The legal concept of artificial intelligence: the debate surrounding the definition of AI System in the AI Act

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ABSTRACT: The concept of AI has always been controversial because there is no broad consensus on its definition. This is problematic from a legal perspective, as laws require precise and specific definitions, especially for concepts that have a direct impact on the scope and reach of the regulation, having this choice technological, economical and legal implications. During the European Union's AI Act legislative process, there has been a debate on the legal definition of AI, with diverging definitions of AI System being proposed by the different bodies of the European Union.

KEYWORDS: Artificial Intelligence; legal definitions; AI Act; legislative process; European Union institutions

1. Introduction

In the last few years, a lot has been written and talked about artificial intelligence (AI), and not only by computer scientists, but also by economists, sociologists, philosophers…etc. Nowadays, you can find a paper or research on AI and any other research topic, even astrology.[1] This has led to what we could call a hyperinflation of academic articles about AI. This scenario is natural, as this

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[1] P. SARATHI, *Application of Big Data and Machine Learning for Astrological Predictions*, in *Computational Intelligence in Pattern Recognition*, Singapore, 2022, 1-12.

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technology attracts sheer fascination. A fascination that sometimes comes from science fiction,[2] but also from the game-changing implications that are expected from the introduction of this technology into our lives.

This phenomenon also occurs in legal disciplines. Most people would consider legal research on AI as something new, but we can find papers on this matter as old as from the 1980s[3] and the 1990s.[4] The difference nowadays is the ubiquity, and the soaring number of papers submitted every year about this topic. The growth in the number of published articles on these subjects can be explained by both the current technological and the regulatory context. Recent developments in AI, especially in machine learning during the last decade as a consequence of the increased availability of data and the growth in computer power to process it, have led to what has been called by experts as a new "AI summer", the term used for periods of time of accelerated progress and application in the field of AI.[5] Consequently, several countries and international organisations have been working during the last years towards the regulation of AI, in order to tackle the legal challenges that may arise from the introduction of this technology into the market.

However, there is an issue that has received less attention in this field: the legal definition of AI.[6] This may be explained both by the absence of a widely accepted technical definition of AI and by the lack of specific regulation in force, which has led to an absence of applicable legal definitions. It is interesting to note that in recent years there has been a proliferation of literature on the legal implications of AI, but when the time comes to talk about the legal definition of this technology, this issue has been either ignored or tackled as something ancillary and in a superficial way, without any reflection on what the specific object of regulation should be. This is surprising, given that the issue is of the utmost importance, as depending on how AI is legally defined, the scope of regulation will vary, with the different alternatives having several legal, technological and economic implications.

In this context, we can wonder which option would be better for the legal definition of AI. A technical definition that is consistent with what is considered as AI by computer scientists? Or would a broad definition be better, encompassing a broad range of computer-based technologies? Maybe should we aim for context-specific definitions (bearing in mind the differences between typologies of AI in different scenarios)? Or even consider whether a legal definition of AI is needed at all (and therefore regulated around uses and outputs, rather than specific technologies)?

[2] The European Parliament Resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics introduced the subject with a reference to Mary Shelley's Frankenstein.

[3] S.N. LEHMAN-WILZIG, *Frankenstein unbound Towards a legal definition of artificial intelligence*, in *Futures*, 13, 6, 1981, 442-457. Available at: https://doi.org/10.1016/0016-3287(81)90100-2.

[4] C. KARNOW, *Liability for distributed artificial intelligences*, in *Berkeley Technology Law Journal*, 11, 1, 1996, 147-204.

[5] H. A. KAUTZ, *The third AI summer: AAAI Robert S. Engelmore memorial lecture*, in *AI Magazine*, 43, 1, 2022, 111. Available at: https://onlinelibrary.wiley.com/doi/epdf/10.1002/aaai.12036.

[6] Generally considered "legal definitions remain under-examined by legal and social science scholarship, and legislative drafting manuals pay scant attention to this part of the drafting process, with few manuals offering tactical or substantive guidance", R. RICHARDSON, *Defining and Demystifying Automated Decision Systems*, in *Maryland Law Review*, 81, 3, 2022, 790. Available at: https://digitalcommons.law.umaryland.edu/mlr/vol81/iss3/2.

2. A brief approach to the technical concept of AI

If you ask an AI expert for a commonly accepted definition of AI, he or she will tell you that there is none. Oliviero Stock, one of the greatest and most recognised researchers in Artificial Intelligence, once said that if you asked a hundred AI researchers to define AI, you would receive a hundred different definitions (perhaps even more).[7]

Regarding AI as a discipline, McCarthy, one of the 'fathers of AI' defined it as "the science and engineering of creating intelligent machines".[8] Russell and Norvig consider that is "the study of (intelligent) agents that receive precepts from the environment and take action".[9]

One of the main problems related to this definition is the very term of "intelligence", existing as many definitions of AI as there are approaches and definitions of what intelligence is,[10] which is one of the main reasons why there is no widely accepted definition of AI or consensus on what intelligence is, being almost a philosophical question.[11] Intelligence can be considered as the ability to behave or think intelligently.[12] However, what should be the benchmark here? Should it be acting or thinking as a human does? As the reader may agree from experience, humans do not always behave or think with intelligence. For this reason, other authors consider intelligence as behaving or thinking 'rationally', meaning this that the subject can choose the best possible option, i.e. the one that maximises the subject's utility function.[13] Still, rationality is also a hard to define concept because it is difficult to determine when it is achieved (how often does a system need to take optimal actions to be considered rational?).[14] All in all, the reference to intelligence is a vague and broad concept whose openness may be desirable for scientific and research purposes, but which should be carefully considered if it is desirable to be included when trying to design a definition for other purposes, for example, in a legal definition, which requires precision and certainty in its elements.[15]

As defining AI is challenging, an alternative path would be to define it as the specific techniques and approaches that are considered as AI. The problem here, is that there is not a commonly accepted taxonomy or classification of these AI techniques and approaches. Several different classifications can be found within the AI community that use this term to refer to specific techniques (including machine learning, rule-based modelling, logic-based approaches, search and optimization techniques, genetic

[7] P. Traverso, *Breve introduzione tecnica all'intelligenza artificiale*, in *DPCE Online*, 51, 1, 2022, 157, Available at: https://www.dpceonline.it/index.php/dpceonline/article/view/1565/1547.

[8] J. McCarthy, *'What is Artificial Intelligence?'*, Stanford, 2007, 2. Available at: https://perma.cc/QL9Y-AY8A.

[9] P. Norvig, S.J. Russell, *Artificial Intelligence-A Modern Approach*, Upper Saddle River, 2020, 20.

[10] P. Wang, *What do you mean by "AI"?*, in P. Wang, B. Goertzel, S. Franklin (eds.), *Proceedings of the First Conference on Artificial General Intelligence*, 2008, 362.

[11] H. Ruschemeier, *AI as a challenge for legal regulation: the scope of application of the artificial intelligence act proposal*, in *ERA Forum*, 23(3), 2023, 365.

[12] P. Norvig, S.J. Russell, *op. cit.*, 21-22.

[13] *Ibidem*.

[14] J. Schuett, *Defining the Scope of AI Regulations, in Law, Innovation and Technology*, Legal Priorities Project Working Paper Series, 15, 1, 2023, 64. Available at: https://www.tandfonline.com/doi/epdf/10.1080/17579961.2023.2184135?needAccess=true.

[15] J. Schuett, *op. cit.*, 11.

algorithms, etc.).[16] Some others classify as AI any technique used for specific goals (computer vision, natural language processing, robotics, learning or reasoning).[17] In order to simplify the analysis, we can use one of the most general categorizations of AI, the one that differentiates between symbolic/logic-based AI and subsymbolic/data-driven AI,[18] notwithstanding the possibility of the development of AI systems by combining both categories.[19] This taxonomy has been followed, with some differences in the terminology, but similar in its essence, in several international frameworks for the classification of AI systems in the context of its regulation, such as the OECD,[20] the European Commission[21] or the United Nations.[22] We must bear in mind that this classification is an oversimplification of the universe of AI systems and their typologies, and that some of the techniques that will be cited can be considered in one or the other approach, depending on how they are specifically implemented. Nevertheless, we will use it for discussion purposes and to get a first notion of what AI is.

2.1. Logic-driven/symbolic AI

'Logic', 'knowledge-based' or 'symbolic' AI, works by defining a formal model of a certain phenomenon, encoding knowledge with symbols and structures using logics or reasoning processes, and then 'introducing it' into a computer, that will analyse the said model to verify its characteristics and properties or to generate solutions, enabling a computer system to solve a problem or achieve a desired goal automatically.[23]

The most prominent example of this category of AI are 'expert systems', which owe their name to the fact that the model is built by encoding knowledge from experts in a specific field, such as medical doctors, chemists, lawyers, etc. This type of systems were responsible of the 'second AI summer' between the late 1970s and the late 1980s.[24] We can use MYCIN as an example, an expert system developed in 1972 that was able to perform medical diagnosis through blood tests using rules and knowledge encoded in the model from the knowledge of doctors and practitioners.[25]

Usually, symbolic, logic- and knowledge-based approaches allow building AI systems that are highly explainable (as the solutions given are derived from the knowledge introduced in the model or from

[16] I. H. Sarker, *AI-Based Modeling: Techniques, Applications and Research Issues Towards Automation, Intelligent and Smart Systems*, in *SN Computer Science*, 3, 2022, 2. Available at: https://doi.org/10.1007/s42979-022-01043-x.

[17] This enumeration is based on the topics covered in P. Norvig, S.J. Russell, *op.cit*.

[18] ISO 22989:2022, clause 5.9; E. Ilkou, M. Koutraki, *Symbolic Vs Sub-symbolic AI Methods: Friends or Enemies?*, 2022.

[19] P. Traverso, *op. cit.*, 158

[20] OECD, *Framework for the classification of AI systems*, 2022, 44. Available at: https://t.ly/Nmn10.

