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Potentialities and Margins for Improvement of the European AI Alliance, an Example of Participatory Democracy in the Field of AI at EU Level

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ABSTRACT

This contribution focuses on the dialogue with stakeholders in drafting EU acts in the field of AI, with particular reference to the so-called "European AI Alliance", which can be defined as the best example of "participatory democracy in the field of AI on European level". After understanding what the AI Alliance is and how it works, and after making some considerations on its nature, the paper focuses on its role in the context of the drafting of EU acts, such as the Ethics Guidelines for Trustworthy AI and the AI Act Proposal. In the end, it will be possible to make some conclusive remarks and to formulate some suggestions, concerning the future of the AI Alliance and the need to exploit and improve it also, and especially, after the (eventual) adoption of the AI Act and of the other legislative proposals currently under discussion.

Keywords: European AI Alliance, Ethics Guidelines for Trustworthy AI, AI Act Proposal, stakeholder consultation, participatory democracy, e-democracy, artificial intelligence

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1. Introduction: Premises, Research Questions and Methodology

The European Union is concretely interested in regulating AI since 2018, when the European Commission (EC) adopted a Communication entitled "Artificial Intelligence for Europe" (COM/2018/237 final), which clearly highlights the need to balance two conflicting interests. Indeed, on the one hand, AI technologies must be strongly *promoted*, since they can bring a wide array of economic and societal benefits across the entire spectrum of industries and social activities; moreover, it is in the EU's interest to further establish the Union's technological leadership and to ensure that Europeans can benefit from new technologies. On the other hand, however, the individuals and the society must be prevented from the risks and the negative consequences deriving from those technologies: for this reason, it is necessary to ensure an "appropriate ethical and legal framework" based on the Union's values and in line with the Charter of Fundamental Rights of the EU (European Commission 2018, 3). To better understand such expression, it must be specified that in this field ethics and law are perceived as inevitably complementary: ethics can help interpretating the law or can recommend behaviours that are not directly required or mandated by law (Renda, 2021, 655); in other words, the law provides the rules of the game, but does not indicate how to play well according to the rules (Floridi, 2019, 261-262). To develop the abovementioned ethical and legal framework, according to the EC, there is the strong need of a "cooperation with stakeholders" (European Commission, 2018, 3): given the scale of the challenges associated with AI, the full mobilisation of a diverse set of participants, including businesses, consumer organisations, trade unions, and other representatives of civil society bodies is essential. Therefore, the Commission announced the creation of a broad multi-stakeholder platform to work on all aspects of AI: we refer to the so-called "European AI Alliance" (European Commission, 2018, 17).

Given the above, this contribution will focus on the dialogue with stakeholders in drafting EU acts, both non-binding and binding, in the field of AI, with particular reference to the role of the European AI Alliance, which can be defined as the best example of "participatory democracy in the field of AI on European level" (Harasimiuk, Braun, 2021, 46). In particular, the article aims at answering two specific research questions, i.e. what the current potentialities of the abovementioned Alliance are, and how a similar instrument can be exploited and improved in the future. In order to do so, first of all, it will be necessary to examine what such platform is and how it works, also from a purely technical point of view, and to make some general considerations on its nature. Then, it will be possible to get to the heart of the paper and concentrate on the role of the Alliance in the drafting of two extremely important, although very different, EU acts concerning AI: the Ethics Guidelines for Trustworthy AI and the AI Act Proposal. Finally, thanks to the elements collected, the contribution will try to give an answer to the two research questions formulated above.

2. The Genesis of the European AI Alliance and its Material Functioning

The Alliance was launched in June 2018 and quickly attracted many adherents (2,656 participants had registered as of 4 February 2019; on the point see: Renda 2019, 44). With regard to its material functioning, it is hosted by the so-called "Futurium" online platform: the latter was originally developed in the framework of "Digital Futures", a foresight project initiated by the European Commission's Directorate General for Communications Networks, Content and Technology (DG CONNECT) in July 2011 and concluded in 2013. Subsequently, however, Futurium remained active, and turned into a space on which to experiment with new policymaking models based on scientific evidence and stakeholder participation (Accordino, 2013, 321). It combines the informal character of social networks, the simplicity of

wikis and the methodological approach of foresights¹, with the main aim of maximally engaging stakeholders in the co-creation of the futures that they want (European Commission, 2013, 5).

