributed to a sense of mistrust among the environmental group participants.
- *Lack of focus on pollution prevention.* The bulk of the CSI negotiations reportedly did *not* focus on pollution prevention strategies, let alone innovation, thus falling well below EPA's original expectations.

5.5 The Performance Track initiative: rise and fall

In 1999, two years after the GAO report, EPA issued a report by an independent contractor evaluating some 40 CSI projects (Bruninga, 1999). The report concluded that, although there had been a small number of sector-specific modifications, EPA had made little progress in addressing broad regulatory changes through CSI, and CSI successes were not being integrated into core EPA programs. The program was later replaced by the Bush Administration's *National Environmental Performance Track* program, which focused on creating partnerships with individual firms in which the firms agree to exceed regulatory requirements, implement environmental management systems, work closely with their communities, and set three-year goals to continuously improve their environmental performance, in exchange for reduced priority status for inspections, reduced regulatory, administrative, and reporting requirements and positive public recognition. In a recent paper, Coglianesi and Nash (2014) argued that the results of the Performance Track program were also disappointing: for example, although 500 industrial facilities participated in Performance Track at any given time, they note that this number represents a tiny fraction of facilities potentially eligible to apply.

Overall, the key problems with negotiated compliance programs at EPA were *low participation, loose governance and the lack of dramatic environmental progress*. Low participation was attributed to insufficient inducements to encourage industry participation and disincentives that cause firms to consider participation undesirable⁴⁶. Loose governance ended up resulting in lack of

⁴⁶ For example, EPA's notoriously underperforming Climate Wise program has been strongly criticized for relatively weak participation incentives.

real monitoring of compliance, especially in Performance Track⁴⁷. In addition, scholars like Lyon and Maxwell asserted that public voluntary programs “are generally weak tools adopted when the political will to take stronger action is missing”; in other words, voluntary programs were utilized specifically because the agency lacked statutory authority to regulate more stringently, and also due to Congressional stalemate in addressing environmental policy.

A final addition to this list of problems, not fully identified in the literature, is the likelihood that the public, voluntary nature of these programs led to some degree of adverse selection: in other words, rather than the firms willing to lead on environmental performance, the firms willing to “greenwash” would be the perfect candidate for the Performance Track. For example, Coglianese and Nash (2014) report that “while Performance Track members are not necessarily the strongest environmental performers, they appear to have been generally strongest in their desire for public recognition”.

5.6 Consequences of the U.S. experience for the “innovation deals” in Europe

In its Staff Working Document on “Better Regulation for Innovation-driven Investment”, the European Commission announces that it will pilot so-call “innovation deals”. More recently, a more detailed explanation of the Innovation Deals was provided by the Commission along with a first call for participation, which will lead to the selection of up to five deals⁴⁸. The Commission has clarified that these deals would be a new way to address EU regulatory obstacles to innovation in an open and transparent manner, in the form of a voluntary cooperation between innovators, national/regional/local authorities and Commission services to better achieve EU policy objectives. In addition, Innovation Deals are being piloted as one of the actions under the Circular Economy Action Plan and in the pilot phase will operate only in the area of the Circular Economy. An important feature of Innovation Deals is that they seem to be destined to specific cases in which legislation must be clarified, or interpreted, not amended. They are, in this respect, presented as a “bottom-up” tool for addressing cases in which legislation is difficult to interpret for new players, but never as a way to change EU or national law. That said, of course, in case the evidence gathered reinforces the view that a regulatory or legislative obstacle acts as a barrier to innovation, the Commission services may consider launching further evaluation, consultation and assessment of the impact of this regulatory obstacle, thus complementing and feeding into the REFIT programme.