[21] European Commission's High Level Expert Group on Artificial Intelligence, *A Definition of AI: Main Capabilities and Disciplines*, December 2018, 3-4. Available at: https://ec.europa.eu/futurium/en/system/files/ged/ai_hleg_definition_of_ai_18_december_1.pdf.

[22] United Nations, *UNESCO's Ethics of AI Recommendation*, 2021. Available at: https://unesdoc.unesco.org/ark:/48223/pf0000380455.

[23] P. Traverso, *op. cit.*, 158.

[24] H. A. Kautz, *op. cit.*, 109.

[25] R. de Kleijn, *Artificial Intelligence Versus Biological Intelligence: A Historical Overview*, in B. Custers, E. Fosch-Villaronga (eds.), *Law and Artificial Intelligence*, The Hague, 2022, 33. Available at: https://doi.org/10.1007/978-94-6265-523-2_2.

logical rules embedded in the model) and deliver great performance in the areas they are implemented in. For example, MYCIN was able to diagnose blood test samples with the same or even better accuracy than human doctors.[26]

The problem with this approach is the difficulty of translating complex phenomena into models that can be used by a computer. This is problematic, as the real world is full of complex scenarios, so this approach is not suitable for all fields or contexts. However, this does not mean that model-based AI is something that belong to the past, some call this 'old AI' or GOFAI (good old-fashioned artificial intelligence) but nowadays it is still successfully used in major industrial applications.[27]

2.2. Data-driven AI/subsymbolic AI

In this approach, the model used by the system is not designed and introduced into the computer; instead, it is built 'from the inside', implicitly encoding knowledge through statistical approaches and the processing of experience or data.[28] There are several techniques and approaches that build the model through encoding information from data or experience, such as machine learning, neural networks, probabilistic models (Markov Models, Support Vector Machines-SVM), evolutionary computation, etc…

The most prominent example of this category of AI systems (at least during the last decade) is 'machine learning', an approach where the AI model is built by giving the system a series of data and examples from which it learns. This learning can be supervised or unsupervised by a human or it can work by reinforcement.[29] The archetypical example of machine learning systems is 'neural networks', specifically what is known as 'deep learning', that consists in a set of layered neural networks working together.

Machine learning is usually considered as something recent because of the outstanding developments using this approach in the last decade, but the theoretical foundations of this technology date back to the 1960s[30] and the 1980s.[31] However, at that time there was not enough computing power to make machine learning work[32] as it does today.

Related to machine learning and deep learning, another term that has gained popularity in the last years is 'foundation models', that can be defined as "models trained on broad data that can be adapted

[26] R. DE KLEIJN, *op. cit.*, 33.
[27] P. TRAVERSO, *op. cit.*, 156.
[28] ISO 22989:2022, clause 5.9.
[29] P. TRAVERSO, *op. cit.*, 158.
[30] The Rosenblatt's Perceptron was the first attempt to create a neural network. F. ROSENBLATT, *The perceptron: A probabilistic Model for Information Storage and Organization in the Brain*, in *Psychological Review*, 65 (6), 1958, 386-408.
[31] The backpropagation for training multilayer networks: D. RUMELHART, G. HINTON, and R. WILLIAMS. *Learning Representations by Back-Propagating Errors*, in *Nature*, 323, 1986, 533-536. And the works on convolutional networks: Y. LECUN, B. BOSER, J.S. DENKER, D. HENDERSON, R. E. HOWARD, W. HUBBARD, and L.D. JACKEL, *Backpropagation Applied to Handwritten Zip Code Recognition*, in *Neural Computation*, 1(4), 1989, 541-551.
[32] N.C. THOMPSON ET AL., *The computational limits of deep learning*, 2020, 4. Available at: https://arxiv.org/pdf/2007.05558.pdf?mod=djemAIPro.

to a wide range of downstream tasks"[33] of which "large language models" (such as ChatGPT), which are foundation models used for natural language processing that allows for general-purpose language understanding and text or other content generation, are the most applied examples nowadays.

The main advantage of data-driven approaches is that enable to model complex and otherwise unmanageable phenomena that would be impossible to design or model using symbolic or logic-based approaches.[34] The paradigmatic example would be image recognition, where a neural network can be trained on a dataset of images in order to learn to recognize patterns and features within a set of images by adjusting its internal parameters. Once trained, the neural network will be able to accurately identify objects or patterns in new images, a task that using a symbolic AI approach would not be possible, as the complexity and variability of the data make it challenging to define explicit rules for image recognition. Machine learning systems, especially neural networks, have thrived during the last decade because of the availability of vast amounts of data (usually referred as *Big Data*) and increasing computational power.[35]

Nevertheless, machine learning cannot be implemented in every scenario, this approach requires contexts with abundant available data, few outliers and stability.[36] However, in scenarios dealing with high levels of uncertainty or where there is insufficient data available, this approach cannot be properly implemented or is bound to perform poorly.[37]

In addition, machine learning is associated with some problems resulting from the automated learning process and the way these systems work, such as opacity, complexity and lack of explainability, which we can summarise in the fact that there is a risk that the process followed by the system to reach an output may be unintelligible (as it derives from inferred relationships found by the system that are beyond the human cognitive reach).[38] For example, a spam filter may classify an email as spam based on the weight to a word or group of words but may not be any explanation of why certain words are given more weight to be considered as part of a spam (for example, words related to scams or phishing strategies such as 'click' or related to money may be logic that have a high weight for being considered as spam, but maybe others such as 'will' or 'visit' may not be that intuitive).[39]

There are other risks that are related to the data used to train the system, such as biases or malfunctions due to the under- or over-representation of certain collectives or categories of subjects, because certain variables or characteristics of the data used to train the system have not been considered, or due to errors in the collection and categorisation of data, among other causes.[40] For example, if a facial

[33] R. BOMASHANI ET AL., *On the Opportunities and Risks of Foundation Models*, 2021, 3. Available at: https://doi.org/10.48550/arXiv.2108.07258.

[34] P. TRAVERSO, *op. cit.,* 164.

[35] C. AGGAHRWAL, *Neural Networks and Deep Learning – a textbook*, Cham, 2018, 4; THOMPSON ET AL., *op. cit.,* 4.

[36] R. BENJAMINS, I. SALAZAR, *El Mito del Algoritmo*, Madrid, 2020, 208.

[37] C. AGGAHRWAL, *op. cit*., 26.

[38] A. BARREDO ARRIETA ET AL., *Explainable Artificial Intelligence (XAI): Concepts, taxonomies, opportunities and challenges toward responsible AI*, in *Information Fusion*, 58, 2020, 7.

[39] J. BURRELL, *How the machine 'thinks': Understanding opacity in machine learning algorithms*, in *Big Data & Society*, 3, 1, 2016, 8-9. Available at: https://journals.sagepub.com/doi/pdf/10.1177/2053951715622512.

[40] R. SRINIVASAN, A. CHANDER, *Biases in AI Systems: A survey for practitioners*, in *Queue*, 19, 2, 2021, 45-55.

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recognition system is fed with many images of light-skinned people and only a few of dark-skinned people, it will perform poorly while trying to recognise dark-skinned faces.[41]

2.3. Hybrid systems

The former categories must not be seen as self-contained and closed to each other. Some techniques can be used to work under symbolic and subsymbolic data, such as Bayesian models, and AI systems can be developed with a combination of these approaches in what are called 'Hybrid models'. For example, Natural Language Processing (NLP) algorithms combine statistical and symbolic approaches;[42] neurosymbolic approaches combine deep learning with symbolic rules to bring together the accuracy and utility of neural networks with the explainability and comprehensibility of knowledge-based approaches.[43]

3. The definition of AI systems in the European Commission's Proposal for an AI Act

Before 2023, there were not many legal definitions of AI systems. Instead, it could be found some limited national initiatives (such as in Canada),[44] working definitions (European Commission's High Level Expert Group), soft law proposals (OECD) and proposals for regulation that were undergoing their legislative process (the AI Act in the European Union and the Algorithmic Liability Act in the USA).
The European Commission's proposal for an AI Act was not the first to attempt to introduce or suggest a legal definition of AI, but it has been the most relevant and debated regulatory initiative for the regulation of AI since it was published in April 2021, being the first initiative trying to comprehensively regulate the development and use of AI systems at a supranational level.[45]

3.1. A relevant precedent to the AI Act: The OECD definition of AI system

Before we start the analysis of the definition included in the AI Act and its evolution, we will comment on the most relevant legal definition proposed before the European Commission published the AI Act proposal: the definition included in the OECD Recommendations on Artificial intelligence published in 2019, in which AI systems defined as: *"*Machine-based systems that can, for a given set of human de-

[41] *Ibidem*, 48.
[42] OECD, *Framework for the classification of AI systems*, 2022, 44.
[43] M. GARNELO, M. SHANAHAN, *Reconciling deep learning with symbolic artificial intelligence: representing objects and relations*, in *Current Opinion in Behavioral Sciences*, 29, 2019, 17-23. Available at: https://doi.org/10.1016/j.cobeha.2018.12.010; D. GUNNING ET AL., *XAI—Explainable artificial intelligence*, in *Science Robotics*, 4, 37, 2019.
[44] Government of Canada, *Directive on Automated Decision-Making*. 2023, April 25th. Available at: https://www.tbs-sct.canada.ca/pol/doc-eng.aspx?id=32592.
[45] European Commission, *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*, 21.4.2021, COM (2021) 206 final, 2021/0106(COD). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52021PC0206.

fined objectives, make predictions, recommendations or decisions, influencing real or virtual environments, and are designed to operate with varying levels of autonomy"[46] (hereafter, the OECD 2019 definition).[47]

The main elements of this definition are the reference to autonomy; the human defined objectives; the reference to specific outputs (predictions, recommendations or decisions) and the impact in real or virtual environments, explicitly stating that these systems can have an impact beyond the physical environment where the hardware in which the AI is embedded is located, probably in an effort to emphasise that AI goes beyond just robots. It was notable the absence of the word 'intelligence' in the wording, contrarily to other proposed definitions at the time, such as the Commission's High Level Experts Group,[48] an approach that seems to acknowledge the difficulties generated by the indeterminacy of this concept (as commented in Section 2). However, it has also been pointed out that, even if it was a solid plain-language definition, it could be challenging to implement without specific examples of what is and is not AI.[49]

As we will see in the following sections, this has been one of the most influential and impactful proposals for a legal definition of AI, influencing not only the definition in the European Union's AI Act and its legislative process, but also in other regions, such as in the USA, where this definition was integrally incorporated by the National Artificial Intelligence Initiative Act of 2020 (15 U.S.C. 9401 (3)).

