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Why a special issue on definitions and concepts in biolaw?*

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Concepts and definitions play a central role in law as they allow, respectively, to name and describe, as well as delimit a real or fictional entity, and ensure a common understanding of it, with a view to legally qualifying it in order to associate it with a legal regime. By focusing on the conceptual dimension, we intend to go beyond an approach based purely on notions. As far as possible, the discussion will focus on concepts, rather than notions, the latter being regarded here as a necessary preliminary step to any reflection on the former. We offer to consider that a notional analysis entails the identification of all criteria that may be used to recognize an element of reality, in an exhaustive manner, by identifying and examining each criterion, without necessarily determining their relative relevance for identifying that reality. In contrast, a conceptual analysis requires selecting only those criteria that are relevant for identifying the element of reality, and assigning to each selected criterion its proper weight and position in order to reveal the typical features of the object described. For the science of law—as a scholarly discourse on law—the act of conceptualization lies at the core of the scientific approach. Numerous studies in legal theory, or more broadly in fundamental legal research, have addressed this topic.[1]

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1 For some specific examples, see : L.-M. Schmit, *Les définitions en droit privé*, Presses de l'Université Toulouse Capitole, Librairie générale de droit et de jurisprudence, 2017, https://doi.org/10.4000/books.putc.2335; D. Truchet, "Les définitions législatives," in R. Drago (dir.), *La confection de la loi*, PUF, 2005, p. 193 ; C. Eiseinmann, « Quelques problèmes de méthodologie des définitions et des classifications en science juridique », *APD*, 1966, pp. 25–43 ; C. Wolmark, *La définition prétorienne. Étude en droit du travail*, Thèse, Univ. Paris 10, Dalloz, coll. Nouvelle bibliothèque de thèses, 2007; A. Rey, "Polysémie du terme définition," in *La définition*, Colloque du Centre d'étude du lexique, Larousse, coll. Langue et Langage, 1990.

In the field of biolaw—understood here as the body of legal norms and legal questions pertaining to the biological domain and/or arising from technological advances in biomedicine, and more broadly in biotechnology—definitions and concepts present particular challenges that have rarely been addressed directly and transversally within legal scholarship.[2] Yet, definitions and concepts are of critical importance in this area, given the continuously evolving and unpredictable nature of scientific practices, and the absence of consensus around many scientific definitions. The establishment of definitions thus constitutes a fundamental concern for biolaw, as it enables the law to apprehend and orient such practices in a coherent and effective manner. While biolaw may itself be approached as a concept within the science of law, it is considered here, first and foremost, as a domain of legal inquiry, forming the subject matter of the present study. Nevertheless, the scholarly work produced within this domain contributes to the conceptual framing of biolaw, whose usage—as a doctrinal category—would benefit from greater consistency and theoretical refinement.

This thematic raises a series of concrete and pressing legal questions: Can legislation or regulation meaningfully define emerging innovations in biomedicine or biotechnology while these developments remain in flux, or in fields characterized by scientific and technological uncertainty? To what extent may legal or regulatory definitions diverge from those adopted by the scientific community, and under what conditions is such divergence justified? What normative legitimacy does the legal scholar or legislator possess in departing from scientific definitions? Is it preferable, in certain contexts, to refrain from defining a given object of regulation, due to the inherent difficulties in tracking developments within dynamic and highly technical fields? Under what circumstances, and for what reasons, have legislators or regulatory authorities chosen to define—or to abstain from defining—biomedical innovations or biotechnologies? When and why has the law opted to regulate on the basis of the *intended use* of a given technology rather than the *intrinsic nature* of the object itself?

While legal literature generally focuses on the legal or regulatory frameworks to be adopted and on the challenges posed to such regulation by biomedical and biotechnological innovations, this special issue focuses instead on how legislation—or regulation more broadly—defines or fails to define these innovations, and on the consequences that definitions and concepts may have for their development.

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2 By way of exception, particular mention should be made of M. Glinel, *Qualification juridique et délimitation des compétences normatives de l'Union européenne : l'exemple des biotechnologies*, Thèse Droit, Université Toulouse Capitole, 2023.

I. Language Conventions: "Concept" and "Definition"

In order to structure discussions and understanding in the use of the terms "concept" and "definition", we suggest that authors retain certain conventions of language around the meaning and uses of these terms in this special issue.

Thus, we suggest to call:

- *name* of the concept, the designation given to the concept,
- *definition* of the concept, the proposition formed by a linguistic statement aimed at identifying a given reality (which comes under the name of the concept) on the basis of its typicality,
- the *extension* of the concept, all the situations covered by the concept, which it can be used to qualify.[3]

For instance, "Chair" is the name of the concept used to describe "a piece of furniture with backrest and no arms that is designed for one person to sit", which is the definition of the concept. All the pieces of furniture with backrest and no arms that are designed for one person to sit are extensions of the concept (they are chairs). In a statement referring to a concept, it is possible to identify the concept in its three dimensions: its name, its definition or its extension.

