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*Big Data for the Regulatory Process. Systematization and Treatment of Information from and for Regulation through Impact Analysis**

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ABSTRACT Impact Analysis, as a tool for regulatory-making processes, is a very valuable element for introducing information and knowledge to help law/rule-makers and it enables the assessment of rules in terms of effectiveness. In this paper we intend to show the great potential to exploit the enormous amounts of data currently available (big data) and how it is recognised as a tool with high potential for advantages in data management, processing and analysis. This instrument provides knowledge about the reality that surrounds legal norms but also, on the other hand, generates knowledge about regulations themselves and how they work in social context in terms of improving regulation quality.

KEYWORDS: Big Data - Regulatory Impact Analysis - Evidence-Based Policymaking - Data-Driven Rulemaking

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1. *Introduction*

It is not the purpose of this contribution to reflect on how the law responds or should respond and react to the growing use of artificial intelligence systems. Nor is it about analysing the legal problems that arise from their increasingly widespread use, nor how these can be addressed from a legal perspective. What is outlined here is how the possibilities offered by these new systems can be taken advantage of in the legal field, especially in the areas of generating legal knowledge and legal decision making, specifically in making and amending regulations.[1] We believe that the value of information and of the current management and processing systems has not yet been exploited in this direction, specifically, in relation to the opportunities that, for the identification, systematization and statistical analysis of large amounts of data, Regulatory Impact Analysis offers.

Impact Analysis, as instruments for the preparation of the legal regulation, allow a link between them and the social reality from which they arise and bring us closer to the knowledge of both realities, which, we believe, should not be considered as being unrelated. The information that Impact Analysis aspire to contain provides us with knowledge of the proposed regulation, as well as of the social environment and the relationships between them. The institutionalization of this instrument implies the realization of an Impact Analysis for each proposal or modification of a legal regulation. Circumscribing itself to the matters regulated by the projected regulation allows for the orientation of this identification, management and processing of the information through its relationship to it. Thus, in the development of this mechanism in each regulatory project, its capacity and potential to generate knowledge on the legal regulation and its relationship with the reality from which it arises and on which it is projected is observed.

The enormous amount of information available today can and should be exploited by 'the legislator'. The phenomenon commonly known today as big data can be defined and thought of in terms of the characteristics that the 'V's' give to information. That is, among others: volume, variety, velocity, variability, veracity or value. However, this dispersed and immeasurable

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[1] Some recent scholarly work is, for example, I. Bar-Siman-Tov, *Legislatures and legislation in the age of artificial intelligence*, in *The Theory and Practice of Legislation*, vol. 13, issue 3, 2025, 267–291.

information has already been used by the market or other (sub) systems to generate knowledge of this reality, act and decide accordingly. The legal world is beginning to take its first steps. So are public institutions in the so-called evidence based policies. Data – the oil of the 21st century – are a resource for analysing the reality that filters through and among which are included human conducts related to social relationships and behaviour that the law aims to order. The possibilities that the new information and communication technologies offer for the elaboration of regulations have not yet been widely exploited. Not only in order to enable communication of information, for example, with citizens[2] but neither to automate steps in the formal rulemaking procedure.[3] It is about deepening and influencing the direct use by the regulatory powers of the information and knowledge generated by the new data storage and analysis systems. These allow in a clearly different and profitable way to describe, analyse or forecast the functioning of legal rules, the context to which they refer, and significantly the relationships between the two. Something to which we believe the Impact Analysis can contribute greatly with its more ambitious conception and which goes beyond its identification with a mere formal procedure, among others, of the law-making process.

We are not referring here, therefore, to automated decisions but to a somewhat more primary, earlier or simpler approach to the possibilities that new technologies offer for generating information and knowledge to aid decision making. Specifically, the regulatory decision and law making decisions. A reflection, not so much on the normativity that artificial intelligence means and implies, but in relation to the possibilities and the need for a science of regulations in the digital era.[4] Or, alternatively, a reflection on a way to provide a variety of scientific knowledge that enriches public-policy making without replacing it.

