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RESEARCH ARTICLE

The politics of Artificial Intelligence regulation and governance reform in the European Union

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Abstract
This paper explores political drivers and policy process of the reform of the framework for Artificial Intelligence regulation and governance in the European Union (EU). Since 2017, the EU has been developing an integrated policy to tighten control and to ensure consumer protection and fundamental rights. This policy reform is theoretically interesting, raising the question of which conceptual approaches better explain it, and it is also empirically relevant, addressing the link between risk regulation and digital market integration in Europe. This paper explores the policy reform mainly by using two case study methods—process tracing and congruence procedure—using a variety of primary and secondary sources. It evaluates the analytical leverage of three theoretical frameworks and a set of derived testable hypotheses concerning the co-evolution of global economic competition, institutional structure, and policy preferences of domestic actors in shaping incremental approach to AI regulation in the EU. It is argued that all three are key drivers shaping the reform and explain the various stages of the policymaking process, namely problem definition, agenda-setting, and decision-making, as well as the main features of the outcome.

Keywords Artificial Intelligence regulation · Governance · European Union · Digital market integration · Incremental reform

Introduction

The EU economic and financial crisis has brought into the spotlight the political salience of digital markets governance. In the Artificial Intelligence (AI) sector, which is perceived to foster economic growth and job creation if properly governed, the development of AI applications had to be followed by complement regulatory change. After the launch of the European 2020 strategy to exit the crisis (EC, 2010a) and the setting up of a digital agenda for Europe (EC, 2010b), there has been intense activity in the EU concerning the regulation of digital markets, including the AI sector. In February 2020, the European Commission (EC) undertook a significant reform through a White Paper, which is designed to tighten control and to ensure a human-centric, ethical approach to the use of AI products

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and services (EC, 2020). Based on the White Paper, the EC issued on April 2021 a proposal for an Artificial Intelligence Act (the proposal) (EC, 2021a). If adopted, this new piece of legislation will be implementing rules on AI systems and integrating them into existing EU legislative frameworks. It is also the first overarching political vision and long-term strategy adopted for AI worldwide (Parliament, 2021).

This article addresses the question of what has driven the reform of the framework for AI regulation and governance in the EU. It thus continues literature discussions on why and how regulation of emerging technologies occurs in the EU (Goyal et al., 2021). This paper draws upon the concept of incremental reform and its evolution in the area of AI. In order to do so, it sketches out the EU's policy problem and response, evaluating whether the response represents a major change, or whether it is an incremental adjustment. It then investigates what has shaped the EU response by paying particular attention to the political and economic dimensions. The focus on these dimensions is warranted because a considerable body of public policy and political economy literature considers political and economic factors as drivers for integrated policies or incremental reforms in the EU (e.g., Rayner & Howlett, 2009; Schout & Jordan, 2008).

Theoretically, this work corresponds with three main bodies of the literature reviewed in the section 'Analytical Framework.' First, there is an academic discussion concerning the EU's efforts to 'globalize' its risk regulation and how economic competition can lead to the strengthening of its health, safety, and environmental rules. This body of political economy literature is linked to the second discussion on theories of European integration in the following section. Third, there is the theoretical debate concerning the influence of domestic politics on EU policymaking. An initial review of policy documents indicates the predominant role of these issues in recent debates. It is argued that sequencing different theoretical approaches—global economic competition, EU institutional structure, and policy preferences of domestic actors, explains the various stages of the policy process, namely the brain storming stage (setting motivation), agenda-setting, and decision-making, as well as the main features of the outcome (for an overview of theoretical dialogue in the study of the EU, see Jupille et al., 2003).

The EU's regulatory reform on AI is an important research topic for three main reasons. First, it provides the framework for regulatory changes in Member States. Second, the EU is one of the largest jurisdictions in the world; it is increasingly active in shaping global regulation for digital markets in international fora, and it is one of the main interlocutors facing the USA and China in policy debates on this issue (Brattberg et al., 2020). Third, recent policy changes in AI are typical for policy processes on emerging technologies in the EU (Greer & Trump, 2019; Justo-Hanani & Dayan, 2015). Therefore, this case represents an important contribution to similar debates.

Before proceeding, some clarifications are needed. First, this research does not attempt to evaluate the (in)effectiveness of the policy reform. Rather, it sets out to explain the political dynamics underpinning it. Second, the regulatory reform is far from being completed. Therefore, this paper deals with an unfolding tale that may have unexpected twists. Third, due to space constrains, the analysis of the policymaking process at the EU level is not supplemented by an analysis of the events in Member States. However, the positions taken by national governments and by influential interest groups are discussed as part of the 'preferences of domestic actors' explanation.

The paper is organized as follows: The second section presents the analytical framework by discussing the emerging regulatory framework. This section also presents the explanatory framework by reviewing plausible theoretical explanations and deriving testable hypotheses. The third section explores the policy evolution over the period from 2017 to

2021. The fourth section interprets the policy history by evaluating the explanatory power of the theoretical hypotheses. The final section draws some conclusions on the value added by sequencing theories as opposed to more traditional meta-theoretical approaches.

The analytical framework

Background: the policy problem

AI in the EU faces many risk and safety problems (EC, 2021a; Parliament, 2021). National governments and advocacy groups are concerned about potential violations of fundamental rights of citizens and businesses associated with AI systems (EC, 2021b). These include privacy, bias, inequality, and security issues, as well as the general capability of computer power to control society. Specific concerns include AI systems that manipulate human behavior to circumvent users' free will (e.g., biometric identification, or 'social scoring' by governments) (EC, 2021b). With the European debates on the regulation of disruptive technologies as a backdrop (EC, 2018b), the debate on AI focuses on risk management structure and oversight capacities (EC, 2021a; EC, 2021b).

Among several policy problems, a major one relates to establishing governance and norms relationship within this sector (Ulnicane et al., 2021). Critics have pointed to ethical challenges and emphasized liability and consumer safety (Floridi, 2019; Taeihagh, 2021). Given that technological uncertainties are exceptionally high, a fundamental issue is whether and how existing regulation can be used or adapted to the complexity of this realm (EC, 2020).