The statement "I sat on a chair" uses the name of the concept, the statement "I sat on a piece of furniture with backrest and no arms that is designed for one person to sit", its definition, and the statement "I sat on the dining room chair", an extension of the concept. Language can perfectly well use the name of the concept, its definition or its extension separately, even if, in our example, the proposition that constitutes the extension of the concept uses its name ("the chair in the dining room" is a "chair", so the term "chair" is used to designate it).

Law, insofar as it is formulated on the basis of linguistic statements, can therefore either use the name of a concept, define it or extend it. Indeed, while applicable law often defines the concepts it uses as a fundamental method to determine the scope of legal rights and obligations it establishes, it is also full of concepts that are named without being defined. In that context, European Union (EU) law is a good example of the efforts made to define various legal concepts in a dedicated article at the beginning of directives and regulations although one can wonder about the definitions of those that are named without being defined. For instance, in the field of biolaw where the EU medicines legislation may apply, the proposal of reform of the pharmaceutical legislation is significantly showing the efforts made to define

[3] Here we take up a distinction, the conceptual triangle, generally attributed to C. K. Ogden and I. A. Richards, *The Meaning of Meaning*, Hartcourt, Brace & World, 1923.

concepts and make them accessible in increasing the number of definitions available from 33 in the current community code[4] to 70 definitions in its proposed revision.[5] Some of these definitions already exist but are scattered in various other law texts including guidelines such as 'vaccines',[6] while other are currently being named without being defined such as 'non-clinical'. Nevertheless, it should be highlighted that the proposed reform of pharmaceutical legislation provides for a definition of this latter term.[7] In contrast to the proposed reform of pharmaceutical legislation, Regulation (EU) 2024/1938 on quality and safety standards for substances of human origin intended for human application (hereinafter the "SoHO Regulation")[8] will eliminate the existing legal definitions of blood, cells, and tissues, in favor of a new legal concept: "substances of human origin."

Thus, Article 3(1) of the SoHO Regulation provides: "For the purposes of this Regulation, the following definitions apply: 'substance of human origin' or 'SoHO' means any substance collected from the human body, whether it contains cells or not and whether those cells are living or not, including SoHO preparations resulting from the processing of such substance." The provision thereby introduces the name of the concept with the legal term "substance of human origin" while also providing its definition. As to the extension of the concept, any substance retrieved from the human body—regardless of whether it contains cells, and whether those cells are living or not—may fall within the definition of a "substance of human origin." This would encompass, for example, blood and its components, cells, tissues, microbiota, human-origin urine or feces, and breast milk.

With this clarification, there are several types of statements that can mobilise each of the elements of the concept. Statements *of* the law, which are directly stated in a legal text[9] have to be distinguished from statements *about* the law. The latter comes

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4 Article 1, Directive 2001/83/CE of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (6 November 2001) [2001] *OJ L*311/67.

5 Article 4, Proposal for a Directive of the European Parliament and the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC, COM(2023) 192 final.

6 EMA, Guideline on clinical evaluation of vaccines, 16 January 2023, EMEA/CHMP/VWP/164653/05 Rev. 1.

7 Article 4(11), Proposal for a Directive, COM(2023) 192 final, *op. cit.*

8 Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (13 June 2024) [2024] OJ L1938.

9 For instance, "No medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities," Article 6(1), Directive 2001/83/EC, *op. cit.*

from a discourse about the law.[10] Hence, we suggest that when the concept is *in* the law (when the law uses the word designating—or naming—the concept, when it defines or extends the concept), it is a *legal concept*. If the concept is in statements *about* the law, or at least in scholarly discourse on the law, we suggest to say that it is a *concept of the science of law*. This is the case, for example, with the concept of 'biomedical innovation', used in the ANR funded I-BioLex project mentioned below. The term is not used by positive law but by the science of law.

Given the subject of this special issue, our scholarly discussions will also include other discourses that may mobilise concepts in their three dimensions. In particular, we will use general scientific discourses, not only those of the science of law. Here, we suggest to write *scientific concept* to refer as a qualifier that may be applied according to discipline (scientific discourse in medicine (medical concept), philosophy (philosophical concept), sociology (sociological concept), etc.). On the other hand, discourse that can be described as common (that uses the common and/or intuitive sense of a given reality, and that is not based on any scientific approach) will be described as a *common concept*.