2. *Regulatory Impact Analysis as a Tool for the Preparation of Legal Regulations*

Regulatory impact analysis is an instrument for assisting public decision making that has also been applied to various types of regulatory decisions.[5] This instrument has expanded worldwide through the impulse of two international institutions such as the OECD and the EU.[6]

Despite being centred in the hands of the Executive power (instead of Legislative power) and its drafting procedures, its relevance for the processes of making legal regulations comes from the growing protagonism of this power in the exercise of regulatory functions. This is either because they are directly the drafters and authors of the proposals, or because of the weight they have, at least in many continental European countries, in the drafting of the texts that are finally passed by the legislative power and Parliament. The public administration behind the proposals has more and better resources for information management than some parliamentary support and advisory bodies.

The instrument (Impact Analysis, herein referred to as 'IA') has been incorporated into numerous legal systems around the world,[7] to the point of characterizing a certain homogenization of the processes of regulation making worldwide.[8] Furthermore, although it acquires some connotations or others depending on the legal-political context from which we treat it, it seems to have certain shared characteristics on which to build

[2] L. Arroyo Jiménez, *Participación electrónica y elaboración de normas administrativas en España y en los Estados Unidos de América,* in M. Delgado (dir.), *La reforma de la Administración electrónica: una oportunidad para la innovación desde el derecho,* Madrid, INAP, 2017, 231-258.

[3] E.M. Álvarez González, *La función normativa y la técnica legislativa en España. Una nueva herramienta: la inteligencia artificial*, Valencia, Tirant Lo Blanch, 2022; E.M. Álvarez González, *Artificial intelligence as a Tool to Make Better Regulations,* in *European Review of Digital Administration & Law*, 2022, vol. 3, issue 2, 207-224. DOI: www.erdalreview.eu/free-download/979122180798118.pdf.

[4] H. Hydén, *Sociology of Law as the Science of Norms*, NY, Routledge, 2022.

[5] A. Alemanno and A. Meuwesse, *Impact Assessment of EU Non-Legislative Rulemaking. The Missing Link in 'New Comitology',* in *European Law Journal*, vol. 19, no. 1, Oxford, 2013, 76-92.

[6] The driving force behind this instrument today at the international level are institutions such as the European Union, (https://commissiono.europa.eu/law/law-making-process/planning-and-proposing-law/impact-assessments_en) and the OECD (www.oecd.org/gov/regulatory-policy/ria.htm).

[7] C.A. Dunlop and C.M. Radaelli, *The Politics and Economics of Impact Assessment*, in C.A. Dunlop and C.M. Radaelli (eds.), *International Handbook of Regulatory Impact Assessment*, Cheltenham, Edward Elgar Publishing, 2016.

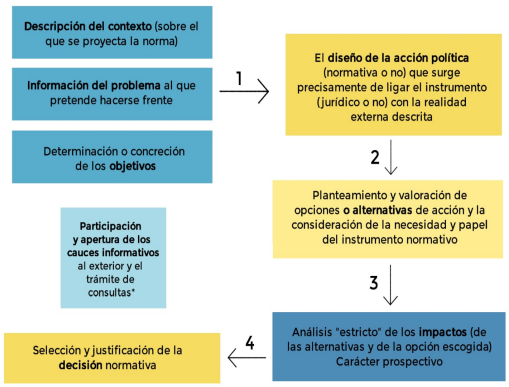
[8] E. Donelan, *Regulatory Governance. Policy Making, Legislative Drafting and Law Reform,* Palgrave Macmillan, 2022.

common ground for its consideration as an instrument or method, currently available and institutionalized to process and treat information in the elaboration of legal regulations of different types.