3.2. The definition in the European Commission's Proposal for an AI Act

The European Commission's Proposal defined AI system in its article 3 (1) as: "software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with".

If we break the definition down, it has five main elements: (i) software; (ii) developed with one or more of the techniques and approaches listed in Annex I; (iii) for a given set of human-defined objectives; (iv) that can generate outputs such as content, predictions, recommendations, or decisions; (v) influencing the environments they interact with.

This definition had some common elements with the OECD 2019 definition, such as the reference to the human-defined objectives; the predictions, recommendations, and decisions as outputs, and the influence on the environment.

There were also several differences, such as the lack of reference to autonomy[50] and considering content as one of the possible outputs (premonitory of the relevance that generative AI systems such as

[46] OECD, *Recommendation of the Council on Artificial Intelligence*, OECD/LEGAL/0449, 22nd May 2019. Available at: https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0449.

[47] It should be noted that this definition would later be updated by the OECD in 2023 (see Section 6.3).

[48] The HLEG defined AI as "systems that display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals". HIGH LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE, *A Definition of AI: Main Capabilities and Disciplines*, December 2019. Available at: https://ec.europa.eu/futurium/en/system/files/ged/ai_hleg_definition_of_ai_18_december_1.pdf.

[49] CENTER FOR SECURITY AND EMERGING TECHNOLOGY, *AI Definitions Affect Policymaking*, 2020, 3.

[50] However, this reference to the autonomy of AI systems was mentioned in recital (6) of the Commission's Proposal.

Chat GPT would have in the following years). However, the most notable differences are the use of the term 'software', rather than 'machine-based system', and the reference to the Annex I of the Regulation, so that not just any type of software can be considered as AI, it must be developed using one of the techniques listed in the said annex. The techniques in Annex I were: "(a) Machine learning approaches, including supervised, unsupervised and reinforcement learning, (b) Logic- and knowledge-based approaches, including expert systems or knowledge representation, (c) Statistical approaches, Bayesian estimation, search and optimization methods".

Letters (a) and (b) of the Annex I, referred to machine learning and logic or knowledge-based approaches, which could be roughly thought of or classified as the 'data-driven AI' and 'symbolic AI' approaches considered when we examined the technical concept of AI in section 2.

However, there is also a list of techniques in letter (c): the statistical approaches, Bayesian estimation and search and optimisation methods. These approaches can be considered as data-driven or logic-based, depending on how the specific technique implemented, e.g. some search and optimization techniques as heuristic approaches and genetic algorithms, or because of its characteristics (Bayesian estimation is a hybrid approach). Nonetheless, the problematic point here would be the reference to 'software' developed with these letter c) approaches, as not only systems developed with machine learning and even some logic-based approaches usually rely on these approaches, but also almost any other kind of software does.[51] As we will see in section 4, some pointed out that the inclusion of the methods and techniques listed in letter (c) of Annex I would mean that virtually any present or future computer program would fall within the scope of the AI Act.[52]

The Commission opted for a definition of AI that combined requirements related to some characteristics of the system (ability to produce certain outputs for a set of human-defined objectives influencing their environment) with a list of closed techniques that are considered as AI (the techniques in Annex I). This could be seen as an attempt to narrow the definition of AI systems (if compared with the OECD definition) by targeting specific techniques and approaches, although this list was developed using broad categories that could include not only what is generally considered to be AI, but also conventional software.

3.3. Why the legal definition of AI in the AI Act is important

The legal definition of 'AI systems' included in the AI Act is of the utmost importance for two reasons. First, a clear definition provides legal certainty[53] and allows to define which specific systems and technological developments are covered by the regulation, a crucial matter for determining the subjects that will bear with legal duties.[54] The material scope of the regulation will not be the same if we use a

[51] P. GLAUNER, *An Assessment of the AI Regulation Proposed by the European Commission*, 2021, 4.
[52] *Ibidem*.
[53] N. T. NIKOLINAKOS, *EU Policy and Legal Framework for Artificial Intelligence, Robotics and Related Technologies – The AI Act*, Athens, 2023, 351.
[54] N. SMUHA ET AL., *How the EU can achieve legally trustworthy AI: a response to the European Commission's proposal for an Artificial Intelligence Act*, Birmingham, 2021, 14.

definition which includes in the concept of AI system a regular computer program, as opposed to another that would only consider as AI those developed using specific techniques or approaches, or that fulfil specific characteristics.

It was also expected that other countries or international organisations could use the definition in the AI Act as a reference for new regulations, an outcome that would be desirable in order to build a common legal regulatory landscape, based on the same or at least similar concepts and definitions, especially taking into account the potential international and cross-border outreach of this technology.[55]

In addition, the legal definition of AI systems in the context of the AI Act is a matter that exceeds the own scope and effects of this regulation, as it is expected that the definitions provided by this Act will be used in future European Union legislation (for example, the Proposal for a Directive on AI Liability refers in its article 2 to the definition of 'AI system' used in the AI Act).[56] If the same broad definition is used in the AI Act, with the argument that it is preferable to encompass more technological developments in this regulation to ensure that all of them follow the specific requirements and obligations devised for high-risk uses or to forbid their use, this same broad scope will be used in this Directive and other future regulations, that will likely have different objectives and scopes. The same argument could be used in the opposite direction, if the definition is too narrow, there is a risk of that systems that could be considered as AI will be excluded from potential regulation because they are not in the list of technical approaches or do not meet the requirements of this legal definition.

The alternative to solve this issue would be not using the definition in the AI Act as a reference in other EU regulations and, instead, design tailored definitions of AI systems for each of these new laws. The risk of this approach is that each regulation could use different or inconsistent definitions, so systems developed with the same technical approaches or with the same characteristics would be considered as AI depending on their specific use or if they fall within the scope of a regulation (or not). For example, an AI system under the AI Act might not be considered as an AI system under the Artificial Intelligence Liability Directive or other regulations.

We must clarify here that the discussion is not only about whether a category of systems would fall under the scope of a regulation or not. A system may be classified as AI under the definition of the AI Act but may not fall within the scope of its regulation because it may not be used for high-risk or prohibited purposes. If each law has its own definition, there is a risk that the same system might not even be considered as AI under other regulations. We can also think of the opposite scenario: a system that is not considered an AI system under the AI Act could be considered an AI system under other regulations, regardless of whether these regulations could be applied to that system, as it may fall outside their regulatory scope. This scenario would risk creating inconsistencies in the governance of AI systems in the European Union.

[55] O.J. ERDÉLYI, J. GOLDSMITH, *Regulating artificial intelligence: Proposal for a global solution*, in *Government Information Quarterly*, 39, 4, 2022, 2-3.

[56] Proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive), 28.9.2022, COM (2022) 496 final. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0496.

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4. The debate surrounding the definition of AI systems in the AI Act

After the European Commission published its proposal for an AI Act, a period for public consultancy and for stakeholders to provide feedback to the Commission on the content and objectives of the AI Act was opened.[57] The feedback provided by the stakeholders included, among other issues, many comments aimed at the definition. Some stakeholders considered that the definition was alright as it was, but many considered that the definition had some flaws, some pointing out that it was over-inclusive (especially from the corporate environment)[58] and others under-inclusive.[59]
These debates around the legal definition of AI in the AI Act can be simplified to the following two positions: 1) the definition should be broad, even including regular software and 2) the definition of AI system should be narrow, limited to specific approaches that are considered as AI.

4.1. Broad definition

This stance considers that the definition of AI system in the AI act must be devised so it includes not only techniques that are considered as AI but also other categories of software. It is argued that this approach ensures a better protection of both individual and collective human rights from automated decision-making and the use of software for automation.[60] The rationale behind this approach is that there are not significant differences between the risks associated with software and AI, so regulation should be algorithm-agnostic[61] and the scope should be on specific uses and applications of that software and the risks associated with those specific uses or contexts.[62]
Some even suggest that the scope of the regulation should be changed to focus on algorithmic and automated decision-making systems,[63] and that consideration should be given to changing the name of the law to something like a "Software Act" rather than an AI Act.[64] This approach would be similar to the followed by other countries such as in the USA with its 2022 Algorithmic Accountability Act (not yet approved)[65] or the Canadian Directive on automated decision-making.[66]

[57] Feedback resulting from the public consultancy available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12527-Artificial-intelligence-ethical-and-legal-requirements/feedback_en?p_id=24212003.
[58] See the feedback from DIGITALEUROPE, Developers Alliance, Intel and IBM.
[59] See the feedback from Algorithm Watch, Alliance for Internet of Things Innovation, Finnish Center for Artificial Intelligence.
[60] H. RUSCHEMEIER, *op. cit.*, 372.
[61] J. ELLUL, *Should we regulate Artificial Intelligence or some uses of software*, in *Discover Artificial Intelligence*, 2, 5, 2022, 2; P. HACKER, *The European AI liability directives – Critique of a half-hearted approach and lessons for the future*, in *Computer Law & Security Review*, 51, 2023, 9.
[62] SHERPA PROJECT, *Feedback to the European Commission on its Proposal for a legal act of the European Parliament and the Council laying down requirements for Artificial Intelligence*, 2021, 2; RUSCHEMEIER, *op. cit.*, 366.
[63] ALGORITHM WATCH, *Submission to the European Commission's Consultation on a Draft Artificial Intelligence (AI) Act*, August 2021, 2. Available at: https://algorithmwatch.org/en/wp-content/uploads/2021/08/EU-AI-Act-Consultation-Submission-by-AlgorithmWatch-August-2021.pdf.
[64] N. SMUHA ET AL., *op. cit.*, 15; H. RUSCHEMEIER, *op. cit.*, 367.
[65] Algorithmic Accountability Act of 2022. Available at: https://www.congress.gov/117/bills/s3572/BILLS-117s3572is.pdf.
[66] Directive on Automated Decision-Making, 2023-04-25. Available at: https://www.tbs-sct.canada.ca/pol/doc-eng.aspx?id=32592.