The Futurium platform is divided in "groups": the AI Alliance is a "group" of such platform. In order to interact with such group, a two-step procedure is required. Firstly, it is essential to sign in with an "EU Login" account: as well known, the latter is the European Commission's user authentication service, which allows authorised users to access a wide range of Commission web services, using a single email address and password³. Secondly, it is indispensable to request membership, by filling an ad hoc form; the fields that must be completed are the following: "Country" (mandatory field); "Why would you like to join the European AI Alliance, and what would your contribution be to the discussion on Artificial Intelligence in Europe?" (optional field); "Do you have a twitter account? We would love to follow your updates! You can share with us your twitter handle here" (optional field); "In what capacity are you applying?", and the options are "Join the European AI Alliance in my own name" and "Join the European AI Alliance as representative of my organization"; "Which interest would you like to represent in the European AI Alliance?", and the options are "Government". "Public International Organisations", "Consumer Organisation", "Industry", "Consultancy", "Professionals association", "NGO", "Academia", "Think Tank", "Trade Union", "Financial Institution",

¹ "Foresight" is defined by the European Commission as "the discipline of exploring, anticipating and shaping the future", that "helps build and use collective intelligence in a structured and systematic way to anticipate developments and better prepare for change" (European Commission 2020 B, 3).

² On the point see: https://futurium.ec.europa.eu/it/groups.

³ On the point see: https://webgate.ec.europa.eu/cas/about.html?loginRequestId=ECAS_LR-58698054-

HZxImIentw1ReeQORZZp1dFCAUZpSgzodFTzK85NBtjkenqLe7tNwjuEof9eUwEk5nC8bfKJjUidUBguT2RRWF-yntOf97TTHq0GemtNMIM6i-

 $tHEYJqgKNwxhZxjxkZnDEX6bdJsdyJcfMix835ZT5yzLEVdcjJYkzzndgIjPiZ0zd54zGV8\\ ALUt200st9iERizu0.$

"Organisation representing churches and religious communities" (mandatory field)⁴.

Once the form has been submitted, it is necessary to wait for the approval of the request, which generally does not take more than few hours. After the approval, it is possible to fully exploit the potential of the AI Alliance, which is further divided in "sections". In the section "Open Library" it is possible to find key documents and evidence on how the AI ecosystem is currently shaped in Europe and around the world; its aim is to provide a space for sharing reliable and up-to-date resources from the AI community to the AI community⁵. The section "Forum", instead, is dedicated to "your thoughts, ideas, questions and any other content that you would like to share with us"6. In the section "Trustworthy AI in practice", members of the AI Alliance share practices that help in building an AI ecosystem of trust in Europe and around the world⁷. In the section "Events", "you can browse the content of past AI Alliance events while in the feed below you can find a list of past and future events linking to the discussions of the AI Alliance"8. Finally, there is the "AI Alliance Blog", defined as a space where EU policymakers, experts and guest contributors share their thoughts, experience and work in reflection to a specific policy area of AI. Members of the AI Alliance can contribute to the blog, following a validation from the editorial team⁹.

It is worth mentioning the fact that so far the Alliance has also organised several assemblies and conferences, during which extremely significant matters were debated. The "First European AI Alliance Assembly", held in Brussels on 26 June 2019, marked the one-year anniversary of the creation of the platform and was the occasion not only to discuss the perspectives of the European strategy on AI, including its impact on the economy and society,

⁴ On the point see: https://futurium.ec.europa.eu/en/european-ai-alliance/request-membership-form.

⁵ On the point see: https://futurium.ec.europa.eu/en/european-ai-alliance/document.

⁶ On the point see: https://futurium.ec.europa.eu/en/european-ai-alliance/forum-discussion.

⁷ On the point see: https://futurium.ec.europa.eu/en/european-ai-alliance/best-practices.