Among some attempts to define IA we can highlight that of Kirckpatrick & Parker[9] who describe it as a 'method of public policy analysis that aims to assist the policy maker in the design, implementation and evaluation of improvements in regulatory systems, offering a methodology to analyse the possible and actual consequences of regulatory proposals and existing regulations' Issalys,[10] for his part, identifies IA as 'that work of a scientific nature, carried out by public administration, intended for decision making political leaders, but whose results are likely to be made public'. And Radaelli and Francesco[11] for their part understand IA as the 'systematic and mandatory assessment of how primary and/or secondary legislation could affect certain categories of stakeholders, economic sectors and the environment. Systematic would mean consistent and not sporadic or random, and mandatory in the sense that it is not a voluntary activity. Essentially, IA is a type of administrative procedure, generally used in the pre-legislative phase of legislation planning'.

Looking more closely at the European IA model, this is an instrument for the policy of *better regulation* (among others, evaluation or public consultations) to help decision making and the planning of state interventions in the analysis of evidence, with special consideration of the impact that the intervention could cause. *It is a tool to help structure reflection and conduct analysis to inform planning policy.*[12] It thus reacts to previous work that helps the decision and the design of the measure.

Based on a study of the different scholarly attempts at definition, and in consideration of legal and material observation in different countries and in the European model, we now venture to offer an IA model of our own, which we present in the following diagram, and in which we identify a series of elements that constantly appear. Following this framework, the endeavour to synthesize, the RIA would consist of a process with which to organize information and its analysis for the planning of regulatory proposals. It would be a process that allows the identification, selection and collection of relevant information for the regulation and its systematization for its analysis. A tool designed to support the decision that ends up shaping the legal regulation and improving its design based on the knowledge of reality, of the regulation itself and based on the forecast of the effects that the rule might have on its surroundings. An attempt at a graphic illustration would look as follows:



Prepared by the author

In the blue elements of this diagram, one can observe that information capable of generating knowledge is essential and consubstantial to the process. What information we collect and how we process it is what concerns us now. Following this model or applicative blueprint, the instrument allows us to reflect on the inclusion of *big data* and the massive statistical treatment of information in the regulatory-creative procedure. It also allows us to consider its value for the quality of the regulation, in terms of its phronetic quality or practice focused on the effectiveness of the regulation[13] and its

[9] C. Kirckpatrick and D. Parker *Regulatory Impact Assessment. Towards Better Regulation?,* CRC series on Competition, Regulation and development, Cheltenham, Edward Eldar Publishing, UK, 2007.
[10] P. Issalys, *Analyse d'impact et production normative: de l'efficacité à la légitimité*, in *Revista da Faculdade de Direito da Universidade Federal de Minas Gerais*, Número Especial: Jornadas Jurídicas Brasil-Canadá, 2013, 246.
[11] C.M. Radaelli and F. De Francesco, *Regulatory Impact Assessment*, in *The Oxford Handbook of Regulation*, Oxford University Press, 2010, 279.
[12] European Commission, *Commission Staff Working Document. Better Regulation Guidelines*, Brussels, 2021, https://commissiono.europa.eu/system/files/2021-11/swd2021_305_eno.pdf.
[13] A. Figueroa Laraudogoitia, (coord.) *Los Procesos de*

value for the decision maker.

