

AI for regulation and the (EU) regulation of AI

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Abstract: The uses of AI in lawmaking and rulemaking are emerging around the world and risk affecting, among the others, the rights of non-discrimination and fairness, transparency or to be heard (as component of the right to a good administration). The application of AI to draft laws or regulations, or to support ex ante regulatory impact assessment or ex post evaluation, as well as the performing of public consultations or rule as a code, seem to have been forgotten by the EU AI Act. The chapter therefore examines real or potential uses of AI for regulation, to which follows an analysis of the content of the EU AI Act to identify if and how the regulation of AI intervenes. What emerges is a risk-based ex-ante approach, like that of the EU Act, which is not agile and therefore only partially ready for the challenges posed by the AI for regulation.

Keywords: lawmaking; rulemaking; artificial intelligence; risk-based approach; consultation; impact assessment; simplification; better regulation.

1. AI for regulation neglected by the European regulation of AI

The use of AI in the public sector is now an established reality, and its spread affects the core States functions: the administrative, the judiciary, and the legislative¹.

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Despite the considerable worldwide attention to the *regulation of AI*², a less discussed topic has regarded *AI for regulation*³. The impact does not seem, however, less relevant and hardly any other means can encroach so deeply and pervasively on fundamental rights across sectors as law-making and rulemaking. The chapter is organised as follows.

It addresses the potential benefits and risks of the emerging role of AI in law and rule-making (**section 2**), e.g. IA writing a piece of legislation/regulation, or part of it; drafting working documents of administrative agencies; increasing accessibility to law and regulation; clustering amendments; translating norms and documents, or forms; performing administrative and organisational tasks (**section 2.1**). Likewise, the analysis delves into the effects of rule as a code, for automatic adjudication or self-assessment compliance (**section 2.2**). Furthermore, the chapter focuses on the benefits and risks of employing AI in consultations, to map stakeholders or to cluster comments received (**section 2.3**). Moving on, the focal point is on how AI can lead to greater affirmation of the use of ex-ante regulatory impact assessment to overcome the known obstacles of data collection and

¹ An analysis of how AI has the power to play a crucial role in the life cycle of rules has been recently offered in N. RANGONE, Artificial intelligence challenging core state functions: a focus on law-making and rule-making, in *Revista de Derecho Público*, 8, 2023, pp. 95 – 126.

² Among the several contributions, see C. COGLIANESE, A Framework for Governmental Use of Machine Learning (Dec. 8, 2020) (report to the Admin. Conf. of the U.S.); C. COGLIANESE / C. CRUM, Taking training seriously: human guidance and management-based regulation of artificial intelligence, in *U. of Penn Law School, Public Law Research Paper No. 24-08*, 2024; D.F. ENGSTROM ET AL., Government by Algorithm: Artificial Intelligence in Federal Administrative Agencies (Feb. 2020) (report to the Admin. Conf. of the U.S.); C. REED, How should we regulate artificial intelligence?, in *Philosophical Transactions of the Royal Society A: Mathematical, Physical and Engineering Sciences*, 376, 2128, 2018; A.A. GAVOOR, The Impending Judicial Regulation Of Artificial Intelligence In The Administrative State, in *Notre Dame Law Review*, 97, 2, pp. 180-188.

³ Studies are limited, but some first examples are A. DRAHMANN /A. MEUWESE, AI and Lawmaking: An Overview, in B. CUSTERS / E. FOSCH-VILLARONGA (eds.) *Law and Artificial Intelligence. Regulating AI and Applying AI in Legal Practice*, Den Haag, Springer, 2022, p. 434 ff.; D. KORYZIS ET AL., ParlTech: Transformation Framework for the Digital Parliament, in *Big Data and Cognitive Computing*, 5, 1, 2021, p. 15; F. FITSILIS ET AL., Guidelines on the Introduction and Use of Artificial Intelligence in the Parliamentary Workspace. figshare. Online resource; F. FITSILIS / G. MIKROS (EDS.), Smart Parliaments. Data-Driven Democracy, in *ELF study: Techno-Politics Series 4*, 2022; P. F. BRESCIANI / M. PALMIRANI, Constitutional opportunities and risks of AI in the law-making process, in *Federalismi.it*, 2, 2024; INTER-PARLIAMENTARY UNION, World e-Parliament Report, 2022 (a first edition was published in 2020); F. FITSILIS, Artificial intelligence (AI) in parliaments - preliminary analysis of the Eduskunta experiment, in *The Journal of Legislative studies*, 27, 4, 2021, pp. 621 – 633; Y. M. CITINO, L'intelligenza artificiale applicata ai processi decisionali parlamentari: una griglia di funzioni e una stima dei rischi per la neutralità delle tecnologie, in *Rassegna parlamentare*, 64, 3, 2022, p. 629.

analysis⁴ (**section 2.4**). Accordingly, the analysis covers the potential uses and risks of AI to simplify and ex-post evaluate the regulatory stock (**section 2.5**). The examples provided show that AI has the power to play a crucial role in the life-cycle of rules, by performing time-consuming tasks, increasing access to knowledge base, and enhancing the ability of institutions to draft effective rules and to declutter the regulatory stock. AI might also amplify the effectiveness of better regulation tools, thus improving the effectiveness of rules. At the same time, however, AI also challenges the rule of law. It may hinder the guarantees of participation or discriminate stakeholders taking part in consultation and compromise the quality of information available to decision-makers; it might be biased for or against a de-regulatory or pro-regulatory approach; it may decrease human autonomy or the making of political choices, thus challenging the democratic representation the separation of powers and the rule of law, as well as questioning the very legitimacy of rules⁵. All these points lead to the following questions, addressed in **section 3**: is the EU AI Act⁶ dealing with such risks? If not, are there any guarantees in the EU AI Act that can be implemented to AI in law and rule-making, at least by way of interpretation?

⁴ G. SARTOR, The way forward for better regulation in the EU: better focus, synergies, data and technology, Study for the European Parliament, PE 736.129, 2022, p. 20; OECD, Better Regulation across the European Union, Paris, OECD Publishing, 2022, p. 76.

⁵ N. RANGONE, Artificial intelligence challenging core state functions: a focus on law-making and rule-making, cit., p. 118.

⁶ EUROPEAN PARLIAMENT / THE COUNCIL, Regulation of the European Parliament and of the Council laying down harmonized rules on artificial intelligence and amending Regulations [...], 2021/0106 (COD), PE-CONS 24/24, Brussels, 14 May 2024. Among the most recent contributions, see C. NOVELLI ET AL., A robust governance for the AI Act, AI Office, AI Board, Scientific Panel and National Authorities, in *ssrn.it* (https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4817755); P. HACKER, AI Regulation in Europe: from the AI Act to future Regulatory Challenges, in I. AJUNWA / J. ADAMS-PRASSL (EDS.), *Oxford Handbook of Algorithmic Governance and the Law*, Oxford, Oxford University Press, 2024, forthcoming; P. Hacker, Comments on the Final Trilogue Version of the AI Act, in *ssrn.it* (https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4757603).

The analysis results in some considerations on the “agility”⁷ of the EU AI Act, and on how to ensure human oversight⁸ and the guardrails of transparency⁹ and explainability¹⁰. The latter with respect to unaddressed cases or borderline applications - which will often occur in digital innovation (**section 4**).

2. The emerging role of AI in law and rule-making

AI provides disruptive benefits to rule-makers and law-makers, not only by performing time-consuming tasks, but also by increasing access to data that would not otherwise be attainable by humans only¹¹. At the same time, an uncontrolled use of AI in rule-making and law-making could easily lead to issues of discrimination, challenges to democratic representation, and, more generally, undesirable and unwanted effects¹². The latter are odds that should not be underestimated, and at least needing to be evaluated from a regulatory perspective. The possible benefits and risks are analysed below with respect to legislating and regulating, as well as for the tools commonly used to improve the quality of law and regulation, i.e. consultation, impact assessment, simplification.

⁷ To be interpreted as the ability “to bridge the growing gap between the slower timescale of regulatory development and the faster timescale of innovation while also protecting the transparency, accountability, rigor, and relevance of our regulatory system” (H. R. KING, Regulation Must Become Agile to Remain Relevant, in *The Regulatory Review*, August 2, 2023). See also OECD, Recommendation of the Council for Agile Regulatory Governance to Harness Innovation, C/MIN (2021)23/Final, Paris, 2021; S. DENNING, *The Age for Agile: How Smart Companies Are Transforming the Way Work Gets Done*, New York, AMACOM, 2018.

⁸ As already emphasized by the European Commission Independent High-Level Expert Group on Artificial Intelligence, *Ethics Guidelines for Trustworthy AI*, 8 April 2019.

⁹ See C. COGLIANESE / D. LEHR, Transparency and algorithmic governance, in *Administrative Law Review*, 71, 1, 2019.

¹⁰ See F. SOVRANO ET AL., Making Things Explainable vs Explaining: Requirements and Challenges under the GDPR, in V. RODRIGUEZ-DONCEL ET AL. (EDS.), *AI Approaches to the Complexity of Legal Systems XI-XII*, Den Haag, Springer, 2021, p. 169; L. FLORIDI / J. COWLS, A Unified Framework of Five Principles for AI in Society, in *Harvard Data Science Review*, 1, 1, 2019.

¹¹ N. RANGONE, Artificial intelligence challenging core state functions: a focus on law-making and rule-making, cit., p. 118.

¹² C. COGLIANESE / A. LAI, Antitrust by Algorithm, in *Stanford Computational Antitrust*, 2, 2022, p. 21.

2.1 The boundaries between core and ancillary uses in legislation and regulation

Uses of AI by Parliaments have undergone a relevant increase in recent times¹³. Back in the 2020, 10% of Parliaments reported the use of AI-based tools¹⁴, and 6% disclosed using legislative drafting applications¹⁵. There are not such specific data on uses for regulation, but consider that, in 2023, more than 700 AI systems have been identified as in use by US federal agencies¹⁶. Similarly, more than 800 cases have been revealed within the EU¹⁷.

The AI uses described below are organised in applications “core” to law-making or rule-making, “quasi-core”, and “ancillary administrative activities”¹⁸ (i.e., that do not affect the actual legislative or regulatory functions).

The “core” practices include the following categories.

Write a law/regulation, or a part of it. Experimentation with the use of digital tools for drafting is relatively old, even before the pervasive advent of AI. An example is the conversion, by the U.S. Congress, of the whole legal code into XML data structure¹⁹. The latter in order develop a system that provides starting

¹³ This is also evidenced by a recent technical seminar held on 18 April at the Italian Chamber of Deputies, entitled “The use of AI for parliamentary research and documentation” and attended by over 30 countries. The seminar was organised by the Italian Chamber of Deputies and the European Centre for Parliamentary Research and Documentation (ECPRD) and was participated by civil servants, lecturers, researchers and AI developers. During the two days of meetings, the three working sessions were divided into: i) criteria and limits for the use of generative AI for parliamentary documentation, ii) artificial intelligence systems at the service of the Parliament and its exponents, and iii) technologies to increasingly enhance the transparency of parliamentary work. See the press release of the Chamber of Deputies No. 2454 of 16 April 2024: <https://comunicazione.camera.it/comunicati-stampa/19-2454>. The seminar is available on the ECPRD website, but only for authorised users: https://ecprd.secure.europarl.europa.eu/ecprd/public/calendar_of_events. Another evidence is the establishment in 2019 of a parliamentary group on AI within the Global Parliamentary Network of the Organization for Economic Co-operation and Development (OECD), see <https://oecd.ai/en/parliamentary-group-on-ai>.

¹⁴ INTER-PARLIAMENTARY UNION, World e-Parliament Report 2020, 2021, p. 16.

¹⁵ *Ibid.*

¹⁶ See the full U.S. AI use case inventory published on the AI.gov website: <https://ai.gov/ai-use-cases/>.

¹⁷ See the “Innovative Public Services Explorer” tool developed by the EU Joint Research Center: <https://ipsoeu.github.io/ips-explorer/>.

¹⁸ The wording is from the whereas (61) of the EU AI Act.

¹⁹ See the official website: <https://xml.house.gov/>.

templates based on the specific type of act, in accordance to drafting standards²⁰. In the EU, the development of LEOS²¹ (Open-Source software for editing legislation) dates back to 2016, starting with LegIT and now LegisWrite (an AI tool used to type, draft and translate acts and related documents²²). AI systems, even more with the employment of large language models, are increasingly able to “produce a rough but credible first legislative draft”²³, and such a capability will supposedly increase over time. For instance, the council of the City of Porto Alegre in Brazil approved an ordinance crafted by OpenAI's ChatGPT, without being aware of it²⁴. Furthermore, Italy is using algorithmic tools to support the writing of amendments in law-making proceedings²⁵. The use of AI to support bills and amendments’ drafting is also experienced in the Scottish and UK Parliament²⁶, as well as in the European Parliament through the "AT4AM”

²⁰ See the official website: <https://xcential.com/legispro/drafting/>.