However, there are also several drawbacks to this approach. First, it could mean an excessive broadening of the scope of the regulation, as almost any kind of software, present or future, would be considered as AI[67] and, as such, be subject to regulation. Conversely, some authors considered that the use of a closed list would mean limiting the AI Act to existing technologies, and therefore excluding future technological developments.[68] In any case, both situations could lead to legal uncertainty for developers, operators and users of AI systems.[69]

The risk at this point was that, given the aims and purposes of the AI Act, this approach could hamper innovation as it could mean overburdening a high number of companies without any real benefit, even more if we bear in mind the associated costs in terms of money and time that regulation entails for companies.[70] Compliance costs are estimated to amount from around five thousand to four hundred thousand euros[71] (although the precision of these estimations is controversial).[72] This is especially relevant in sectors such as finance or the development of medical devices, that are already heavily regulated and under several compliance requirements. In addition, the comparison with other countries' regulations is not useful, as the cited American or Canadian regulations were far less ambitious and with a more limited scope than the AI Act, as the former only applies to large companies[73] and the latter just to public entities.[74] Apart from big tech corporations, the AI Act will also apply to small and medium sized companies and, even with adaptations for these kind of companies, this approach could unnecessarily stifle innovation as a consequence of overburdening developers of regular software (i.e. that are not generally considered as AI), with smaller companies likely to be most affected.[75]

This approach is argued that, instead of addressing specific concerns about the development and use of AI, the AI Act would apply to a much broader set of systems that do not need regulatory intervention

[67] M. EBERS ET AL., *The European Commission's Proposal for an Artificial Intelligence Act – A Critical Assessment by Members of the Robotics and AI Law Society (RAILS)*, in *Multidisciplinary scientific journal*, 4, 2021, 590. Available at: https://doi.org/10.3390/j4040043; P. GLAUNER, *op. cit.*, 4; EUROPEAN AI FORUM, *Feedback to the European Commission's regulation proposal on the Artificial Intelligence Act*, 2021, 1. Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12527-Artificial-intelligence-ethical-and-legal-requirements/F2665603_en.

[68] G. FINOCCHIARO, *The regulation of artificial intelligence*, in *AI & Society*, 2023, 6. Available at: https://doi.org/10.1007/s00146-023-01650-z.

[69] K. HENCKEL, *Issues of conflicting laws – a closer look at the EU's approach to artificial intelligence*, in *Nederlands Internationaal Privaatrecht*, 12, 2023, 203. Available at: http://www.nipr-online.eu/pdf/2023-12.pdf; H. RUSCHEMEIER, *op. cit.*, 368.

[70] J. MÖKANDER, M. AXENTE, F. CASOLARI ET AL., *Conformity Assessments and Post-market Monitoring: A Guide to the Role of Auditing in the Proposed European AI Regulation*, in *Minds & Machines*, 32, 2022, 258; G. FINOCCHIARO, *op. cit.*, 6.

[71] CENTER FOR DATA INNOVATION, *The AI Act Should Be Technology-Neutral*, 2023, 2.

[72] M. HAATAJA, J.J. BRYSON, *What costs should we expect from the EU's AI Act?*, 2021, 5-6.

[73] Sec. 2. (7) of the Algorithmic Accountability Act of 2022 considers as a "covered entity" as any person, partnership or corporation that use automated decision-making systems and fulfils some requisites: have more than 50 Million $ in annual turnover or more than 250 Million $ in equity, use or control more than 1 Million consumers, households or consumer devices.

[74] Art. 9 of the Directive on Automated Decision-Making provides that the Directive applies to all institutions subject to the Policy on Service and Digital (that only applies to Government of Canada organizations and departments) unless excluded by specific acts.

[75] G. FINOCCHIARO, *op. cit.*, 6.

in these terms (or at least with the necessary scope for the specific problems of AI). Some points out that the idea that a single regulation could provide solutions to the issues associated with each one of these technologies is problematic,[76] if not futile,[77] and that a better definition would limit the scope of the proposed regulation to those technologies that pose novel risks.

4.2. Narrow definition

This approach advocates for a definition of AI system that only considers as such those developed with specific techniques. The most cited approaches while referring to this stance are machine learning and knowledge-based (letters (a) and (b) of Annex I of the AI Act Proposal).[78] The aim would be to regulate what is actually considered as AI and not traditional software. For that matter, even if other software approaches could be considered as AI, the regulation would only focus on a limited group of technical approaches, as those are which raise novel risks and issues for individual and collective rights.
However, there is no consensus on this approach either, with some voices arguing that only machine learning approaches should be considered as AI by this Act, as the systems developed using these approaches are the ones that truly cause problems regarding unforeseeability, black box algorithms, opacity problems and so on, which do not arise from logic-based systems.[79] This could be considered as a functional approach, because even if AI experts consider systems developed with knowledge-based approaches as AI, they would be deliberately left out of the Act´s definition for the sake of legal certainty, as it is easier to define just machine learning systems than AI systems in general,[80] with the purpose of tackling the specific issues generated by the development and use of the automated learning approaches. On the contrary, some consider that systems developed using knowledge-based approaches can pose the same risks to health and safety as data-based AI, as these systems can generate better explanations than machine learning systems and may, for example, cause users to follow incorrect or biased advice or outputs, assuming that the system is correct because the given explanation is plausible.[81]
The argued benefits of this stance are that it gives a better scope for the specific problems and challenges posed by AI, which are different from the problems raised by more basic software.[82] In both

[76] J. Mökander et al., *op. cit.*, 245.
[77] H. Ruschemeier, *op. cit.*, 366.
[78] See note 57.
[79] European Parliament Committee on Legal Affairs, *Draft Opinion of the Committee on Legal Affairs on the proposal for a regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act)* 2021/0106 (COD), 2nd March 2022, 139. Available at: https://www.europarl.europa.eu/doceo/document/JURI-PA-719827_EN.pdf.
[80] N. Smuha et al., *op. cit.*, 15.
[81] Governance in AI Research Group, *Comments from the Governance in AI Research Group (GAIRG) on the proposed EU AI Regulation*, 2021, 1. Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12527-Artificial-intelligence-ethical-and-legal-requirements/F2665609_en.
[82] See a collection of the arguments from the corporations and business associations: N.T. Nikolinakos, *op. cit.*, 354-361.

cases, the more limited scope of the regulation may help the different parties to allocate their resources more effectively,[83] allowing for a manageable and more in-depth supervision by the authorities. This also avoids overburdening traditional or regular software developers unnecessarily.

This approach of narrowing the definition also has its downsides. There is a risk of an excessive limitation of the effects of the AI Act. There are software and computer systems not developed with machine learning and logic-based based approaches that pose similar risks to individual and collective rights and would not be addressed by the regulation just because of a formal definition that is limited to the listed approaches.[84]

Moreover, some consider that this narrow definition would not be technologically neutral. The principle of technological neutrality states that regulations should avoid favouring or discriminating specific technologies over others.[85] If a regulation lists a group of specific technological methods and approaches that would be under obligations and restrictions, this creates incentives for developers not to use them.[86] This may also provide an incentive to find other techniques and develop strategies to circumvent regulation, as the use of a technique or approach not listed would mean that the regulation would not apply to that technology.[87]

However, technological neutrality does not necessarily require that the exact same rules apply to different technologies.[88] Technology-specific regulation is acceptable when there are existing differences between technologies in terms of effects or functionalities.[89] Regulation may target specific technologies when their effects and functionalities differ from those of other technologies, as it may happen when a technology has specific risks associated with its use, requiring the creation of specific rules to avoid, mitigate and manage them. If AI is a technology that poses new risks and traditional or simpler software does not, then to unnecessarily including the latter in a regulation would violate technological neutrality, as it would mean imposing burdens and restrictions on a technology when it is not necessary.[90]

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[83] J. MÖKANDER ET AL., *op. cit.*, 258.

[84] N. SMUHA ET AL., *op. cit.*, 15. EUROPEAN AI FORUM, *op. cit.*, 1: An alternative to tackle this issue would be adding a clause stating that regulation will apply to software or systems that have equivalent effects than the technologies defined as AI.

[85] B.J. KOOPS, *Should ICT Regulation Be Technology-Neutral?*, in B.J. KOOPS ET AL., *Starting points for ICT regulation. Deconstructing prevalent policy one-liners*, IT & law series, The Hague, 9, 2006, 8. Available at: https://ssrn.com/abstract=918746.

[86] CONFEDERATION OF LABORATORIES FOR AI RESEARCH IN EUROPE (CLAIRE), *Response to European Commission's Proposal for AI Regulation and 2021 Coordinated Plan on AI*, The Hague, 2021, 10.

[87] C. MULLER, V. DIGNUM, *Artificial intelligence act, analysis & recommendations*, 2021, 9. Available at: https://ai-lai.nl/wp-content/uploads/2021/08/EU-Proposal-for-Artificial-Intelligence-Act-Analysis-and-Recommendations.pdf; EUROPEAN AI FORUM, *op. cit.*, 1; K. VRANCKAERT ET AL., *KU Leuven Centre for IT and IP Law's Comments to the proposed Artificial Intelligence Act*, 2021, 1. Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12527-Artificial-intelligence-ethical-and-legal-requirements/F2665491_en; ALGORITHM WATCH, *op. cit.*, 2.