3. *Spain, a Case from Continental Europe*

Of North American origin, but essentially due to European influence, regulatory impact analysis has been introduced in Spain some years ago, and its introduction has been gradual and somewhat scattered. For central regulatory powers of the Spanish Government and State General Administration, in 2009 Real Decreto 1083/2009[14] introduced this instrument for the first time in this country. This Real Decreto was approved in implementation of the Government Law and the IA is a report that includes in a single document the traditional reports on necessity, opportunity and the economic public costs. And which could include, through an open clause, the mandatory reports, opinions and prior approvals, as many studies and consultations deemed appropriate to ensure the correctness and legality of the text.[15] Its contents have been progressively extended and its obligatory nature for the Spanish Government and State Genaral Administration appears by legal prescription with the modifications that Law 40/2015, of 1 October, on the Legal Regime of the Public Sector made to Title V of the Government Law.[16] The specific regulation, for central Spanish regulatory powers,[17] appears today in art. 26. 3 of this Government Law and in Real Decreto 931/2017.[18] *Comunidades Autónomas* have also been adopting the instrument.[19] Catalonia, for example, was the first region to incorporate an impact assessment report and a general report with contents similar to the European model in its administrative procedure law in 2010. Others have been incorporating the instrument in general terms,[20] for the drafting of bills and general provisions, some very recently, such as the case of the Valencian Community with Law 1/2022, of 13 April, on Transparency and Good Governance of Valencian Community. It should also be noted that impact analyses on certain issues or sectors, such as gender impact, which are included in the general model, have also been incorporated, some even earlier.

IA is formally identified in our legal system as a formal report called *memoria análisis de impacto normativo* (hereinafter MAIN), one report among others for drafting regulations and used in the law-making process by the executive branch. However, not limiting ourselves to this restricted concept, and taking into account its reality from a scholarly perspective, its observation in comparative law and on the European Commission's model, it is a process itself that will end up summarising its results in a report. A process that aims to systematise and analyse the most relevant information for the public regulatory decision-maker, and also for citizens, and which will take the form of a report, as part of the regulatory justification.

Specifically, and focusing on the Spanish Government and State General Administration, MAIN contains information on: opportunity and need of the proposal, its content and legal analysis of how it fits into the legal system and how it fits into the order of competences distribution, the economic and budgetary impact and effects on competition, market unity and competitiveness, identification of the administrative burdens and citizens, gender impact, a summary of the

implementación de las normas jurídicas, Vitoria, IVAP Instituto Vasco de Administración Pública, 1995.

[14] Real Decreto 1083/2009, de 3 de julio, por el que se regula la memoria del análisis de impacto normativo.

[15] Artículo 1 del Real Decreto 1083/2009: 1. El presente real decreto tiene por objeto desarrollar las previsiones contenidas en los artículos 22.2 y 24.1.a) y 24.1.b), párrafo segundo, de la Ley 50/1997, de 27 de noviembre, del Gobierno. 2. Las memorias, estudios e informes que se contemplan en los artículos a que se refiere el apartado anterior se incluirán en un único documento que se denominará 'Memoria del análisis de impacto normativo', que deberá redactar el órgano o centro directivo proponente del proyecto normativo de forma simultánea a la elaboración de este.

[16] Ley 50/1997, de 27 de noviembre, del Gobierno.

[17] It should be noted that the *Comunidades Autónomas* (regional authorities) in Spain have their own regulatory powers. And also, the communes, although they do not have the capacity to approve regulations with the status of law.

[18] Real Decreto 931/2017, de 27 de octubre, por el que se regula la Memoria del Análisis de Impacto Normativo.

[19] Improvements relating to the enhancement of regulatory quality established by Law 39/2015, on Common Administrative Procedure, left out this IA instrument in general, despite the fact that it did appear in Article 161.3 of the preliminary draft of this law. A. Boix Palop, *La participación electrónica como mecanismo para la mejora de la calidad normativa en la elaboración de reglamentos y otras disposiciones tras la reforma administrativa de 2015* in Martin Delgado (dir.), *La reforma de la Administración electrónica: una oportunidad para la innovación desde el derecho*, Madrid, INAP, 2017, 259-282.

[20] In this sense, *general nature* should be understood as a report that orders impact analysis reports of sectoral content such as gender.

main contributions received in public consultation process, impact due to climate change, and any other relevant aspects.[21] These basic contents, with an open clause for the incorporation of any others, are those contemplated in the law, which in turn are developed and specified by RD 931/2017.