Based on the U.S. experience described in the previous section, there are important concerns on the suitability of innovation deals as a stand-alone tool that could foster systemic innovation and promote progress. First, is it important to avoid that *Innovation Deals are inspired by a desire to reduce regulation, rather than to improve it*. As already mentioned above, regulation often has a positive impact on innovation, and certainly a clearer regulation, other things being equal, is better than an obscure one. But this does not mean that less regulation should be the objective in innovation deals. So far, the Commission seems to have confined Innovation Deals to cases in which there are “perceived” regulatory and legislative obstacles to specific types of innovation, and the Commission can work in the direction of clarifying the regulatory framework and its application to avoid chilling effects generated by regulatory uncertainty. But only the first pilots will clarify if requests coming from stakeholders will aim at mere clarification of the application of EU legislation, or will take the form of simplification requests.

Second, *the likely nature of innovation deals make them ill-suited for more disruptive, systemic innovation*. As a matter of fact, due to their negotiated nature innovation deals can suffer from an “incumbency” problem, and as such would lend themselves more easily to incremental innovation, rather than substantial market reshuffling.

⁴⁷ See Coglianese and Nash, 2014. In January 2006, the non-profit advocacy group Environmental Integrity Project (“EIP”) joined with about thirty local and regional environmental organizations to support Walke’s letter. EIP argued further that some Performance Track members were delivering less than top performance — noting that fourteen members “appear to have violated one or more federal environmental laws” at least six times in the previous twelve quarters. EIP also issued a briefing paper that argued that “some of the manufacturers reaping Performance Track rewards are releasing more toxic pollution to the environment than they were before signing up for the program.”²⁵⁸ EIP questioned the wisdom of relaxing inspections and reporting requirements for facilities that were increasing their pollution levels.²⁵⁹ At about the same time, EPA’s Office of Inspector General (“IG”) opened an investigation into Performance Track and, in a report issued in 2007, reached conclusions similar to those expressed by the environmental groups.

⁴⁸ See <https://ec.europa.eu/research/innovation-deals/index.cfm>; and

Third, and relatedly, *the governance of Innovation Deals should be clarified in a number of aspects*. How will Innovation Deals be selected, where would the applications originate (REFIT stakeholder platform), whether there would be multi-stakeholder advisory boards to avoid incumbency problems, whether the Regulatory Scrutiny Board would advise on their implementation and compatibility with existing regulatory frameworks; how would trust be built and nurtured, and what arrangements will be in place to sufficiently avoid adverse selection problems (offering an easy way out to firms that cannot comply with legislation for reasons related to their own inadequacies). In addition, there are important question marks on how to offer legal certainty (guidelines on selection, due process, time horizon, monitoring of compliance, evaluation); how to ensure technology neutrality and avoid the incumbency problem; and how to deal with multi-level governance, especially for what concerns the powers of the European Commission to request clarifications in national and local legislation. Since it seems clear that it will be Member State authorities that will have to report on their implementation and results, it is still unclear how Innovation Deals are going to work, in a context in which communication between the EU and national level is not always effective and rapid. The involvement of all levels of government should also be accompanied by the involvement of all relevant stakeholders. And also, a weak rule of law in specific Member States should be taken into account.

Overall, *it is important to offer more certainty as regards the scope of the instrument*. If the Innovation Deals are only related to possible “clarification, enhanced guidance, existing flexibility and/or demonstration of the innovative solution” (see the SWD of 15 December 2015), then it is also important to clarify that their use is not going to be a “magic bullet” solution that will bring Europe back to growth, let alone sustainable development. If anything, it would mark an enhanced attention to possible obstacles to innovation disseminated throughout the “downstream” phase of EU legislation, i.e. the delivery and enforcement phases. The reasonable expectation is that most of these obstacles will be found in national legislation, or at least in national practices in the implementation and enforcement of EU rules: that said, it is not clear whether the Commission’s attempt to clarify or streamline national enforcement practices would be well received by Member States, or if it will be seen as a wild card for the Commission, which will lead it to go *ultra vires* and bypass other EU institutions to recommend and *de facto* impose regulatory changes on lower levels of government.

