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Regulation and Innovation in the European Union:

The European Commission and the Council in the early stages of the policy process

Mauro Bussani, Giacinto della Cananea, Claudio M. Radaelli, and Gaia Taffoni THE COMMON CORE OF ADMINISTRATIVE LAWS IN EUROPE WORKING PAPERS SERIES – ISSUE N. 01/2021

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Regulation and Innovation in the European Union:

The European Commission and the Council in the early stages of the policy process

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Abstract

Innovation permeates the regulatory policy vision of European Union in the framework of the so-called 'better regulation' agenda. Even though both the Council and the Commission recognize the nexus between regulation and innovation, they seem to have different strategies. For the Commission, the need to steer innovation towards certain objectives justifies the introduction of new regulations. For the Council, new regulations should be appraised in terms of their likely impact on innovation. Empirically, we will test whether there are two different approaches by examining evidence from the Conclusions of the Competitiveness Council, think tanks reports on the innovation principle, and the text of the Commission's regulatory proposals, including impact assessments (IAs), in the field of the Digital agenda of the EU. We find that the Commission is more interested in harnessing innovation towards goals such as 'socially responsible innovation. The findings contribute to the literature on EU regulation and innovation, showing how behind a common agenda for digital innovation the institutions of the EU have different approaches.

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1. Motivation

With the post-pandemic plans for the recovery and resiliency, the European Union (EU) is revising the breadth and scope of its policies for innovation. The time may have come for a bold paradigmatic change based on the ecological transition, the governance of digital markets, and sustainable competitiveness. Innovation is a key to this ambitious vision (European Commission, 2019a; 2019b). Innovation is in a sense a cause of the desired effect; that is, to achieve the goals of recovery, transition and resiliency the EU needs innovation. But one can also reason that the EU wants a certain type of growth. Indeed, the Commission's Communication on better regulation of April 2021 grounds the future of EU regulation in the sustainable development goals (European Commission, 2021). In this sense, not only is innovation needed to prevent environmental degradation (mindful of the classic argument presented by Stewart, 1981), but sustainable and socially inclusive innovation is the effect of having embraced a certain vision of growth and sustainability.

Because of un-determined character of innovation, its relationship with regulation is a field of research where, at least conceptually, different options exist – a continuum from innovation as foundation of regulatory choice to regulation as key instrument to harness innovation. Empirically, the early stages of the policy process of the EU offer a laboratory where the Member States sitting in the Council and the Commission make their choices in framing new regulatory proposals in one point on the continuum. The Commission has the Treaty right to initiate legislation. But, as we will observe, the Competitiveness Council has invited the Commission to frame innovation in specific ways.

The question that then arises whether the Commission and the Council are on the same page when they talk about the central place of innovation in the EU paradigmatic change. Although there is wide and generalized consensus across the Member States and the services of the Commission about the policy change of the post-pandemic resiliency and growth, its contours may hide ideational ambiguity and different ways to frame innovation in the context of regulatory choices. Sustainable competitiveness and socially responsible innovation are labels that, *per se*, do not identify who makes the judgement call on this or that innovation (to decide which one is socially responsible, and which one is not, for example) and on the basis of what kind of regulatory or policy foundation and/or evidence.

Ultimately, the choice boils down on what the EU institutions do in practice, how they motivate their regulatory choices, what they say in the preparatory documents. At this stage in the policy process (this working paper was finalized in November 2021), only an empirical lens can tell us if innovation is considered a process or outcome that must be harnessed, controlled, and regulated – so that it brings the attributes ("social", "ecological" and so on) the EU is looking for. To illustrate: by observing the early stages of the publication of the Commission's impact assessments supporting proposals for new regulations, we can see whether innovation itself is de-facto a foundation of regulatory choice – meaning that proposed regulations are appraised fundamentally on the basis of their contribution to innovation.

The reference to impact assessments also reminds us of the so-called better regulation agenda of the Commission (European Commission, 2021) where some high-level principles are framed and illustrated. Better regulation is part of the context we examine here, including the Regulatory Scrutiny Board (RSB) – a regulatory oversight institution that provides opinions on the impact assessments¹. At the moment of finalizing the empirical research for our contribution, there was no sufficient empirical material about the discussion of recent regulatory proposals affecting innovation in the European Parliament. This is, therefore, an aspect which will have to be further considered.

Meanwhile, our analysis focuses on how the relationship between regulation and innovation is considered by the Commission and the Council. Does the Council, acting as principal, determines the standards of appraisal to the agent, that is the Commission, or can the Commission operate with significative degrees of discretion? Without necessarily embracing principal-agent thinking (see Delreux and Adriansen, 2017 on the EU), the choices made by the Commission in response to the invitations of the Competitiveness Council may reveal that, behind the consensus on the ecological-sustainable-resilient paradigm for growth and a new trajectory for EU integration, there may be conflicts on who (Member States or the Commission) decides on the exact EU policy trajectory.

Moreover, the rise of innovation on the EU agenda takes us into the territory of the precautionary principle. Established by the Treaties, the precautionary principle is a basic pillar of regulatory choice under conditions of radical uncertainty. If innovation becomes prominent on the agenda of the EU, and even more so if it becomes a foundation of regulatory choice, its relationship with precaution must be carefully appraised, and, if necessary, re-evaluated.