[88] B. A. GREENBERG, *Rethinking Technology Neutrality*, in *Minnesota Law Review*, 207, 2016,1522-1523; G. GAGLIANI, *Cybersecurity, Technological Neutrality, and International Trade Law*, in *Journal of International Economic Law*, 23, 3, 2020, 732.

[89] B.J. KOOPS, *op.cit.*, 8.

[90] P. GLAUNER, *op. cit.*, 4; CENTER FOR DATA INNOVATION, *op. cit.*, 6.

5. The evolution of the definition of AI system during the legislative process of the AI Act

With the publication by the Commission of its proposal in April 2021, the European legislative process for the AI Act began. The main milestones in this process were the publication of the General Approach of the Council of the European Union (the Council's Proposal, hereafter) and the Final Position of the European Parliament (the Parliament's Proposal, hereafter). Each text included amendments and changes, with the definition of AI system being affected in both proposals.

5.1. The definition in the Council of the EU's General Approach

The Council of the European Union adopted on 25 November 2022 its "General Approach" for the AI Act. In this document, the Council proposed to amend the Commission's definition of AI system as follows: "system that is designed to operate with elements of autonomy and that, based on machine and/or human-provided data and inputs, infers how to achieve a given set of objectives using machine learning and/or logic- and knowledge based approaches, and produces system-generated outputs such as content (generative AI systems), predictions, recommendations or decisions, influencing the environments with which the AI system interacts".

The term "software" was replaced by "system". In practice, this change should not be of a great practical significance, even if 'system' is a broader concept than software, as 'system' refers to an arrangement of elements that together exhibit behaviour or meaning that its individual components do not, enabling to consider as part of the AI system other physical or logical elements different from the software that conforms the AI.[91] However, the Commission's definition could also be used to include physical parts of the AI systems, since it is the hardware where the software that conforms the AI is embedded (although some expressed concern about the possibility of hardware being left out of the definition).[92]

The most relevant change was the suppression of Annex I from the Act. As a consequence, the Council replaced the reference to said annex in the definition with a reference to machine learning and logic- and knowledge-based approaches, which corresponded to the letters (a) and (b) of the Annex I. At first glance, this may seem like letter c) approaches (that is, statistical techniques, Bayesian models and search and optimisation techniques) were left out of the definition and the scope of the regulation, but this needs to be qualified. The Council's Proposal added two recitals, 6a and 6b, in which it was defined what should be understood by 'machine learning' and 'logic- and knowledge-based' approaches, including, apart from the techniques and methods already cited in letters a) and b) of Annex I, other techniques, namely logistic regression, Bayesian estimation and search and optimisation methods.

The techniques in the former letter c) of the Annex I were not really supressed from the material scope of the Council's Proposal, but rather relocated into the definitions of the other two main approaches, meaning this that the risk of over-including basic software that might not be generally considered as

[91] INCOSE, *Systems Engineering and System Definitions*, 2019, 3. Available at: https://www.incose.org/docs/default-source/default-document-library/final_-se-definition.pdf.

[92] N.T. NIKOLINAKOS, *op. cit.*, 354.

AI would persist.[93] However, as the Council used the expression "developed with", it seems that the objective was to limit the application of the Act to the use of statistical techniques, Bayesian and search and optimisation models used for the development of AI systems. As a consequence, software developed with these techniques would not be considered as AI systems if they were not to be used to develop a machine learning or a logic- or knowledge-based AI system. The main goal of the Council with these amendments was to provide criteria "for distinguishing AI from more classical software systems".[94]

There were other significant changes in this definition. An explicit reference to the autonomy of the AI system was included ("elements of autonomy") and the requirement that the objectives must be established by humans disappears, being now just a "set of defined objectives". It was also added in the definition a reference on how the AI system operates, that is, inferring how to achieve a given set of objectives from a set of human or machine-provided data and inputs.

Other (apparently) less relevant changes in the definition were, regarding the possible outputs of the AI system, a reference to "system-generated outputs" was added (although it is not clear what was the objective of this requirement or what could be considered as a non-system-generated output)[95] and it was specified that "content" referred to "generative AI systems".[96]

All in all, the Council´s definition was an attempt to narrow the definition (compared to the Commission's proposal), with the aim of distinguishing between AI and simpler software and simplifying the application of the law, focusing on the two main categories of AI systems, namely machine learning and logic- or knowledge-based approaches (both understood broadly not in strict technical terms). However, this narrowing of the definition is not as harsh as it might appear, as the techniques of the former Annex I that were not mentioned in the new definition of the Act (i.e. those included in the letter c of that Annex) were included in the recitals that defined what had to be considered as AI systems developed through these approaches.

5.2. The definition in the European Parliament proposed amendments

On 14 June 2023, the European Parliament reached an agreement on its final position on the AI Act.[97] Among other amendments, the Parliament proposed the following definition for AI systems: "a ma-

[93] P. HACKER, *op.cit.*, 8.

[94] Council of the European Union, *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* – General approach, 25 November 2022, 4. Available at: https://data.consilium.europa.eu/doc/document/ST-14954-2022-INIT/en/pdf.

[95] *Ibidem*.

[96] This change had no practical implications, although it did serve to highlight the relevance of this type of systems, as would be demonstrated when ChatGPT was released days after the General Approach was adopted, with all the public expectation that this and other generative AI system generated in the following months. Forbes, *A Short History of ChatGPT: How We Got To Where We Are Today*, 23 May 2023.

[97] Amendments adopted by the European Parliament on 14 June 2023 on the proposal for a regulation of the European Parliament and of the Council on laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts (COM(2021)0206 – C9-0146/2021 – 2021/0106(COD)).

chine-based system that is designed to operate with varying levels of autonomy and that can, for explicit or implicit objectives, generate output such as predictions, recommendations, or decisions influencing physical or virtual environments".

This definition, like the Council's, removed the reference to Annex I and replaced the term "software" with "machine-based systems". Contrary to the Council's proposal, the Parliament did not replace the reference to the Annex with a list of techniques and approaches in the definition. These changes were made in order to align the definition of AI system in the AI Act with the 2019 OECD definition, as it was explicitly stated by the European Parliament in the amended recital (6) of the Act, which expressed that the notion of AI system in the Regulation should be "aligned with the work of international organisations working on artificial intelligence" in order to "ensure legal certainty, harmonisation and wide acceptance".[98]

It is interesting to note that the European Parliament agreed upon this definition despite the recommendations made in a Draft Opinion issued by the Legal Affairs Committee of the European Parliament, which proposed a definition with a narrow approach, similar to the one followed by the Council in its proposal,[99] although the Committee's definition was even narrower, as it limited the definition to systems developed through automated learning techniques (letter (a) of Annex I),[100] leaving also logic-based AI systems (letter (b) of Annex I)[101] outside the scope of the Regulation.

In terms of technological neutrality, the Parliament's definition could be considered as better than the Commission's or the Council's, as it did not list a set of technologies to be regulated. This definition was broad (as it allowed several technologies to be covered) and open to the future (as it was easier to include new technological developments and technical approaches). Nevertheless, it could also be argued that the reference to "machine-based systems" was still overly broad, which could lead to an over-regulation of conventional software, even if this software has been in the market for decades,[102] which would not be in line with the amended Recital (6) that now declares that the definition of AI systems should be based on 'key characteristics of AI' such as "its learning, reasoning or modelling capabilities". Yet, none of these characteristics were included in the definition of article 3 (1).

The only element that could be used as a benchmark that could be consistent with these key characteristics is the requirement that the system must be designed to operate with "varying levels of autonomy". The amended recital (6) considers autonomy as having "some degree of independence of actions from human controls and of capabilities to operate without human intervention". The problem of the concept of autonomy is that, as it happens with the term 'intelligence', is a broad term and very difficult to define in a satisfactory way.[103]

[98] *Ibidem*.

[99] EUROPEAN PARLIAMENT COMMITTEE ON LEGAL AFFAIRS, *op. cit.*, 139.

[100] However, the Committee's letter (a) of Annex I included together with Machine learning also "optimization approaches, including but not limited to evolutionary computing" so, even if this was narrower than the Council's proposal, it was not limited just to machine learning techniques, it also included the concept of "optimization approaches", in which a wide range of techniques can be included, from probabilistic methods and heuristics to genetic algorithms.

[101] N.T. NIKOLINAKOS, *op. cit.*, 364.

[102] J. MÖKANDER ET AL., *op. cit.*, 245.

[103] H. RUSCHEMEIER, *op. cit.*, 366.

Another relevant amendment in the Parliament's definition was the removal of the reference to 'content' as a possible output. At first sight, this could look like just automated decision and decision assistance systems (AI systems that produce predictions, recommendations or decisions) would be within the scope of the regulation. However, this was only apparent, as another amendment in the recital (6) of the Act specifically provided that 'content' had to be considered as a 'prediction',[104] maybe to stay consistent with the wording of the 2019 OECD definition, that did not include 'content' as a possible output.

Another element amended by the Parliament in article 3(1) was the reference to the objectives, where the expression "human-defined" was replaced by "explicit or implicit". The Parliament introduces this change to "underscore that AI systems can operate according to explicit human-defined objectives or to implicit objectives" and that the "objectives of the AI system may be different from the intended purpose of the system in a specific context"[105]. Some authors consider this change as a mistake, as it opens the door to sci-fi scenarios where the AI could have objectives of its own.[106] Nonetheless, implicit objectives are considered by some experts as the goals that are embedded in the design of the AI system in order to achieve its intended purpose, rather than explicitly set by humans. For example, an explicit objective for an autonomous car would be driving from A to B. The implicit objectives would be to do so without killing any pedestrians, colliding with other cars, or violating traffic laws.[107]

Apart from the definition of AI system, the Parliament introduced into the AI Act the debate on the regulation of "foundation models",[108] which would end up being one of the most debated issues during the trilogues. As this matter exceeds the scope of this article, that is the analysis of the legal concept of AI, we will not discuss it in depth. It will suffice to note that the debate regarding foundation models is not whether they can be considered as AI systems, as they are developed through machine learning approaches, and under all the definitions analysed they would be considered as under the scope of the AI Act. Instead, the debate is about the problems that arise from the Act's risk-based approach, that classifies systems under one or another category depending on the risk of their 'intended use'. This classification based on the intended use is problematic regarding foundation models and general-purpose AI systems, as they can be implemented in wide range of applications, raising questions of whether it has to comply with all the obligations related to each and every possible high-risk application for which it may be used. The Council's Spanish presidency and the Parliament supported a binding

[104] *Ibidem*.