²¹ There are three new experimental features of LEOS; “i) suggest pertinent normative definitions using similarity with the bill topic; ii) suggest the pertinent normative reference using the thematic similarity with the bill; iii) take into consideration the temporal information and the nested normative references” (M. PALMIRANI ET. AL., Legal Drafting supported by AI: enhancing LEOS, in *Ital-IA 2024: 4th National Conference on Artificial Intelligence, organized by CINI, May 29-30, 2024, Naples, Italy*). Other known cases include i) detecting patterns that could be avoided in legal drafting leading to better regulation and clear legislation; ii) comparing the transposition of EU Directive in domestic legislative to measure the relationship and identify divergences; iii) AI classification to detect derogations and connect them with the initial obligations; iv) supporting the assessment of an act’s digital readiness (see: <https://joinup.ec.europa.eu/collection/justice-law-and-security/solution/leos-open-source-software-editing-legislation/document/drafting-legislation-era-ai-and-digitisation>).

²² Which is also planned to be replaced by EdiT (<https://joinup.ec.europa.eu/collection/justice-law-and-security/solution/leos-open-source-software-editing-legislation/faqs#q1>).

²³ D. LOVRIC, The future of legislative drafting: a strategic approach, Paper for Canadian Institute for the Administration of Justice-CIAJ Legislative Drafting Conference, 8-9 September 2022, Ottawa, p. 6.

²⁴ The news was firstly shared by the Councilman Ramiro Rosàrio on X.com and then delved into by The Washington Post (<https://www.washingtonpost.com/nation/2023/12/04/ai-written-law-porto-alegre-brazil/>).

²⁵ “This system allows the user to directly edit the text of the provision and obtain the corresponding amendment proposal structured in the form of an amendment, according to the rules of technical drafting of legislative texts” (L. TAFANI, A Legislative Drafter’s Perspective, in *ChatGPT series*, April 13, 2023, <https://betterregulation.lumsa.it/chatgpt-essay-series-legislative-drafters-perspective>).

²⁶ M. LYNC, Lawmaker – the new legislative drafting service of the UK and Scotland, in *The Loophole*, 2, 2022, pp. 24-39.

system²⁷. The Chamber of Deputies in Argentina is then developing an AI tool to draft legislation, which also considers the gender perspective²⁸.

Despite the usefulness of the above-mentioned AI features, they do not come without risks. For instance, the use of AI might limit the legislator's autonomy of judgment²⁹, as well as the political discretion³⁰. In the sensitive context of legislative drafting, erroneous terms or poorly thought-out constructions can heavily influence the substance and subsequent interpretations of the content of the law. It should be then considered that legislative drafting is a dynamic and forward-looking activity, which is not merely writing a prescription, but fits into a complex system of norms and social values and principles³¹.

Assessing the consistency of the flow with the regulatory stock. Many AI applications around the world are trained to avoid legislative overlapping. For instance, the Ulysses AI-driven system (developed by the Brazilian Chamber of Deputies) analyses semantic similarities between existing legislation and new proposals/amendments, and shows how those would change the norms³². A system used in the U.S. Congress allows to verify how legislative language changes throughout the amending process, and includes the impact, comparison and cross-reference with existing laws³³.

²⁷ E. GRIGLIO / C. MARCHETTI, La “specialità” delle sfide tecnologiche applicate al drafting parlamentare: dal quadro comparato all’esperienza del Senato italiano, in *Osservatorio delle fonti*, 3, 2022, p. 371. See also from the EU website: <https://joinup.ec.europa.eu/collection/justice-law-and-security/solution/at4am-all>.

²⁸ See the interview with the Director for Innovation, Planning and New Technologies of the Argentine Chamber of Deputies, published on the Inter-Parliamentary Union website: <https://www.ipu.org/innovation-tracker/story/argentina-first-steps-towards-ai-driven-chamber-deputies>.

²⁹ P. F. BRESCIANI / M. PALMIRANI, Constitutional opportunities and risks of AI in the law-making process, cit., p. 12.

³⁰ Y. M. CITINO, L’intelligenza artificiale applicata ai processi decisionali parlamentari: una griglia di funzioni e una stima dei rischi per la neutralità delle tecnologie, cit., p. 659; E. GRIGLIO / C. MARCHETTI, La “specialità” delle sfide tecnologiche applicate al drafting parlamentare: dal quadro comparato all’esperienza del Senato italiano, cit., p. 370.

³¹ H. XANTHAKI, Legislative drafting: a new sub-discipline of law is born, in *IALS Student Law Review*, 1, 1, 2013, pp. 57-70.

³² For a comprehensive analysis, see H. O. ALBUQUERQUE ET AL., UlyssesNERQ: Expanding Queries from Brazilian Portuguese Legislative Documents through Named Entity Recognition, in *16th International Conference on Computational Processing of Portuguese (PROPOR 2024)*. *Qualis A4*; D. PRESSATO ET AL., Natural Language Processing Application in Legislative Activity: A Case Study of Similar Amendments in the Brazilian Senate, in *16th International Conference on Computational Processing of Portuguese (PROPOR 2024)*. *Qualis A4*.

³³ See the quarterly report (H-154 The Capitol) of the Acting Clerk of the House, Kevin F. McCumber (April 15, 2024): https://cha.house.gov/_cache/files/b/5/b5f74525-7067-4ace-

These applications provide relevant support in decision-making but rise some concerns. Firstly, the AI might be trained on datasets that have inherent biases; thus, leading the system to favour certain legislative outcomes or underestimating the importance of specific types of amendments. Secondly, lawmakers may become too reliant on the AI system's recommendations, potentially reducing the depth of their independent analysis or overriding their intuition and domain expertise. Thirdly, although the AI system may identify semantic similarities or inconsistencies in existing legislation, its accuracy in predicting the real-world impacts of legislative changes could be limited by the complexity of legal language and the variability of interpretation. There is, as such, a risk of weakening the democratic control of the lawmaking process³⁴. Lastly, the same tool risks being used adversely, as happened in the Italian Senate, where two senators presented 82 million amendments produced by an algorithm³⁵.

The second category, following an order by importance of the impact, regards the systems with a “*quasi-core*” relevance to rule or law-making.

Drafting working documents of administrative agencies. The Federal Student Aid of the U.S. Department of Education uses AI to generate drafts of documents, emails, and presentation materials, and summarize public content on StudentAid.gov³⁶. The Office of the Under Secretary of the same Agency uses AI to suggest document first drafts³⁷. Moreover, the US Department of Homeland Security uses natural language processing and large language models for text generation in daily work³⁸. The same Agency developed a tool, called FEMA OCFO GPT³⁹, to generate answers to questions submitted by citizens. The EU Commission is using text mining and other relevant methods to “support the

9574-6c9dc4941871/6634771634381FAFEB43146DAE896B9A.clerk-qr13-comparative-print.pdf; A. HERSHOWITZ / S. MADOR-HAIM, “Comparative Prints Suite” of the United States House of Representatives: NLP for Tracking Changes in Bills and Laws, in G. SILENO AT AL. (EDS.), *Legal Knowledge and Information Systems*, Maastricht, IOS Press, 2023, pp. 379 – 382.

³⁴ P. F. BRESCIANI / M. PALMIRANI, Constitutional opportunities and risks of AI in the law-making process, cit., p. 16.

³⁵ A. CARDONE, Algoritmi e ICT nel procedimento legislativo: quale sorte per la democrazia rappresentativa?, in *Osservatorio sulle fonti*, 2, 2022, pp. 376-377.

³⁶ See the inventory of U.S. Department of Education AI Use-Cases: <https://www2.ed.gov/about/offices/list/ocio/technology/ai-inventory/index.html>.

³⁷ *Ibid.*

³⁸ See the U.S. Department of Homeland Security Artificial Intelligence Use Case Inventory: https://www.dhs.gov/data/AI_inventory

³⁹ *Ibid.*

drafting of non-sensitive content” and “support the simplification of texts”⁴⁰. The Commission is also experimenting the use of “smart semantic search” and “smart drafting allowing for re-use of past replies from similar complaints to be used by antitrust case handlers dealing with complaints (through generative AI)⁴¹.

These uses result of less basic danger to the maintenance of the democratic state, with respect to the already seen writing of a law or regulation. However, even such applications conceal possible risks that must be taken into account. Consider, for example, the possibility of inadvertently perpetuating biases presents in historical data, potentially reinforcing disparities in educational opportunities. In addition, AI-generated materials could lead to students receiving incorrect or misleading guidance on financial aid options, eligibility criteria, or application procedures. In addition, relying solely on AI suggestions for writing materials may cause context-specific nuances or considerations that human writers might pick up to be overlooked, resulting in failed citizen support. Concerning the FEMA's system, consider how AI-generated responses to citizen requests during emergencies need to be accurate, timely (and sometimes empathetic) to provide effective support and information, with potential consequences for public safety and trust.

*Increase law and regulation accessibility*⁴². The already mentioned Brazilian Ulysses system includes a tool to increase people accessibility of the legislative framework. The latter by providing real-time information updated based on users’ identified interests⁴³. In the same vein, the European Parliament is using AI in a

⁴⁰ EUROPEAN COMMISSION, Communication to the Commission, Artificial Intelligence in the European Commission (AI@EC). A strategic vision to foster the development and use of lawful, safe and trustworthy Artificial Intelligence systems in the European Commission, C (2024) 380 final, 24.1.2024, p. 9.

⁴¹ *Ivi*, p. 9.

⁴² In order to improve a high-quality accessibility of information by members of the Austrian Parliament (thus avoiding fake news and inaccurate data), AI is also used to find, filter and deliver information on most important current news to the member of the parliament (<https://www.ipu.org/innovation-tracker/story/austria-uses-ai-keep-mps-informed>). Despite, at first glance, this might be considered an application of ancillary nature, collecting information for decision-makers hides the risk of parliamentarians' overconfidence on the results of a system that might be biased (e.g. toward certain sources instead to others). Moreover, this AI application might result in an oversimplification of the reality, potentially not emphasising what are the real problems that should be addressed by lawmaking. Such use also hides another issue, as the potential automation bias in deferring to AI-driven insights, rather than conduction an independent and critical reasoning.

⁴³ The suite encloses an algorithm able to categorise legislative content in specific subjects chosen by public users, with real-time update of the output, based on the identified users’ change of interest during the research.

dashboard⁴⁴, which allows researchers and citizens to view historical documents, such as meeting transcripts⁴⁵, as well as to extract a summary from the document⁴⁶. An Italian startup is also working with the EU and the Italian Institute of Legal Informatics and Judicial Systems⁴⁷ to develop an AI-powered interface to EUR-Lex⁴⁸. The latter to make it accessible to non-experts, such as citizens and small businesses, by providing an interface capable of “understanding” complex legal texts and produce simplified explanations (through large language models and retrieval augmented reality). The EU Commission developed a tool, called Publio, “for supporting users in their discovery of EU law and EU publication, thus also contributing to greater accessibility”⁴⁹.

One of the main issues has been identified by the EU Parliament itself, that underlined how generative AI posed risks in potential distortion of historical narratives; thus, requiring a rigorous testing phase⁵⁰. Moreover, the use of speech recognition technology may produce errors or inaccuracies in transcribing parliamentary debates or discussions, potentially leading to misunderstandings or misrepresentations of proceedings. Risks that become more relevant if encompassing the aim of providing simplified explanations in sensitive contexts, as for a legal database (EUR-Lex) used by parliamentarians, as well as by lawyers and judges. Furthermore, over-reliance on AI-generated explanations may diminish citizens' critical thinking skills or understanding of legal principles, leading to a loss of informed decision-making.

Amendments' clusterization. Many countries (e.g. Italy⁵¹ and Brazil⁵²) are experimenting the usage of AI to cluster similarly worded amendments (with

⁴⁴ The dashboard is accessible at the following link: <https://archidash.europarl.europa.eu/ep-archives-anonymous-dashboard>. For additional details, see also <https://aws.amazon.com/it/partners/success/european-parliament-pwc/>.

⁴⁵ Handwritten texts have been digitalised through optical character recognition (<https://aws.amazon.com/it/partners/success/european-parliament-pwc/>).

⁴⁶ Besides, the related search mechanism is adapted to the EU's multilingual dimension and offers tailored suggestions (also narrowing the search results) by understanding users' intents (*ibid.*).

⁴⁷ See the relevant website: <https://www.aplus.ai/post/welcome-chat-eur-lex-the-conversational-ai-that-enhances-european-laws-accessibility>.

⁴⁸ It is the online portal providing access to EU law. See <https://eur-lex.europa.eu/content/welcome/about.html?locale=it>

⁴⁹ EUROPEAN COMMISSION, Communication to the Commission, Artificial Intelligence in the European Commission (AI@EC), cit., p. 8.

⁵⁰ *Ibid.*

⁵¹ L. TAFANI, A Legislative Drafter's Perspective, cit.

⁵² As part of the already mentioned Ulysses suite. See the description of “Ulysses 4” given by the “Bussola Tech” blog: <https://library.bussola-tech.co/p/ulysses-chamber-deputies-brazil>.

humans reviewing and approving the system’s results, that is also being updated with the ability to look for semantic similarities).

The tool, as such, does not present significant risks, but if bad designed could lead to relevant parliamentary proposals to be overlooked (e.g. losing amendments that the system identifies as similar in terms of the words used, but which have a different impact on the text).

*Translating norms and documents*⁵³. At EU level, a system called “eTranslation” is used by the European institutions for translation into the 24 official languages and other “geopolitically or socio-economically relevant languages”⁵⁴. Here, too, the potential is exponential, and the risks appear almost nil. However, linguistic nuances can lead to translations providing discordant interpretations, thus having an impact on the content of the legislation.

The last category includes *ancillary uses*.