On these premises, we proceed as follows. Section 2 briefly mentions the role of ideas in public policy clarifying the policy concept of innovation (Cino-Pagliarello, 2021, Kamkhaji and Radaelli, 2021). Section 3 presents some approaches to innovation. It provides a review of the literature on the different meanings and concepts of

¹ In 2015, with the renewed Better Regulation Agenda, the Commission established the Regulatory Scrutiny Board (RSB). The RSB is an independent body within the Commission that provides quality control on impact assessments and evaluations. The RSB's opinions can be 'positive', 'positive with reservations' or 'negative'. Moreover, since the beginning of 2020 the Commission reinforced the RSB mandate including the link to the EU strategic foresight. The RSB is composed of seven members: three external experts, three high-level Commission officials and a chair that belongs to the Commission Director-General. <u>https://ec.europa.eu/info/law/law-making-process/regulatory-scrutiny-board_en.</u>

innovation. Section 4 explores regulation models, focusing on their variety and their relationship with the notion(s) of innovation. Section 5 considers the precautionary and innovation principles as two possible foundations of regulatory choice. This section also addresses the question whether innovation is embraced differently by the Council and the Commission, with Section 6 following on in empirical mode – to show how the Commission is placed toward innovation. The two positions (Council and Commission) are not necessarily incompatible, since one can steer innovation without harming it. But they are different in terms of framing the foundation of regulatory choice. The conclusion wraps up the main arguments and findings of the paper and suggests the ways forward to expand the knowledge on innovation and EU regulation, contributing to the literature on regulation in the EU and to the literature on the relationship between Council and Commission.

2. Framing concepts in public policy

Public policies are defined by their meanings as well as by their substantive content (Cino-Pagliarello, 2021; for a review see Kamkhaji and Radaelli, 2021). Complex organizations like the EU often are characterized by internal conflict on both levels. For example, the Council and the Commission may have different opinions about the content of a policy. At the same time, these two actors may also seek to frame or define policy concepts in different ways. The tensions and conflicts over the framing of policy concepts reflect different goals about who should be in control of a given initiative. The so-called polysemy of EU public policies (Cino-Pagliarello, 2021) indicates that there often exists a certain degree of ambiguity behind the surface of consensus for a long-term goal (such as 'growth' or 'ecological transition').

In turn, this ambiguity is not fortuitous. Rather, it is the manifestation that there is a territory where actors compete for defining a given problem or solution in this or that way – and, by doing so, ideas about policy design impact in major ways on the stakeholders (Ingram and Schneider, 1993). As is well known, policy ideas do not fluctuate in vacuum, but are articulated and sponsored by actors with their distinctive interests (Kamkhaji and Radaelli, 2021). When looking at the role of ideas, we ought to be mindful of the actors that push them, and their interests – Kamkhaji and Radaelli (2021) refer to this as micro-foundation of ideational analysis.

Since meanings and definitions of public policy are not made of thin air, we will connect the contested meanings of innovation to an ever-ending tension in the process of European integration, that is, who (Member States or supra-national institutions) is in control of the trajectory of the EU. We also need to consider the broader legal context in which the meaning of innovation is handled in the EU. For this reason, we will cover the Treaty-based precautionary principle and show its relationship with innovation. But, before we explore that, some preliminary questions must be considered: what does the concept of innovation include? Which attributes of innovation may give rise to political conflict over problem definition? Similarly, what is potentially ambiguous and polysemic in regulation, and what implications can this ambiguity have on actors involved in the regulatory craft?

3. Different meanings of innovation

Innovation can be regarded as being the process of generating creative ideas and implementing them in useful new products, processes, and procedures (see Amabile and Fisher, 2015; Barak and Usher, 2019; Bilton, 2015). Yet, a review of the definitions of innovation used across disciplines reveal different perspectives and interpretations, bearing different emphases on its components (Amabile et al. 1996; OECD, 2016; Rogers, 2003; Schumpeter, 1934).

Some perspectives can be briefly delineated. A first perspective stresses that innovation is 'something that has been changed': in this sense, "innovation is taking what exists, adding value and exploiting that either commercially, politically, socially, or artistically" (Smith, 1999; from the same perspective see also Kanter, 1983; Lindfors and Hilmola, 2016; Miron-Spektor, Herez and Naveh, 2011). The emphasis is thus placed upon the dimension of substantive change. Another perspective is more procedural. It underlines that innovation "is the process of making changes, large and small, radical and incremental, to products, processes, and services that results in the introduction of something new for the organization that adds value to customers and contributes to the knowledge store of the organization" (O'Sullivan and Dooley, 2009).

Needless to say, since the status quo is generally resistant to major shifts in policy, it is important to understand how change can be achieved. This is why a third perspective starts from the assumption that the pre-existing equilibrium between interests can be problematic. It thus focuses on the 'problem-solving' nature of innovation, pointing to it as a "complex activity which proceeds from the conceptualization of a new idea to a solution of the problem and then to the actual utilization of economic or social value" (Myers and Marquis, 1969:1; see also the definitions offered by Kanter, 1983; Lindfors and Hilmola, 2016; Miron-Spektor et al. 2011). Further, the combination of process and outcome as basic components of the definition is highlighted by those who see innovation as the "production or adoption, assimilation, and exploitation of a value-added novelty in economic and social spheres; renewal and enlargement of products, services, and markets; development of new methods of production; and establishment of new management systems. It is both a process and an outcome" (Crossan and Apaydin, 2010; but see also Rogers, 2003).

Innovation has been studied extensively, and many different definitions of innovation exist. For example, Baregheh, Rowley and Sambrook, 2009, scrutinized 60 definitions of innovation over time and across disciplines, but mostly in the field of business, and identified key recurring attributes: nature of innovation, type of innovation, stages of innovation, social context, aim of innovation, and mean of innovation. What is still lacking is a critical mass of multidisciplinary analysis of what is defined by innovation.

An effort in this direction has been made by Morad, Ragonis and Barak (2021). According to them, the definition issue can be approached from the process and the level of innovation perspectives. Innovation processes concern the generation of innovation and the adoption of innovation. The generation of innovation is an iterative process of creating "new and useful ideas or solutions to a problem or a need, that consists of designing, creating, and developing. The process of generating an innovation results in an innovative outcome such as a new product, service, method, or technology. This process also includes diffusion, which is the process of disseminating the innovative outcome among participants in a social system" (Morad et al. 2021). The adoption of innovation refers to the process of accepting and making full use of an innovative outcome: "This is a process of change that results in the assimilation of the outcome and includes: initiation, which is the consciousness of innovation, attitude formation, decision to adopt; and implementation, which includes trial implementation and continuous implementation" (Ibid.).