[105] Recital (6) of the amendments adopted by the European Parliament on 14 June 2023 to the proposal for a regulation of the European Parliament and of the Council on laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts (COM(2021)0206 – C9-0146/2021 – 2021/0106(COD)).

[106] L. Floridi, *On the Brussels-Washington Consensus About the Legal Definition of Artifcial Intelligence*, in *Philosophy & Technology*, 36, 87, 2023, 87.

[107] Center for Human-Compatible Artificial Intelligence, *Center for Human-Compatible AI Position Paper on the EU Artificial Intelligence Act*, Berkeley, 2021, 6. Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12527-Artificial-intelligence-ethical-and-legal-requirements/F2665648_en.

[108] The Council's proposal also introduced the regulation of general purpose AI systems, although not with the specific scope of foundation models.

regulation on these models[109] but France, Germany and Italy advocated for a self-regulation approach through voluntary codes.[110]

5.3. Comparative between the Council's and the Parliament's proposals

After analysing the definitions proposed by the Council and the Parliament proposed definitions, we can draw some conclusions with the similarities, but also with the differences between the two proposals. Both definitions:

- replaced the word software for a "system" based definition,
- deleted the list of techniques and approaches in Annex I,
- added to the definition the reference to autonomy which was in recital (6) of the Commission's proposal,
- amended the reference to objectives.

Apart from these amendments, one of the most significant changes to this definition, which is common to both proposals, is found outside Article 3(1), in the recitals of the Regulation. Both proposals amended recital 6 to explicitly state that the definition should be based on the 'key characteristics' of 'artificial intelligence' (that replaces the word software used in the Commission's Proposal). Such "key characteristics" are its "learning, reasoning and modelling capabilities" so as to distinguish it from "simpler software systems and programming approaches".

The Council added (in the same recital 6) a clarification: "A system that uses rules defined solely by natural persons to automatically execute operations should not be considered an AI system". It seems that what would distinguish AI from software would be the ability to make inferences using the model of the system, so that it can define its own rules to generate outputs to achieve its objectives, i.e. the rules of the system are not only defined by its programmer, but also by the system itself while implementing the model. This clarification was not added by the Parliament in recital 6.

Turning to the differences between the two proposed definitions for article 3 (1), the Council kept the Commission's approach of targeting specific techniques for the development of AI systems. Although the Council's definition only mentioned "machine learning" and "logic- or knowledge-based" approaches, if we consider the content of recitals 6a and 6b of the Council's proposal, these approaches had to be understood in broad terms, encompassing techniques that would not technically be considered as one or the other (for example, search and optimisation techniques include evolutionary computation, that would not technically be considered as machine learning). The practical difference of the Council's amendments would be that systems developed through statistical approaches, search and optimization techniques, and probabilistic methods (letter c of the Commission's Annex I) that were not to be used to develop a machine learning or a logic-/knowledge-based AI would not be considered as AI systems. This would exclude, at least on paper, "simpler software" (in words of the Recital

[109] Spanish presidency pitches obligations for foundation models in EU's AI law, EURACTIV, 7 November 2023 Available at: https://www.euractiv.com/section/artificial-intelligence/news/spanish-presidency-pitches-obligations-for-foundation-models-in-eus-ai-law/.

[110] France, Germany, Italy push for 'mandatory self-regulation' for foundation models in EU's AI law, EURACTIV, 19 November 2023, Available at: https://www.euractiv.com/section/artificial-intelligence/news/france-germany-italy-push-for-mandatory-self-regulation-for-foundation-models-in-eus-ai-law/.

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6 of the Council's proposal) such as productivity computer programs (such as text processors, spreadsheets, email clients) or traditional content editing tools (video, image or audio), even though these programs may be powered with artificial intelligence (for example, spreadsheets may use AI tools to improve the user experience or email clients can use spam filters).
Conversely, the Parliament's definition opted to change the focus from a specific list of techniques and approaches to specific characteristics that were considered to be defining for AI systems, as stated in Recital 6 of the proposal, these elements being its "learning, reasoning or modelling capabilities". If this approach were taken, this definition would have similar effects to the Council's definition, as only software developed using AI techniques would have these learning (machine learning), reasoning (logic- or knowledge-based) modelling abilities (machine learning, search and optimisation techniques, Bayesian models, etc.). However, none of these characteristics made it into the definition in article 3 (1). The only element of this definition that could be used to infer any of these characteristics is through the element of "being designed to operate with varying levels of autonomy", combined with the other of the elements of the definition (the ability to generate outputs for explicit or implicit objectives). It was not clear if, with the Parliament's definition, would be possible to accomplish the stated objective of distinguishing between simple software and AI.
In Section 8 we will deepen the discussion of the difference between software and AI.

6. AI system definitions in other regulations

Although the EU has been the most determined actor at the international level to push for AI regulation in recent years, especially since 2021 with the publication by the Commission's proposal for an AI Act, in the second semester of 2023 the United States (US) and China swiftly adopted their own regulations, trying to get ahead of the EU in establishing a regulatory framework for AI. While all these regulations aim to regulate AI from the perspective of imposing obligations on producers and users, they do not share the same focus and scope. The Chinese Law is aimed only at generative AI services offered to the public, whereas the US Executive Order does not establish a comprehensive regulation for AI, instead sets out a regulatory agenda and guiding principles for the future regulation of AI in the US. Thus, even if these regulations were adopted before the EU AI Act, their purpose and content cannot be compared, as the European regulation is bound to be much more comprehensive and far-reaching than the others. An analysis of the content of these regulations is beyond the scope of this work, so we will focus only on the proposed definitions of AI systems in these laws.

6.1. China

The Chinese government passed an "Order with Provisional Measures for Generative AI Services" that came into force on 15 August 2023.[111] This law does not provide for a definition of AI systems, but in

[111] East Asia Forum, *The future of AI policy in China*, 27 September 2023. Available at: https://www.eastasiaforum.org/2023/09/27/the-future-of-ai-policy-in-china/#:~:text=On%2015%20August%202023%2C%20a,that%20specifically%20targets%20generative%20AI.

its article 22.a) defines "generative artificial intelligence technology" as "models and relevant technologies with the ability to generate content such as text, pictures, audio and video".[112]
On the one hand, it is difficult to compare this definition with the definition in the context of the AI Act, as it is focused on a specific type: generative AI systems. On the other hand, it is interesting that the definition focuses only on the ability of the "model" or the "relevant technology" to generate certain outputs, without targeting any kind of specific techniques.
This approach would be similar to the 'narrow definition' stance in that this regulation only targets a specific type of AI systems (generative AI) and sets rules and obligations for it and does not attempt to cover other technologies or types of AI systems. However, this definition could also be considered as broad, as the only requirement is that the model is able to "generate text, pictures, audio, video and other content", which could allow other types of systems that are not considered as AI to be covered by this regulation.
While this definition could be considered as technologically neutral and future-proof, as it does not target specific technical approaches and is possible to include future technologies in this definition, it also bears the risk of not being very precise. The use of the term 'model' can be considered as relevant in the context of AI, but the term 'relevant' or 'related technology' is less as clear. May a productivity tool, such a text processor or a spreadsheet, that allows the generation of graphics from data, be considered as a 'relevant' or 'related technology' that generates 'pictures' or 'other content'? Nevertheless, looking at the content of the measures, it is clear that the regulation is aimed at machine learning AI systems and with foundation models in mind (as terms such as training algorithms, training data, labelling or pre-training are used throughout the text).

6.2. United States

A few months later, on 30 October 2023, the USA adopted its Executive Order on AI.[113] This regulation contains three relevant definitions in its sec. 3: "Artificial Intelligence", "AI Model" and "AI system".
The definition of "Artificial Intelligence" in sec.3 (b) refers to 15 U.S.C. 9401 (3) which, as commented in Section 3.1 of this article, was introduced by the National Artificial Intelligence Initiative Act of 2020 as follows: "machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments. Artificial intelligence systems use machine- and human-based inputs to perceive real and virtual environments; abstract such perceptions into models through analysis in an automated manner; and use model inference to formulate options for information or action."

[112]Translation retrieved from: https://www.chinalawtranslate.com/en/generative-ai-interim/. Some unofficial translations use the term "related technologies" instead of relevant, see: https://www.twobirds.com/en/insights/2023/china/what-you-need-to-know-about-china's-new-generative-ai-measures#:~:text=The%20Generative%20AI%20Measures%20require%20that%20if%20the%20generative%20AI,algorithm%20%2D%20both%20of%20which%20are.

[113] The White House. October 30, 2023. Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence: https://www.whitehouse.gov/briefing-room/presidential-actions/2023/10/30/executive-order-on-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence/.

While the US regulation is new, the definition of AI used in it is not, as the Executive Order refers to the definition introduced by the National Artificial Intelligence Initiative Act of 2020, which adhered to the structure and content of the 2019 OECD definition, although extended with some additional elements that were considered by the Expert Group on AI at the OECD,[114] namely the requirements of "using inputs to perceive their environment", "the automatic abstraction of the perceptions into models", and the "ability to make inferences from the model to formulate options". These elements replace the reference to "operate with varying levels of autonomy" in the 2019 OECD definition, which explains in more detail how AI systems operate than (although the OECD itself ruled out using this wording in its definition).