Administrative and organisational tasks. Among the many examples, the already mentioned Ulysses suite in Brazil is used to simplify the workflow of

⁵³ The Immigration and Customs Enforcement Office of the US Department of Homeland Security uses machine learning to translate documents for over 100 different languages (<https://www.opm.gov/data/ai-inventory/>). The US Small Business Administration uses AI to convert handwritten entries on specific standard forms submitted by clients (*ibid.*). Potential risks include over-reliance on machine translation that, without human oversight, leads to misinterpretation of documents crucial to the evaluation of a citizen’s claim or residence permit. Even worse, it might be biased to prefer certain profiles of people.

⁵⁴ EUROPEAN COMMISSION, Communication to the Commission, Artificial Intelligence in the European Commission (AI@EC), cit., p. 8.

parliamentary officials⁵⁵ or of the politicians⁵⁶. Besides, the experimentation of an AI pilot in the Argentinian Chamber of Deputies includes a prediction of the competent parliamentary committee that shall work on a proposal (so to improve efficiency)⁵⁷. The US Department of Labor uses AI to convert speech to text for internal meetings⁵⁸ and a similar system is tested by the European Commission to create minutes or data analysis, as well as to subtitle conferences⁵⁹. A similar solution has been implemented in Spain, along with language inclusivity through an automatic translation used, for instance, for a Senator's speech given in Basque⁶⁰. Estonian parliament uses speech recognition technology to create verbatim reports of its sittings to be published⁶¹. If badly designed, such examples

⁵⁵ A specific module enhances the legislative process through machine learning and natural language processing. In particular, the system allows a semi-automated distribution of parliamentary requests by member of parliaments to specialized legislative counsel groups, reducing cognitive bias and inefficiency previously experienced with manual handling. The system interprets complex legislative language to ensure requests are assigned to and handled by the most competent consultants on the matter. Such a module offers three recommendations for each request, promoting objectivity and accuracy in task allocation, thereby streamlining the legislative workflow. Another algorithm within the system performs conversion from voice to text, as a tool to support proceedings, discussions and debates (both as a record-keeping and for public dissemination). The system is also useful for real-time analysis of ongoing debates and it will enclose a speaker recognition function (<https://library.bussola-tech.co/p/ulysses-chamber-deputies-brazil>). A similar system has been developed in Argentina, where an algorithm was developed to create a system able to retrieve reports from parliamentary sessions. See: <https://www.ipu.org/innovation-tracker/story/argentina-first-steps-towards-ai-driven-chamber-deputies>.

⁵⁶ An algorithm, within the suite, allows members of the Parliament to engage in deliberations remotely (a similar system is used in the Parliament of New South Wales in Australia, with the support of NovaWorks which offers a wide range of solutions for governments. See <https://www.novaworks.com.au/solutions-for-government/>), through biometric authentication. Another module, less relevant to our research, is the application of facial recognition for the communication purposes of parliamentarians. See <https://library.bussola-tech.co/p/ulysses-chamber-deputies-brazil>.

⁵⁷ See the already mentioned interview to the Director of Innovation, Planning and New Technologies at the Argentinian Chamber of Deputies: <https://www.ipu.org/innovation-tracker/story/argentina-first-steps-towards-ai-driven-chamber-deputies>.

⁵⁸ See the U.S. Department of Labor Artificial Intelligence Use Case Inventory: <https://www.dol.gov/agencies/oasam/centers-offices/ocio/ai-inventory>.

⁵⁹ EUROPEAN COMMISSION, Communication to the Commission, Artificial Intelligence in the European Commission (AI@EC), cit., p. 8.

⁶⁰ See the analysis provided by the Bùssola Tech blog: <https://library.bussola-tech.co/p/transforming-the-past-and-shaping>. Such tool becomes crucial since Spanish Parliament approved the use of all official languages (Catalan, Basque and Galician).

⁶¹ See from the official governmental website: <https://e-estonia.com/estonian-parliament-uses-speech-recognition-technology-to-create-verbatim-records/>.

might have a negative impact on the efficiency of the institutions, but would hardly (or at least, on their own) pose a risk to fundamental rights.

To conclude⁶², by virtue of the cases addressed above (which to a good extent are only prime examples), it seems appropriate for legislators and regulators to pay attention to the uses of AI in their environment. The latter to strike the right balance between innovation - that is in most cases a favourable opportunity- and risks prevention. As such, the basic guardrail would be for users to be clearly informed that they are communicating with an AI system; that such systems do not intervene without the supervision of a human (apart for clear administrative and organizational tasks); that the human oversight includes – proportionally to the risk – an expert and interdisciplinary approach to solve potential biased over-reliance or aversion. Besides, in developing an AI system, the ultimate goal should be to simplify activities and speed-up processes, but without leading to worsen already human “trends” (such as over- and unweighted regulatory production). The above needs might also lead to accept and favour, in grey areas, self-regulations by regulators or lawmakers, preferably informed by a principle-based approach.

⁶² Apart from specific risks, as a more general one, there is also who wrote about democratic systems switching towards algocracies and epistocracies (P. F. BRESCIANI / M. PALMIRANI, Constitutional opportunities and risks of AI in the law-making process, cit., p. 8). The latter through a potential increase in the use of AI, that gradually leads to hindering the independence of members of Parliament and their ability to represent those who put them in that role. It has been stressed the need to special caution to avoid limitations that AI can impose on parliamentary debate (ivi, p. 11). The risk would be for the *intentio machinae* to replace the *intentio legislatoris* (Y. M. CITINO, L'intelligenza artificiale applicata ai processi decisionali parlamentari: una griglia di funzioni e una stima dei rischi per la neutralità delle tecnologie, cit., pp. 660 ff.), a certainly undesirable outcome that might invest both core uses and supportive ones.

2.2 The rule as code in the face of the rule of law

The concept of machine processable rules, or rule as code (RaC) and more generally digital-ready legislation⁶³, has caught the attention in recent years⁶⁴. RaC enables a computer to read the logic of a law, regulation, as well as guidelines, or administrative decisions⁶⁵. This approach is endorsed by the digital ready principle enacted at EU level⁶⁶ and could open the door to a new era in which rules would preferably be written in a dual format, the traditional and the codified.

The RaC provides many advantages and possible applications in law and rule-making.

Firstly, since the code requires clarity, precision and plain language, RaC incentivizes the improvement of *legislative drafting*⁶⁷, and allows the automated detection of overlapping between new proposals and existing rules; thus supporting the *simplification of the regulatory stock*⁶⁸. Secondly, RaC eases *ex ante regulatory impact assessment* (e.g., by automatic assessment and ability to

⁶³ See, for instance, the Danish “Guidance on digital-ready legislation. On incorporating digitization and implementation in the preparation of legislation”, 2018 (https://en.digst.dk/media/20206/en_guidance-regarding-digital-ready-legislation-2018.pdf). According to the Danish Guidance, “the rules should be worded clearly and simply, unambiguously and consistently. Simple rules do not necessarily mean a brief law text. It may require more words to make it unambiguous and clear what the rules are. This does not, however, change the overall legal principle that superfluous words in the law text should be avoided” (pp. 8 – 9). In the same vein is the European Commission, Better Regulation Toolbox, 2023, Tool#28 “Digital-ready policymaking”, p. 230.

⁶⁴ Among the several classifications and definitions of rule as code (RaC) system, those have been distinguished into machine readable and machine executable implementations (T. BARRACLOUGH ET AL., *Legislation as Code For New Zealand: Opportunities, Risks, and Recommendations*, in *New Zealand Law Foundation Research Reports*, 2021, <https://hamish.dev/research/lac/index>).

⁶⁵ “Once rules are encoded, they can be tested, and that testing can be done automatically” (J. MORRIS, *Rules as Code: How Technology May change the Language in which Legislation is Written, and What it Might Mean for Lawyers of Tomorrow*, in *Techshow 2021*, February 5, 2021, pp. 2-16).

⁶⁶ EUROPEAN COMMISSION, *Communication 2030 Digital Compass: the European way for the Digital Decade*, COM (2021) 118., COM (2021) 118; European Commission, *Better Regulation Toolbox*, 2023, p. 230 ff.

⁶⁷ N. RANGONE, *Artificial intelligence challenging core State functions. A focus on law-making and rule-making*, cit., p. 104.

⁶⁸ M. WADDINGTON, *Research Note. Rules as Code*, in *Law in Context*, 37, 1, 2020, pp. 179-186.

forecast whether a regulatory option would be successful)⁶⁹ and *ex-post evaluation* (e.g., by directly encoding the evaluation by set parameters of the effectiveness, efficiency and the continuing adequacy of the norm).

In addition, RaC allows not only *automatic adjudication or adjudication by AI*, which would need to be considered a *core* application to law or rule-making, but also a full traceability of it. New Zealand was among the first countries researching the use of “Better Rules and Legislation as Code” (even if now apparently less active)⁷⁰. For instance, some sections of the Immigration Act were coded to calculate if an applicant had been in the State enough to satisfy a specific clause, as well as some parts of the Social Security Act in order to be used within the “Smart Start” system for financial help for child subsidy⁷¹.

On a different perspective, rules and code might also potentially help each other. Specifically, in France, the National Research Institute is developing a coding language for RaC, called Catala, which is “designed to achieve *semantic equivalence with law itself*”⁷² and particularly referred to coding tax law. Catala stands out for employing “literate programming”⁷³, a method that combines legislative-style text with corresponding code annotations. This technique significantly aids non-technical stakeholders like policy-makers and lawyers, providing clarity on how the code reflects the underlying legal or regulatory principles⁷⁴. At the same time, the tool ultimate aim is to “ensure that the software [a such, the code within it] behaves as expected”⁷⁵.

Moreover, RaC enables regulatees to *self-assessment compliance*. For instance, in France, the OpenFisca open-source platform “enables collaboratively modelling laws and regulation [...] making them computable over open APIs for

⁶⁹ J. MORRIS, Rules as Code: How Technology May change the Language in which Legislation is Written, and What it Might Mean for Lawyers of Tomorrow, cit., pp. 5-8.

⁷⁰ See from the official governmental website: <https://www.digital.govt.nz/blog/what-is-better-rules/>.

⁷¹ See the official website: <https://smartstart.services.govt.nz>.

⁷² See the official website: <https://catala-lang.org/en/about>. For a detailed analysis, see S. B. LAWSKY, Coding the Code: Catala and Computationally Accessible Tax Law, in *SMU Law Review*, 75, 3, 2022, pp. 535 ff.

⁷³ As defined in the official website, *ibid*.

⁷⁴ This approach ensures that those without a technical background can follow the logical representation of laws or rules within the code, facilitating better understanding and collaboration across disciplines. The system has been listed by the French government as “awesome”, meaning free software sponsored by one or more public administrations and easy to be replicated (<https://code.gouv.fr/fr/awesome/>).

⁷⁵ As defined in the official website, note 68.

developers, data scientists and researchers”⁷⁶. The system is used within the “Mes aides”⁷⁷ tool developed by the French government⁷⁸, which allows citizens to simulate their entitlement to social benefits⁷⁹, as a potentially *quasi-core* application able to have an impact on citizens’ lives. The Belgian Federal Public Service Mobility is developing a system to translate the vast landscape of aviation laws and regulation into an online aircraft registration system⁸⁰, to allow users to check whether they comply or not with relevant regulation⁸¹.

However, RaC is not without risks, such as leading to oversimplification or distortion of the content⁸²; leaving limited discretion in adjudication⁸³ (“automation-versus-human debate”⁸⁴); resulting in an incorrect or inappropriate outputs that may challenge the rule of law⁸⁵. In addition, RaC implies a loss of

⁷⁶ See from the official website: <https://openfisca.org/en/>.

⁷⁷ See from the official website: https://www.mesdroits sociaux.gouv.fr/accueil/?utm_source=mes-aides-ameni&utm_medium=alternative.

⁷⁸ Also now adopted in Barcelona, see from the official website: <https://lesmevesajudes.barcelona.cat/>.

⁷⁹ Similarly, the United Arab Emirates’ Ministry of Finance recently started to focus on translating laws into manageable and comprehensible algorithms with OpenFisca (<https://wam.ae/en/details/1395303200712>).

⁸⁰ Such system has been listed in the “Case Study Library” of the OECD Observatory of Public Sector Innovation (<https://oecd-opsi.org/innovations/aviation-portal/>).

⁸¹ As of now, the tool is supporting the registration, allowing a drop of 50 % in work by the public administration, but not yet fully automated. See *ibid*.

⁸² E. MICHEL /A. WHALEY, Regulatory technology: replacing law with computer code, in *LSE Legal Studies Working Paper*, 14, 2018, pp. 1-27.

⁸³ “As a consequence, the law would be more legislative because it would be the legislature that directly decides the shape of the law, without the need for downstream assistance from judges or administrative bureaucrats” (M. A. LIVERMORE, Rules by rules, in R. WHALEN (ED.), *Computational Legal Studies. The Promise and Challenge of Data-Driven Legal Research*, Cheltenham-Northampton, Edward Elgar Publishing, 2020, pp. 238-264).

⁸⁴ R. BINNS, Human judgment in algorithmic loops: individual justice and automated decision-making, in *Regulation & Governance*, 16, 1, 2022, pp. 197-211.