As for the levels of innovation, Morad, Ragonis and Barak distinguish between novelty and change, the latter implying taking something and making it different, the former involving a significant breakthrough compared with what already existed. But they consider, more importantly, the distinction between incremental and radical innovation. Incremental innovations are "improvements within existing architectures or suggestions of solutions for enhancing and extending current products", while radical innovations are defined as "revolutionary or pioneering and brand-new ideas that create new and unexpected fields by applying alternative sets of values". Such innovation may be also identified into "regeneration, change of intensity, reorganization, change of volume or other external quality" (Ibid.).

Legally, too, innovation is differentiated. Although government may directly interfere with market innovation in various ways, it may also, and often does, provide incentives for both individuals and regulated firms to undertake investment which is necessary to generate social innovation. Regulatory programs may either dispense certain activities from the effects of general prohibitions, for example that of state aids under Article 107 TFEU, or provide funds for firms that intend to develop and adopt socially preferable processes and products, for example catalytic converters for automobiles or the recycling of smartphone batteries. There may be constraints and incentives that emerge from regulation and both require justification (Mashaw and Harfst, 1987: 273).

In conclusion, the malleability of concepts allows actors a wide range of options when it comes to moving from an idea to concrete policy proposals. Although at the level of the official declarations this may not be visible, since all EU actors appear aligned behind the same key-words of resiliency, growth, and the ecological-digital transition, the development of concrete policy initiatives is a litmus test to see who wants what from a certain idea or concept. Regulation, in turn, is a platform of possibilities, where the conceptual box includes several discourses of what is regulation for and options about specific policy choices and models.

4. Regulation: A look inside the conceptual box

Regulation consists of a large array of elements, including compliance, and effectiveness, formal and informal controls (Levi-Faur, 2011; Bussani 2018). Needless to say, while the gold standard for regulation is to serve the public interest, there are regulations that mainly serves private interests. The commonly envisioned goal of regulation as beneficial to the public interest can by no means be taken for granted, also because it is hard to maintain that all actors in a competing business, social, political environment share the same values, needs, and interests (Papaevangelou, 2021). This is why regulation is itself a product of different framings and ideational

power dynamics. Western legal systems may be represented as "contested sites of meaning, where dominant ideas and values provide the framework for contestation and for advancing alternative understandings and practices" (Sieder and Witchell, 2001: 203; but see also Maravall, 2003; Jacob, 1996; Horwitz, 1977).

From this perspective, a large spectrum of models of regulation is available. At the two ends of the spectrum, there are top-down regulation and self-regulation. The latter refers primarily to non-state (often self-organized industry groups), "voluntary and 'non-binding" agreements and rules (Gorwa, 2019; Bietti, 2020; Suzor, 2019). This type of regulation, needless to say, aims to consolidate an actor's (or a cluster of actors) self-governance, that is, their independence from the power of a hierarchically higher authority to hold them to account (Papaevangelou, 2021; Bussani 2019), notably in a market context (Stewart, 1981). By contrast, top-down (or 'command-and-control') is usually adopted by public authorities in the form of official legislation, or "hard law", in order to achieve the goals that look socially desirable. This model can work as a platform upon which other types of regulation are built. Its legitimacy may vary depending on the procedures which underpin and drive the state of affairs (e.g., democratic processes, political representation, notice and comment, etc.), but its grip on the regulated field usually is strong because there commonly are legal sanctions for those who do not abide by the rules.

The problem with the top-down model is that it can be cumbersome and counterproductive, from the perspective of innovation (Papaevangelou, 2021; see also Bostoen, 2018). Especially when dealing with ever-changing phenomena such as the array of innovation processes, regulation developed by a single authority risks being ineffective, inconsistent with foundational needs and with goals allegedly pursued. One way of mitigating such risk is usually found by the literature in 'nudge' (see seminal work by Thaler and Sunstein, 2008; Einfeld and Blomkamp, 2021; Whitehead et al. 2014), 'co-design' (see Einfeld and Blomkamp, 2015; Kimbell, 2015) and 'co-regulation' (see Abbott and Snidal, 2009; Black, 2008; Cammaerts and Mansell, 2020; Papaevangelou 2021). The objective here is to attenuate the unilateral and hierarchical nature of regulation.

Another way, which is more relevant for the policy initiatives discussed here is to foster innovation by embracing regulatory experimentation and flexibility. Already in the staff working paper Better Regulations for Innovation-Driven Investment (European Commission, 2016), the Commission described how flexible rules can encourage innovation. Usually known because of some of its products, like regulatory sandboxes, experimental regulations have been recognized as drivers toward a resilient, sustainable and future-proof regulatory frameworks. Experimental regulations, defined as legally binding instruments that establish the temporary regulation of a societal problem, often in derogation from an existing rule (Ranchordas, 2021). were not highly received in the past, both at the EU and national level. Recently, digital technologies have called for new ways to regulate in more agile and flexible ways. These developments opened the way to experimentation clauses and regulatory sandboxes. As we shall see later, the Commission has officially encouraged national authorities to set up regulatory sandboxes in the AI Regulation proposal (COM (2021): 206) thus allowing for controlled environment to test innovative technologies in derogation from existing regulations. The Commission has also identified regulatory sandboxes as an emerging approach in the recently updated better regulation toolbox². By adding the new tool #69 to the list, the Commission recognizes regulatory sandboxes as instruments that help keeping up with innovation. This novelty, however, needs to be contextualized in the wider frame of the new better regulation agenda of the Commission. The *Communication on Better Regulation* of April 2021 pointed toward simplification and burdens reductions more than regulation for innovation (European Commission, 2021). Similarly, the new guidelines setting out the requirements of the policy-cycle do not mention neither innovation nor any of the regulatory tips on how to incorporate innovation in the early stages of law-making³.

The Commission is for the ecological and digital transformation of the economy and society. It acknowledges regulatory schemes that enable innovation, notably with the new better regulation tool #69. This, however, is not accompanied by the recognition of innovation as a regulatory principle. Both the Communication and the Guidance, in fact, do not elevate Innovation to a key aspect, a foundation, of regulatory choice. To understand this, we need to consider two foundations of regulatory choice.