The reform to be explained

The dependent variable of this research is the reform of the framework for AI regulation and governance in the EU. Prior to the reform, the policy was based on three core principles, the first being national regulation, coupled with mutual recognition and minimal harmonization (though EU-level regulation was more developed for data privacy protection, and product liability) (EC, 2021b, pp. 5). The second principle was national supervision with some cooperation, either bilaterally on the basis of memoranda of understanding between sectoral authorities, or multilaterally in the form of 'technical' forums (ISO, OECD AI Policy Observatory) (JRC, 2019). Third, there were non-legally binding international standards, such as the principles for developing responsible AI set by multinational corporations like IBM, Intel and Microsoft (Pauwels, 2019). In addition, there was no broad definition for 'AI' in the EU that covers new techniques and algorithms, such as machine learning and facial recognition (Renda, 2019).

The EU policy framework established in 2020[1] is based on a complex multilevel system of EU rule-making and enhanced coordination between national competent authorities underpinned by a newly created EU committee (Parliament's special committee on AI in a digital age (AIDA), setup in June 2020) and by independent expert groups (e.g., The High-Level Expert Group on AI (HLEG), and AI Watch both established in 2018). The division

[1] European Commission's Strategy for data, presented on 19 February 2020 (IP/20/273), which consists of a White Paper on AI (COM(2020) 65 final), Communication on 'A European Strategy for Data' (COM(2020) 66 final), Communication on Shaping Europe's' Digital Future (COM(2020) 67 final) and Commission Report on Safety and Liability Implications, the Internet of Thing and Robotics (COM(2020) 64).

of responsibilities between sectoral competent authorities (e.g., healthcare, transport) is maintained (EC, 2021a). The so-called coordinated plan for AI 'made in Europe' signed in 2018 is also to be incorporated into EU legislation, as described below.

In terms of regulation, the 'first step' involves classification of AI systems according to their risk ('risk-based' approach). For example, AI systems presenting 'unacceptable risk' would be prohibited (e.g., some biometric identification systems). 'High-risk' systems, such as those that impact employment equality would be subjected to stringent safety and liability standards (EC, 2021c). Producers and services providers should be required to ensure that these systems meet a mandatory ex-ante 'conformity assessment' before their release into the market. 'Black box' AI systems that human cannot interpret, such as medical devises and self-driving cars, are another example for 'high-risk' uses (EC, 2021b). For AI systems that are not considered high-risk, the proposal suggests voluntary codes of conduct and other measures in support of innovations, such as regulatory sandboxes and obligation to consider interests of Small and Medium-Sized Enterprises (SMEs) (EC, 2021a; EC, 2021c).

In any new legal instrument, a definition of 'AI' will need to be flexible to accommodate technical progress while being precise enough to provide legal certainty. The EC provided a first definition, which was further refined by the HLEG, and in the proposal (EC, 2020; EC, 2021a, Article 3).

The 'second step' consists of the assessment of existing EU horizontal and sectoral legislations from the viewpoint of consumer safety and fundamental rights (EC, 2021a). For example, software is a key part of any AI service, but existing EU product safety regime covers only risks from products and not from services. Therefore, the EC considered whether new requirements should be introduced for ensuring safety of software (EC, 2020, p. 14). The case of biometric recognition is another example for an AI system that might be restricted under horizontal law already in place—the General Data Protection Regulation (GDPR) (EP, 2016; EC, 2021a).

The 'third step' is the governance structure that ensures capacity-building of national authorities to fulfil their mandate (EC, 2021a). It should guarantee stakeholders participation. Businesses, researchers, consumer organizations and other sectorial networks should be consulted on implementation issues.

Three general features of the *regulatory outcome* stand out. First, the proposed reform should be seen as incremental rather than radical.[2] The main regulatory measures are built upon existing laws (e.g., GDPR). The new rules that set in place safety requirements for a range of new machinery products (e.g., 3D printers, robots to lawnmowers) are due to be incorporated into EU legislation, the so-called new Machinery Regulation, which is also a revision of the existing Machinery Directive (EC, 2021c).

Second, the regulatory proposal primarily concerns high-risk uses rather than the AI sector as a whole. On the one hand, the draft legislation provides a rather restrictive definition of what counts as high risk (EC, 2021a). On the other hand, some commentators (including within the Parliament) have argued that the legislation is vague in key areas, and not strong enough on crucial points (EURACTIVE, 2021). What is important for the argument of this paper is that AI policy reform was informed by a new (yet incomplete) political consensus regarding gradual and incremental pattern of regulatory development.

It is noteworthy that the preference for incremental approach seems a common feature of regulatory policies on emerging technologies in the EU in the last two decades. Not only

[2] An incremental approach can be defined as a policy design for change, by which many gradual, small policy changes are enacted over a long period of time, and contains a mix of policy instruments and aims (Rayner & Howlett, 2009).

the preference for incremental approach is common, but also the fact that such reforms have occurred at a relatively early phase of technologies' development. Justo-Hanani and Dayan (2014, 2016) pointed to incremental approach adopted to nanotechnology risk regulation, with gradual adjustments to existing sectoral laws. A similar pattern occurred in the case of automated vehicles (EC, 2018), and CRISPR gene-editing (Asquer & Krachkovskaya, 2021). For most of these technologies, the period between mid-2000 and 2020 is associated with accelerated development. Such reforms can be associated with the financial economic crisis. Following the crisis, there was a persistent demand in Europe for investment in research and innovation as sources of future growth (EC, 2010a), which accelerated technological development under conditions of significant uncertainties regarding their effect. In this new challenging environment, a gradual regulatory reform became an alternative which offered a fertile ground for further development, while at the same time provided social and environmental protection by reflexive risk governance (Justo-Hanani & Dayan, 2015).

The explanatory framework

In order to avoid omitted variable bias, empirical studies should uncover more than one mechanisms through which policy change can occur (Howlett & Cashore, 2009), which is why this section discusses a range of explanations derived from alternative theories. This study focuses on three theoretical frameworks that constitute the most plausible alternatives derived from preliminary data investigation. These are: global economic competitiveness, EU institutional structure, and policy preferences of domestic actors (see Table 1 for summaries of hypotheses and their empirical testing).