⁸ On the point see: https://futurium.ec.europa.eu/en/european-ai-alliance/events.

⁹ On the point see: https://futurium.ec.europa.eu/en/european-ai-alliance/blog.

but also to present the most important results achieved by the Alliance that far¹⁰. The "Second European AI Alliance Assembly", held online on 9 October 2020, was followed by more than 1400 viewers and was particularly focused on building an ecosystem of excellence and trust in AI¹¹. The "High-Level Conference on AI", held in Slovenia between 14 and 15 September 2021, featured over 80 selected high-level speakers and about 2000 participants, and was aimed at marking another important milestone to bring policymaking efforts to turn Europe into a global hub of excellence and trust in AI¹². Moreover, the Alliance also contributed to other events, such as "European AI Excellence and Trust in the world", held between 15 and 16 March 2022, that leveraged the international stage offered by Expo Dubai to present how Europe sees the opportunities and complexities that AI may bring, as well as the initiatives undertaken by the Commission¹³.

3. General Considerations on the AI Alliance as an E-Democracy Tool

As a result of what has been said so far, the European AI Alliance can be defined as a space dedicated to all legal, technical and economic implications of AI, which brings together legislators, citizens, academics, practitioners, public authorities, civil society, business, consumer organisations and other stakeholders in an open and multidisciplinary community that exchanges resources. Such resources, that can be shared in text, audio and video format, can include scientific publications, papers on specific topics, databases of AI

 $^{^{10}}$ On the point see: https://digital-strategy.ec.europa.eu/en/events/first-european-ai-alliance-assembly.

¹¹ On the point see: https://digital-strategy.ec.europa.eu/en/events/second-european-ai-alliance-assembly.

¹² On the point see: https://digital-strategy.ec.europa.eu/en/events/high-level-conference-on-ai-from-ambition-to-action.

¹³ On the point see: https://digital-strategy.ec.europa.eu/en/events/european-ai-excellence-and-trust-world.

incidents, recordings from webinars, interviews, websites, but also simple ideas, questions and much more¹⁴.

It is now even clearer why at European level the Alliance can be defined as the best example, in the field of AI, of "e-democracy", or "e-participation", or even "digital democracy". Such widely applied terms describe a broad scope of practices of online engagement of the public in political decisionmaking and opinion forming (on the point see: Hennen, van Keulen, Korthagen, Aichholzer, Lindner and Nielsen, 2020). Thanks to information and communication technology (ICT) and computer-mediated communication (CMC), it becomes possible to enhance the participation of citizens and to practice democracy without the limits of time, space and other physical conditions (on the point see: Lindner and Aichholzer, 2020, 16; Hacker and van Dijk, 2000, 1). To be even more specific, ICT and CMC have the following positive effects on democracy: they increase the scale and speed of providing information, consequently creating more informed citizens; they lessen certain obstacles to political participation, such as apathy, shyness and disabilities; they create new ways of organising the debate, thanks to subjectspecific groups for discussion; they remove distorting mediators like journalists, representatives and parties; they solve some problems of representative democracy such as territorial bases of constituencies; they allow politics to respond more directly to citizen concerns (on the point see: Lindner and Aichholzer, 2020, 18; Hacker and van Dijk, 2000, 4).

Given the above, the efforts of the European Union to promote and apply e-democracy tools appear unsurprising. As well known, the Treaty of Lisbon has put special emphasis on strengthening democratic elements in the EU. To our ends, some of the most relevant provisions of the post-Lisbon TEU are art. 10, according to which "[...] 3. Every citizen shall have the right to participate in the democratic life of the Union [...]", and art. 11, that states as follows: "1. The institutions shall, by appropriate means, give citizens and

¹⁴ On the point see: https://futurium.ec.europa.eu/en/european-ai-alliance/pages/about.

representative associations the opportunity to make known and publicly exchange their views in all areas of Union action. 2. The institutions shall maintain an open, transparent and regular dialogue with representative associations and civil society. 3. The European Commission shall carry out broad consultations with parties concerned in order to ensure that the Union's actions are coherent and transparent [...]". In line with such provisions, the EU introduced several participatory democracy instruments, with the potential to stimulate public debate on European issues and to involve European citizens and organised civil society in policymaking at the EU level (on the point see: Lindner and Aichholzer, 2020, 24).