At the time of this presentation a new guide should have been approved in our country for the development of the instrument. The 2010 guide is still in force and the MAINs follow the outline of this model, essentially the one provided for in *Annex I or Executive Summary Sheet.*[22] MAINs appear as a mixed or hybrid form, derived from the original checklists, the European model and the organization in a single document of the reports or explanatory memoranda, as traditional drafts of the necessary background information that accompanied the bills once they had been drafted for presentation to the Parliament.[23] The contents of the MAINs are often of an argumentative justificatory rather than descriptive and rarely do they refer to specialised (in-depth or quasi-scientific) studies or analyses to support them. An analysis of these MAINs[24] leads to the conclusion that, rather than being true systematising-information mechanisms for the decision-maker and to publicise public information, they are a formal compliance procedure, which can be seen, if you will, as a somewhat more extensive justification of the regulatory measure.

In this respect, MAINs move away from the main purpose of the IA, which is to enlighten the decision-makers and to serve as a resource for their action. Considering it a process, whose reflection will then have the character of a memory (rather than be a memory itself), is more in line with its nature as a mechanism or resource for decision-making and as a tool for the improvement of its product, the legal rule. This therefore implies a broad conception of IA, which is somewhat different from the content and structure of formally and normatively required reports in this country. Nevertheless, we must bear in mind that they determine the information that must be collected today by this instrument in our context.

If we briefly summarize the main contents of the MAIN, we can appreciate the lack of coincidence between current Spanish IA and IA of the European Commission, but its presentation brings us closer to what we should understand as IA today. And it allows us to approach a somewhat more theoretical, abstract or ambitious conception of IA in which its entity as a process or instrument for the improvement of regulatory quality stands out. A perspective that connects with and synthesises a large part of the proposals developed by Boix Palop and Gimeno Fernández[25] for the articulation of a new model of regulatory production and evaluation.

4. *New Resources for a New Way of Making Regulations*

The large amount of data and information and its accessibility in real time or the constant generation of evolving series provides a new and unprecedented dimension of the available information and the possibilities of its processing by new technologies. Recently, it has been possible to observe reality in a new way and we can see, for example, how automation and computerization provides scholars with never-before imagined information. The channel or medium that the use of new technologies implies for acts and thoughts of subjects offers an unprecedented amount of data available for analysis. Another example is the data on certain aspects of reality, such as the environment, originating worldwide. All these are resources that are also available to public regulators and decision makers today.

As we have said, and according to the previous model, AIs can be characterized as mechanisms for information identification, management, and processing to generate knowledge for legal decision makers and providing them with tools to improve regulation planning. Therefore, we consider

[21] Article 26 Ley 50/1997, de 27 de noviembre, del Gobierno.
[22] https://portal.mineco.gob.es/RecursosArticulo/mineco/economia/ficheros/guia_metodologica_aino.pdf.
[23] Article 88 Spanish Constitution.
[24] S. Sieira Mucientes, *La necesaria objetividad en la evaluación ex ante de la calidad de las normas. Estudio de la memoria de análisis del impacto normativo en la familia*, in *Revista de las Cortes Generales*, no. 107, 2019, 137-194, https://doi.org/10.33426/rcg/2019/107/1442
[25] A. Boix Palop and C. Giméno Fernández, *La mejora de la calidad normativa. Estudio comparado de procedimientos para la elaboración de normas e instrumentos para la mejora y evaluación de su calidad*, Valencia, Publicacions de la Universitat de València, 2020.

them particularly suitable for thinking about the current phenomenon of *big data* and its use in the process of drafting regulations. This, perhaps, implies a first consideration regarding the use and incorporation of ICTs in the regulatory process.

In this sense and following Arroyo Jiménez[26] in relation to *eRulemaking* in the United States, being as it is as a leading country in the exploration of these mechanisms, *it allows for the improvement of administration procedures of regulation making from the perspective of their own functions*. Without evaluating or reflecting on the administrative status of regulation-making procedures or the functions of the procedure themselves, we will summarize the benefits that ICTs provide to these functions according to this author, which we consider to be fully valid. These are to increase the legitimacy of the measures by allowing new participatory channels and greater transparency and dissemination, as well as to increase the efficiency of administrative action, and reduce costs. There is also an increase in compliance by the recipients of the regulation and the administration itself, presupposing greater knowledge, acceptance and possibility of judicial control.