What all these concepts have in common is the tendency to focus on plurality of actors (influential Member States, EC, Parliament and their experts, and industry), and stressing the importance of economic interests and institutions in mutually stabilizing each other in shaping integrated policy change. Better understanding of the causes and outcomes in this policy area is thus a helpful step toward better understanding how incremental regulatory reforms occur (For the merit of 'evolutionary' and processual perspectives in the study of integrated policy strategies, see Rayner & Howlett, 2009; Candel & Biesbroek, 2016).

Global economic competitiveness

Regulatory competition theories highlight the importance of highly competitive global marketplace, which generates pressure for regulatory change either at the national level or in regional blocks (e.g., Esty & Geradin, 2000; Stigler, 1971). Vogel (1995, 2012) shows that international competition for business and investment does not necessarily lead to downward pressures on environmental and consumer safety standards, but may push their level upward. His work regarded EU market integration as a 'trading up' system, whereby Member States are keen to set more stringent rules that are in line with both the Single Market and their economic interests. Relatedly, the impact of the EU risk regulation extends beyond Europe. As Vogel (2012, pp. 15) explains: 'as a result of the Single Market's economic importance, the growth of its regulatory capacity, and the relative stringency of its regulatory standards, global business regulations are increasingly being shaped by the EU.'

A similar approach was also taken by Biedenkopf (2018), Bradford (2020), Damro (2012) and others, who highlight the EU's global regulatory impact, and how it shapes environmental, health and safety standards, with the aim of 'exporting' them to the rest

Table 1 Explanatory framework and main empirical findings

Theoretical explanations	Hypotheses	Empirical testing	Relevance of the explanatory factor
Competitive interests Antecedent variable in the causal sequence	EU level: Regulatory process is motivated by cross-border exchange of AI systems, risk of regulatory failure	Cross-border exchange and regulatory fragmentation; integrated policy was expected to generate competitive advantages Motivating factor	Hypothesis confirmed Highly relevant
	Global level: Regulatory process is motivated by global competition, and regulatory leadership ambition	Coordinated policy expected to stimulate competition, and to maintain the EU's position as a global rule-exporter Motivating factor	Hypothesis confirmed Highly relevant
EU institutional structure Necessary but not sufficient to establish causation	EU institutions as policy entrepreneurs	The EC and expert groups played a crucial role at the problem definition and the agenda-setting stages, acting as policy entrepreneurs. The Parliament and Council were more active at the decision-making stage	Hypothesis confirmed
	The regulatory outcome reflected the preference of the EC for Better Regulation in the form of incremental approach	Regulatory outcome reflected principles of EC's Better regulation: proportionality, incremental change; innovation-friendly measures (e.g., codes of conduct)	Hypothesis confirmed
Domestic preferences Difficult to assess whether policy preferences of domestic actors or EU institutional structure have more explanatory power	Powerful interest groups lobbied their national governments for policy reform	Industry groups were active through both domestic and supranational channels	Hypothesis confirmed
	Powerful Member States together with their MEPs were significant actors in the policymaking process	Powerful Member States with their MEPs were most influential in the decision-making stage	Hypothesis confirmed
	The policy outcome reflects the preferences of national governments to delegate authority to EU institutions	The regulatory outcome conforms to the preferences of the main industrial Member States, but also of supranational actors	Hypothesis confirmed

of the world. In the case of digital markets, this dynamic fits into a broader vision of economic integration, as summarized by Jean-Claude Juncker (2018), the former President of the EC: 'it is because of our Single Market, the largest in the world, that we can set standards for big data, AI, and automation and that we are able to uphold Europeans' values, rights and identities in doing so. But we can only do so if we stand united.' This discussion can be linked to debates on varieties in administrative capacities across Europe (e.g., Candel & Biesbroek, 2016; Schout & Jordan, 2008) in that the persistent diversity of national approaches hinders the effectiveness of the European competition policy. Therefore, administrative capacity to deal with risk and uncertainties needs to be closely coordinated, otherwise there will be limited ability to leverage the EU external regulatory power (Bach & Newman, 2007). Synthesizing this literature, it is possible to suggest the following hypotheses:

H1 At the EU level, the Digital Single Market strategy (DSM) (EC, 2015a) substantially increased the exchange of AI products and services among the Member States, increasing the risk of regulatory failures threatening the stability of the Single Market, as well as the erosion of sound regulatory standards. Thus, cross-border exchange in AI applications made regulatory coordination economically essential.

H2 Taking a global perspective, the rapidly increasing AI markets, global competition to attract investments, the need to close the gap with the USA and China, and the ambition to maintain the EU position as a global rule-exporter, all these factors pressed for making progress on coordinated regulation.

EU institutional structure

According to the institutional structure approach, which to a large extent includes the supranational governance theory, the push factors in the process of integration are transnational exchange, legal provisions framing integration, and the entrepreneurship of well-resourced supranational institutions (Jupille & Caporaso, 1999; Sweet & Sandholtz, 1997).

Supranational policymaking is partly consistent with the neofunctionalist logic for European integration, which emphasizes economic spillovers and functional needs (Haas, 1968). Insofar as policy integration involves political, economic, and technical cooperation around newly identified social risks, there is a scope for supranational entrepreneurship (Selin & Vandeveer, 2015; Smith, 2010).

Scholars who explain EU governance from supranational perspective focus on the role of bureaucracy in driving forward policy integration (Nugent & Rhinard, 2019). The EC, in particular, develops its own ideas on the topics and objectives of coordination, and sets its own strategies as an agenda setter (Princen, 2011). These explanations coincide with the EC's Better Regulation agenda that aims to improve the regulatory environment for competitive market (EC, 2015b. According to this perspective competition and policy integration go hand-in-hand (Zahariadis, 2002). Part of the Better Regulation agenda is to streamline regulations in order to return to 'what is strictly necessary,' including the reduction of disproportional burdens that stand in the way of stronger growth rates and jobs. It includes the reliance on diversity of regulatory tools, such as impact assessment and incremental approach. It also relates to the role of independent policy experts as part of the policymaking process (Schout & Jordan, 2008).