With even more specific reference to e-participation tools, also their importance has been highlighted by EU institutions on several occasions (on the point see: Hennen, 2020, 47). In particular, according to the 2010 European Commission Communication "The European eGovernment Action Plan 2011-2015 Harnessing ICT to promote smart, sustainable & innovative Government" (COM/2010/743 final), the new ICT tools for governance and policy modelling improve the ability of people to have their voice heard and make suggestions for policy actions in the Member States and the European Union as a whole (European Commission, 2010, 8). Moreover, the importance of digital tools to involve citizens, businesses and stakeholders in the decision-making process is emphasised by the Better Regulation Agenda as well (on the point see: Rose, 2020, 222)¹⁵.

It is clear, therefore, that the AI Alliance cannot be read as an isolated phenomenon. On the contrary, it must be considered as one of the digital tools promoted by the European Union to enhance the participation of the public in opinion forming and decision making. As such, it presents most of the features and of the advantages that have just been described. Its peculiarity, however, relies on the fact that it deals only with one subject matter, i.e.

¹⁵ On the point see also: https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation_en#have-your-say--share-your-views-and-ideas.

artificial intelligence, which is characterised by a very high level of specificity.

4. The Role of the AI Alliance with Reference to the "Ethics Guidelines for Trustworthy AI"

After understanding what the AI Alliance is and how it works, and after making some general considerations on its nature, it is now possible, as anticipated, to focus on its role in the context of the drafting of EU acts, both non-binding and binding, in the field at stake.

In March 2018, the European Commission issued a call for applications for the creation of an expert group on artificial intelligence¹⁶. In June 2018, based on a transparent and competitive selection process from nearly 500 excellent applications received, the Commission appointed 52 experts to the new "High Level Expert Group on Artificial Intelligence", better known as "AI HLEG"¹⁷. Some of the members were selected among independent experts and academics, while others among representatives of vested interests (Renda 2021, 654).

The AI HLEG was immediately tasked with the definition of guidelines for the ethical development and use of artificial intelligence: an objective which is perfectly consistent with the already mentioned need to ensure an "appropriate ethical and legal framework". After the publication of a first draft of the document on 18 December 2018¹⁸, the ultimate version of the so-called "Ethics Guidelines for Trustworthy Artificial Intelligence" was finally presented on 8 April 2019¹⁹.

¹⁶ On the point see: https://ec.europa.eu/commission/presscorner/detail/en/IP_18_1381.

¹⁷ On the point see: https://digital-strategy.ec.europa.eu/en/news/commission-appoints-expert-group-ai-and-launches-european-ai-alliance.

¹⁸ On the point see: https://digital-strategy.ec.europa.eu/en/library/draft-ethics-guidelines-trustworthy-ai.

¹⁹ On the point see: https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai.

The Guidelines, which are non-legally binding, aim at setting out a framework for achieving Trustworthy AI (AI HLEG 2019, 2). Chapter I ("Foundations of Trustworthy AI") identifies and describes *four ethical principles*, that must be adhered to in order to ensure ethical and robust AI.

The first one is "Respect for human autonomy", according to which humans interacting with AI systems must be able to keep full and effective self-determination over themselves and be able to partake in the democratic process: in particular, AI systems should not unjustifiably subordinate, coerce, deceive, manipulate, condition or herd humans; instead, they should be designed to augment, complement and empower human cognitive, social and cultural skills. The second principle is "Prevention of harm", according to which AI systems should neither cause nor exacerbate harm or otherwise adversely affect human beings; they must be technically robust and it should be ensured that they are not open to malicious use. The third principle is "Fairness", which has both a substantive and a procedural dimension: the first one implies a commitment to ensuring equal and just distribution of both benefits and costs and ensuring that individuals and groups are free from unfair bias, discrimination and stigmatization; the second one entails the ability to contest and seek effective redress against decisions made by AI systems and by the humans operating them. The fourth and last ethical principle is "Explicability", according to which processes need to be transparent, the capabilities and purpose of AI systems openly communicated, and decisions – to the extent possible – explainable to those directly and indirectly affected (AI HLEG 2019, 12-13).