5. Two foundations of regulatory choice

After pointing out the ideational complexity of innovation and regulation, we now connect them considering the foundations of regulatory choice. What principles or foundations should a regulator follow? Regulating innovation often includes a delicate, future-oriented balancing act between different ways of intervention and of *laissez-faire*, between positive and negative effects in a context of uncertainty. Policy-makers face the choice of allowing behavior (such as commercializing a new product) where the costs (ultimately) outweigh the benefits (false negative) or prohibiting something where the benefits (would ultimately) outweigh the costs (false positive). As foundation of regulatory choice, precaution is more likely to accept false positives than false negatives (Majone, 2002).

In 2002, the EU Commission issued a communication concerning the precautionary principle. It defined its scope of application, that is, the contexts in which scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen for the Community' (European Commission, 2000: 1). The Treaty of Lisbon enshrined the principle of precaution into the treaties. Under Article 191 TFEU, the principle applies within the Union's environmental policy. It can be used to evaluate the legality of a particular regulation or intervention. EU courts have later shown their willingness to include it within the general principles of EU law (CFI, Case T-74/00, *Artegodan*; Craig and de Burça, 2015). Practically, it serves to ensure that, under conditions of incomplete knowledge and scientific incompleteness,

² European Commission, *Better regulation toolbox* (25 November 2021) available at:

https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-andhow/better-regulation-guidelines-and-toolbox en Accessed July 2022

³ European Commission, *Better regulation guidelines* (3 November 2021) available at:

https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-andhow/better-regulation-guidelines-and-toolbox en Accessed July 2022

regulators stick to high levels of protection and give priority to concerns for the possible negative effects on the environment and health.

When drawing on precaution, EU decision-makers must still meet the requirements of proportionality, non-discrimination, and consistency with comparable measures already in place. Their policy choice must be anchored to an examination of benefits and costs of action and inaction. Further, this decision ought to be subject to review, and must bear responsibility for producing future scientific evidence (European Commission, 2000: 3).

And yet, precaution is not the only way one can pin down foundations. Over the last ten years or so, innovation as foundation of regulatory choice has also emerged in the context of a major effort of the EU institutions to support growth. On the other hand, innovation is increasingly relevant in the context of the post-pandemic recovery and resiliency plan. Viewed as policy foundation for regulation, innovation would lead regulators to avoid false positives as much as possible. The implications are therefore the opposite of those of precaution.

The innovation principle was initially developed by a pro-business think tank, the European Risk Forum (ERF, 2011) with the aim of anchoring regulatory choice to the paradigm of evidence-based policy, dynamic efficiency, and growth. The principle is defined by ERF (2015:3) as: "whenever the EU's institutions consider regulatory proposals, the impact on innovation should be fully assessed and addressed". Thus, the ERF points to a specific stage of the EU policy process where the principle should be deployed. This is the stage of policy formulation. In the EU, policy formulation is a prerogative of the European Commission, which adopts impact assessment as single template to appraise a large number of economic, social and environmental impacts of different stakeholders and the environment. In a strong formulation, one could argue that if the principle applies, the regulatory options considered in impact assessment should do no harm to innovation. Or, if harm is done, this should be justified by higher, demonstrable, social benefits. In brief, in this perspective, innovation is at the heart of regulation.

More recently, another perspective has emerged. Innovation has been embraced by the Council of Competitiveness (Council of the European Union, 2016) and by the 2019 Finnish Presidency high-level conference on innovation (Taffoni, 2020). On 27 February 2020 the Competitiveness Council adopted Conclusions endorsing the innovation principle (reiterating the 2016 EU Council Conclusion), calling on the Commission to further determine its use (Council of the European Union, 2020). Endorsing the innovation principle is the closest we get to innovation as foundation of regulatory choice, at least in the EU context. This approach is different from a precautionary approach that would consider innovation as something that must be harnessed to produce the desired effects in terms of sustainability and digital-ecological transitions.

The substantive implications of these contrasting views will be considered below. Meanwhile, we draw attention on the institutional implications, in light of what we said earlier with regard to the Council as principal. It is not always the case that the agent complies with the instructions of the principal. The Commission is legally bound by the precautionary principle when the conditions of radical uncertainty apply. Precaution is not the only foundation we find in the Treaty. Suffice it to mention subsidiarity and proportionality. However, precaution is the foundation that can be used to explain why the Commission is not unconditionally persuaded by the innovation principle (for details, see Taffoni, 2020). Another reason is that the Commission, when examining new proposals, follows the impact assessment procedure – which does not contemplate the innovation principle.

These findings suggest three remarks. The first is of normative nature. There has always been much in the institutional life of the EU that has been regulated not by rules, but by general principles or standards. The principle of due process elaborated by the ECJ (della Cananea, 2016) and the standards of conduct in public life defined by the EU Ombudsman exemplify this tradition and converge in strengthening the necessity of procedural rectitude. These are general principles and standards, because they apply across all EU policies. One might have thought that the same would happen with regard to innovation. The reality has proven otherwise, in the sense that innovation is regarded as an objective of EU policies, as distinct from a general principle or standard. To be sure, this is so because not all EU institutions have showed their willingness to accept it. The existing legal regime thus reveals not only a distinction between precaution and innovation, because the former is a principle and the latter is a policy goal, but also some tension between them.

The second comment concerns the underlying policy strategies. Although there is *prima facie* consensus on the critical role of innovation for the recovery, the ecological transition, and the digital future of Europe, there are two different interpretations on the table:

- (a) the innovation principle points towards innovation as foundation of regulatory choice, or at least a fundamental dimension of regulatory choice,
- (b) innovation as process to be steered and regulated in specific ways in order to achieve certain goals (like sustainability, trustworthiness, or social inclusion).

In the former case innovation is the subject of the regulatory enterprise so to speak, in the latter it is the object of regulation. For the Commission, the need to steer innovation towards certain objectives justifies the introduction of new regulations. For the Council, proposed regulations should be appraised to check whether they harm innovation.