In the case of AI policy, the causal mechanism suggests that transnational economic and digital exchange (e.g., trade in services, networks) intensified by rule-based integration, together with proactive and skillful supranational actors, facilitated policy change. Two testable hypotheses can be derived:

H3 Supranational agents such as the EC, the European Parliament ('Parliament') and their expert groups played a crucial role. It should be taken into consideration that their influence can be subtle, e.g., by framing problems, proposing solutions, and ruling out alternatives. Process tracing is instrumental in detecting their preferences and their respective degree of influence.

H4 The regulatory outcome reflected the preference of the EC for Better Regulation in the form of incremental approach. This hypothesis can be tested using congruence procedure.

Policy preferences of domestic actors

An alternative explanation focuses on the role of Member States in driving policy change. This explanation coincides with a liberal intergovernmentalist account to European integration, which assumes that political factors driving EU-level actions are domestic in character (Moravcsik, 1993).

Domestic politics explanations portray the process of EU decision-making on global trade-related issues as a result of a series of rational choices made by powerful national governments pursuing the interests of dominant domestic groups (Büthe, 2007; Meunier & Nicolaïdis, 2006).

Usually, scholars working on domestic politics perspective articulate their analysis into three steps. First, there is the process of preference formation whereby national governments aggregate domestic preferences for trade-related policies and articulate them in EU forums (Zahariadis, 2002). Preferences of Member States are determined by comparative advantages, and they are also affected by interdependence, which explains the convergence of preferences across Member States (Moravcsik, 1993). Second, intergovernmental negotiations take place on the preferred solutions (Kelemen, 2010). The outcome of EU negotiations depends on the power and resources available to the Member States, their size and strength in global trade markets, and on the growing power of the Parliament where safety and consumer protection interests are relatively influential in shaping EU legislation (Hix & Hoyland, 2013; Vogel, 2012). Third, there is a delegation of authority to EU institutions acting as agents of the Member States and operating to increase coordination (Jacoby & Meunier, 2010).[3]

In the AI case, the causal mechanism presumed by domestic politics is the following: the convergence or congruence of domestic preferences on the AI regulation made it possible to reach an agreement on a new field of economic integration under a single EU framework. The configuration of domestic preferences, together with policy preferences of Members of the Parliament (MEPs), explain the outcome. Three testable hypotheses can be derived:

[3] For a recent case of delegation of authority on trade-environmental problem, see Justo-Hanani & Dayan, 2020).

H5 at the domestic level, powerful interest groups—mainly the AI sector and dominant companies therein—by virtue of their size and internationalization of their markets, lobbied their national governments for a reform of EU policy. This hypothesis also provides a link to global regulatory competition for it considers how the latter affect the preferences of domestic forces.

H6 national governments—especially those of Member States which are relatively advanced in technology infrastructure,[4] together with their MEPs, were significant actors in the policymaking process. This hypothesis is evaluated through process tracing.

H7 the policy outcome reflects the preferences of national governments to delegate authority to EU institutions. This hypothesis is mainly assessed on the basis of the congruence procedure.

Methodology

This paper applies a process-tracing method and congruence analysis to the search for necessary and (or) sufficient conditions that lead to a specific outcome, and to understand the mechanisms that link casual factors to outcomes (Beach & Pedersen, 2019). The method of process tracing consists of analyzing data on actions, events, and expectations that link putative causes to observed effects. The main purpose is to figure out 'what causes what' by reconstructing the chain of events (Morgan, 2016). The search for answers is based on 'configurational' thinking, especially the assumption that a number of causal factors work together to create an outcome (Blatter & Haverland, 2012, pp. 81). According to this logic, theoretical predictions regarding the dependent variable are compared with the real outcome. If the real outcome is consistent with the predictions, then there is at least a presumption of a causal relationship. On the basis of these observations, this paper draws conclusions on the role of causal conditions in the policy process and outcome.

The relevance of the explanatory factors was determined based on primary and secondary sources. First, we identified a variety of primary data (key policy documents, calls and responses for consultations, reports, declarations, formal press releases, and legislative texts) published by EU institutions, Member States, and Experts. We focused on those that were about the policymaking process (40 publications). Technical reports and expert documents were validated by a thorough review of EU documents, which include details on their adoption or justification. Second, we identified secondary data sources relevant to the policy evolution from the crucial formative period of 2017–2021. These include newspaper coverage, online sites and web-news, interest groups position papers, documentary record on legislative debates, as well as relevant literature on AI regulation in the EU (60 publications).

To figure out necessary and/or sufficient conditions, actions, events, and actor preferences were categorized based on their context and time period. For example, the evolving intra-EU and global economic concerns were classified under 'economic competitiveness.' Activities of EU institutions involved in law-making (EC, Parliament, Council, including advocacy by various actors at these venues) were classified under 'EU institutional

[4] i.e., Belgium, Denmark, Estonia, Finland, Ireland, Luxembourg, the Netherlands, Norway, and Sweden, the so-called digital front-runners (Mckinsey & Company, 2020).

structure.' Governments' preferences were classified under 'domestic preferences and bargaining power.' Subsequently, we arranged the data to understand the sequence of events and reconstruct the policy process.

An overview of the policy evolution

Based on the literature on policymaking in the EU (Wallace et al., 2015), the process of regulatory reform can be divided into three main stages: the 'brain storming' stage of problem definition (setting motivation); the agenda-setting stage; and the political decision-making stage.

The 'brain storming stage'

In 2017, the Parliament's Committee on Legal Affairs adopted a non-binding text entitled 'Report with recommendation to the EC on Civil Law Rules on Robotics' (Parliament, 2017). European Council's conclusions on digital economy identified a 'sense of urgency to address emerging trends—such as AI' and asked the EC to put forward a European approach to AI by early 2018 (European Council, 2017).

In April 2018, the EC began to engage with AI regulation, issuing a communication entitled 'Artificial Intelligence for Europe' (EC, 2018a). This was followed by another document issued in December 2018, with the presentation of a coordinated plan (EC, 2018b) and a declaration of cooperation between Member States exploring issues such as the relevance of EU existing rules on product liability in the context of AI (EC, 2018c). Ethics and regulatory frameworks were identified as being in particular need of coordination (EC, 2018b; see also Stix, 2019). A first draft of ethical guidelines was published by HLEG on behalf of the EC at the end of 2018 (HLEG, 2018).