Chapter II of the Guidelines ("Realising Trustworthy AI"), instead, translates the four ethical principles of Chapter I into *seven key requirements* that AI systems should implement and meet throughout their entire life cycle. Such requirements are the following: (1) "human agency and oversight"; (2) "technical robustness and safety"; (3) "privacy and data governance"; (4) "transparency"; (5) "diversity, non-discrimination and fairness"; (6)

"environmental and societal well-being" and (7) "accountability" (AI HLEG 2019, 14-24).

However, the most innovative feature of the document, which stands out compared to other existing ethical AI frameworks, is its Chapter III ("Assessing Trustworthy AI"). The latter, indeed, sets out a concrete assessment list to operationalise the seven requirements of Chapter II; in other words, it is a list of questions that offer AI practitioners practical guidance (on the point see: Renda 2021, 661). For example, with reference to the first requirement, i.e. "human agency and oversight", one of the questions is the following: "Is the AI system implemented in work and labour process? If so, did you consider the task allocation between the AI system and humans for meaningful interactions and appropriate human oversight and control?". With reference to the second requirement, i.e. "technical robustness and safety", one of the questions is the following: "Did you assess potential forms of attacks to which the AI system could be vulnerable?". And so on (AI HLEG 2019, 24-31).

After illustrating what the "Ethics Guidelines for Trustworthy Artificial Intelligence" are, it is now essential to understand the role of stakeholder consultation, and more specifically of the AI Alliance, in their drafting. On the point, it can be said that *the AI Alliance literally steered the work of the AI HLEG*, and this happened *before* and *after* the adoption of the Guidelines²⁰.

With regard to the phase that preceded the adoption of the Guidelines, it has already been mentioned the fact that a first draft of the document was presented on 18 December 2018. It must now be highlighted that, on such draft, an open consultation was launched through the European AI Alliance, in order to achieve a revised and improved version of the Guidelines²¹. During such consultation, which lasted until 1 February 2019, 506 contributions were

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²⁰ On the point see: https://digital-strategy.ec.europa.eu/en/policies/european-ai-alliance.

²¹ On the point see: https://ec.europa.eu/futurium/en/ai-alliance-consultation/guidelines.1.html.

received through the dedicated web form and shared with the AI HLEG²², that drafted the final document actually taking into consideration many of the suggestions received (on the point see: Barrio Andrés 2021).

Let's make some examples. The links between the different chapters of the Guidelines were made more explicit: as seen, the three Chapters logically flow one from the other. The terminology was brought in line with the terms used in Regulation (EU) 2016/679 (the well-known GDPR, "General Data Protection Regulation"). The revised Guidelines now contain a section dedicated to dealing with tensions between ethical principles. The previously existing reference to the "do good" principle was removed, as it was not found to be a principle that could be a moral imperative in each and every case (e.g. when pursuing fundamental research) and it seemed not well suited in the context of AI; however, it is now clearly stated that one of the goals of Trustworthy AI is to improve individual and collective wellbeing. References have also been included under the principle of respect for human autonomy, which includes the need for particular attention to the working environment.

The improved instrument contains a new requirement, since it also focuses on the societal and environmental impact of AI systems: this requirement addresses the need to consider the environment and other sentient beings as stakeholders, and to ensure sustainable and environmentally friendly AI systems; the need to consider the environment and other living beings was also explicitly stated under the ethical principle of prevention of harm and included in the definition of human-centric AI. The Guidelines' assessment list – operationalising the key requirements – was revised in light of the revisions made to the requirements themselves. And it would be possible to make many more examples. Ultimately, it could be stated that the extensive consultation throughout the AI Alliance induced the Expert Group to be more ambitious and to adopt in the final document a broader approach if compared to the one of the first draft (Renda, 2021, 654).

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²² On the point see: https://ec.europa.eu/futurium/en/ethics-guidelines-trustworthy-ai/stakeholder-consultation-guidelines-first-draft.html.