Thus, a concept, in its *name*, *definition* or *extension*, may be qualified as:

- *a legal concept* if it is contained in provisions of positive law (an applicable legal text whatever its source or status is (Act, Decree, Decision of a court. . .) at a given time in a given legal order);
- *a concept of the science of law* when it is used in scholarly discourse on the law;
- *a scientific concept* (of philosophy, medicine, sociology, etc.) when it is used by a scientific discourse other than legal discourse;
- *a common concept* when the known dimensions (name, definition and/or extension) of this concept are based on common, non-scientific elements.

Legal concepts can draw upon scientific concepts, common concepts, and concepts from the science of law. For instance, the legal concept of "substance of human origin" incorporates not only other legal concepts such as "SoHO preparations"[11] and "processing"[12] which will thus become concepts within the science of law, but also scientific concepts such as "living or non-living cells" and the common concept of "human body".

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[10] For instance, on the same topic: "The obligation to secure a marketing authorisation, warranting safety and efficacy of medicines, was introduced for all medicines marketed within the then European Economic Community (EEC), setting in motion the EU's precautionary approach to risk of harm from medicines." T. K. Hervey, Health law, in S. Garben, L. Gormley, *The Oxford Encylopedia of EU Law [OEEUL]*, June 2022.

[11] "A type of SoHO that: (a) has been subjected to processing and, where relevant, one or more other SoHO activities referred to in Article 2(1), point (c); (b) has a specific clinical indication; and (c) is intended for human application to a SoHO recipient or is intended for distribution". Article 3(37), SoHO Regulation, *op. cit.*

[12] "'Processing' means any operation involved in the handling of SoHO, including, but not limited to, washing, shaping, separation, decontamination, sterilisation, preservation and packaging, except for the preparatory handling of SoHO for immediate human application during a surgical intervention, without the SoHO being removed from the surgical field before they are applied". Article 3(23), SoHO Regulation, *op. cit.*

II. Context: A special issue within the I-BioLex Project

This special issue is part of the ANR funded I-BioLex research project titled "Fragmentation and Defragmentation of the Law of Biomedical Innovations" (2021-2025), which aims to explore and explain the processes of fragmentation and defragmentation of law, as well as to analyze their developments over time within the field of European law concerning biomedical innovations.[13] To this end, the project draws on the state of the art in three main areas that inform the discussions on the definitions and concepts of biolaw contained in this special issue.

First, while much of the legal scholarship in this domain highlights the issues related to the legal regulation of biomedical or biotechnological innovations, or complex health technologies,[14] two main trends can be identified. On the one hand, innovations challenge existing legal frameworks.[15] On the other hand, innovations are shaped by the way in which law is constructed and implemented.[16] While the majority of legal literature aligns with the first trend, the I-BioLex project embraces both trends by considering this dual movement between law and biomedical innovations (known as "co-production" in socio-legal studies),[17] as well as the context in which the law is adopted. Regarding this special issue, this means that the work undertaken addresses legal definitions and concepts in biolaw that are not only questioned by the development of biotechnological innovations but also exert an influence on these very innovations.

Second, the temporality of positive law is frequently called into question by the pace of biomedical or biotechnological innovations (often referred to as the so-called "law lag"): the time required for the creation, adoption, and implementation of legal norms may lead to their early obsolescence in regulating constantly evolving innovations. While many scholars in legal science argue that the law must follow or respond to the development of such innovations,[18] others have highlighted the anticipatory potential of law.[19] The temporal relationship between the creation,

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13 For more information on this project, please visit the project website here.

14 In this respect, see in particular: M. Flear, A.-M. Farrell, T. Hervey, T. Murphy, European Law and New Health Technologies, Oxford University Press, Oxford 2013, 477 p.

15 In this respect, see in particular: A. Mahalatchimy, E. Rial-Sebbag (dir.), *L'Humain médicament*, *Quaderni* n° 81, printemps 2013, Éditions de la Maison des sciences de l'homme Paris, 194 p.

16 In this respect, see in particular: C. Chabannon, et al., *Les unités de thérapie cellulaire à l'épreuve de la règlementation sur les médicaments de thérapie innovante*, *Médecine/Sciences*, mai 2014, 30 (5), pp. 576–583.

17 S. Jasanoff, *States of knowledge: the co- production of knowledge and social order*, Routledge 2004.

18 R. Brownsword, K. Yeung, "*Regulating Technologies: Legal futures, regulatory frames and technological fixes*," Hart Publishing 2008, pp. 3–22.