The HLEG was then asked by the EC to make recommendations for future policy for trustworthy AI. A broad multi-stakeholder platform, the European AI Alliance, steered by the HLEG, met several times between June and November 2018. The mandate of the HLEG (chaired by Pekka Ala-Pietilä, Chairman of the steering group of Finland's AI Programme, former president of Nokia) was to: 1) draft ethical guidelines, covering issues such as fairness, safety, consumer protection, and non-discrimination and 2) define a policy and innovation strategy to build competitiveness in key domain.

The main conclusions of the second deliverable were that a regulatory regime needs to encompass governance and risk management to stimulate competition, focusing on qualitative factors such as the quality of protection and administrative oversight capacities (HLEG, 2019, pp. 39–40).

In the 'brain storming' stage, the main concern was regulatory fragmentation stemming from divergent national approaches (EESC, 2017). This varied from countries that had already prioritized ethics and consumer safety standards in their national strategies (e.g., France, Finland, Germany, Denmark, Sweden, Estonia), to countries that had not (e.g., Portugal, Slovenia), which would likely be counter-productive given the size of Europe's global competitors. A solution to this divergence was found in the calibration of the principle of 'ecosystem of trust.' A 'Single Market for trustworthy AI' approach would result in three components: (1) lawful, (2) ethical, and (3) robust, in line with the core tenets of the EU: fundamental rights, democracy, and the rule of law (HLEG, 2019). The suggestion of a Single Market for trustworthy AI made by the HLEG and supported by other stakeholders

and Member States was welcomed by the EC and included in the Communication 'Building Trust in Human-Centric AI' as a 'working hypothesis' (EC, 2019). Moreover, the EC declared its intension to bring the Union's human-centric approach to the global stage and to build an international consensus on AI ethics (EC, 2019).

Overall, quite early in the discussion, agreement was reached on key policy principles, such as 'trustworthy human-centric approach' for 'leveraging Europe in the global race for AI', which justifies 'regulatory coordination' aimed at 'building a competitive advantage' and 'enforcing standards on the global market' (EC, 2019; See also Renda, 2019). In order to achieve these objectives, the EC presented a gradual, adaptive policy approach. It stated 'given how fast AI is evolving, the regulatory framework must leave room to cater for further development. Any changes should be limited to clearly identified problems.' (EC, 2019, p. 10). In the document issued in 2019 (EC, 2019), the EC summarized the work carried out in the preparatory phase and presented policy options, largely based on these principles. By adopting the core principles, the EC with its independent expert groups was able to set the terms of the debate (problem definition), which also informed the subsequent stage of drafting the proposal (agenda-setting).

The agenda-setting stage

In October 2019, incoming EC President, Ursula Von der Leyen, has promised to pass AI legislation within her first 100 days in office (Von der Leyen, 2019, pp 13). The approach favored by the EC was to ensure AI is developed in ways that respect people's rights and earn their trust. At the confirmation hearing before the Parliament, Executive Vice President of the European Commission for 'A Europe Fit for the Digital Age', Margrethe Vestager, emphasized that Europe's regulatory stance is what will distinguish it from its competitors: 'Some say China has all the data and the US has all the money. But in Europe, we have purpose [and] a lot to build on' (cited in Kelly, 2019).

Before the White Paper was put forward, Angela Merkel's government tasked a new Commission with the aim of producing recommendations for rules on algorithms and AI in Germany and the EU (Meyer, 2019). The regulatory regime devised by the Data Ethics Commission (DEC, 2019) was centered on risk-adaptive approach (the greater the potential of harm, the more stringent the requirements) (DEC, 2019, pp. 5, 20, 21). Such regime is based on targeting AI and algorithms according to their level of risks: mandatory labeling requirements for applications with some potential of harm; licensing procedures or preliminary check for applications with regular, significant, or serious potential harm; and complete or partial ban of applications with untenable potential of harm. The DEC also recommended a new EU horizontal regulation plus sectoral measures (DEC, 2019, pp. 21). All these elements, even though with some modifications, were incorporated into the White Paper, as explained below.

In February 2020, the EC published a White Paper, outlining three legislative approaches (EC, 2020). One is to build on new rules plus existing legislation, with the aim of codifying and revising (where necessary) relevant directives, including GDPR, Product Liability Directive, Race Equality Directive, General Product Safety Directive, e-Commerce Directive, and directives and regulations on motor vehicles, their trailers, systems, and components (EC, 2020). Second is to export its values (respect of human rights, protection of privacy and personal data) across the world, like it did with the GDPR. Third is to advance a risk-based approach, where high-risk AI applications, which pose significant risks for fundament rights and safety, may be subject to mandatory requirements and a

prior conformity assessment before they can be launched onto the market (EC, 2020, pp. 23). The White Paper, however, stated that the reform should not hamper innovation.

The White Paper reaffirmed the objective of the Union being a global leader in the development of trustworthy and ethical AI, as requested by the Council (EC, 2020, pp. 8). It also responded to explicit requests from the Parliament and the European Council, which have repeatedly called for legislative action to ensure a well-functioning internal market, where both benefits and risks of AI are adequately addressed (See description in EC, 2021a).

The proposed EU measures were considered proportionate, especially for SMEs. The EC was of the view that it should follow a risk-based approach, rather than radical policy change for the whole AI sector (EC, 2020, p. 17; See also EC, 2021a).

The White Paper released by the EC matched almost all the main objectives set by the German DEC a few months earlier. As remarked in *Fortune* and *Politico* (Delcker, 2019; Meyer, 2019), a new 'catch-all' horizontal legislation was not part of the recommendations circulated by the HLEG in June 2019. It was inserted by the EC at a later stage (October 2019), substantially incorporating the main points articulated in the report on EU new legislation produced by the DEC. The White Paper officially proposed in February 2020 ended the preparatory stage, after which the political 'ordinary legislative procedure' stage unfolded.