However, what is particularly relevant in this work is the value that ICTs give to another of the purposes of the regulatory drafting procedure that the author points out: improving the quality of the regulation itself. This allows the regulatory decision makers to obtain additional information and thus improve their knowledge of the degree of public satisfaction and its suitability for solving a problem, as well as to determine the positive and negative impacts of regulatory measures and of alternative courses of action. We believe that AI can make a huge contribution in this sense, whether we understand it as a step inserted in the procedure of the elaboration of the regulation or as a procedure in itself, but whose purpose is precisely to be a mechanism to obtain, systematize and process information to help regulatory planning.

The application of ICTs in *eRulemaking* also means that, to a large extent, the gathering of information for the process of drafting the regulation derives from external participation, whether it be from citizens or affected stakeholders. ICTs allow not only to facilitate information gathering, but also to incorporate a new type of information into the process: *big data*, massive data and its use for computational analysis. As Dolors Canals[27] points out, law is facing complexities and uncertainties that require the collecting and processing large volumes of data that only ICTs and artificial intelligence seem to make possible.

AI, understood as a process, would allow us to incorporate the possibilities that ICT and big data provide for the regulatory decision maker without getting too lost in the so-called 'Vs' that characterize these data (volume, variety, velocity, variability, veracity or value). A conception of the IA in this sense, a generic procedural model, which can be adapted to each regulated matter with a certain ease, would allow overcoming difficulties of practical applicability. As Nicoletta Rangone (2023) points out, this is still a pending task,[28] but its advantages include: greater efficiency in the processing of IAs, allowing a greater and faster use of existing knowledge or data that generate them, rapid linkage with other existing regulations, and codification of the rule (legal fact-consequence assumption) that facilitates the measurement of specific impacts of the different alternatives designed or facilitates the measurement of administrative burdens by establishing automatic quantification systems.[29] This author identifies two conditions for the contribution, which we fully accept and set out in a slightly more developed form. The need for clear, clean and quality data, as well as their availability (we could even consider

[26] L. Arroyo Jiménez, *Participación electrónica y elaboración de normas administrativas en España y en los Estados Unidos de América*, in M. Delgado (dir.), *La reforma de la Administración electrónica: una oportunidad para la innovación desde el derecho*, Madrid, INAP, 2017, 231-258.

[27] D. Canals Ametller, *El proceso normativo ante el avance tecnológico y la transformación digital (inteligencia artificial, redes sociales y datos masivos),* in *Revista General de Derecho Administrativo,* no. 50, Iustel, 2019.

[28] NO. Rangone, *Artificial Intelligence challenging core State functions: a focus on Law-Making and Rule-Making*, in *Revista de Derecho Público Teoría y Método*, vol. 8, Marcial Pons, 2023, 114 *et seq*: *AI could certainly play a supportive role in IA, while at the moment it is of very limited application....*

[29] Further advantages or difficulties of this linkage are discussed in S. Matallana Villegas, *El uso de la Inteligencia Artificial en el análisis de impacto normativo*, in *Ius et Scientia*, vol. 9, no. 1, Sevilla, 2023, 9-22.

the creation of specific databases if necessary, as they are relevant data for the standard). And, on the other hand, the requirement for transparency for decision-makers and the public on the purpose of data collection or how they are interpreted.

We believe, however, that the element of dynamism or cyclical nature of the IA, as an instrument that accompanies the entire life of the norm, avoids the inconvenience of failed predictions of predictive analysis on static data, allowing, when errors are observed, channels for the corrected reformulation of the normative text. And we reject from the outset, in our model, the unquestioning acceptance of human behavioural predictions made by the tool. Even though it may be a means to gain knowledge about the phenomenon.