Moreover, as anticipated, the AI Alliance played a crucial role also *after* the adoption of the Guidelines: with the publication of such instrument on 8 April 2019, in particular, the Alliance continued its work in order to further enhance the already described assessment list of Chapter III. Indeed, it must be highlighted that the list contained in the 2019 Guidelines was designed from the very beginning to be a "pilot version" and to be developed during a "piloting process" in close collaboration with stakeholders across the public and private sector. More specifically, the idea was to involve companies, organisations and institutions, but also all other interested stakeholders (AI HLEG, 2019, 24).

The piloting phase took place from 26 June 2019 until 1 December 2019, and during such period the interested parties shared through the AI Alliance their best practices on how to achieve trustworthy AI²³. Thanks to the contributions received during the piloting process, where over 350 stakeholders participated, on 17 July 2020 the High-Level Expert Group on AI presented the ultimate version of the so-called "Assessment List for Trustworthy Artificial Intelligence", better known as ALTAI (AI HLEG, 2020). The list is also available in a web-based tool version, that can be accessed through the AI Alliance platform and that translates the principles into an accessible and dynamic checklist that guides developers and deployers of AI in implementing such principles in practice²⁴.

It is worth highlighting that the 2020 assessment list is much more detailed and complete if compared to the one included in Chapter III of the 2019 Guidelines. More specifically, the revision entailed a tailoring of the list to the specific use cases and the development of additional guidance on legal compliance, as well as on how to address specific risks through ad hoc procedures (Renda, 2021, 661). Consequently, all interested subjects, such as developers and deployers of AI systems, are better supported by the new

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²³ On the point see: https://ec.europa.eu/futurium/en/ethics-guidelines-trustworthy-ai/pilot-assessment-list-ethics-guidelines-trustworthy-ai.html.

²⁴ On the point see: https://digital-strategy.ec.europa.eu/en/library/assessment-list-trustworthy-artificial-intelligence-altai-self-assessment.

instrument, and such improvement largely happened thanks to the work of the European AI Alliance.

5. The Role of the AI Alliance with Reference to the Legislative Proposals in the Field of AI

After the presentation of the 2020 ALTAI, the AI HLEG's mandate closed. The AI Alliance, however, continued to play a significant role also with regard to the subsequent EU initiatives in the field of AI: we refer, in particular, to the proposals of legislative acts.

On 2 February 2020, the European Commission adopted the White Paper "On Artificial Intelligence – A European approach to excellence and trust" (COM/2020/65 final). In such document it is clearly stated that, in addition to the Guidelines, a binding European regulatory framework would build trust among consumers and businesses in AI, and therefore speed up the uptake of the technology (European Commission, 2020 A, 9-10). For this reason, the Commission launched a broad consultation of Member States civil society, industry and academics, of concrete proposals for a European approach to AI (European Commission, 2020 A, 25).

The abovementioned consultation actually took place between 19 February 2020 and 14 June 2020²⁵, and the AI Alliance played once more a crucial function: over 1215 contributions were received through the online questionnaire and communication channels of the AI Alliance. Going into detail, 42% of respondents requested the introduction of a new regulatory framework on AI, another 33% thought that the current legislation may need to be modified in order to address the gaps identified, while only 3% agreed that current legislation is fully sufficient. Concerning the scope, 43% agreed that the introduction of new compulsory requirements should only be limited to high-risk AI applications, while another 31% doubt such limitation.

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²⁵ On the point see: https://digital-strategy.ec.europa.eu/en/library/white-paper-artificial-intelligence-public-consultation-towards-european-approach-excellence-and.

Moreover, participants voiced doubts on the public use of remote biometric identification systems: 28% of them supported a general ban of this technology in public spaces; another 29% required a specific EU guideline or legislation before such systems may be used in publicly accessible spaces; 20% wanted to see more requirements or conditions for remote biometric identification. With regard to enforcement, a wide percentage of the respondents (i.e. 62%) supported a combination of ex-post and ex-ante market surveillance systems. Ultimately, it can be said that the large majority of the participants argued that the Commission should go further in the protection of fundamental rights *vis-à-vis* artificial intelligence (European Commission, 2020 C).