Thirdly and finally, it is challenging to test these conjectures on the framing of innovation and regulation in clear-cut ways, as well as establishing whether the Commission weighs precaution more heavily than innovation. But a simple empirical exploration is possible. Specifically, we will seek to examine how the Commission's thinking is empirically visible in the justification of the new regulatory interventions that should shape the recovery first and the sustainable future of the EU in the medium term. In the context of policy formulation, the Commission presents both draft legislation and the impact assessment of the proposals. In turn, the impact assessments are examined by the RSB of the Commission (Radaelli, 2021).

5. Empirical analysis

We carried out an empirical analysis of a sample of recent EU proposals in the fields that mark the vision for the future of EU growth. We considered five proposals and supporting impact assessment (IA): Digital Services Act (DSA), Digital Market Act (DMA), the Proposal for a Regulation on Markets in Crypto-assets (MiCA), the Proposal on a Pilot regime for market infrastructures based on distributed ledger technology (DLT), and the Proposal for a Regulation laying down harmonized rules on Artificial Intelligence (Artificial Intelligence Act).

Title	Legal reference of the proposal as in EUR-Lex	Reference of the Impact assessment	Opinion of the Regulatory Scrutiny Board and date
Proposal for a Regulation on a Single Market for Digital Services - DSA	COM (2020) 825 15/12/2020	SWD (2020) 348 SWD (2020) 349 15/12/2020	SEC (2020) 432 Opinion: Positive with reservations 6/11/2020
Proposal for a Regulation on Contestable and Fair Markets in the Digital Sector - DMA	COM (2020) 842 15/12/2020	SWD (2020) 363 SWD (2020) 364 15/12/2020	SEC (2020) 437 Opinion: Positive with reservations 19/1/2021
Proposal for a Regulation on Markets in Crypto Assets - MiCA	COM (2020) 593 24/9/2020	SWD (2020) 380 SWD (2020) 381 24/9/2020	SEC (2020)306 Opinion: Positive with reservations 29/5/2020
Proposal for a Regulation on a Pilot regime for market infrastructures based on distributed ledger technology - DLT	COM (2020) 594 24/9/2020	SWD (2020) 201 SWD (2020) 202 24/9/2020	SEC (2020)308 Opinion: Positive with reservations 29/5/2020
Proposal for a Regulation laying down harmonized rules on artificial intelligence (Artificial Intelligence act)	COM (2021) 206 21/4/2021	SWD (2021) 84 SWD (2021) 85 21/4/2021	SEC (2021) 167 Opinion: Positive 22/3/2021

Table 1: The EU Digital agenda: Selection of regulatory proposals

Given the amount of text to code and interpret, in this working paper we provide a simple test based on the search in text for the word 'innovation'. We then retrieved all paragraphs containing references to innovation and used them for the empirical analysis we present below.

With this caveat, our read of the corpus is that for the Commission regulation is an instrument to tame innovation so that it leads to sustainable, inclusive and humancentered outcomes. Interestingly, the verb 'to harness' is also mentioned in the OECD draft recommendation on Agile Regulatory Governance (OECD, 2021).

Within the limits of our text-search approach, we did not find evidence that the Commission is systematically bound to the innovation principle. Nowhere did we find text suggesting that for the Commission innovation is a foundational regulatory principle, neither is it a test against which proposals should be systematically appraised. However, the texts suggest that there is pressure for innovation coming both from the Commission and the RSB opinions.

In the field of the Digital Single Market, the two proposals of Digital Services Act (DSA) and Digital Market Act (DMA) have a large impact on the way tech companies will deliver internet and digital services to European citizens. The DSA outlines the possibility of eliminating legal uncertainty with new modern legal framework that would ensure that digital service providers act in responsible ways, in order to protect civil rights and create a trustworthy environment for users. For the Commission this means that what matters is to ensure that innovations in the digital market do not harm consumers.

The DSA proposal and its impact assessment set out a system of legal liabilities for the content that is shared and used by online platforms. Innovation is thus recognized as the object of the regulation that is set to drive innovators to act in a responsible way: "An intervention is needed in order to have a safe online environment, allowing and strengthening the conditions for innovative digital services, protecting users' fundamental rights and establishing a supervision of the digital services" (SWD(2020) 348) and again "the core objectives of the Directive is to establish framework conditions for digital innovations and allowing such innovations while protecting users' freedom of expression" (Ibid.).

The DMA recognizes that traditional EU competition policy is not enough to deal and protect digital markets and platforms. With the DMA, the Commission's objective is to improve competition and innovation through regulation of the monopolistic trend in the sector. Innovation is thus one of the objectives of the wider competition policy vision of the Commission. The proposal, appraised in the DMA's IA, explores the regulatory conditions for proper innovative developments to proposer. The IA recognized that "small online platforms are hampered in scaling broadly [...] and this leads to a risk of reduced benefits from social gains deriving from innovation" (SWD (2020) 363). Innovation here is harnessed by imposing competition rules to digital gatekeepers. The main problems identified by the Commission regard: unfair practices, structural competition problems and ineffective institutional oversight. Innovation is going to be positively affected by the proposal, however the IA is not directed to measure the effects of proposed rules on innovation (as the innovation principle would demand).

The proposed regulation of Markets in Crypto Assets (MiCA) and the Pilot DLT regime for market infrastructures are part of the Digital Finance Strategy Package. The two regulatory proposals aim at regulating which tokens will classify as financial instruments and which ones are going to be qualified as 'crypto-assets'. The Pilot DLT regulation introduces a sandbox regime. The aim of the two regulations is to provide greater legal certainty, to "support finance in terms of innovation and competition" (COM (2020)594), to promote "the uptake of responsible innovation" (Ibid.) and put in place safeguards for investors.

The impact on innovation is considered in this case, somewhat in line with the innovation principle. We find that among the indicators used for monitoring the preferred options in the IA, *Supporting Innovation* is listed as the second Objective under the category of 'Effectiveness'. The reasoning of the Commission is that via regulation one can reap the "the benefits of the digital age" (SWD (2020) 380) and this is done by creating a favorable legal framework and by removing obstacles to the application of new technologies. Regulation is here portraited as a lever for responsible innovation.