The decision-making stage

The working method of the EC was to canvass opinions from a variety of policy actors in an open consultation, which took place between February 2020 and June 2020 (EC, 2020). There was a clear intention to propose legislation by early 2021.

The Parliament endorsed the goal of the White Paper, but in order to increase its power to enforce consumer rights, several MEPs revived earlier demand for a new agency responsible for compliance with ethical principles (Parliament, 2020),[5] which had previously been neglected during the negotiation of the White Paper. In the previous mandate, as part of a 2017 resolution on Civil Law Rules on Robotics, the Parliament had called upon the EC to 'consider' whether an EU Agency for Robotics and AI could be worth establishing in the future (Parliament, 2017). The question of parliamentary scrutiny was resolved in June 2020, when a special committee was established as Rules of Procedure of the Parliament, that is, the power to establish any special committees at any time of its choosing (Parliament, 2020a).

The Parliament has also undertaken a considerable amount of work since the release of the White Paper. In October 2020, it adopted a number of resolutions in line with the White Paper, covering ethics, civil liability, and intellectual property (e.g. Parliament, 2020b, c).

The White Paper raised some objections from several Member States. Ireland (digital frontrunner) expressed concern about too much regulation suggested for emerging markets and criticized the lack of a clear understanding of the regulatory acquis. One of Ireland's key messages was that 'rather than trying to evaluate all possible consequences in an ex-ante fashion, it might be appropriate to adopt an approach that leans more upon incremental learning' (Government of Ireland, 2020, p.3). The Netherlands, which is also a digital frontrunner, welcomed the EC's approach of distinguishing between high-risk and low-risk

[5] Report by Rapporteur García del Blanco (Socialists & Democrats).

for the time being. Like Ireland, it stressed to 'maintain this "learning approach" in the process of seeking proportional risk mitigation' (Government of Netherlands, 2020, pp. 3).

In general, most of the respondents in the stakeholder consultations were in favor of risk-based approach: 'using risk-based framework was considered a better option than blanket regulation of all AI systems. The types of risks and threats should be based on a sector-by-sector and case-by-case approach' (EC, 2021a).

Understandably, stakeholders' interests varied depending on the type of risk. For instance, in the public consultation on the White Paper, safety was found to be important issues to be addressed. 72% among SMEs, 83% of large businesses, 80% of academic and other research institutions, 88% of civil society organizations, 73% among EU citizens, all of which found safety to be an important or very important concern (EC, 2021b).

Likewise, regulatory sandboxes were welcomed by certain stakeholders, especially businesses. As for the enforcement models, more than 50%, especially from the business associations, were in favor of a combination of an ex ante self-assessment and an ex post enforcement for high-risk AI systems (EC, 2021b, Sect. 2.2). It seems clear from the consultation results that the adoption of incremental approach is in line with business' preferences. These results indicate that firms and powerful Member States believed that there is a positive link between this approach and gaining economic advantage.

The European industry lobby was active in the policymaking process. In the meetings declared by the EC President Von der Leyen, and the French Internal Market and Services Commissioner Breton, the main players were the Digitising European Industry (DEI) group (which represents the digital technology industry in Europe through national hubs); the European Round Table of Industrialists (ERT) and BUSINESSEUROPE (which represent enterprises of all sizes in Europe). Other participants include Paris Artificial Intelligence Research Institute (PRAIRIE) initiative; CLAIRE (international research alliances); and the AI4EU (private sector and academic institutions from twenty-one Member States). German industry representatives have made clear their views on the importance of promoting research and development, and adaptive regulation. For instance, from the point of view of the German Banking Industry Committee (2020), new regulatory frameworks must not lead to over-regulation. A risk-based approach was generally considered appropriate. As remarked in Global Policy Watch (Bildt et al., 2020), German business convinced politicians that its position as a globally strong industry (automotive manufacturing, robotics, and biomedical) can only be safeguarded if it shapes the conditions for the global market, and that norm-setting power can be a potent tool for Germany's continued global success. This position was reflected in the updated federal strategy (German Federal Government, 2020).

Global companies worked closely with the EC and the HLEG, responding to consultations. The concept of trustworthy human-centric AI was backed up by large Big-Tech companies, such as Google, Amazon, IBM, Microsoft, and Facebook (Stix, 2019), which have headquarters in the large Member States. However, policy preferences of the EC and international companies were not homogeneous, as in the case of Google. The EC proposed to put forward further legislative requirements for safety and liability. In Google's view, 'the current liability framework remains fit for purpose, being both effective and technology neutral, so sweeping changes are not needed' (Google, 2020). Overall, from industry response to the White Paper, it can be assumed that policy design was supported by both industry preferences and the EU institutions.

In April 2021, the EC submitted the proposal for AI act, accompanied by impact assessment (EC, 2021b). As required in the Commission's Better Regulation Guidelines, the impact assessment compared a number of policy options. Based on consultation with

stakeholders and experts, the EC concluded that the adoption of horizontal act plus voluntary codes of conduct for non-high-risk systems is the most effective and cost-efficient policy option (EC, 2021b). A cost–benefit assessment associated with implementation further demonstrated the proportionality of the proposal. As explicitly stated (EC, 2021a, Sect. 1.1):

> 'this proposal presents a balanced and proportionate horizontal regulatory approach to AI that is limited to the minimum necessary required to address the risks and problems linked to AI, without unduly constraining or hindering technological development or otherwise disproportionate increasing the cost of placing AI solutions on the market.'

Interpreting the policy evolution

This section interprets the policy evolution by evaluating the explanatory power of the theoretical hypotheses.

The role of global economic competitiveness

Two main sets of structural economic factors can be extrapolated as setting the background for the reform. First, the DSM increased the interdependence of digital markets, challenging existing regulation of products and services in the EU. It also triggered the use of AI systems in public sectors, further stimulated by the EU Coordinated Action Plan (EC, 2018b). Furthermore, international competition is fiercer than ever with massive investments and data in the USA and China (EC, 2018b: Sect. 1; EC, 2020; See also McKinsey & Company, 2019). All these changes furthered the pressure for coordinating the regulatory framework in the EU. As the EC put it:

> 'Products and services are increasingly interlinked and digitized. In this context, it is of utmost importance to avoid market fragmentation in strategic sectors such as artificial intelligence, including by strengthening key enablers (e.g. common standards and fast communication networks). A real Single Market with an integral digital dimension will make it easier for business to scale up and trade across borders and thereby further boost investments' (EC, 2018b, section 2.1).