⁸⁵ Even if not modern representations of rule as code, two examples help to better understand the risks. The first one is the Australian *Pintarich v Deputy Commissioner of Taxation [2018] HCASL 322*. A taxpayer received an automatic-generated letter from the Australian Taxation Office which waived the majority of the general interest charge on tax debt. The Office informed the taxpayer that he was actually liable to pay, as the letter was generated as an error. The interesting part of the case is that the Full Federal Court found that the automatic-generated letter was not equivalent to the mental process of an authorised officer reaching a conclusion, and, as such, no decision had been made. Another more developed case has been the “Robodebt” scheme. Robodebt utilized automated data matching between income tax and social welfare records, employing a method called “income averaging”. This approach distributed employer-reported earnings uniformly across each fortnight of a financial year to

procedural guarantees⁸⁶. As such, it would be pivotal for regulation to anticipate not only safeguards to the use of rule as a code, but also to assess the risks arising from associated application in the rules' life cycle, such as in an automation of the impact assessment or ex-post evaluation.

2.3 AI versus inclusiveness and representativeness in consultations

The rise of digitization increased exponentially the participation in consultations, while leaving unsolved the problem of limited inclusion of citizens and small firms⁸⁷. In addition, the huge number of comments provided in consultation and the phenomenon of mass campaign challenge the ability of decision-makers to thoroughly assess the position provided; thus, affecting the quality of information available and the quality of law and regulation as a result⁸⁸. The two problems of limited weak interests' involvement and the increased number of participants in

evaluate individuals' income and their eligibility for benefits. If a discrepancy arose between this averaged income and the income recipients actually reported during their benefit period, the system automatically generated a debt notice for those welfare recipients. The wrong design of the system led to a class action settlement of more than 1.8 billion of Australian dollars (A. WITT ET AL., Encoding legislation: a methodology for enhancing technical validation, legal alignment and interdisciplinarity, in *Artificial intelligence and law*, 1, 2023, p. 3).

⁸⁶ On the one hand, "rulemaking by code fails to satisfy the notice-and-comment requirement"; on the other hand, automatic adjudication "endanger the basic right to be given notice of an agency's intended actions" (D. K. CITRON, Technological Due Process, in *Washington University Law Review*, 85, 6, 2008, pp. 1249-1313). Several potential answers to this problem have been developed by M. A. LIVERMORE, *Rules by rules*, cit., p. 257-260. According to C. COGLIANESE: "whether any particular algorithmic system will satisfy the standards of due process will depend on how well that system works and on the adequate validation of its performance" (C. COGLIANESE, Regulating by robot. Administrative Decision Making in the Machine-Learning Era, in *Georgetown Law Journal*, 105, 2017, pp. 1147 ff.). It has also been argued that rule as code risk leading to "computational legalisms" related to "the sheer speed of code's execution. (...) Its lack of delay collapses the hermeneutic gap, because not only does text (the source code) constitute both rule and reality, but its application is pre-determined and imposed immediately at the point of execution" (L. DIVER, Computational legalism and the affordance of delay in law, in *Journal of Cross-disciplinary Research in Computational Law*, 1, 1, 2021, pp. 2-15).

⁸⁷ N. RANGONE, Artificial intelligence challenging core State functions: a focus on law-making and rule-making, cit., p. 112. On how to use language and consultation techniques appropriate to the target audience, see N. RANGONE, Improving consultation to ensure the European Union's democratic legitimacy: From traditional procedural requirements to behavioural insights, in *European Law Journal*, 28, 4-6, pp. 154 – 171.

⁸⁸ S. BALLA ET AL., Mass, computer-generated, and fraudulent comments (June 1, 2021) (report to the Admin. Conf. of the U.S.), p. 21.

consultations (mostly of better organised firms) are linked, and risk allowing rent seeking, regulatory capture⁸⁹, if not corruption⁹⁰.

Actual debate on consultation is focused on how to improve inclusiveness⁹¹, while avoiding rule-makers being overwhelmed by comments and losing the core of information provided⁹². Some approaches might be helpful in limiting the number of comments to those that really fit-in (e.g. make it clear which is the problem at stake and which are is the jurisdiction of the decision-maker who launched the consultation)⁹³, as well as improving inclusiveness (by embracing consultation techniques aimed at ease citizens' and small firms' participation)⁹⁴.

⁸⁹ M. TURNER / Q. WENINGER, *Meeting with costly participation: An empirical analysis*, in *The Review of Economic Studies*, 72, 2005, p. 247 ff.

⁹⁰ C.A. DUNLOP ET AL., Does consultation count for corruption? The causal relations in the EU-28, in *Journal of European Public Policy*, 27, 11, pp. 1718 ff.; M. DE BENEDETTO, *Corruption from a regulatory perspective*, Oxford, Hart, 2021, pp. 114-115.

⁹¹ A. ALEMANNI, Levelling the EU participatory playing field: A legal and policy analysis of the Commission's public consultations in light of the principle of political equality, in *European Law Journal*, 26, 1 – 2, 2020, p. 114 ff.; S. Ranchordas, Consultations, citizens narratives and evidence-based regulation. The strange case of consultation on collaborative economy, in *European Journal of Law Reform*, 19, 1, 2017, pp. 52 ff.

⁹² C. R. FARINA ET AL., Rulemaking vs. Democracy: Judging and Nudging Public Participation That Counts, in *Environmental Law Reporter*, 44, 2014, pp. 10670 ff.

⁹³ Possible remedies include informing them of the real possibility of influencing final decision (e.g. by informing of consultation scope, and what are the limits of public authorities' jurisdiction). See N. RANGONE, *Improving consultation to ensure the European Union's democratic legitimacy. From traditional procedural requirements to behavioural insight*, cit.). Addressing this issue is all the more important because its consequences might feed the position of those who claim that public authorities should not take into consideration opinions without elaboration or deliberation (Comment from Richard J. Pierce on Mass Comments, Computer-Generated Comments and Fraudulent Comments, May 25, 2021, Administrative Conference of US-ACUS) and thus challenging the role of consultation in democratizing regulation. On this misconception about citizen's participation, claiming that "the mass public knows relatively little about regulatory policy, and much of what it does know is wrong" (M.F. CUÉLLAR, Rethinking Regulatory Democracy, in *Administrative Law Review*, 57, 2005, p. 423).

⁹⁴ Some have been experienced in the European Union and on national level, such as on-line forums, citizens dialogues, randomly selected samples of citizens (European Commission, Better Regulation Toolbox, 2023, p. 455), "interactive digital tools that aim at promoting empathy across citizens or societal groups" (A. RENDA, Assessment of current initiatives of the European commission on better regulation, Study for the European Parliament requested by the JURI committee, PE 734.766, June 2022, p. 22). This technique is regularly experienced in Iceland and the Netherlands (OECD, Regulatory Policy Outlook, Paris, OECD Publishing, 2021). In addition, scholars have underlined that seminars and community listening sessions during comment periods (S. KATZEN, Public input in rule-making, in *The regulatory review*, March 7, 2022) can ease citizens' participation. The conclusion of the Conference on the future of Europe suggests a new instrument: the "citizens' assemblies", which involve people

AI might support in reaching both aims. The potential use of AI for public consultations can be divided into three categories: mapping stakeholders to tailor consultation methods and documents to be accessible; reorganization and analysis of comments collected in consultations with extremely high participation rates; identification of “missing stakeholders” (or better, unconsidered ones).

Mapping stakeholders. The interest groups identification is the first consultation step whose inadequacy can make futile all efforts in the attempt to improve inclusiveness. The stakeholders' mapping step is indeed pivotal to provide decision-makers with crucial information on “who” are the stakeholders that should be consulted and “how” to address them in an effective way. According to the EC Better Regulation Toolbox, the main stakeholder categories of the European Commission are citizens, businesses, trade, business and professional associations, non-governmental organisations, consultancy, research and academia, organisations representing regional, local and municipal authorities, other public or mixed sub-national entities, national and international public authorities⁹⁵. This is a non-exhaustive and generic list, which needs to be organized to identify interested parties to a given consultation process. Specifically, the latter is to map those i) who are directly/indirectly/potentially impacted; ii) whose help is needed in order to make a regulation work; iii) who studied or have a specific know-how over the topic; iv) who will show an interest on the issue consulted on and so increase an effective participation⁹⁶. To the best

randomly selected to represent the cultural identities and the diversity of society (A. ALEMANNI, Towards a permanent citizens' participatory mechanism in the EU, Study Requested by the AFCO committee of the European Parliament, 2022). Otherwise, targeted consultation, such as roundtables, focus-groups meetings, or hearings might support the collection of SME or start-ups' views (EUROPEAN COMMISSION, Better Regulation Toolbox, 2021, p. 172). In short, the need emerged to find new paths to vehicle “missed stakeholders” voices. The so-called “missing stakeholders” are “those directly affected by the proposed rule who are historically unlikely to participate in the traditional comment process” (ADMINISTRATIVE CONFERENCE OF THE UNITED STATES, *Adoption of Recommendations and Statement Regarding Administrative Practice and Procedure, Federal Register 76269, 78, 242/2013, p. 76271*).

⁹⁵ EUROPEAN COMMISSION, *Better Regulation Toolbox*, 2023, TOOL#53, “The consultation strategy”.

⁹⁶ The Toolbox also highlights as an even more detailed clustering can be reached by: 1) distinguishing the stakeholders' groups which may be affected by the initiative in a significantly different way and determining their level of interest; 2) differentiating the potential different ways stakeholders are affected within a specific group (e.g., can we assume all citizens have the same skill, knowledge and interest in the issue addressed? See B. FRAUSSEN ET AL., Conceptualizing consultation approaches: identifying combinations of consultation tools and analyzing their implications for stakeholder diversity, in *Policy Sciences*,

of our knowledge, there are not public uses of AI to *map stakeholders* for consultations. However, some potential applications might include natural language processing to scan historical data from public records (past consultation submissions, surveys, and social networks discussions) to predict which groups might be interested in consultation processes (e.g. based on their demographic profiles and jobs). Geospatial Analysis could also be used to identify regional groups most affected by certain policies or regulations. For instance, within the “Citizen Engagement Working Group of the Hampton Roads Sea Level Rise Preparedness and Resilience Intergovernmental Planning Pilot Project”⁹⁷ an AI system (“weTable tool”), was used to solicit and document local knowledge, by facilitating community-wide discussion and enhancing participatory mapping. As the basis for the consultation, applications of AI to such aim might indirectly influence the outcome of the process, and as such to be interpreted as *quasi-core* relevance to rule or law-making.

Clustering comments received. AI supports law-makers and rule-makers in reorganizing and analysing comments, e.g., clustering comments, identifying duplicates, or summarizing the overall comment sentiment. The EU proposes a complex example of the first category, through a system previously called “Doris” and now evolved into “Doris+”⁹⁸. The latter is a tool owned by the Secretariat-General and developed for the DGs of the Commission. The system is hosted in the amazon web service cloud and gathers data from the EU Survey and the Have your Say Portal. After the extractions from such sources, the

53, 1, 2022, p. 489); 3) determining the level of influence that different stakeholders might have over the decision-making. Surprisingly, none of these steps mentions the different ability of understanding the topic and the availability of economic resources as a determinant factor to make their voice heard (this was demonstrated with regard to firms: “unequal resources among organizations lead to inequalities in participation, frequency of participation, lobbying sophistication, and lobbying success. Many organizations do not have the baseline level of resources to engage in sophisticated lobbying”, D. P. CARPENTER ET AL., *Inequality in Administrative Democracy: Methods and Evidence from Financial Rulemaking*, in *ssrn.it* (<https://ssrn.com/abstract=4770520>), p. 38.

⁹⁷ J. E. YUSUF ET AL., *Participatory GIS as a tool for stakeholder engagement in building resilience to sea level rise: A demonstration project*, in *Marine Technology Society Journal*, 52, 2, 2018, pp. 45-55. See also S. MARAN / G. STELLA, *A participatory Web GIS for stakeholders' engagement in the development of the electricity grid*, in *Conference: The 14th International Multi-Conference on Society, Cybernetics and Informatics: IMSCI 2020*.

⁹⁸ “DORIS+ is a corporate tool for the European Commission that provides analysis and visualization of the results of Open Public Consultations done with EU Survey and Better Regulation Portal” (See the joinup EU official website: https://joinup.ec.europa.eu/collection/doris/solution/doris-plus?f%5B0%5D=solution_content_bundle%3Adocument).

information is organized for further processing and divided into two categories: consultations’ replies with text, and without. The ones with text are subdivided into batches of 1000 or 10, if containing an attachment that also needs to be translated. Feedback without text (closed questions) are aggregated to identify and calculate equal replies. Furthermore, replies with text are sent to a system that identifies the language and executes an automatic translation in English. The translated text is stored into the cloud, where another system detects similar key phrases, entities, and topics in the texts⁹⁹, and performs a sentiment analysis¹⁰⁰. The results are, at the end, showed to DGs in a visualisation tool which highlights data in an organized way and through dynamic graphs¹⁰¹ (DORIS public consultation dashboard)¹⁰².

A system experimented by the UK Policy Lab also includes a tool called “top themes”¹⁰³. The latter is designed to help policymakers identify key issues from consultations, quickly and impartially, by grouping similar responses into thematic clusters. A complementary tool, the sentiment analysis prototype, evaluates the emotional tone of responses (categorizing them according to Robert Plutchik's wheel of emotions)¹⁰⁴; therefore, helping policymakers understand public reactions, refining policy delivery, and developing communication

⁹⁹ Up to 30 terms, in order of importance, that were associated with the attachment text” and the “the id contained in feedback which associates with an answer text enclosed in the consultation document” (*ibid.*).