Regulation as a mean for taming innovation is visible in the proposal to regulate Artificial Intelligence (AI). Here the innovative capacity brought about the technological development is wide and touches upon many societal aspects and sectors. The Commission is committed to two main objectives. On one hand, the Commission presents itself as protecting users and citizens from undue AI applications, while on the other hand it aims at defining a regulatory regime that is flexible and experimental enough to not stifle the innovative capacities of AI technologies. Moreover, the Commission encourages Member States to use experimental regulatory mechanisms that concur to consolidate an anticipatory approach to regulating the innovation.

In the field of Artificial Intelligence, the scope of the Commission is thus one of regulating the new technological innovation in order to have a responsible, fair and competitive environment. The commitment to innovation is also present with reference to the objective of creating a legal framework "that is innovation-friendly, future-proof and resilient" (COM (2021) 206). Artificial Intelligence – the Commission reasons – must be governed as innovation to ensure the respect of human rights and a safe environment. The Commission indeed describes how experimental approaches such as regulatory sandboxes can harness innovation.

When looking at the IA on Artificial Intelligence, innovation is intended as multiple AI applications. The IA looks at the effects that this technology has on market share by different providers. In the IA, innovation is appraised independently from competition. Here we find the concern that low-quality regulations might stifle innovations. This is also the main point in the section on Consultation with the stakeholders, where the IA states that innovation should not be negatively impacted by excessive administrative burdens and red tape. The aim of the regulatory actions is thus twofold; that is, on the one hand to protect citizens, consumers and investors from the deployment of unregulated technologies and, on the other, to support innovation.

Turning to the opinions issued by the Regulatory Scrutiny Board (RSB) on the IAs, at first sight we find no direct textual reference to innovation. The RSB does not identify systemic omissions related to innovation and, most importantly, does not seem to be reasoning on innovation as a test against which the initiatives should be assessed. Nonetheless the opinions consider a number of aspects that frame, albeit in an indirect way, innovation.

Innovations are seen as intrinsically risky. The RSB reports on MiCA and DLT identify that the two innovations are not properly regulated, and the Commission needs to better "assess the risks that unregulated crypto assets will play after the implementation of this initiative" (SEC (2021) 308). These RSB opinions indicate that the two innovations – the DLT and Crypto Assets – must be well regulated to bring in positive attributes (e.g. responsible innovation). However, the RSB opinion on the DMA's IA clearly states that the report should demonstrate how each of the services identified has effects on "reduced innovation" (SEC (2020)437). This signals the attention to the impact of the proposal on innovation, even though the Board remains necessarily vague on the definition of innovation – the RSB can only check on the quality of evidence presented in the IA, it does not and cannot provide definitions.

The first opinion of the Regulatory Scrutiny Board (RSB) on the IA accompanying the AI regulation is negative. The general concern is a non-sufficient elaboration on the costs and barriers that the proposed regulation could impose on those SMEs active in the AI market. Similarly, the RSB asks for a better explanation of how experimental regulative solutions such as sandboxes could alleviate burdens to SMEs (SEC (2022) 167). In the first negative report the focus is not on the innovation *per se* or on the lack of risk assessment. The focus is rather on the costs and barriers that could be encountered by SMEs and on the scant evidence available on the effects of sandboxes. The second report recognizes the improvements made in clarifying some key issues and thus gives a positive opinion. However, the RSB reiterates that further clarifications are needed on the possible barriers for SMEs to enter regulatory sandboxes as well as certain markets.

It is hard to come to a single judgement of the empirical evidence. The Commission's services and the RSB pay attention to innovation, in some cases as a process to be supported by regulatory flexibility, but there seems to be more pressure for innovation as object to be steered and governed towards precise goals. However, we did not find explicit endorsements and usages of the innovation principle by the Commission or the RSB. In the meantime, the proposals are being discussed by the European Parliament and the Council. The evidence will be clearer and more comprehensive as the discussion evolves, especially if substantive amendments introduced by either the European Parliament or the Council are subject to IA.

6. Discussion

Our findings suggest some implications that deserve a brief discussion before we conclude. From an institutional viewpoint, the regulatory power in the EU is shared between various sites of authority and this division of authority has produced a large volume of documents dealing with innovation, including opinions and reports, but a clear strategy has not yet emerged. The way in which the decision-making process works weakens the potentiality of innovation. Within the Council the states have distinct interests and are reluctant to accept real change and the Commission is too cautions. The least that can be said is that ambitious intents which were enounced at

the beginning of this process have thus far given rise to modest results. It remains to be seen whether the intervention of the EU co-legislator, the European Parliament, can be significant and this is an additional reason suggesting that further analysis are interesting as well as important.

From a legal viewpoint, when considering how innovation is handled at least two things become evident. On the one hand, in this area regulation is not based on the same type of legal forms which are used in other areas, including competition, where the agreement about the goals of competition made it possible to devise rules accordingly. Arguably, it is precisely because there is no strong political consensus about the meaning and significance of innovation that the approach based on legal instruments having binding effects (Craig, 2003:329), an approach which "bites" anti-competitive conducts, is replaced by a much milder one.

On the other hand, however, to borrow Hart's well-known distinction between two types of legal standards (Hart, 1994: 131), it would be inaccurate to say that an approach based on invariable standards is replaced by variable standards. The reality is that innovation, as suggested earlier, is neither a general principle of law nor a standard but, rather, an objective of regulation. It remains to be seen which is its real legal relevance and significance. To give just an example, the fact that innovation in the European Commission's Better Regulation Toolbox (European Commission 2021c; SWD (2021) 305 final) only comes almost at the end of a long list of tools may suggest that it has a low relevance and significance, though further analysis will be necessary when the ongoing process is completed.