19 A. Faulkner, *Regulatory policy as innovation: constructing rules of engagement of a technological zone for tissue engineering in the European Union*, Research Policy, 2009, 38, pp. 596–615.

implementation, and evolution of legal norms and the development of biomedical innovations constitutes another key dimension of the I-BioLex project. In this context, legal definitions and concepts in biolaw may be understood as indicators of the relationship between the objectives of adaptability and coherence in biolaw, and its regulatory functions—whether reactive, anticipatory, or abstentionist—in the governance of biomedical or biotechnological innovations.

Third and finally, the I-BioLex project explores the processes of fragmentation and defragmentation in the law governing biomedical innovations. While the phenomenon of legal fragmentation has been widely discussed in international law—primarily from the perspective of the problems it generates[20]—the I-BioLex project approaches fragmentation and defragmentation as co-existing processes, rather than as antagonistic forces. These processes are thus understood either as legal strategies employed in response to the development of biomedical innovations, or as contingent responses reflecting shifts in political and legal contexts. In this respect, they reveal a fundamental tension between, on the one hand, the objective of supporting the development of a particular biomedical or biotechnological innovation—often through the creation of specific legal definitions and concepts—and, on the other, the desire not to hinder the development of other innovations by maintaining alternative definitions and legal concepts tied to broader legal categories, procedures, or regulatory regimes applicable to other biolaw-related objects. The evolution, complementarity, overlap, opposition, presence, or absence of legal definitions and concepts within biolaw thus contribute directly to the implementation of fragmentation and defragmentation processes in this area of law.

III. Content and Development of this special issue

Beyond the language conventions suggested to contributors, this special issue is structured around three main orientations.

First, the domain in question is that of biolaw, understood in a broad sense as the body of law relating to the biological realm—whether concerning human, animal, or plant biological material—whether regulated in its natural state or transformed into a health product, a biomedical innovation, or, more broadly, a biotechnological innovation extending beyond the medical field. Contributions are therefore not limited to the medical or health sectors, even if those remain predominant;[21] they may also pertain to other areas, notably environmental law,[22] insofar as they fall within the regulatory governance of the biological domain.

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[20] A.-C. Martineau, *Le débat sur la fragmentation du droit international – Une analyse critique*, Bruylant, 2015.

[21] See the contributions of Matthieu Guerriaud; Katrina Peherudoff and Elena Pires; Audrey Lebret; Gauthier Chassang, Lisa Feriol, and Noémie Dubruel; Adrien Bottacci; Eloïse Gennet and Aurélie Mahalatchimy.

[22] See the contributions of Estelle Brosset and Valentine Delcroix.

Second, the dossier seeks to engage with multiple legal orders, whether European, international, or national levels, with a preference—though not a requirement—for comparative approaches. Accordingly, while most contributions address European Union law,[23] some extend to cover both EU law and that of the Council of Europe,[24] and in some cases also integrate national legal frameworks,[25] or examine EU law alongside the legal standards developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).[26]

Third, this special issue aims to combine positive legal analyses focused on one or more definitions or concepts in biolaw[27] with more cross-cutting analyses stemming from the science of law, addressing broader reflections on several or all of these definitions and concepts.[28]

In addition, two key features characterize this special issue.

First, the contributions are published in either English or French, as the editors deliberately sought to gather analyses from a diversity of legal cultures on the special issue's central theme. While most of the legal scholars involved at the project's inception come from a continental legal tradition, the use of English has opened the door to contributions from researchers outside that tradition. It also facilitates, at the very least, the expansion of future discussions beyond the Francophone world, where legal discourse is particularly shaped by the centrality of the concept of *qualification*—a term that only partially aligns with the notion of *subsumption*, often used in English-language legal theory.

Second, the special issue is intended to be dynamic. This reflects the specific temporal relationship between law and biomedical or biotechnological innovations—or more broadly, biolaw—as outlined above. In this regard, the online and open-access format provided by *Confluence des droits_La Revue* offers the opportunity for this special issue to be enriched over time, through contributions from the legal scholarly community and, more broadly, from the field of science and technology studies. While the special issue initiates and brings together discussions on the legal definitions and concepts of biolaw, it is designed to be progressively expanded and continuously developed in an accessible and collaborative space.

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23 See the contributions of Estelle Brosset, Valentine Delcroix, Katrina Peherudoff and Elena Pires, Eloïse Gennet and Aurélie Mahalatchimy.

24 See the contributions of Audrey Lebret, and of Gauthier Chassang, Lisa Feriol, and Noémie Dubruel.

25 See the contributions of Xavier Bioy, and Adrien Bottacci.

26 See the contribution of Matthieu Guerriaud.

27 This is the case not only of contributions relating to substances of human origin, organoids, gene therapy medicinal products, biomedical innovations and genetically modified organisms, but also to the human species, privacy and unmet medical needs.

28 On this approach, see Marie Glinel's contribution and Xavier Magnon's synthesis.