¹⁰⁰ “The sentiment analysis determines the general attitude of the interviewee with regard to a question of the public consultation. It doesn’t focus on the specific articulate emotions. The attitude is represented through four different values: positive, negative, neutral and mixed”. Besides, “the sentiment the text has with choices [neutral, positive, negative, mixed]” (*ibid.*). It is also highlighted by the European Commission as “de-duplication of results are important for key phrases and entities to avoid too much similar words in a single text to skew results for the aggregate”, but it is not specified if the latter is done manually or within the system (*ibid.*).

¹⁰¹ “Kibana provides interactive charts, pre-built aggregations and filters, and geospatial support” (*ibid.*).

¹⁰² EUROPEAN COMMISSION, Communication to the Commission, Artificial Intelligence in the European Commission (AI@EC), cit., p. 8. Besides such system, another one is under development and testing phase by the European Commission to analyse the feedback provided by the public in order to help develop new legislative proposals (p. 10).

¹⁰³ S. BENNETT / N. CUTLER, Lab Long Read: Policy Consultations – Part 2: A role for data science?, in *openpolicy.blog.gov.uk* (<https://openpolicy.blog.gov.uk/2019/10/28/lab-long-read-policy-consultations-part-2-role-of-data-science/>).

¹⁰⁴ On these kinds of tools, see M. M. ABBASI / A. P. BELTIUKOV, Summarizing Emotions from Text Using Plutchik’s Wheel of Emotions, in *Proceedings of the 7th Scientific Conference on Information Technologies for Intelligent Decision Making Support (ITIDS 2019)* (2019), pp. 291 ff.

strategies¹⁰⁵. A similar model, called i.AI¹⁰⁶ and developed in the UK by the Department of Health and Social Care, uses large language model to label and summarise each common recurring theme, previously extracted through natural language processing. In the US, the USDA and the CDO Council collaborated to develop a tool allowing rulemaking personnel to focus on the most pertinent comments, and offering unified responses to clusters of similar comments¹⁰⁷.

These applications aim to alleviate the resource-intensive and subjective process of sorting thousands of responses, freeing policymakers to focus on developing creative policy solutions and considering broader implications. They allow a significant time saving¹⁰⁸, and prevents decision-makers being affected by information overload bias¹⁰⁹. However, they do not come without risks. For instance, if AI systems are trained on biased data (such as tendency to give more relevance to some geographic location and related industry needs), they may inherit and amplify those biases in their analysis. Moreover, an inadequate clustering of comments (combination of different groups of stakeholders showing similar position) could lead to unfair representation or prioritization of certain groups' opinions over others (e.g. making an opinion appear majoritarian, while it is not), which can undermine the value of the information provided to rule-makers and thus of the final regulation¹¹⁰. At the same time, overusing these tools could lead to decision-makers relying too heavily on AI systems and neglecting the value of human judgment in interpreting and assessing contributions. Besides, the criteria and algorithms used to cluster, analyse, and rank responses may lack

¹⁰⁵ It also aids in recognizing certain negative emotions, like anger, emerge, that can inform different response strategies. Additionally, sentiment analysis can support workforce well-being by helping managers assist staff working on sensitive topics. See note 101.

¹⁰⁶ See the official website from the UK Government: <https://ai.gov.uk/projects/consultations/>.

¹⁰⁷ FEDERAL CDO COUNCIL, Implementing federal-wide comment analysis tools, Final Recommendations, June 2021 (https://resources.data.gov/assets/documents/CDOC_Recommendations_Report_Comment_Analysis_FINAL.pdf).

¹⁰⁸ M. A. LIVERMORE ET AL., Computationally Assisted Regulatory Participation, in *Notre Dame Law Review*, 93, 3, 2018, pp. 977-1034.

¹⁰⁹ N. RANGONE, Improving consultation to ensure the European Union's democratic legitimacy: From traditional procedural requirements to behavioural insights, cit., p. 154-171.

¹¹⁰ Although the 2023 EC Better Regulation Toolbox (#tool 54, pt. 1.3.1 and 1.3.2) acknowledges that clustering groups in consultations' feedback can be achieved through computational tools, the EC rarely details its computational methodologies in the synopsis reports attached to legislative proposals. The EC currently conducts stakeholder clustering in a non-standardized, case-by-case manner. Given this context, our analysis recommends that the EC and rule-makers in general consider utilizing computational tools for analyzing consultations' feedback to perform stakeholder clustering (F. DI PORTO ET AL., Smarter consultations: clustering stakeholders through AI, *forthcoming*).

transparency, making it difficult for stakeholders to understand how decisions on their contributions are being made. The latter could reduce trust in the process and raise questions about accountability. Similarly, clustering and ranking responses by theme can result in the loss of nuanced perspectives. Complex opinions might be grouped under broad categories, which could distort or overlook important subtleties in the data. On a different perspective, if stakeholders understand how these systems work, they might try to manipulate public opinion by gaming the AI analysis to their advantage.

The applications described, used to cluster comments received and offer unified responses, have a direct impact on the content of the consultation and on the results that will be then used for the rules' cycle. Besides, this is a pivotal point of contact and dialogue between public and private subjects, with the risks to increase the crisis of confidence. As such, such uses shall be interpreted as *core* relevance to rule or law-making.

Improve inclusiveness. The fundamental aim to overcome the lack of inclusiveness might be addressed by easing the voice of marginalised to be heard and even by identifying the under voiced. The first objective can be reached by using LLM to transform citizens' narrative into technical language that is more likely to be considered by the regulators. The second objective requires more innovative approaches. For instance, the already mentioned UK Policy Lab developed a "participation live flow" system aimed at providing real-time demographic analysis of responses and making clear whether certain groups are underrepresented¹¹¹. Among the risks, the AI may fail to recognize underrepresented stakeholders correctly, inadvertently perpetuating existing biases and favouring certain categories. If AI systems consistently identify certain groups as underrepresented and focus consultation efforts on them, this could inadvertently create feedback loops where the same groups are repeatedly prioritized over others. Similarly, the AI might categorize demographic groups based on wrong predefined characteristics, which could lead to an overly simplistic view of stakeholder needs and obscure more complex, intersectional identities. As such, the above uses, following the logic used with previous cases, might be considered a *quasi-core* application to rule or law-making.

¹¹¹ S. BENNETT / N. CUTLER, Lab Long Read: Policy Consultations – Part 2: A role for data science?, cit. Similarly, after the collection of all contributions, the system might be used to identify if certain groups were more likely to answer questions in other forms, thus suggesting the use of different consultation techniques.

It is also worth mentioning a study carried out by the UK Department for Transport¹¹² aimed at gathering knowledge on the views from the wide public and stakeholders on the use of AI to analyse consultation responses¹¹³. Members of the wide public held a general high-level of comfort for the use of AI for such a purpose. However, some perplexities were also shared. First, regarding accuracy in the outputs with misinterpretations of open text responses (e.g., feedback including multiple issues; rhetorical techniques; slangs and spelling mistakes or generally badly written responses which may be difficult to interpret even for a human)¹¹⁴. Interestingly, another identified issue included the fear of potential biases, regarding potentially marginalised groups¹¹⁵. On the other hand, stakeholders highlighted as they generally prefer quality of the analysis over speed¹¹⁶. As such, they focused more on the need to ensure similar quality to the human production.

2.4 Actual and potential uses of AI in ex-ante impact assessment

The inherent characteristics of impact assessment¹¹⁷ have led to the idea that AI should play supportive role, but cannot replace completely humans in this exercise¹¹⁸. Nevertheless some interesting actual and potential application are emerging. The EU is investigating the potential use of AI to “carry out impact assessments of major legal proposals” and “assess the impact of new legislation

¹¹² U.K. DEPARTMENT FOR TRANSPORT, Using AI in consultations and correspondence, in *Thinks Insights & Strategy research report*, September 2023 (<https://assets.publishing.service.gov.uk/media/654e6f078a2ed4000d720d12/using-ai-in-consultations-and-correspondence.pdf>).

¹¹³ The research engaged 91 participants across three strands of data collection: i) three 3-hour deliberative workshops with 71 participants across the UK; ii) 60-minute in-depth interviews with 'engaged' citizens (i.e. members of the public who have either responded to a UK Government consultation or sent correspondence to a UK Government department their local council in the past 2- years); iii) nine 60-minute in-depth interviews with DfT stakeholders (*ibid.*)

¹¹⁴ U.K. DEPARTMENT FOR TRANSPORT, Using AI in consultations and correspondence, cit., p. 28.

¹¹⁵ *Ivi*, p. 37.

¹¹⁶ Besides, they even questioned the actual need of AI for the offices to be quicker in their analysis, where they suggest the slow trend might actually depends on agreeing or not with the results (*ivi*, p. 30-31).

¹¹⁷ Which requires a broad approach and policy coherence, and that should provide causal connection and not mere correlation, by also being proportional to the issue at stake.

¹¹⁸ N. RANGONE, Artificial intelligence challenging core state functions: a focus on law-making and rule-making, cit., p. 114.

on existing European and national legislation”¹¹⁹. AI could have a crucial role in achieving a satisfactory degree of use and effectiveness of a pivotal tool for better regulation, as the impact assessment (IA). The AI, but also the digitalization more broadly (e.g., databases to enhance the only once principle), leads to important development prospects for data collection and analysis¹²⁰. Those are two of the weak points for the IA, that oftentimes “fails to properly analyse the existing regulatory environment”¹²¹ (“which can lead to a bias to more regulatory interventions”¹²²), as well as to provide true quantitative analysis of impacts of all relevant regulatory options.

An analysis of possible uses can follow precisely what are the phases of an IA, as the problem definition and the policy goals (and even a more specific and evidence-based understanding of the actual need to intervene); the identification of regulatory options; the assessment of their potential impacts; the identification of the preferred option.

Problem definition. AI might help in increasing access to knowledge base that would not otherwise be attainable. Data mining could be used to extract information from diverse data sources to reveal problem patterns (e.g., academic research databases¹²³, studies and policy documents from research entities or international organisations, or public dataset¹²⁴ to find relevant scientific studies or certified data)¹²⁵. For instance, the Italian national statistical institute (ISTAT)

¹¹⁹ EUROPEAN COMMISSION, Communication to the Commission, Artificial Intelligence in the European Commission (AI@EC), cit., p. 9.

¹²⁰ With regard to the European Commission IAs, “the Board acknowledges that the assessment of impacts can be constrained by limited data availability and raise analytical challenges” (Regulatory Scrutiny Board, Annual report 2022, p. 17). “In several cases services preparing an impact assessment did not pay sufficient attention to the adequate reporting or timely development of an adequate data collection approach as recommended in the better regulation guidelines and toolbox” (Regulatory Scrutiny Board, Annual report 2023, p. 20).

¹²¹ CENTRE FOR EUROPEAN REFORM, Better regulation in Europe. An action plan for the next Commission, 2024, p. 9.

¹²² *Ibid.*

¹²³ B. C. E. DOOLING / M. LIVERMORE, Bot-Generated Comments on Government Proposals Could Be Useful Someday, in *slate.com* (<https://slate.com/technology/2021/06/bot-generated-comments-on-regulatory-proposals-could-be-useful.html>).

¹²⁴ E. EGAN, Generative AI Offers Federal Agencies Common-Sense Opportunities to Simplify and Improve How They Work, in *Information technology and Innovation Foundation*, June 28, 2023.

¹²⁵ For instance, among the examples of AI systems in development, the European Commission mentions the use of “AI to search for and make available scientific evidence for EU policy making” (EUROPEAN COMMISSION, Communication to the Commission, Artificial Intelligence in the EUROPEAN COMMISSION (AI@EC), cit., p. 9).

delivered a platform (IstatData)¹²⁶ enabling natural language-based searches on datasets contained in its archives¹²⁷. Clustering algorithms might be used to identify common and emerging patterns in the analysed documentation. LLM could then be implemented to analyze large bodies of text to identify key challenges and societal needs. Besides, sentiment analysis could also be used to highlight key pain points in the analyses.

Identifying regulatory options. IA is essential in trying to predict the possible impacts of a policy by understanding the causal effects of a regulatory intervention¹²⁸. The latter requires identifying and comparing the effects of different options. AI could help to identify if a regulatory option is redundant or incompatible with existing regulations, if any¹²⁹. For instance, the Australian Office of Impact Analysis is using digital tools “to identify overlapping regulatory processes across Australian Government agencies or jurisdiction”¹³⁰. The Regulatory Quality Improvement Assistance Office of the Brazilian Health Regulatory Agency developed a “regulatory observatory”, which is used to monitor all “plans, projects and ongoing processes on the regulatory agenda, organized by subject theme and status”¹³¹ for regulatory planning. Besides, an interoperability between databases of different Countries might be propaedeutic for a knowledge-based AI to suggest feasible options based on historical precedents. Those applications are also useful for the simplification of the regulatory stock (see section 2.5).

Assessing potential impacts of each regulatory option. The German Federal Statistical Office recently presented an ongoing experiment to speed up the identification of parts of draft regulatory texts that affect compliance costs, as well as the source of the costs (e.g., through understanding who the affected

¹²⁶ See from the website: <https://esploradati.istat.it/databrowser/#/it/dw/dashboards>.