7. Conclusions

Our contribution has shown the importance of framing concepts and policy ideas in the law-making process of the EU by observing an apparently unproblematic issue: innovation. The official rhetoric is unanimous in arguing that the resilience, recovery, the ecological and digital transition need innovation. And yet, behind the consensus for an emerging policy paradigm of ecological, digital, and sustainable growth lies uncertainty on the role and meaning of innovation in the regulatory choices of the EU. Whilst the Council invited the Commission to consider innovation as a foundation of regulatory choice, the evidence we presented suggests a different interpretation; that is, the Commission feels that the role of the EU is to harness innovation in order to bring it in line with the goals of resiliency and sustainability of the post-pandemic growth. This, however, does not mean that the precautionary principle takes central stage – quite the opposite, we did not find any reference to precaution in the documents we examined.

All this points to a set of regulatory choices taken without a definitive anchorage to foundations of regulatory choice. This has implications for those who care about the trajectory of integration. Our contribution shows that although the political choices of integration are often discussed at the level of inter-governmental conferences and the visions of European leaders, looking at specific policy domains with a granular approach provides insights on how the Member States and the Commission settle or do not settle their contrasting 'ideas of Europe'.

This conclusion is mitigated by the observation that procedure matters. The Commission cannot just decide on its own where innovation should sit in the grand scheme of EU things. In fact, the Commission ought to follow the steps and analyses of the IA process, as well as the recommendations and decisions of the Regulatory Scrutiny Board (whose mandate, however, is written by the Commission). Needless to say, we do not claim that EU ideas are produced in a vacuum. Nor do we take a normative position. We do not argue that innovation should be a foundation of regulatory choice, or the opposite. Our aim is to show the lack of clarity behind an apparent consensus – something that should worry both academics and policymakers. The European Parliament has an important voice in this story, all the proposal examined were, by the end of November 2021, in the process of being considered by the MEPs.

Our contribution also paves the way for future research. In the short term, it will be possible to expand the empirical base of our analysis by considering other proposals (for example in the domain of climate) and above all appraise the position of the European Parliament. In the foreseeable future, behind the surface of rhetorical endorsements of innovation, the EU institutions will carry on jockeying with one another in terms of who defines the EU policies and the trajectory of regulation.

Appendix Innovation in Regulatory Proposals and Impact Assessments

Name of proposal	the	Innovation in the text of the Proposal	Innovation in the text of the Impact Assessment
Digital Service (DSA)		"Faced with the evolving problems, Member States will continue to legislate independently. The legal fragmentation with the resulting patchwork of national measures will not just fail to effectively tackle illegal activities and protect citizens' fundamental rights throughout the EU, it will also hinder new, innovative services from scaling up in the internal market, cementing the position of the few players which can afford the additional compliance costs. This leaves the rule setting and enforcement mostly to very large private companies, with ever-growing information asymmetry between online services, their users and public authorities. []" (COM 2020/825 p 3) "The preferred option would support the access to the internal market for European Union intermediary service providers and their ability to scale-up by reducing costs related to the legal fragmentation. While costs for compliance with due diligence obligations are expected, it is estimated this is offset by reducing the current fragmentation through harmonization. It is expected to have a positive impact on competitiveness, innovation and investment in digital services, in particular European Union start-ups and scale-ups offering platform business models but also, to varying extents, on sectors underpinned and amplified by digital commerce". (COM 2020/825 p 3-4)	
Digital Markets (DMA)	Act	"Innovation would remain concentrated within a small number of gatekeepers, ultimately limiting consumers' possibility to access innovation and data-friendly services provided by a larger number of platforms than gatekeepers" (COM 2020/842 p 91)	"Point 6.3 <u>Competition and Innovation</u> When business compete more fairly on their merits these incentivises them to innovate. Greater competition spurs innovation. The IA recognises that 'network effects drive higher concentration which may hinder innovation because it remains concentrated among a reduced number

		of players. At the same time, gatekeepers – due to their impact on the entire ecosystem - are able to set innovation trends for their sector and even beyond (i.e. to non-platform companies). This has the double effect of spreading gatekeepers' innovative solutions to smaller players but could also limit the emergence of other types of innovation. Although the online platform sector invests heavily in innovation, smaller companies that depend on gatekeepers are discouraged from innovating so as not to compete with the gatekeeper Preventing patents or pre-emptive activities, for instance, is one way to gain monopoly power and to increase barriers to entry. If this pattern is dominant, the pace of innovation in the long run slows down. [] A more efficient Digital Single Market with the right incentives to innovate should contribute to a more competitive EU digital economy. The measures under consideration are the most effective in increasing market contestability and can be expected to contribute to lower prices for business users due to increased competitive pressure. For instance, promoting switching through e.g. rules against the misuse of data, self- preferencing, or lack of inter-operability can enhance competition and contribute to dynamic patterns of innovation." (SWD (2020) 363 p. 82) <u>6.3 Competition and Innovation</u> "Point 285 'Option 1 is expected to have a positive and quick impact on <u>overall</u> innovation and competitiveness since it would immediately create a fairer and more balanced business environment for business users and platforms". "Options 2 and 3 would in principle affect more platforms, including those that are expected to enjoy an entrenched gatekeeper position in the near future. In theory this could have a direct negative impact on the innovation incentives of some smaller gatekeepers." (SWD (2020) 364 p. 83)
		(2020) 304 p. 03)
Regulation of	"This proposal is part of the Digital	Objective 2 is identified as "Supporting
Markets in Crypto Assets	Finance package, a package of measures to further enable and support the potential of digital finance	Innovation". (SWD (2020) 380 p. 65)