Furthermore, this definition does not reflect recent debates surrounding the legal definition of AI, keeping the element of the 'human-defined objectives', leaving 'content' out of the list of possible outputs, and referring to 'real or virtual' environments. As we will see in the following subsection, the OECD updated its definition just a few weeks after the adoption of this executive order, making this definition outdated, at least when compared with the new OECD definition, which was one of the main references for this definition of AI.

Moving to the other relevant definitions, "AI system" (sec. 3 (e)) means: "any data system, software, hardware, application, tool, or utility that operates in whole or in part using AI".

Meanwhile, "AI model" (sec. 3 (c)) is defined as: "a component of an information system that implements AI technology and uses computational, statistical, or machine-learning techniques to produce outputs from a given set of inputs".

The definition "AI system" clarifies that not just any kind of software can be considered as AI, only software that operates using AI. Besides, the "AI model" definition can be seen as a list of approaches to developing AI systems, although it is broad and general in its terms, as the reference to computational, statistical, or machine learning techniques to build the model is not very specific. All in all, these definitions provide additional information on what is to be considered as AI under the US regulation, although they are general definitions and do not provide with specific or new relevant criteria, compared to other definitions.

6.3. The update of the OECD definition

The OECD updated its definition of AI System on 8 November 2023.[115] Now, the OECD defines an AI system as: "a machine-based system that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that [can] influence physical or virtual environments. Different AI systems vary in their levels of autonomy and adaptiveness after deployment" (hereafter, the OECD 2023 definition).

[114] Expert Group on AI at the OECD, *Scoping the OECD AI principles: Deliberations of the Expert Group on Artificial Intelligence at the OECD (AIGO)*, 2018, 7. Available at: https://read.oecd-ilibrary.org/science-and-technology/scoping-the-oecd-ai-principles_d62f618a-en#page7.

[115] OECD updates definition of Artificial Intelligence 'to inform EU's AI Act', EURACTIV, 9 November 2023: https://www.euractiv.com/section/artificial-intelligence/news/oecd-updates-definition-of-artificial-intelligence-to-inform-eus-ai-act/.

Compared to the 2019 definition, the main structure of the definition remains the same, although some changes have been made:[116]

- the "human defined objectives" are replaced with a reference to "explicit or implicit objectives", in order to differentiate between the objectives directly programmed into the system and those derived from a set of rules specified by a human, or when the system is capable of learning new objectives.[117]
- the replacement of the verb "make", for "infers, from the input it receives, how to generate outputs", to underscore how an AI system works: receiving and processing inputs that are computed through its models and algorithms into outputs.[118]
- "content" is added as one of the possible outputs, with the aim to clarify that the definition applies to generative AI systems,[119] as a result of the outburst of this type of AI systems in 2023.
- A new element, the "adaptiveness after deployment" of the system is included.

The OECD definition, which has served as a reference for other regulations, such as the US Executive Order or for the European Parliament's proposal, also reflects the results of the debates surrounding this definition since 2019:

- the addition of "content" as a possible output, that was from the beginning in the European Commission's definition,
- the "ability to infer" that was included in the Council's Proposal,
- the reference to "implicit or explicit objectives" or the use of the word "physical" instead of "real" environments, both in the Parliament's definition.

We will discuss the elements of this definition further in the next section, together with an analysis of how this definition influenced the final text of the AI Act.

7. The end of the trilogues: the final definition of "AI system" in the AI Act

After the European Parliament reached its political agreement on 14 June 2023, the legislative process continued in following months with the "trilogues", the negotiations between the Commission, the European Parliament, and the Council of the European Union on the content of the AI Act, which concluded with a political agreement on 8 December 2023.[120]

Although the final version of the AI Act was not available at the time of writing, the texts of the agreements reached during the trilogues were. One of the published texts included the agreed version of

[116] OECD, *Updates to the OECD's definition of an AI system explained*, November 29, 2023: https://oecd.ai/en/wonk/ai-system-definition-update.

[117] *Ibidem*.

[118] *Ibidem*.

[119] OECD, *Recommendation of the Council on Artificial Intelligence*, see section "2023 revision to update the definition of an "AI System" and next steps": https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0449.

[120] European Union squares the circle on the world's first AI rulebook, EURACTIV, 9 December 2023. Available at: https://www.euractiv.com/section/artificial-intelligence/news/european-union-squares-the-circle-on-the-worlds-first-ai-rulebook/.

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Article 3(1) of the AI Act:[121] "An AI system is machine-based system designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments".

We must bear in mind that this text was not definitive at the time of writing, as both the Council and the Parliament had yet to vote on the final text, which will become a regulation in the first months of 2024, although it is highly likely that this definition will be the final one.

This definition is closer to that of the Parliament rather than the Council's or the Commission´s definitions, as it does not attempt to define a closed list of technical approaches to be considered as AI. The similarities with the Parliament's definition are that keeps:

- the requirement that the system is "designed to operate with varying levels of autonomy" (this was also in the Council's definition),
- the list of possible outputs (except for the reference to "content"),
- the reference to "explicit or implicit objectives",
- and the mention to the "physical and virtual environments".

However, there are some differences with the Parliament's definition that are relevant, some of which reflect the changes in the OECD 2023 definition. Firstly, "content" as a possible output has been kept in the definition, as it was in the Commission's and the Council's definitions (although the reference to generative AI systems is not included, as it was in the latter) and in the OECD 2023 definition. The alternative followed by the Parliament of considering "content" as a type of "prediction" did not make it into the final text. This change could be seen as positive, as it is better to include content as an output in the article than in a recital, which has no normative value beyond its importance for interpretative matters. Content is one of the possible outputs that has drawn more attention regarding AI and its effects on society and citizens' rights during the last year,[122] with the generative AI outburst since ChatGPT was released in December 2022 (and all the generative AI applications released during 2023).[123]

Furthermore, two new elements are added to the definition compared to the Parliament's proposal: the "exhibition of adaptiveness after deployment" and the ability to "infer how to generate outputs from the input it receives". Both elements are in line with the OECD 2023 definition.[124]

The key elements of the definition are the abilities "to operate with different levels of autonomy" and to "infer from the received inputs how to generate outputs". How these elements are interpreted should be the cornerstone for determining when we are dealing with an AI system in the context of the AI Act and (foreseeable) future European Union regulation.

[121] Final Draft of the AI Act, January 21, 2024. Available at: https://artificialintelligenceact.eu/wp-content/uploads/2024/01/AIA-Final-Draft-21-January-2024.pdf.

[122] US Federal Trade Commission, *Generative Artificial Intelligence and the Creative Economy Staff Report: Perspectives and Takeaways*, December 2023, 3. Available at: https://www.ftc.gov/system/files/ftc_gov/pdf/12-15-2023AICEStaffReport.pdf.

[123] See note 96.

[124] It needs to be noted that the "ability to infer" element was in the Council's proposal.

Regarding the element of the ability to "operate with varying levels of autonomy", the difficulty of defining an attribute such as autonomy has already been discussed above when analysing the Parliament's definition and its recital 6 (see Section 5.2). The references to having "some degree of independence of action" and the "capabilities to operate without human intervention" that were used in the Parliament's proposal ultimately made into the recital 6 of the final draft of the AI Act. While the approach of considering autonomy as a gradual and non-dichotomous variable is correct (the AI Act use expressions such as "levels of autonomy" and "degree of independence"), the aforementioned problems arising from their vagueness and lack of clarity will persist, and it seems that challenges may arise in defining the point at which the minimum level of autonomy is reached in order to determine when we are dealing with an AI system rather than non-AI software.

Meanwhile, establishing the meaning and scope of the ability to "infer" is also difficult. Even though this element was included in the Council's proposed definition (see Section 5.1), there was no explanation or argument as to why it was included, neither in the recitals nor in the explanatory documents during the discussions on the compromise text. Neither did the OECD Recommendations provided any definition, explanation, or clarification in this regard, although according to some sources, this element was added to account for the process of receiving inputs that are computed into outputs by system's models and algorithms.[125] The only reference that could be used was the definition included in ISO standards, which defines "inference" as the "process of reasoning by which conclusions are derived from known premises".[126]

Probably because of this context, it has been included in the final draft an extensive explanation of what should be understood as this "capability to infer" in recital 6, where it is defined as both the "process of translating inputs into outputs", and also to the "capability to derive models and algorithms from data", going beyond "basic data processing" and enabling the "key characteristics" that the Parliament's proposal made reference to: the capacities to "learn, reason or model". The ability to infer is the key characteristic to differentiate AI systems from simpler software and programming approaches (more about this issue in Section 8).

With regard to "adaptiveness", there is no indication in the available texts of the AI Act trilogues as to how this element might be interpreted. In the context of the OECD 2023 definition, it was included to emphasize that some AI systems "can continue to evolve after their design and deployment".[127] Recital 6 in the final draft of the AI Act refers to this element as the "self-learning capabilities" that an AI system can exhibit after deployment. However, the extent to which this element could potentially contribute to the definition of AI systems is limited by the wording used, as it is only optional under both the AI Act ("may exhibit adaptiveness") and the OECD (different systems "vary… in their levels of…adaptiveness").

In sum, what appears to be the final definition of AI systems in the AI Act (pending the vote on the definitive text) abandons the path of targeting specific techniques to delimit what is AI from what is

[125] OECD, *Updates to the OECD's definition of an AI system explained*, November 29, 2023: https://oecd.ai/en/wonk/ai-system-definition-update.

[126] ISO 22989:2022, clause 3.1.7.

[127] OECD, *Updates to the OECD's definition of an AI system explained*, see note 125.

not for the sake of technological neutrality,[128] to ensure that the regulation adapts to future technological changes (future-proof) and to align with other international texts. Instead, the definition is based in the distinctive elements and characteristics of AI. Although the final definition incorporates elements that provide criteria for distinguishing what should be considered as AI from what should not, it also introduces important components of uncertainty, to the extent that the elements used are difficult to define, such as the capacity to operate autonomously or the ability to infer how to generate outputs from the inputs received. It is foreseeable that we will have to wait for the publication of guidelines by the future European Artificial Intelligence Board/Office or a similar working group or body.