¹²⁷ ISTAT, Relazione al Parlamento sulle attività dell’Istat e degli uffici del sistema statistico nazionale e stato di attuazione del programma statistico nazionale (art. 24, D. Lgs. n. 322 del 1989) - anno 2022, 2023, pp. 69 ff.

¹²⁸ G. SARTOR, The way forward for better regulation in the EU: better focus, synergies, data and technology, cit., p. 20.

¹²⁹ The U.S. Center for Medicare & Medicaid Services is exploring the use of AI for prospective and retrospective analysis (C. M. SHARKEY, Algorithmic tools in retrospective review of agency rules, cit., p. 33).

¹³⁰ WORLD TRADE ORGANIZATION, Committee on Technical Barriers to Trade, Thematic Session on the Use of Digital Technologies and Tools in Good Regulatory Practices, G/TBT/GEN/367, 20 December 2023, p. 1.

¹³¹ *Ivi*, p. 2.

recipients are and at what cadence)¹³². The experiment aims to combine two sources of data to lead the system to identify words related to changes in compliance costs. The first source is a database (“OnDEA”) where compliance costs of laws from 2012 onward are stored¹³³, and the second source is through the web scraping of online law databases for the corresponding law texts. The intent is to combine these two sources to train a machine learning system that can predict in which paragraphs of a text an amendment may influence compliance costs (and in which others would not)¹³⁴. Within the compliance costs specifically, the Office is experimenting a way to accelerate the estimation through machine learning. A simplified procedure is already in place to estimate annual compliance costs of businesses up to 100,000 euros per year, and now the new system should expand the estimation on citizens and public administrations; one-time costs (and not only yearly); and by testing a broader range of methods (such as neuronal network and decision trees)¹³⁵. Such tool requires the creation of training data sets based on current databases with measured costs; model building which may vary for each norm recipient; comparison of different machine learning models; and extraction of the best one for each scenario. Besides the compliance costs, AI can then support the identification of the administrative burdens introduced by the regulatory options and estimate their cost through the “standard cost model”¹³⁶. Portugal is amid an innovation shift in the approach to the regulatory impact assessment¹³⁷. Deep learning was used to “identify information obligations within legal texts”¹³⁸ and recognize patterns linked to administrative burdens to train a system. The latter has been proven successful in highlighting paragraphs including administrative burdens through natural language processing, and the effectiveness could be improved with a

¹³² See the presentation given by the Statistisches Bundesamt: S. WALPRECHT / C. LEWERENZ, *Facilitating Regulatory Impact Assessments: The Benefits of Machine Learning in Legislation*, 04.04.2024 (https://www.destatis.de/EN/About-Us/Events/Machine-Learning/Slides/s2_walprecht.pdf?__blob=publicationFile).

¹³³ *Ibid.*

¹³⁴ *Ibid.*

¹³⁵ *Ibid.*

¹³⁶ For more details on the formula used and the methodology, see EUROPEAN COMMISSION, *Better Regulation Toolbox*, 2023, Tool#28, p. 522 ff.; P. COLETTI, *Standard Cost Model*, in C. A. DUNLOP / C. M. RADELLI (EDS.), *Handbook of Regulatory Impact Assessment*, Cheltenham-Northampton, Edward Elgar Publishing, 2017, pp. 93 – 107.

¹³⁷ In particular, the Technical Unit for Legislative Impact Assessment experimented a system developed in collaboration with the NOVA Information Management School (see <https://www.ijournalse.org/index.php/ESJ/article/view/2193/pdf>).

¹³⁸ *Ibid.*

larger dataset of laws used for the training phase. The research is also reaching a new range, through an EU-funded project (“AI4AI@EU”) to pilot the use of AI to analyse the transposition of EU legislation (comparing existing national legislation with new obligations) and identifying instances of “gold plating” (that is, to go beyond the minimum level of a directive or regulation being implemented)¹³⁹. Clearly, an unmonitored analysis based on faulty or uncontrolled data may lead to erroneous indications of the potential consequence of a given regulatory option, pointing towards the wrong one or favouring the status quo, where this would not be what is needed.

Lastly, rules as code, whose risks have been discussed in section 2.2, could lead to an even simpler automated testing of the impact of new proposals or amendments (thus improving the ability to forecast whether a regulatory option can reach the expected outcomes)¹⁴⁰. A use case concerns the development of OpenFisca and its use in the LexImpact tool by the National Assembly to analyze the impact of amendments to French tax law¹⁴¹.

Comparing the options to identify the preferred one for the given context. After having analyzed the impacts of the proposed regulatory options, it could be possible to take advantage of the increasing use of AI systems for the application of techniques, such as the “Analytic Hierarchy Process”¹⁴². Specifically, such

¹³⁹ The project has been selected in 2022 and funded by the EU through the Technical Support Instrument of the DG Reform (https://reform-support.ec.europa.eu/our-projects/country-factsheets/portugal_en and <https://www.planapp.gov.pt/project/artificial-intelligence-for-better-regulation/>).

¹⁴⁰ “Computer systems can generate random fact scenarios, enter those fact scenarios into the rules, and calculate the consequences. Those consequences can then be compared to expected outcomes. For example, a proposed amendment to a piece of tax legislation might be intended not to increase anyone’s taxes. You can specify a fact scenario, and the taxes owing that you expect before and after the change, and determine whether or not it has the expected effect. But you can also state generally that no outcome should result in increased taxes, and have the computer randomly generate any number of fact scenarios and test them to see if that condition is ever violated. (...) The development of OpenFisca [an open source library for the Python programming language] and its use in the LexImpact tool [by the National Assembly] for analyzing the impact of amendments to French tax law are the most direct real-world example of the use of Rule as Code today” (J. MORRIS, *Rules as Code: How Technology May change the Language in which Legislation is Written, and What it Might Mean for Lawyers of Tomorrow*, cit., p. 7-8; see also <https://beta.gouv.fr/startups/leximpact.html>).

¹⁴¹ *Ibid.*

¹⁴² Some experiments concerning the application to AI with the integration of the analytic hierarchy process include decision-making scenarios for cybersecurity (I. SVODOBA / D. LANDE, *Enhancing Multi-Criteria Decision Analysis with AI: Integrating Analytic Hierarchy Process and GPT-4 for Automated Decision Support*, in *arXiv preprint:2402.07404*) and a more general analysis on large scale decision making with evaluations of all possible

tools provide a rational framework for a needed decision by quantifying its criteria and alternative options, and for relating those elements to the overall goal. For these actual and potential applications to work, the availability and quality of data is key. Otherwise, inaccurate analyses are produced, which in turn could lead to inadequate rules. In addition, poor data quality must be read in the sense of “contextualization” of the data: training data must be collected having in mind the use that the system will make of it, and the possible interpretations that it will give with respect to the regulatory context. Furthermore, IA is forward looking: if fed mainly by historical data, it risks leading to an under-evaluation of new entrants and new risks¹⁴³ and supporting the wrong assumption that people’s behaviour is always consistent¹⁴⁴. The uses described, being in support of some tasks within a broader work required within an ex-ante impact assessment, and given the lack of direct relationship to the outside world, may potentially be considered as *quasi-core* to rule or law-making - while still maintaining in fact the not remote risk of influencing the rules’ cycle.

Apart from the above-discussed uses, AI can also be pivotal to train the employees and disseminate an understanding of the importance of the IA within the agency; as well as to tackle motivational and knowledge-based barriers that obstacle participation in consultations carried out within IA proceedings. For instance, the already mentioned Brazilian Health Regulatory Agency developed a chatbot (called ARRtemis)¹⁴⁵, that can be used by employees to ask questions about IAs’ steps, procedures and agenda. Besides, the office developed a regulatory assessment panel¹⁴⁶, powered by Microsoft Power BI, to show

alternatives (M.A. ALVES ET AL., Machine Learning-Driven Approach for Large Scale Decision Making with the Analytic Hierarchy Process, in *Mathematics*, 11, 3, pp. 627 ff.).

¹⁴³ R. BALDWIN / J. BLACK, Really Responsive Risk-Based Regulation, in *Law & Policy*, 32, 2, 2010, pp. 181-213; p. 205-206.

¹⁴⁴ “The radical uncertainty of the future is exacerbated by the fact that predictions impact the behavior they supposedly predict” (M. HILDEBRANDT, Code-driven Law: Freezing the Future and Scaling the Past, in S.

DEAKIN / C. MARKOU (EDS.), *Is law computable? Critical perspectives on law and artificial intelligence*, Oxford-New York, Hart, 2020, pp. 73 ff.). In addition, people may react strategically to elude detection (D. F. ENGSTROM ET AL., Government by Algorithm: Artificial Intelligence in Federal Administrative Agencies, cit., p. 86 ff.).

¹⁴⁵ See from the official website: <https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2022/anvisa-lanca-assistente-virtual-interna>.

¹⁴⁶ Which can be accessed at the following link from the Agencia Nacional de Vigilancia Sanitaria

(<https://app.powerbi.com/view?r=eyJrIjoiODQwZWlxMjAtYTAwYi00ZWZlTg0NzQtMjQ1NGFiMDVka0UyIiwidCI6ImI2N2FmMjNmLWMzZjMtNGQzNS04MGM3LWI3MDg1ZjVIZGQ4MSJ9>).

information about IAs with user-friendly graphs (e.g., one panel shows data on ongoing IAs with status, time and internal distribution; another panel provides the calendar with the scheduled activities).

2.5 Actual and potential uses of AI in simplification and ex-post evaluation

The use of AI to *simplify existing law and regulation* has attracted attention following a recommendation of the Administrative Conference of the United States on “Using Algorithmic Tools in Retrospective Review of Agency Rules”¹⁴⁷. The document outlines key strategies to pinpoint outdated or redundant rules, typographical mistakes, or incorrect cross-references. It also covers strategies for addressing problems arising from intersecting or overlapping rules or standards. Additionally, it explains how agencies can develop these tools to enhance transparency, encourage public involvement, and ensure accountability. The recommendation is based on a groundbreaking report that described ongoing pilots in the US, such as the “Regulatory Clean Up Initiative”¹⁴⁸ to identify mistakes in rules through natural language processing, or the “RegExplorer”¹⁴⁹ system to identify burdensome, ineffective or obsolete regulations. Another tool, called “QuantGov”¹⁵⁰ is used by the Transportation Department’s Office of the Chief Information Officer to estimate the regulatory load by identifying content within massive quantities of rules, and by making prediction about what is written in the documents. In the EU, Portugal implemented the Normative Acts Control System (called Scan) for automated monitoring and control of compliance with regulations to identify potential needs to review existing norms¹⁵¹. Such uses have a direct impact on the quality of rules, risking amendments and simplifications with major consequences for citizens and businesses. As such, they might be considered in the category of *core* uses for rule or law-making.

IA for *ex post evaluation of existing law and regulation* is of very limited application to the best of our knowledge. This might be due to the fact that this tool is not as well developed as the impact assessment, and is rarely among the

¹⁴⁷ C. M. SHARKEY, Algorithmic Retrospective Review of Agency Rules, cit.

¹⁴⁸ *Ivi*, p. 9 ff.

¹⁴⁹ *Ibid.*

¹⁵⁰ *Ivi*, p. 13 ff.

¹⁵¹ R. SARAIVA, Rules and Nudging as Code: Is This the Future for Legal Drafting Activities?, in K. MATHIS / A. TOR (EDS.), *Law and Economics of the Digital Transformation*. ILEC 2023. *Economic Analysis of Law in European Legal Scholarship*, 15, Cham., Springer, 2023.

priorities of decision-makers¹⁵². However, the following potential use can be hypothesized. As for the first criteria in evaluation – *effectiveness* (degree of goal achievement) - AI models might simulate what would have happened in the absence of the intervention (e.g., enabling counterfactual analysis); thus allowing for a comparison with the actual outcomes observed. The latter would help in quantifying the net effect of the intervention and understanding its contribution to achieving the desired objectives. AI applied to Bayesian methods could incorporate prior goals identified in an ex-ante impact assessment and update them with observed data to estimate the effectiveness of interventions. The latter might provide decision-makers with probabilistic estimates of intervention effectiveness.

In the *evaluation of efficiency* (relationship between results obtained and resources employed) AI could enhance a more accurate and quick analysis of costs and benefits associated with an intervention. AI-powered simulation techniques might also simulate different scenarios of resource allocation under varying conditions, allowing regulators to explore trade-offs and identify the most efficient allocation strategies (e.g. by analyzing interactions between resources, processes, and outcomes).

AI could also analyze temporal data to assess the *relevance* of a law or regulation over time. Time-series analysis techniques could identify trends and patterns in data to determine whether the intervention remains relevant in changing circumstances. Moreover, AI-powered social media analytics could monitor public sentiment, discussions, and engagement surrounding a law or regulation in real-time. By analyzing social media conversations, AI can gauge public perception, identify emerging issues, and assess the ongoing (perception of) relevance of the intervention. Besides, semantic analysis techniques, including word embeddings and semantic similarity measures, might assess the relevance of a policy or intervention by comparing its language and content to current societal norms and values. By quantifying the semantic distance between policy documents and contemporary discourse, AI could highlight areas where updates or revisions may be necessary.