Other powerful incentives were the expected economic benefits deriving from 'upgrading' the ethical standards, which would strengthen the EU digital market and bring benefits to citizens (e.g., higher protection, trust), SMEs (more venture capital), and larger companies (legal certainty) (EC, 2020). Indeed, in its coordinated plan for AI, the EC emphasized:

> 'Spreading the ethics agenda, while fostering innovation, has the potential to become a competitive advantage for European business on the global marketplace' (EC, 2018b, section F).

Moreover, the reform was instrumental in strengthening the EU's voice in the international fora. The Communication in February 2020 entitled 'Shaping Europe's Digital Future' made clear that the EC's objective was for the EU to 'leverage its regulatory

power' to advance the European approach, precisely at the time when international rules and standards for digital trade were being negotiated (EC, 2020a).[6] This is reaffirmed by its AI strategy:

> 'The EU must ensure that AI is developed and applied in an appropriate framework which promotes innovation and respects the Union's values and fundamental rights. The EU is also well placed to lead this debate on a global stage. This is how the EU can make a difference – and be the champion of an approach to AI that benefits people and society as a whole' (EC, 2018a).

Ulnicane (2022) argues that questions about global competition and leadership have been an important part of AI discourse:

> 'Over recent years, the EU has repeated its intention to be a leader in AI based on its values…in a global arena of AI competition and cooperation, the EU attempts to project itself as a Normative Power Europe.'

In sum, economic competition posed two challenges. Economic interdependence resulting from digital market integration has increased the volume of cross-border exchange in traded goods and data, national regulation and supervision are no longer able to cope and therefore there is the need for regulatory reform at the EU level. Fragmentation of the European market poses a hindrance to the competitiveness of the EU vis-à-vis the USA and China, hence the necessity to promote integration in this sector (Marcus et al., 2019).

Kuhlmann (2001) points out that the governance of emerging technologies in the EU requires consideration of economic competitiveness at three levels: the national, regional, and the evolving global market. It makes *economic competitiveness* a useful analytical point of departure, as an antecedent variable which can be linked either to the governance approach of EU institutions, or to the preferences and bargaining power of domestic actors.

The role of EU institutional structure

Regarding the third hypothesis, supranational actors were crucial at the agenda-setting stage, which began with the EC's coordinated plan in 2018 and further advanced by the HLEG report in 2019. Both the EC, DG CONNECT, and the HLEG acted as policy entrepreneurs by defining problems, namely the lack of fully integrated and appropriately regulated Single Market in AI goods and services, and by proposing concrete solution.

The Council and the Parliament, which were less involved in the brain storming stage (though it led the debate at EU level by urging the EC to put forward a European approach to AI), participated in the co-endorsement of the 2018 coordinated action plan. The Parliament was particularly active in the decision-making process. In the days since the White Paper, the Parliament successfully influenced the formation of a special committee on AI so as to ensure the compliance with the ethical principles (as elaborated in Sect. 3.3).

EU institutional structure explanations would further stress the role played by the Better Regulation agenda in regulatory reform, in line with many supranationalist accounts. In the impact assessment accompanying the proposal, risk-based approach is prescribed as a solution addressing concerns regarding economic impact on firms and public authorities, and

[6] A similar logic has guided the EU in the case of nanotechnology regulation (Justo-Hanani & Dayan, 2016).

the impact on the environment and fundamental rights (EC, 2021b). In terms of *regulatory outcome*, horizontal act plus voluntary codes of conduct indicate the EC's high expectations toward governing the development and use of AI by diverse regulatory and other innovation-friendly measures. This is in line with economic and normative commitments to good governance practices, as widely shared in studies of EU supranationalism. Indeed, the preference of the EC for Better Regulation in the form of gradual, adaptive approach has been gaining support, as reflected in the Parliament's (2021) appraisal of the impact assessment, and in feedbacks received for the Commission's roadmap (EC, 2021d).

In sum, the two hypotheses derived from EU institutional structure are supported by empirical evidence, with some important qualifications. The influence of the EC and expert groups was greater in the brain storming and the agenda-setting stages, when they acted as policy entrepreneurs. The Council and the Parliament were less involved in the brain storming stage (with some exceptions). The Parliament was particularly active in the decision-making process. Finally, the regulatory outcome is largely in accord with the preferences of the EU institutions, first and foremost the EC.

The role of policy preferences of domestic actors

With regard to the influence of domestic politics in the policymaking process, the empirical record suggests that the 'pro-regulation' Member States (e.g., Germany, France, Finland) benefited from political support by social parties and other liberal groups in the Parliament. Since the release of the White Paper, MEPs from leading industrial countries led discussions in different committees and working groups in the Parliament, especially Committee on Legal Affair (JURI), Committee on Employment and Social Affairs (EMPL), and The Committee on Civil Liberties, Justice and Home Affairs (LIBE). The most extensive work was initiated within the JURI committee, which worked on four different reports: ethical aspects of AI and robotics, led by Spanish MEP García del Blanco (Socialists & Democrats); civil liability regime, led by Germen MEP Axel Voss (European People's Party); intellectual property rights, led by French MEP Stéphane Séjourné (Renew); and application of international law on civil and military uses, and criminal justice, led by German MEP Gilles Lebreton (Identity and Democracy Group) (Niklas & Dencik, 2020).

The domestic politics hypothesis also posits that the national preferences are the aggregated preferences of powerful domestic actors, especially dominant companies and economic interest groups. The AI sectors in France, Germany, and Sweden were strongly in favor of the reform because they attracted the lion's share of investment in AI companies over the past decade, but they could not compete globally alone. An additional impetus for Macron was to position France as a destination for digital companies after Brexit. Companies like Uber, Samsung, and Facebook have already opened or announced the creation of centers in Paris. Companies in these sectors are largely transnational and also engage in lobby activities in international forums. There was a clear rationale for coherent EU-level approach that complements Member States' own actions. Previous research indicates that the AI sectors in Germany, France, Sweden, and the Netherlands have an important role in informing the negotiating position of their national governments in the EU forums through domestic policy networks (Brattberg et al., 2020). This indicates the convergence, or at least the congruence of domestic preferences.