The described consultation led to the presentation by the European Commission of the 2021 AI Package, which is introduced by the EC Communication "Fostering a European approach to Artificial Intelligence" (COM/2021/205 final) and comprehends the Proposal for a Regulation of the European Parliament and of the Council "Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act)" (COM/2021/206 final).

Starting from the EC Communication, it describes the AI Package as the outcome of 3 years of intense policymaking on AI at European level, that included extensive stakeholder consultation on the Guidelines and on the ALTAI. Moreover, the Communication stresses the role of the AI Alliance, formed as a platform for stakeholders to debate the technological and societal implications of AI, culminating in a yearly AI Assembly. The result is a Proposal that combines greater safety and fundamental rights protection while supporting innovation, enabling trust without preventing innovation. The existing legislation, indeed, is deemed unable to address specific high risks deriving from certain characteristics of AI, such as the opacity of many algorithms: therefore, there is the strong need of a "risk-based European regulatory approach", i.e. a framework that regulates AI systems depending on the risks deriving from them (European Commission, 2021 A, 1-9).

With regard to the Proposal, the "Explanatory Memorandum" recognises the role of the AI Alliance and, more in general, emphasises the importance of the whole public consultation process that took place, describing it as follows: "It targeted all interested stakeholders from the public and private sectors, including governments, local authorities, commercial and noncommercial organisations, social partners, experts, academics and citizens [...] In total, 1215 contributions were received, of which 352 were from companies or business organisations/associations, 406 from individuals (92%) individuals from EU), 152 on behalf of academic/research institutions, and 73 from public authorities. Civil society's voices were represented by 160 respondents (among which 9 consumers' organisations, 129 nongovernmental organisations and 22 trade unions), 72 respondents contributed as 'others'. Of the 352 business and industry representatives, 222 were companies and business representatives, 41.5% of which were micro, small and medium-sized enterprises. The rest were business associations". The Explanatory Memorandum of the Proposal also remembers that there is a general agreement amongst stakeholders on a need for action, since a large majority agree that legislative gaps exist or that new legislation is needed; overregulation, however, must be avoided. With regard to the content, it is also highlighted that most of the respondents are explicitly in favour of the risk-based approach, which is considered a better option than blanket regulation of all AI systems; risks should be calculated taking into account the impact on rights and safety (European Commission, 2021 B, 7-8).

As widely suggested, the Proposal actually follows a risk-based approach (on the risk-based approach see: De Gregorio and Dunn, 2022, 473-500), that differentiates between uses of AI that create an "unacceptable risk", a "high risk" and "low or minimal risk" (on the AI Act Proposal: Veale and Borgesius, 2021, 97-112; Voss, 2021, 7-17).

AI systems whose use is considered "unacceptable" should be prohibited: among them, it is possible to mention those practices that have a significant potential to manipulate persons through subliminal techniques beyond their consciousness or exploit vulnerabilities of specific vulnerable groups such as children or persons with disabilities in order to materially distort their behaviour in a manner that is likely to cause them or another person psychological or physical harm; the Proposal also prohibits AI-based social scoring for general purposes done by public authorities, and even the use of "real time" remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement, unless certain limited exceptions apply (Title II, i.e. art. 5, of the Proposal). It is worth remembering that those practices, during the consultation, were judged as critical by a large percentage of the respondents: for example, as already mentioned, many participants voiced doubts on the public use of remote biometric identification systems.

The Proposal takes then into consideration AI systems that create a "high risk" to the health and safety or fundamental rights of natural persons; there are, in particular, two main categories of "high risk" AI systems: AI systems intended to be used as safety component of products that are subject to third party ex-ante conformity assessment and stand-alone AI systems with mainly fundamental rights implications (that are explicitly listed in Annex III of the Proposal). Those "high risk" AI systems should be permitted on the European market, but subject to compliance with certain mandatory requirements and an ex-ante conformity assessment (Title III, i.e. articles 6-51). It must be noticed that those requirements, which are already state-of-the-art for many diligent operators, are defined as the result of two years of preparatory work, derived from the Ethics Guidelines of the HLEG, piloted by more than 350 organisations (European Commission, 2021 B, 13): even the rules on "high risk" AI systems, therefore, can be considered *lato sensu* the outcome of the described participatory process.