The 'blue' elements of the model[30] allow us to navigate without too much complexity in the first step of delimiting, identifying, detecting or generating the massive data that we want and intend to be the object of statistical processing and the construction of databases with value for regulation and its effectiveness. It is through these 'blue' elements, related to the context, the problem and the objectives, that we can begin to reflect and work on the necessary, relevant or valuable information and data and/or also their nature. This constitutes an initial, but decisive contribution of AI, insofar as it permits the deliberation and organization of the process of gathering and storage. As a result it is necessary to carry out this task before putting forward descriptive or causality hypotheses linked to statistical processing, for which jurists are traditionally poorly trained. This is a difficulty that is already apparent in early works and which Luhmann[31] pointed out. This would explain the few attempts that have been made in the legal world to try to convert categories into indicators and make references to directly observable empirical variables that are objectives for statistical treatment.

In order to summarize all of the aforementioned, and to provide impact analysis with virtuality for the incorporation and operability of massive data and their treatment in the regulatory drafting process, we understand that the first step is to generate data bases and reflect on the data themselves. Dolors Canals[32] tries to classify massive regulatory data according to their consideration prior to the elaboration of the regulation, after its passing and coming into force, and that related to the regulation and regulatory types themselves (which seem to refer to traditional legal data bases). The connotation of regulatory is acquired at the time at which they are observed for the regulation. We believe that much of the pre- and post-data is the same, but it is precisely its observation at two different points in time that could give variability to the data and provide relevant information. All data can be considered empirical since they derive from the observation of reality and their value for the legal field may reside in the fact that their nature is essentially legal, as is a law or a royal decree, or because they maintain a special relationship or interest with the legal field. IA allows, precisely from the moment the regulation is born, to grant to that area of reality or data, value or linkage for the legal field and to define, determine and contrast the data that are going to be the object of observation and treatment. The observation will be especially close with regards to the application and effective compliance of the regulation and its objectives, and that, carried out ex ante is the only thing that allows the comparative contrast and its subsequent ex post quantification.[33]

However, the difficulty generally lies in the fact that these data must be thought of in terms or ways that allows their quantification, often complex when they refer to dimensions of a social or legal nature. That is why quantitative methodologies of social research should be seriously considered in and by IAs, taking into account the techniques they use to collect data and information for their subsequent statistical treatment. This permits the description and explanation of both the regulation and the law as a social phenomenon

[30] We are talking about the blue highlighted elements of the IA scheme or model proposed graphically at the beginning of this paper, which refer to: description of the context, identification of the problem, specification of objectives and prospective analysis of the impacts of the different regulatory designs.

[31] N. Luhmann, *Sistema jurídico y dogmática jurídica*, Madrid, Centro de Estudios Constitucionales, 1983.

[32] D. Canals Ametller, *El proceso normativo ante el avance tecnológico y la transformación digital (inteligencia artificial, redes sociales y datos masivos),* cit.

[33] F. De Montalvo Jääskeläinen, *La evaluación ex post de las normas: un análisis del nuevo modelo español,* in *Asamblea: revista parlamentaria de la Asamblea de Madrid*, no. 36, 2017, 139-177.

as well as the social reality in which the regulation operates and from which it arises and where it manifests its effects. The process of *operationalization* of the concepts[34] allows us, after the formulation of the problem, to access the empirical investigation. It also permits and implies the generation of a triple nexus which connects the theoretical concepts with the physical operations of measuring and observing and, from these with their mathematical symbols. A process in which legal knowledge cannot be left aside.