The distinction between high-risk and low-risk AI applications in the White Paper is an example of how Germany fostered the EC attempts to meet special requirements for trade.

In addition, Germany advocated for global regulatory leadership according to its values. Indeed, the empirical record suggests that the constructive cooperation between the EC and Germany was an important factor in the emerging reform. Upon the whole, the EC tended to present policy lines that were largely consistent with the German DEC approach, as documented above. As suggested in several policy documents, Commissioner Von der Leyen is widely regarded as favoring risk-based and value-oriented approaches, which chimes with German preferences (Delcker, 2019; Meyer, 2019).

Several other features of the process fit well with domestic politics assumptions, such as pooling sovereignty and the willingness to delegate authority. The regulatory reform can be seen as an effort by the national governments, first and foremost the French and the German, to encourage the creation of a supranational regime. Previous research indicates that it is a geopolitical mindset that made Emmanuel Macron and other French politician push for a European, rather than exclusive national approach (Franke & Sartori, 2019). The gap in global AI governance led to the French belief that centralized EU rules and standards with the administrative capacity to enforce them could manage the changing global economy. Other Member States with large AI centers, such as Finland and the Netherlands, also expressed support in transferring power to the EU level, as demonstrated by their responses to the consultations, press reports, and research papers (e.g., Pöysti, 2019; Government of Netherlands, 2020. For further evidence, see Parliament, 2021). The proposed policy was seen as vital to their global competitiveness. This support was due in part to the incremental nature of the policy. In this sense, the form of the proposal puts AI governance decision-making on a firmly intergovernmental path.

In sum, the three hypotheses derived from 'domestic policy preferences' are confirmed. However, since many of these preferences coincide with those of the EC and the Parliament, it is difficult to assess which has more explanatory power. The creation of harmonized regulation reflects the preferences of the main players, namely the German and French governments, as well as other 'digital frontrunner.' However, it is largely compatible with the preferences of the EC and the Parliament.

On the whole, this analysis has important implications for our understanding of the politics of AI regulation in the EU. It reveals that while the EU institutions represent a necessary condition for the reform, they are not a sufficient one. The relative political strength of pro-regulation Member States has also been critical. The way the EU goes about making integrated AI policy might have changed, if, for example, powerful Member States had changed their preferences regarding supranational regulation. Such 'change in mood or climate has important impact on policy agendas and outcomes' (Kingdon, 1984).

In addition, this analysis describes two causal factors that affect the policy design, namely the 'demand' of the EU institutions for incremental model, and the interests of domestic actors to 'accept' this model. The evidence suggests that both industry and Member States did not appear to broadly favor regulatory status quo; they did not want future AI regulation to be radical, but neither was there pressure to deregulate or maintain the status-quo. This coincided with the EC preferences for proportionate, incremental policy. Thus, both separately, and by their interaction with one another, the EU institutions and domestic actors have had a critical impact on shaping the regulatory outcome.

Two proposals, empirical and methodological, are put forward for further study. Empirically, research on the effectiveness of the reform would be welcome. It will shed light on the impact of sectorial networks in the implementation stage. Methodologically, since the policy process is still ongoing, the sequencing of theories could be re-examined with reference to the final outcome, such as 'smoking gun' and 'straw-in-the-wind' tests, for the

uniqueness and sufficiency of the hypotheses (Van Evera, 1997), in order to understand the complexity of EU risk regulation.

Conclusions

This article analyzed the evolution of EU regulatory policy in the crucial formative period of 2017–2021. It is argued that there is not one single overarching theory that can explain the reform process and its outcome, and that there is a multiplicity of factors at play. Therefore, using different theoretical approaches can explain various phases of the policymaking process as well as certain features of the outcome. *Economic competition*, which set the background for the reform, provides 'input' to other theoretical approaches and also explains the timing of such reform. *EU institutional structure* accounts for the crucial role played by the EC and the HLEG at the brain storming and agenda-setting stages. *Policy preferences of domestic actors* largely account for the decision-making stage in which members of the Parliament, especially social parties and other liberal groups, had (so far) a major bearing on the outcome. A theory of interest formation, which assigns a great deal of weight to powerful domestic economic sectors or companies, can account for the preferences of the most industrial EU governments.

As for the (co)evolutionary perspective chosen to show how regulatory reform happens on the EU level, this research detects a complex process and stresses the way in which economic competition, institutional structure, and domestic political preferences joined together in bringing about incremental instead of radical change.

To bring it all together, sequencing of different theories according to criteria that evaluate the explanatory power of each theory at different stages of the policymaking process can be more useful in capturing the multi-causal mechanisms at work than an overall model of policy process. There is a significant explanatory value added in a less parsimonious and less monolithic theoretical framework (Howlett & Cashore, 2009). Another example of this stance proclaims that meta-theoretical debate on EU integration has run its course and must give way to theoretical, methodological, and carefully-structured empirical dialogue (Jupille et al., 2003). Moreover, since the theories considered here assign different influence to factors and actors at the global, EU and national levels, a combination of various approaches helps to explain the multilevel governance of the AI sector, where national governments, supranational institutions, and international-oriented industry are involved in policymaking. Therefore, such explanatory framework can also be generalized to other policy changes.

The regulatory reform in the EU is still in progress; therefore, this study is inevitably preliminary. While incremental approach for integrated policy is a welcome development, problems related to the politics of implementation might occur (Rayner & Howlett, 2009), such as opposition from actors that benefit from status quo on specific high-risk uses. It is too early to tell whether the risk-based approach and the actors supporting it will remain influential as concerns regarding competition with the USA and China are re-examined. Yet, the EU continues to propose new rules for 'high-risk' uses to create 'ecosystem of trust,' such as the recently proposed regulation on deepfakes and biometric surveillance (EC, 2021a). It remains to be seen whether the basic philosophy of 'trustworthy human-centric AI' will assist the EU in remaining the most open region for trade and investments in the world.

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