What above are only insights on how AI systems might help solve the limited resources of time and data to simplify and evaluate existing norms. As of now,

¹⁵² Such a tendency might be linked to lack of incentives and motivation to perform such an activity (regulators are seldom mandated to perform the analysis), and limited resources, both as time, collected data, and technical ability to design the evaluation (OECD, Better Regulation Practices across the European Union, 2022, p. 133).

the uses described should probably be considered *quasi-core* for law and rule-making. Those, as mentioned for the ex-ante impact assessment, are a tool to help public authorities “reach well-informed decisions and not a substitute for political decisions within the democratic decision-making process”¹⁵³.

However, there are also risks that may be linked to such uses, leading to false positive outputs. For instance, the system may not be able to understand a complex legal landscape. Outdated, incomplete or biased data used for the training phase might lead to inaccurate or misleading evaluations, by overlooking significant regulatory needs. Moreover, relying heavily on AI for the evaluation could bring a diminishment of human expertise and judgement in the process, and not being able to understand contextual nuances or uncommon scenarios.

Similarly, an AI based simplification system could be distorted by erroneous indications (also coming from the human setting but compounded) on the standards given for the monitoring. The latter leads to the need for a system being used with human oversight, both with the inclusion of experts in the selection of data for training, and to evaluate the outputs regularly.

3. Identifying the gap: the content of the EU AI Act

As seen above, AI has the power to play a crucial role in the life-cycle of rules, by performing time-consuming tasks, increasing access to knowledge base, and enhancing the ability of institutions to draft effective rules and to declutter the regulatory stock. AI might help to deal with ever faster and more constant regulatory production (under political pressure) which still requires time for careful and judicious evaluation. Hardly any other means can encroach so pervasively on fundamental rights - across sectors - as the uncontrolled use of AI in law-making and rule-making. AI might also amplify the effectiveness of better regulation tools, thus improving the effectiveness of rules.

At the same time, however, the rule of law is also challenged by AI. It may hinder the guarantees of participation or discriminate stakeholders taking part in consultation and compromise the quality of information available to decision-makers; it might be biased for or against a de-regulatory or pro-regulatory approach; it may decrease human autonomy or making political choices.

¹⁵³ THE EUROPEAN PARLIAMENT, THE COUNCIL OF THE EU AND THE EUROPEAN COMMISSION, Interinstitutional agreement on Better law-making, 13 April 2016, p. 4.

Therefore, there is a risk to challenge the democratic representation the separation of powers and the rule of law, and questioning the very legitimacy of rules¹⁵⁴.

Is the EU AI Act dealing with such risks? More in general, are the above-mentioned uses of AI systems for law and rule-making under the scope of the EU AI Act? If not, are there any guarantees in the EU AI Act that can be implemented to AI in law and rulemaking, at least by way of interpretation?

The European AI Act is inspired by a risk-based approach, from identifying prohibited practices, through high-risk ones, transparency obligations for certain less impactful AI systems, and a separate focus on general-purpose AI models (GPAIs). The primary aim of the EU AI Act is to ensure the “protection of health, safety, fundamental rights [...], including democracy, the rule of law and environmental protection, to protect against the harmful effects of AI systems in the Union, and to support innovation”¹⁵⁵, both towards natural persons and undertakings. It is stressed that the use and specific application of AI might cause harm to public interests, such as societal or economic ones¹⁵⁶.

The potential impact – if any – of EU AI Act in law and rule-making is addressed below by following such subdivision analytically.

i) Prohibited practices. No practice identified among those prohibited by EU AI Act is relevant to our research¹⁵⁷. It is also right, in general terms, that this should be so: a general prohibition on the use of AI systems within the complex landscape of producing law or regulation, as seen in the previous paragraph, would certainly not be a desirable limitation of innovation.

ii) High risk categorisation. That is the one that dominates in the EU AI Act, and that most presents complexities in balancing what belongs to such a category and what is to be considered less relevant. It should also be considered that the focus of the Regulation is not only on the risks of how systems are designed, but also on how they are used¹⁵⁸. The latter means that deployers should play a pivotal role in the protection of fundamental rights, by identifying risks not foreseen in the designing phase. So much so that even AI systems referred to in Annex III (i.e., remote biometric identification systems, critical infrastructure, education, employment, law enforcement, etc.) are not to be considered high-risk if not posing harm to health, safety or fundamental rights of individuals, “including

¹⁵⁴ N. RANGONE, Artificial intelligence challenging core state functions: a focus on law-making and rule-making, cit., pp. 118 - 119.

¹⁵⁵ Whereas (1). See also art. 1 (1).

¹⁵⁶ Whereas (5).

¹⁵⁷ Art. 5 (1. (a)).

¹⁵⁸ Whereas (93).

by not materially influencing the outcome of decision making”¹⁵⁹. The latter means that deployers (e.g. legislators or regulators)¹⁶⁰ play a pivotal role in the protection of fundamental rights, by identifying risks not foreseen in the designing phase. The AI Act goes so far as to identify systems that are considered at high risk, also based on their uses¹⁶¹. The purpose here is to verify whether risks categorization under the EU AI Act includes the applications described in the paper.

The *AI applications to law-making and rule-making are not excluded at the “sectoral” level* (such as in the case of the use for military, defence or national security uses)¹⁶². Among the “sectors”, the category of “democratic processes”, which might appear to be somehow related to the production of laws¹⁶³, is only related to the use by judicial authorities or alternative dispute resolution bodies¹⁶⁴, along with interference in elections, political campaigns or voting behaviours¹⁶⁵. A simple way to ensure such guarantee would be to broaden the category of ‘democratic processes’ for ‘high risk’ systems. Without mentioning directly rule and law-making (so to avoid a too broad generalization), the EU AI Act might refer to guidelines or checklists drafted by the EC (e.g. EU AI Office) to support national legislator and regulators understand when an AI system shall be considered a potential risk under democratic processes. Such guidelines/checklist should contain both static criteria (based on the type of

¹⁵⁹ Art. 6 (3): “The first subparagraph shall apply where any of the following conditions is fulfilled: (a) the AI system is intended to perform a narrow procedural task; (b) the AI system is intended to improve the result of a previously completed human activity; (c) the AI system is intended to detect decision-making patterns or deviations from prior decision-making patterns and is not meant to replace or influence the previously completed human assessment, without proper human review; or (d) the AI system is intended to perform a preparatory task to an assessment relevant for the purposes of the use cases listed in Annex III. Notwithstanding the first subparagraph, an AI system referred to in Annex III shall always be considered to be high-risk where the AI system performs profiling of natural persons”.

¹⁶⁰ Looking at the subjects referred to in the Act, legislators and regulators do not seem to be excluded by definition, given that a deployer or provider can also be a public authority, agency or other body using AI under its authority (whereas (13)). See also art. 3 (3) and (4) on the definitions of provider and deployer. So much so that the provisions of the Regulation are also applicable to the institutions, bodies and offices of the Union (whereas 23).

¹⁶¹ See Annex I and III.

¹⁶² Whereas (24). See also art. 2 (3).

¹⁶³ The matter under analysis is also not considered among those cases in which a fundamental rights impact assessment is required for the use of AI by public authorities (not being included in the areas listed in point 2 of Annex III – see art. 27).

¹⁶⁴ Whereas (61).

¹⁶⁵ Whereas (63).

system used) and dynamic ones (based on the use made)¹⁶⁶ for the public authorities to understand whether there is a need for mandatory human oversight, and in what form.

Furthermore, *none of the high-risk applications listed in Annex III make any direct reference to law-making or rule-making*. The latter apart from the potential automatic adjudication by AI in the rule as a code (para. 2.2), if used to "access to and enjoyment of essential private services and essential public services and benefits"¹⁶⁷. The applications of AI systems in rules life-cycle seem to be interpreted as not being able in any way to pose significant harm to the fundamental rights (as well as to health and safety) or of natural persons, which is the scope of high-risk classification. As such, core applications (listed in para. 2.1), as drafting legislation or regulation, as well as producing huge quantities of amendments to obstruct parliamentary work, are not considered cases with a high risk on fundamental rights. Also, quasi-core uses, such as clustering amendments, are seen as not posing any risk to fundamental rights, even if leading to reducing independent analysis and overriding intuition and expertise (para. 2.1). The same applies to the uses on consultations (para. 2.3), or for the potential false outputs that might influence an ex-ante impact assessment or an ex-post evaluation and related monitoring (para. 2.4 and 2.5).

Therefore, those applications (described in the paragraphs above) are not subject to any guarantees of protection for high risks, such as the establishment of a risk management system that identifies the potential risks linked to a given AI, with an estimation of the risks reasonably foreseeable, and related implemented management measures¹⁶⁸ or corrective actions and duty of information¹⁶⁹, and share of serious incidents¹⁷⁰ or fundamental rights impact assessment¹⁷¹. Then, for not high-risk systems, the attention to the quality criteria of the data used for training is widely limited¹⁷², as well as the technical documentation to demonstrate that the system complies with the needed requirements¹⁷³, and the

¹⁶⁶ On a potential methodology to be used for AI risk assessment to implement the Regulation, assess the risks and develop internal management systems, see C. NOVELLI ET AL., AI Risk assessment: a scenario-based, proportional methodology for the AI Act, in *Digital Society*, vol. 3, n. 13, 2024

¹⁶⁷ Whereas (58); annex III, point 5.

¹⁶⁸ Art. 9.

¹⁶⁹ Art. 20.

¹⁷⁰ Art. 73.

¹⁷¹ Whereas (96); art. 27.

¹⁷² Art. 10.

¹⁷³ Art. 11

record-keeping of the functioning of the systems¹⁷⁴. Most importantly, what is missing is human oversight as it is provided for high-risk applications¹⁷⁵. As well as a limited attention to an appropriate level of cybersecurity and accuracy of the system¹⁷⁶, which are core for uses in a Parliament and Governments where there is daily basis intervention on the rights and obligations of citizens.

iii) Transparency obligations. While not falling under the high-risk applications, the use of AI in law-making or rule-making might be affected by the transparency obligations imposed to providers and deployers of systems directly interacting with individuals¹⁷⁷, who shall be informed of the interaction with an AI¹⁷⁸. However, this depends on what "interacting with individuals" means, an unclear wording whose interpretation would result in being highly discretionary in the absence of clarification by the European legislator. For instance, is a system used to draft laws or regulations directly interacting with individuals? Does the official translation of a law or a false output an ex-ante impact assessment have a direct interaction? Or should such "interaction" be referred only to systems, such as chatbots (as the one seen for the EUR-LEX use case) that replace one human in communication with another, and are not just a tool supporting the outcome? An extensive interpretation of "interaction with individuals" would be desirable and would also encompass the use of AI for certain applications in lawmaking and rulemaking (e.g., drafting). However, where to draw the line and also ensure legal certainty to providers or deployers?

Besides, "deployers of an AI system that generates or manipulates text which is published with the purpose of informing the public on matters of public interest shall disclose that the text has been artificially generated or manipulated"¹⁷⁹. It should be understood, in this scenario, if "informing the public" might include publication of laws or regulation in official journals or websites, as well as the publications of the results of a consultation. If so, however, the AI Act exempts such duty to information disclosure in case of human review or editorial control, and if someone holds editorial responsibility¹⁸⁰. The latter leads to a blind reliability to human oversight which is not to be sought. As well-known, humans are indeed prone to biases that may heavily influence the oversighting.

¹⁷⁴ Art. 12.

¹⁷⁵ Art. 14.

¹⁷⁶ Art. 15.

¹⁷⁷ Art. 50 (1).

¹⁷⁸ *Ibid.*

¹⁷⁹ Art. 50 (4).

¹⁸⁰ Whereas (134); art. 50 (4).

iv) General-purpose AI models. The last category of systems considered in the Regulation is general-purpose AI models (GPAIs). These applications were not mentioned in the first draft of regulation published in April 2021¹⁸¹, amended after the eruption of ChatGPT, and then described as foundation ones¹⁸². GPAIs are models with characteristics such as “generality and capability to competently perform a wide range of distinct tasks”¹⁸³, based on large amounts of data and trained through several methods. The separate focus from other categories is justified by the definition of GPAIs as models that constitute components of an AI system but are not one on their own (requiring other components, as an interface)¹⁸⁴, even if it is recognized that they might be integrated within an AI system or used directly¹⁸⁵. Clearly, large generative models are given as an example of GPAIs¹⁸⁶, referred to as models that “allow for flexible generation of content, such is in the form of text, audio, images or video, that can readily accommodate a wide range of distinctive tasks”¹⁸⁷.

GPAI with systemic risk. Systems with “high impact capabilities”¹⁸⁸ have to be qualified as of systemic risk. In such a case, providers shall perform model evaluations and document adversarial testing to identify and mitigate system risks¹⁸⁹, and ensure an adequate level of cybersecurity¹⁹⁰.

It is not likely that regulators or Parliaments would be able to develop systems on such a scale of power¹⁹¹. However, the EU AI Act also includes the category of “downstream provider” as “a provider of an AI system, including a general-purpose AI system, which integrates an AI model, regardless of whether the AI model is provided by themselves and vertically integrated or provided by another

¹⁸¹ EUROPEAN COMMISSION, Proposal for a Regulation of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act) and Amending Certain Union Legislative Acts, COM (2021) 206 final, 21.04.2021.

¹⁸² On 14 June 2023, Members of the European Parliament passed a new version of the EU AI Act and introduced a new section to govern foundation models and generative AI (article 28b).