6 MAIN FINDINGS AND POLICY IMPLICATIONS FOR THE EUROPEAN UNION

There is a lot that Europe can and should learn from the U.S. experience described above, particularly in the field of introducing pro-innovation governance arrangements in individual administrations, in regulating for innovation, and in the domain of flexible approaches to regulation. The main findings can be summarised as follows:

- The new strategy for American innovation contains very interesting new initiatives such as the creation of smart, mission-led innovation agencies (e.g. ARPA-E), the launch of innovation labs and toolkits as well as digital service teams inside agencies, and more generally all efforts to mainstream innovation in all administrations through a “whole of government” approach, functional i.a. to open government and open innovation.
- While the better regulation agenda *per se* does not provide very useful suggestions for the EU, pro-innovation stances are to be found in horizontal policies, as well as in dedicated approaches adopted by individual Federal agencies such as the FTC, and in horizontal policies such as competition policy.
- On the contrary, there is no strong evidence that confirms that European innovation is being hampered by the precautionary principle. Solid research demonstrated that in many policy fields the U.S. has adopted a more precautionary approach than the EU. Accordingly, there is no strong argument in favour of replacing the precautionary principle with a more risk-oriented approach to regulation. This finding is further consolidated by the observation of the different balance struck by the two legal systems between *ex ante* risk regulation and *ex post* control exerted by the litigation system (in particular, tort litigation). Of course, this does not mean that the EU regulatory system cannot be made more innovation-friendly: impacts on innovation could be more adequately taken into account in the *ex-ante* and *ex post* evaluation of policies, and, albeit at the margin, through clarification instruments such as innovation deals.
- The experience of the U.S. with “Reg Neg” allows to draw a general lesson: the idea of consensus-based regulation and the practice of negotiated rulemaking and other forms of co-regulation present the risk of embedding incumbency interests into the overall regulatory scheme, tilting its balance against new entrants and smaller players. For example, even scholars that have largely praised Reg Neg for its results (Freeman and Langbein 2000) have noted “the disproportionate costs it imposes on smaller groups with comparatively fewer

resources”, and reported that “whether or not to participate in a reg neg proved a more difficult decision for environmental organizations and other similar groups than for larger parties like big business or state government regulators. Smaller, poorer groups also reported suffering from resource deficits as compared to their larger, richer negotiating partners”.

- The risk of embedding an incumbency bias into regulatory schemes is a serious one, which deserves adequate mitigation strategies.
 - First, the European Commission should seek adequate multi-stakeholder representation in all groups that will be formed to address problems raised by regulated entities invoking an innovation deal. Should the request be purely referred to the need for clarification, the overall impact on the market (but then, also on innovation) is expected to be minimal; but when stakeholders request important changes in implementing measures, the impact of such changes on all stakeholders should be adequately gauged.
 - Second, the European Commission should always ensure that management-based regulation and forms of co-regulation are accompanied by adequate monitoring and enforcement, in order to avoid being captured by information reported by incumbent players.
 - Third, when collecting data and information on possible strategic, systemic changes in policy, the Commission should avoid focusing only on costs, and asking only incumbent players whether there is a need for reform (as currently occurs at least in cumulative cost assessments).

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Regulation has for a long time been considered mainly as an obstacle to innovation, especially with respect to rules that create so-called “red tape”, or administrative burdens. But academics have demonstrated that regulation can greatly facilitate innovation, by creating markets for existing ideas and stimulating entrepreneurship and inventions that contribute to social welfare. This paper looks at the US experience with pro-innovation regulatory approaches, and finds it to be a useful reference for the EU, particularly for what concerns pro-innovation governance arrangements in individual administrations, and in the shaping of innovation-friendly regulation, including through adaptive, flexible regulatory approaches. The new strategy for American innovation, released in October 2015, contains very interesting initiatives such as the creation of smart, mission-led innovation agencies; the launch of innovation labs and toolkits as well as digital service teams inside agencies; and efforts to mainstream innovation in all administrations through a “whole of government” approach. Importantly, an analysis of the US experience suggests that consensus-based regulation and negotiated rulemaking can present the risk of embedding incumbency interests into the overall regulatory scheme, tilting its balance against new entrants and smaller players. This risk deserves adequate mitigation strategies, and should be taken into account when introducing new features such as the “innovation Principle” and “innovation deals” in the EU policymaking process.

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