8. The difference between AI and software

The definition of AI systems in the AI Act should be understood as to refer to artificial intelligence and not "simpler traditional software systems or programming approaches", according to the wording of recital 6 of the draft agreement. However, the question of how to differentiate AI from software requires further analysis.

8.1. Technical and legal differences between AI and software

As there is no generally accepted technical definition of AI, it is not an easy task to draw a clear line to distinguish it from software, existing grey areas between both concepts.[129] While there is no problem to consider complex machine learning systems based on foundational models as AI, the question lies in when the minimum requirements are met, i.e. how high or low the bar to consider a given software as AI is set.

From a technical point of view, there is no consensus on what the elements and characteristics on which the difference between AI and software should be based. According to standards, "software" can be defined as: "all or part of the programs which process or support the processing of digital information" (clause 3.49, ISO 19770.1:2017).

Meanwhile "AI systems" are defined as: "engineered system that generates outputs such as content, forecasts, recommendations or decisions for a given set of human-defined objectives. The engineered system can use various techniques and approaches related to artificial intelligence to develop a model to represent data, knowledge, processes, etc. which can be used to conduct tasks" (clause 3.1.4, ISO 22989:2022).

[128] However, recital 6 of the final draft of the AI Act includes a reference to machine learning and logic- and knowledge-based approaches as techniques that enable inference of AI systems. It is not clear whether this has been added to limit the definition of AI systems only to those developed using such techniques, or if they have been added just as examples or for illustrative purposes. The latter approach makes more sense, as the opposite would be inconsistent with the wording and structure of the definition of "AI system" in the final draft´s article 3 (1), which is aligned with both the Parliament's and the OECD's definitions, which both sought to avoid targeting specific techniques and approaches. Additionally, the verb "include" precedes the mention of both techniques, so it may be understood that this should not "exclude" different techniques than those cited in recital 6.

[129] P. HACKER, *op.cit.*, 9.

From this perspective, the difference between one concept and the other lies in the fact that AI systems do something else than "process or support the processing of information". An AI system "use models to represent inputs in order to generate outputs to achieve a goal". This representation of inputs through the model can be related to the term "inference", which is the process of reasoning a conclusion that derives from the AI model, features, rules, facts or raw data[130]. This ability can be seen as the core difference between AI and software.

In the legal context, there are no regulations that explicitly distinguish between AI and software (which is not surprising, as until recently there were no specific laws on AI). First of all, we cannot even find a legal definition of 'software' that applies generally or across different laws. We have to look at the regulation of specific areas of law where definitions of this and related concepts are used. For example, in copyright law, the term used is 'computer program' that is generally defined as: "a set of instructions capable, when incorporated in a machine-readable medium, of causing a machine having information-processing capabilities to indicate, perform or achieve a particular function, task or result".[131]

In the Medical Devices Regulation, software is considered as a type of medical device according to its article 2 (1).[132] However, as this regulation does not contain a definition of software, we have to resort to the Guidelines developed by the Medical Device Coordination Group, which defines it as: "a set of instructions that processes input data and creates output data".[133]

A similar concept would be "information systems", which in the context of cybercrime is defined as: "a device or group of inter-connected or related devices, one or more of which, pursuant to a programme, automatically processes computer data".[134]

These legal definitions of "software" and "computer programs" are aligned with the definition used in technical standards. The key elements of these definitions are the "set of instructions" (or a program), the "process of data" and the "performance of a function, task or result". We can see that these elements are consistent with the definitions in the ISO standards.

As AI systems "process inputs" to "perform tasks", they could be considered as computer programs or software in the contexts of copyright law, medical devices and cybercrime. However, these definitions do not take into account the essential elements of AI and that these systems do not just involve its software, but also the algorithms and the data or the knowledge used to build their model. This model is what provide the system with reasoning, inference, and decision-making capabilities. Therefore, there is room to design specific definitions that consider these specific elements and characteristics of AI systems, such as the learning or reasoning capabilities and the use of models to represent data, knowledge and processes.

[130] ISO 22989:2022, clause 3.1.17.

[131] Section 1. (i), WIPO Model Provisions on the Protection of Computer Software. Most national laws draw their definitions of "computer program" from this Model.

[132] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

[133] Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745-MDR and Regulation (EU) 2017/746 – IVDR, 5. Available at: https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2019_11_guidance_qualification_classification_software_en_0.pdf.

[134] Art. 2 (a), Directive 2013/40/EU of The European Parliament and The Council of 12 August 2013, on attacks against information systems.

8.2. Proposal for an interpretation of the AI system definition in the AI Act

Based on both the technical and the legal possibility of differentiating between software and AI, we must seek an interpretation of the definition of AI system proposed in the draft text of the AI Act that is consistent with this purpose. As stated in Section 7, key elements of this definition are that AI systems are designed to "operate with varying levels of autonomy" and the "ability to infer" how to generate the outputs to achieve their (explicit or implicit) objectives. These elements have to be interpreted in accordance with the "key characteristics" contained in the recital 6 of the Act, namely, according to the text in the final Draft, their capacities to "define rules to automatically execute operations", to "operate with varying levels of autonomy" and their capacity to "infer", in order to distinguish AI systems from simpler software systems and programming approaches.

For example, a computer program that consist in a statistical analysis software, such as SPSS, that allows data management and analysis through statistical techniques, would not be considered as AI as it just "process data" according to its programmed rules. Conversely, an AI system does not just "process data", in addition, it uses the rules (expert systems or rule-based approaches) or encoded information (from raw data, such as in machine learning) into its model to "infer", that is, "reason", how to generate an expected output (a recommendation, prediction or decision) for its designed or implicit goals.

As the definition is based on specific characteristics that are considered to define how AI systems work, rather than in a list of techniques, the risk of circumvention of the regulation using unlisted approaches or techniques is avoided.

It could be argued that this definition might exclude from regulation software that poses the same risks and problems as the AI systems that the AI Act seeks to regulate. However, there are some arguments against this assumption.

The notion of AI systems does not seem to be built around the objectives and the specific risks that the AI Act seeks to address. The AI Act revolves its scope of regulation mainly around the intended purpose of AI systems, i.e. the specific uses to which these systems are put (according to articles 5 and 6 of the AI Act). Only once this intended purpose is defined, will it be possible to determine whether it may be classified as a prohibited AI practice, a high-risk system, or a limited or minimal risk system and, consequently, if the regulation applies to that specific AI system. Such classification is determined by the context in which the AI system is used and not by its characteristics (with the exception of the transparency provisions of article 52 of the AI Act). Therefore, the definition of AI system is not bound by the objectives of preventing harm associated to the development, placing in the market and use of AI systems in certain contexts, as in accordance with recital 6 of the Act, it should be based on the "key characteristics" of AI.

This approach also allows this definition of AI systems to be used in future regulations in the EU context. As it is not adapted to the specific context and objectives of the AI act, this definition could be used in cross-sectoral regulation, such as the AI Liability Directive, or in the regulation of specific sectors and contexts.

Furthermore, if the definition of AI systems was intended to apply also to software, other already established legal definitions of software, computer program or information systems could have been

used, as it has been done in other contexts, such as intellectual property, medical devices, or cybercrime.

All of the above allows for an interpretation of this definition that is consistent with the aim of the provisional text of recital 6 to distinguish between software and AI. Although we will have to wait for the vote and formal adoption of the AI Act to know the final wording of both the definition in article 3 (1) and the content of the recital 6, it is likely that both will remain as it has been analysed in the lines above, keeping the reference to the "key characteristics" of artificial intelligence to distinguish AI systems from simpler traditional software systems.

9. Final remarks

When it comes to the legal definition of AI, the global trend has been to use broad definitions, based on certain characteristics of the systems to be regulated, as opposed to narrow definitions that considered as AI only those systems developed with the methods and techniques included in more or less closed lists. This is the approach followed in the definition of AI systems in the AI Act, which will be (pending the publication of the final text) aligned with the OECD 2023 definition. The elements and structure of these definitions are likely to be used internationally in the coming years. Proof of this is that the Council of Europe published its Draft Convention on AI on 18 December 2023 in which article 2 uses a definition identical to the OECD definition.[135]

The challenge with these definitions will be how to differentiate which kind of systems are included in this definition and which are excluded. The AI Act attempts to address this issue by explicitly stating that the definition should be based on the key characteristics of AI, namely its learning, reasoning or modelling capabilities, in order to distinguish it from simpler software and programming approaches. This should, in principle, exclude from the regulation software that could not be considered as AI, which may be consistent with the specific wording used for the definition of AI systems, as otherwise other concepts or terms would have been used, since "software" and "computer programs" have been regulated in the past.

In order to ensure that the definition is focused on the intended objective of regulating AI would be to interpret the elements of being designed to operate with "varying levels of autonomy" and "the ability to infer how to generate outputs" in a way that is consistent with the key characteristics of AI. The main risk of this approach to the legal definition of AI systems is that it relies on many indeterminate and broadly interpretable concepts, such as autonomy, infer or reasoning, which introduce a degree of legal uncertainty on which specific systems could be really considered as AI.

In any case, the reaching of an agreement and getting the green light to pass the AI Act in the next months has been a big step forward for the regulation of this technology. The direction in which this step will be taken will depend on how this definition is understood and which specific systems will be

[135]Council of Europe, *Draft Framework Convention on Artificial Intelligence, Human Rights, Democracy and the Rule of Law*, 18 December 2023. Available at: https://rm.coe.int/cai-2023-28-draft-framework-convention/1680ade043.

covered by it, with the implications that this choice will have for the interpretation of the regulation, for determining which actors are subject to it, and for the impact on the development and implementation of AI systems in the European Union.