Always according to the Proposal, if the risk level does not fall in the first two categories, there should be transparency obligations in certain cases (Title IV, i.e. art. 52). Finally, the Proposal encourages national competent authorities to set up "regulatory sandboxes" (Title V, articles 53-55), that

establish a controlled environment to test innovative technologies for a limited time.

In the moment we are writing, the AI Act Proposal is still being discussed by EU institutions: in particular, the Council adopted its "General approach" on 6 December 2022, while the European Parliament adopted its position on 14 June 2023, but there has been no approval yet, since it is still necessary to negotiate a shared text. However, it must be also mentioned the fact that, in the meantime, the European Commission presented other legislative proposals in the field of AI, such as the 2021 Proposal for a Regulation "on general product safety" (COM/2021/346 final) and the 2022 Proposal for a Directive "on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive)", which are as well the result of wide consultations, starting from the one on the White Paper on AI (European Commission, 2022, 7).

6. Conclusions and Suggestions

After analysing the role of stakeholder consultation, and in particular of the European AI Alliance, in drafting EU acts on AI, it is now possible to make some concluding remarks.

Preliminary, it seems evident that in the field of AI, even more than in other fields, the dialogue between EU institutions and stakeholders clearly has two purposes.

The first aim, as already highlighted, is to *enhance the democratic legitimacy of EU decision-making processes*. With regard to AI, extremely relevant clashing interests come at stake: on the one hand, there are the needs to promote new technologies, given the economic and societal benefits that they can bring across the entire spectrum of industries and social activities, and to further establish the EU's technological leadership worldwide; on the other hand, individuals and the society must be prevented from the risks and the negative consequences deriving from those technologies. That's why

involving all the interested parties and taking into consideration their positions and ideas is essential. This also helps to reduce the widespread perception of the 'democratic deficit of the EU' (on such topic see: Hennen, 2020; Neuhold, 2020).

However, there is also a second purpose, which in all likelihood is even prevailing in this specific field, i.e. *increasing the effectiveness of the abovementioned decision-making processes* through the exploitation of the precious competences and experiences of stakeholders such as NGOs, enterprises, academics and so on (on such topic see: Tramontana, 2013). Taking advantage of the knowledge of the specialists of the sector is always very important, but even more with regard to a complex and technical matter such as AI, which remains hardly understandable for the vast majority of the citizens.

Moreover, it is interesting to notice that the dialogue between EU institutions and stakeholders so far has been *continuous*. The consultation, indeed, did not happen just in one moment, but in several occasions and in different phases: after the presentation of the first draft of the Ethics Guidelines for Trustworthy AI, after the publication of the final version of such Guidelines, after the White Paper on AI, and so on. In other words, in the field of AI, until now, EU institutional actors felt the need to ask advice from stakeholders after every single step and before the following ones.

Given the above, it is also possible to formulate some suggestions. According to the writer, indeed, the AI Alliance should allow a deep stakeholder consultation also in the future, not only during the drafting of the AI Act, but also after its (eventual) adoption. The ideal would be to transform it into a permanent medium to institutionalise a constant dialogue on AI policy with affected stakeholders. If exploited in this way, for example, it could help to determine with increasing accuracy the AI systems that must be prohibited, since they create an unacceptable risk, and the ones that must be tightly regulated, since the risk for people's rights and freedoms is high and

the impact of the technology might be unfavourable to individuals or society as a whole (Harasimiuk and Braun, 2021, 46).

In conclusion, it is now evident that a continuous stakeholder consultation is the only way to achieve a framework capable of addressing the new challenges deriving from the unceasing development of AI. For this reason, the AI Alliance should be constantly exploited and improved in the next years in order to allow such consultation; and this should happen also, *rectius* even more, in case of approval of the AI Act and of the other legislative proposals currently under discussion.

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