¹⁸³ Whereas (97); whereas (63).

¹⁸⁴ Whereas (97).

¹⁸⁵ Whereas (101).

¹⁸⁶ Whereas (99).

¹⁸⁷ Whereas (99).

¹⁸⁸ “High-impact capabilities in general-purpose AI models means capabilities that match or exceed the capabilities recorded in the most advanced general-purpose AI models” (Whereas 111). See also whereas (64).

¹⁸⁹ Art. 55 (a); (b).

¹⁹⁰ Art. 55 (d).

¹⁹¹ The floating-point operations need to be greater than 10^{25} (art. 51 (2)).

entity based on contractual relations”¹⁹². A well-known example of use of large generative IA is indeed building a custom GPT based on OpenAI’s API. *It is thus largely possible that such uses, only if based on GPT, will be considered as of systemic risk, with handover obligations in case of systems implemented by downstream providers.* That might be the case for systems used, for instance and only if based on GPT, for translation in citizens narrative or different languages, voice-to-text conversion, drafting norms, or anticipating how a text might be impacted by a new amendment. There are, however, already seen experimentations of large language models internally developed. As per the use of the “i.AI” system in the UK for public consultation (see para. 2.3).

“*Ordinary*” GPAs. Providers of GPAs are asked to prepare and maintain updated technical documentation of the model, regarding - for instance - the training and testing and the results of the evaluation¹⁹³. The latter shall be made available to providers intending to integrate the GPAI in their AI, and publicly available as a detailed summary describing the content used for the training¹⁹⁴. Besides, any output generated by AI systems, including GPAs, are to be marked in a machine-readable format and detectable as artificially generated or manipulated¹⁹⁵. The latter, however, does not apply to tools with an assistive function for standard editing or that do not alter input data or the semantic thereof¹⁹⁶. When can we say that a system is performing more than an assistive function? Is that information disclosure (trademark) enough compared to the risks of an automation bias, oversimplification, distortion of content that may accompany the use of AI for the drafting activity?

Even if we decide to interpret that the tackled cases will have to be respective of the obligations for GPAs, there is another obstacle in the EU AI Act: “it should be understood that the obligations for the providers of general-purpose AI models should apply once the general-purpose AI models are placed on the market”¹⁹⁷.

¹⁹² Whereas (68). More strongly, the Regulation states that other actors (e.g., deployers) are to be considered a provider “if they modify the purpose of an AI system, including a GPAI, which has not been classified as high-risk and has already been placed on the market or put into service in such a way that the AI system concerned becomes a high-risk in accordance with Article 6” (art. 25 (c)). However, as already mentioned, rule and lawmaking seem to be excluded from high-risk systems.

¹⁹³ Art. 53 (1a).

¹⁹⁴ Art. 53 (1b). Besides, the system should include a policy to comply with Union law on copyright and related rights - see art. 53 (1c); there is a general obligation from providers to cooperate with the national competent authorities - see art. 53 (3).

¹⁹⁵ Art. 50 (2).

¹⁹⁶ *Ibid.*

¹⁹⁷ Whereas (97).

The latter is defined, in the EU AI Act, as the “supply of an AI system or a general-purpose AI model for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge”¹⁹⁸. *If law-makers and rule-makers then develop their systems autonomously, the above-described obligations might not apply, not being a commercial activity.* Those would indeed fall under the different definition of “putting into services”, meaning “supply of an AI system for first use directly to the deployer or for own use in the Union for its intended purpose”¹⁹⁹. Besides, the AI Act does not apply to AI systems developed as open-source, as happens for systems developed internally by public authorities for further re-use by other ones²⁰⁰ (e.g., in France²⁰¹ or in Italy²⁰²).

v) *Does the EU AI Act allow to intervene in any other way?* As known, the Commission can introduce delegated acts on the definition of AI system; the criteria that exempt AI from high-risk rules; amending thresholds that classify GPAIs as systemic; technical documentation requirements; conformity assessment; and EU declaration of conformity adding or modifying high-risk AI applications listed in Annex III²⁰³. Such power lasts for an initial (extendable) period of five years²⁰⁴. However, it should be considered that such a procedure takes at least three months. Indeed, any delegated act shall be notified to the European Parliament and to the Council and can enter into force, only if no objection is expressed within three months from the notification of the act²⁰⁵. The latter can also be extended further by three months, if asked by the European Parliament or the Council²⁰⁶. Not even considering that, before the notification, the Commission is required to consult experts designed by each Member State²⁰⁷. However, a modification of the high list might only be intended to include AI systems “to be used in any of the areas listed in Annex III”²⁰⁸.

A last point is about the possibility of some AI application in law-making or rule-making being considered at high risks by a national authority, with the

¹⁹⁸ Art. 3 (10).

¹⁹⁹ Art. 3 (11).

²⁰⁰ Art. 2 (12). If not falling under high-risk AI systems or under article 4 or 50.

²⁰¹ See <https://www.data.gouv.fr/fr/reuses/>.

²⁰² See <https://developers.italia.it/it/come-lo-uso>.

²⁰³ Art. 97.

²⁰⁴ Art. 73.

²⁰⁵ Art. 97 (6).

²⁰⁶ Art. 97 (2).

²⁰⁷ Art. 97 (4).

²⁰⁸ Art. 7 (a).

obligations to inform the Commission and other Member States. However, even in such cases, law-making and rule-making are not considered within the “AI systems presenting a risk” according to the EU AI Act²⁰⁹.

4. Guardrails for AI in law and rule-making

An agile risk-based approach. The EU AI Act undoubtedly has significant pervasiveness, and its implementation will inevitably lead to changes in the AI market. As already mentioned in the first pages, the Act aims to ensure a high level of protection of fundamental rights. Such aim, considering the rights of non-discrimination and fairness, transparency²¹⁰ or to be heard (as component of the right to a good administration²¹¹), seem to have been forgotten if linked to law and rule-making. Indeed, the risk assessment is carried out ex-ante at legislative level (the EU AI Act identifies and ban system with unacceptable risks, while providing stringent regulation for application identified at high risk, and then transparency obligations). Such a structured risk-informed approach carries the risk of missing some cases not considered or not yet imagined, by not implementing a real case-by-case risk assessment. Differently, in other fields, the legislation imposes to a given subject to perform risk assessments (e.g. providers of very large platforms must assess the risks related to their services and implement consequent mitigation measures)²¹², or imposes a risk approach in enforcement (for instance, in planning food safety inspections and requiring a

²⁰⁹ Indeed, following the aim of the EU AI Act to protect any risk to public interest and fundamental rights (Whereas (5)), it introduces a procedure at the national level for dealing with “AI systems presenting a risk” (art. 79). Market surveillance authorities of Member States, if they have sufficient reason to consider that AI systems hide any risks, might carry out an evaluation and require corrective actions or, if not fulfilled, prohibition or restriction on the use of the system. If not restricted to the national territory, the authority shall also inform the Commission and other Member States. However, the definition of “product presenting a risk” (art. 3, point 19 of Regulation (UE) 2019/1020) refers to adverse effects to rights protected by Union harmonisation legislation (Annex I), which fails to include rule or law-making, and as such the obligation of disclosure.

²¹⁰ As rights included in the 2019 Ethics guidelines for trustworthy AI developed by the independent AI HLEG appointed by the Commission.

²¹¹ See J. PONCE SOLÉ, Good Administration and Administrative Procedures, in *Indiana Journal of Global Legal Studies*, 12, 2, 2005, pp. 551 – 588.

²¹² Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act), L 277/1 (Whereas 89 – 90). In a similar vein, according to the GDPR art. 24, the controller shall assess the severity of risks for the right and freedom of natural persons and implement measures to prevent it.

tariff based on the risk level²¹³). In the latter examples, the implementation of a risk-based approach means tailoring actions based on the results of a risk assessment, structured according to criteria of analysis that are either static or dynamic in relevance and constantly updated based on scientific evidence or experience. Such an approach allows to prioritize decisions based on the level of risk to rights that need protection, thus favours residuality of legislative or regulatory intervention and the proportionality of rules²¹⁴. It also helps implement precautionary measures swiftly by quickly identifying risks, and acknowledging the importance of safeguarding specific public interests.

The risk-based "ex-ante" methodology proposed by the EU AI Act can only partially deliver these results. The unpredictability and scientific uncertainty, as limitations of an informed approach to risk, become even more acute and challenging to manage in the implementation of the EU AI Act. The procedures outlined in the EU AI Act prevent indeed flexibility in areas "overlooked" by the regulation.

In a landscape of grey areas (as is the case with law-making and rule-making), we can assume that Member States shall intervene with national regulations, although this practice would lead to uneven guardrails in the European context, which is generally undesirable. Likewise, the legislators and regulators - always inspired by the general framework that is outlined at the European level - should consider self-regulating the development and use of AI within their tasks – as an application of the precautionary principle. The latter would allow both more conscious and dynamic regulation of concrete uses and risks - outside external influence. It is crucial that these possible interventions (national regulation or legislators' and regulators' self-regulations) are informed to an agile approach and ensure an effective human oversight, transparency, explainability, and the use of public datasets to enhance systems' quality. An "agile" approach, on the other hand, should enable criteria for action – at National level and on a case-by-case assessment scenario – in borderline situations, such as the "quasi-core" AI systems for legislation (e.g., amendments' clusterization, mentioned in section 2.1). In addition, the approach should allow dynamic application of tools based

²¹³ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations [...], L 95/1.

²¹⁴ J. BLACK / R. BALDWIN, When Risk-Based Regulation Aims Low: Approaches and Challenges, in *Regulation and Governance*, 6, 1, 2012, pp. 2 ff.; J. BLACK / R. BALDWIN, Really Responsive Risk-Based Regulation, cit., pp. 59 – 94.

on specific situations and ever-changing environments. Moreover, in a risk-informed approach, design and implementation should be interlinked within the regulatory-cycle: understanding the risk, its causes, and characteristics helps design and direct regulatory efforts more effectively.

Human oversight. Such guardrail has often been cited in the cases discussed in the previous paragraphs as central to ensure control, and as a potential solution to core and quasi-core cases, both for supervision of the accuracy of used data and for the output produced.

Human oversight, however, does not solve the guarantee for an AI system to produce false outputs, if the human is influenced by an over reliance on the results of the system and a lack of concrete verification of the path that led to a given result. For this purpose, human oversight should be performed in collaboration between computer scientists and lawyers to ensure that computer architectures incorporate fundamental safeguards against bias, or unreliable assessments, and clearly identify what the AI tasks are (and what the role of humans is). For instance, if AI identifies overlapping rules, it is up to humans to suggest whether the previous rule should be repealed; in impact assessment, humans should instruct the AI on how to balance advantages with disadvantages, or how to value sensitive factors, such as human life, or air quality.

Transparency and explainability. The *core* and *quasi core* applications, as described for legislation and regulation (para. 2.1), as well as for the use of AI in consultation (para. 2.3), ex-ante impact assessment (2.4) and simplification and ex-post evaluation (para. 2.5) should always be indicated with a trademark, even if only partially or in support of a first draft. Moreover, it shall be compulsory to indicate in a footnote or at the end of the document, the specific use made of it, in which parts, and the kind of human intervention. For the sake of transparency of the work of public authorities, definitions within the EU AI Act should be more precise and avoid provisions such as the mentioned AI “directly interacting with individuals” (due to cases where even ancillary uses, as internal organisational and preparatory documents, risk to produce effects towards the outside world).

Public data-sets to enhance systems’ quality. If the way forward is that of a self-regulation by single authorities or a national intervention to govern the use of AI systems for law and rule-making, the opportunity might be seized to take a step further. As evidenced by the Italian government's recent announcement of a new national data agency²¹⁵ (and although that is not an endorsement of such choice),

²¹⁵ See, in Italian, <https://www.ilfoglio.it/politica/2024/05/24/news/il-governo-prepara-un-agenzia-del-dato-per-monitorare-le-nuove-tecnologie-serve-forse-6574995/>.

States are starting to understand the relevance of nationally produced data and the importance of public data in the hands of authorities. The latter, due to institutional data being the result of collection and processing within public authorities, might ensure greater quality and certainty of the used source and thus of the system that feeds from it. In domains such as law and rulemaking, where legislators and regulators have a massive amount of data at their disposal, it would therefore be desirable for the systems to be trained on public datasets. This includes the possibility of having such systems, used in rule and law-making, communicating with administrative enforcement and litigation database – for instance, for the purposes of ex-post evaluation and the proposal of new law or regulation.

Environmental protection. The same attention by individual authorities or States could also be an opportunity to strengthen the focus on environmental protection (where there is growing concern about the impact caused by the development and use of AI systems). A topic that seems to have been lost in the EU AI Act. The latter does not go beyond single mentions of the need to safeguard the environment and sustainability in terms of general values²¹⁶ and possible considerations in codes of conduct²¹⁷ or voluntary additional requirements²¹⁸.

In conclusion, we are faced with an approach of EU AI Act, as described above with regard to legislative and regulatory activity, which in practice is scarcely based on fundamental rights and principles. The latter leads to the need for individual public authorities and member States to regulate the national use cases, by focusing on fundamental rights, which – as seen – do not spare the legislative or regulatory function.

²¹⁶ Whereas (1).

²¹⁷ Whereas (27).

²¹⁸ Whereas (165). See also art. 95.