in terms of innovation and competition while mitigating the risks. It is in line with the Commission priorities to make Europe fit for the digital age and to build a future-ready economy that works for the people." (COM 2020/593 p 2)	Option 3 is considered the most coherent with the Commission's agenda because, amongst the others, it would allow for innovation. The indicators used to evaluate Innovation in the preferred options: "Number and volumes of crypto-asset
"One of the strategy's identified priority areas is ensuring that the EU financial services regulatory framework is innovation-friendly and does not pose obstacles to the application of new technologies. This proposal, together with the proposal on a DLT pilot regime, represents the first concrete action within this area." (ibid.)	issuances in the EU (by category utility tokens, payment tokens) -Market capitalisation of crypto- assets in the EU -Number of entities authorized in the EU as crypto-asset services providers (trading platforms, exchanges, wallet providers) -Number of entities authorized in the EU as 'stablecoin' or global 'stablecoin' issuers
"The second objective is to support innovation. To promote the development of crypto-assets and the wider use of DLT, it is necessary to put in place a safe and proportionate framework to support innovation and fair competition." (ibid. p 3) "Through the introduction of a common EU framework, uniform conditions of operation for firms within the EU can be set, overcoming the differences in national frameworks, which is leading to market fragmentation and reducing the complexity and costs for firms operating in this space. At the same time, it will offer firms full access to the internal market and provide the legal certainty necessary to promote innovation within the crypto-asset market."(ibid. p 6)	-Estimation of the number of EU residents using or investing in crypto- assets -Liquidity of crypto-assets -Number of entities authorized by a NCA as a DLT market infrastructure under the pilot/experimental regime -Volume of transactions traded and settled by DLT market infrastructure (pilot/experimental regime)" (Ibid.) Innovation is also listed as one of the benefits of the final preferred option
"This initiative has four general objectives. The first is to provide legal clarity and certainty to promote the safe development of crypto-assets and use of DLT in financial services. Secondly, the initiative should support innovation and fair competition by creating an enabling framework for the issuance and provision of services related to crypto-assets. The third objective is to ensure a high level of consumer and investor protection and market integrity, and the fourth is to address potential financial stability and monetary policy risks that could	

	arise from an increased use of crypto- assets and DLT" (Ibid p. 146)	
Pilot regime for market infrastructures based on Distributed Ledger Technology (DLT)	"This proposal is part of the Digital Finance package, a package of measures to further enable and support the potential of digital finance in terms of innovation and competition while mitigating the risks." (COM 2020/594 p.1) "One of the strategy's identified priority areas is ensuring that the EU financial services regulatory framework is innovation-friendly and does not pose obstacles to the application of new technologies" (Ibid.) "The second objective is to support innovation. Removing obstacles to the application of new technologies in the financial sector underpins the Commission's digital finance strategy." (Ibid.)	"It is crucial that Europe can reap all the benefits of the digital age and that it strengthens its industry and innovation capacity in a safe and ethical way" (SWD (2020) 201 p. 2) "4.1 General Objective. The initiative should support innovation and fair competition by creating a conducive framework for the issuance of, and the provision of services related to crypto- assets;" (Ibid p. 31) "The opt-in regime would allow service providers to scale up their activities on a cross-border basis in the single market, without stifling innovation". (Ibid. p. 40) "Option 3 presents a clear advantage compared to the others in terms of support to innovation, by building a regime adapted to the specific characteristics of DLT and security tokens" (Ibid. p. 50) "Option 2 could therefore hinder innovation in the EU, by limiting the type of 'stablecoin' arrangements and the business models to be proposed in the EU" (Ibid. p. 55) "Any regulatory restriction on the use and access to 'stablecoins' in the EU could send out a negative signal as how innovation is treated in the single market. Global 'stablecoins' could be potentially be the first mainstream application of blockchain technology in retail financial services and the EU has repeatedly expressed our interest in the potential of that technology for financial markets." (Ibid. p. 56) "The majority of respondents believe the EU should foster innovation, and that any potential new regulation has to provide for efficient and reliable trade and specific functions rather than business models." (Ibid. p. 79)

Regulation laying	"The proposed regulatory framework	which will equally lead to lower cost and an improved quality of services." (Ibid. p 84) "Point 2.2 What are the main problem
down harmonized rules on Artificial Intelligence	 with following specific objectives:[] ensure legal certainty to facilitate investment and innovation" (COM 2021/0106 p 3) "Additional measures are proposed to support innovation [] through regulatory sandboxes" (Ibid. p3) "The promotion of AI-driven innovation is linked to the Data Governance Act" (Ibid. p 5) "The provisions of the regulation are not overly prescriptive and leave room for Member States actions and [] the uptake of measures to foster innovation" (Ibid. p 7) "This proposal imposes some restrictions [] to ensure compliance with overriding reasons of public interest such as [] 'responsible innovation'." (Ibid. p1) "Artificial intelligence requires [] novel forms of regulatory oversight and space for experimentation, while ensuring responsible innovation." (Ibid. p 34) "Specific objective N2: To ensure legal certainty to facilitate investment and innovation in AI." (Ibid. p 91) 	drivers? AI systems have a strong potential to bring benefits, economic growth and enhance EU innovation and global competitiveness." (SWD (2021)84) "Specific objectives of the initiative: ensure legal certainty to facilitate investment and innovation in AI." (Ibid. p 33) "Regulatory Option 3: [] A common system for enforcement and governance of the new rules would also be established applicable across the various sectors complemented with specific measures to support innovation in AI (measures as sandboxes)." (Ibid. p 48) "Stakeholders view: stakeholders suggested different measures targeted at fostering innovation in the public consultation on the White Paper. [] establishing regulatory sandboxes as one potential pathway to better allow for experimentation and innovation." (Ibid. p 61) "6.1.5 Competitiveness and Innovation Under option 1 companies will only undergo the additional costs if they consider that the increased uptake of their products and services will outweigh the additional costs. It will thus not negatively affect innovation and thus the competitiveness of European providers of AI applications. Under option 2 A positive effect on uptake is possible, but less likely for revisions of existing legislation than for ad-hoc legislation addressing a specific issue, since there would be no publicity effect. Innovation would become more expensive only for the specific applications regulated.

Under option 3[]It is possible that AI providers would therefore focus investment on applications that do not fall in the scope of the regulatory framework, since the additional costs of the requirements would make innovations in non-covered AI applications relatively more attractive." (Ibid. p 74)
"Criteria for comparison: ensure legal certainty to facilitate investment and innovation" (Ibid. p 79)
"Stakeholders options: comments highlighted that the requirements must not stifle innovation." (SWD (2021) 84 part 2 p. 11)
"comments against ex-ante assessment as that might be a burden for innovation" (Ibid. p 14)
"Some stakeholders see costs imposed by regulation as an unnecessary burden to competitiveness and innovation" (Ibid. p 17)

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