The large amounts of data available (much of it with variability that can be measured in real time) and the improvements in collection, storage, processing and analysis mechanisms provided by IT systems should be supported by legal expertise and/or legal tools such as IA for system design. It is hoped that these systems, labelled intelligent, will provide useful information and valuable knowledge for any of the moments in the regulatory cycle, in this specific case for the creation and birth of the regulation. But also, and especially, that they monitor said regulation and allow the observation of its 'real' functioning with the aim of making it more effective in the fulfilment of its objectives and in providing solutions of the problems it intends to address. AI would contribute to mitigating one of the major limitations of current artificial-intelligence systems, which is, according to Moisés Barrio,[35] that the systems do not have a real understanding of what they are doing. IAs would provide guidance on how to identify, clean and organise data and basic guidance on the purpose of data processing and analysis. IAs allow for a reflection on the 'human intervention' that would occur in the possible creation of programmes that provide descriptions of reality or possible future predictions about the policy measures taken and the context. The instrument seeks to strengthen the cognitive, motivational element and the transparency of the resources available to the policy-maker. But being aware and always bearing in mind that the result, which the created mathematical and computer application generates, may have errors derived from the design, operation and premises.[36]

5. *An Instrument that Generates Information and Knowledge for and of Regulations. Conclusions*

AIs aspire to feed data and information into the regulation-making process. They also allow us to reflect on what data, what information, how we process that information and for what purpose we use it. From this perspective, we can broach the distinction, in an exercise of accuracy, between data, information and knowledge.[37] IA makes it possible to determine, identify or generate data, produced and constructed by observation, but also transform them into information. This is because it constitutes the observational system that grants criteria of relevance (in our case legal) and is capable of conferring a specific relevance, value or usefulness to the data.[38] This will also result in the correct processing of this information, which generates knowledge for the legal regulation to which it is applied.

The instrument allows for a constant link between legal and social reality (or if you prefer, from a systemic perspective, the rest of the subsystems) that paves the way for a collaborative, complex and dynamic model of regulatory development. A model that is more in line with the new times and that allows us

[34] M.A. Cea D'ancona, *Metodología cuantitativa. Estrategias y técnicas de investigación social*, Síntesis sociología, Madrid, 2001, 123.

[35] M. Barrio Andrés, *Inteligencia artificial: origen, concepto, mito y realidad*, in *El Cronista del Estado Social y democrático de derecho*, no. 100, September-October 2022.

[36] A. Huergo Lora, *Gobernar con algoritmos, gobernar los algoritmos*, in *El Cronista del Estado Social y democrático de derecho*, no. 100, September-October, 2022. Huergo also reflects on the suitability of the contributions of artificial intelligence in administrative procedures of support or those of instrumental nature for 'decisions'. And in terms of the legal effects it may generate.

[37] D. Innerarity, *La democracia del conocimiento. Por una sociedad inteligente*, Barcelona, Paidós, 2011.

[38] D. Innerarity, *La democracia del conocimiento*, cit., 25: Una organización debe tener procedimientos de observación y criterios de relevancia para la construcción de informaciones; solo así podrá generar, a partir de un océano de datos, informaciones útiles para la estrategia y los fines de la organización en el contexto relevante. (…) Para la información vale también, y cada vez más, lo que he dicho acerca de los datos que hay un exceso de información relevante, de tal modo que no es fácil tener una visión general, ni comprender o asimilar toda la información. Esto incrementa el riesgo de elegir la información irrelevante secundaria y dejar pasar la verdaderamente importante. Por eso es necesario gestionar la búsqueda y selección de informaciones de acuerdo con determinados criterios y premisas. En este punto se decide si una organización se queda en un mero recolector de información o es capaz de transformar la gestión de la información en gestión del conocimiento.

to take advantage of new knowledge and information technologies in law-making tasks. However, digitization is not only framed in the opening of new channels of communication with citizens and the recipients of the measures, but also in the generation of information flows that produce knowledge that can be used by public regulatory-decision makers as a valuable and essential resource for their work: the design and adoption of effective legal regulations in complex societies where specialized knowledge plays a fundamental role.[39]

[39] D. Innerarity, *La democracia del conocimiento,* cit. 2011.