

Hanna Spasowska, PhD

ORCID: 0000-0003-4000-5837

hanna.spasowska@mail.umcs.pl

Maria Curie-Skłodowska University (Lublin)

Legislative Inertia in the Era of New Technologies: Biocomputing as a Symptom of the Systemic Dysfunction of Law

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The article addresses the issue of legislative inertia as an inherent feature of the normative system in the context of groundbreaking technological innovations. Biocomputing, i.e., information processing with the use of biological systems, serves as a case study demonstrating the inadequacy of existing legal categories for the phenomena that need regulation. The analysis covers EU law and Polish law and identifies four fundamental normative gaps: the lack of an appropriate legal category for the biocomputer, the inadequacy of the biosafety regime, the conflict of intellectual property regimes, and the unresolved issue of genetic data as a carrier of computational information. The study puts forward proposals for the law as it should stand concerning the inevitable lag of law, including the proposal for a framework law, ratification of the Oviedo Convention, establishment of an interdisciplinary expert council, and reform of legal education.

Introduction

Law and technology remain in a permanent asymmetrical relationship: technological progress precedes the normative response. This asymmetry does not result from negligence or flaws on the part of the legislature – it is a consequence of the nature of the normative system, which regulates existing states rather than future ones, and which, to maintain its legitimacy, requires something that technology does not need: time, reflection, and axiological consensus. For most of legal history, this asymmetry remained within functionally acceptable limits. Innovations were developing at a pace that allowed the legislature to respond normatively before the effects of new technology reached a scale that generated serious legal and social problems.

Today, the situation is fundamentally different. The pace of innovation has become exponential, while the law continues to change in an evolutionary manner. The gap between the emergence of a new technological phenomenon and the regulatory approach to it is no longer a matter of years – it has grown into a generational regulatory lag. Technologies that were the subject of scientific hypotheses a decade ago are now being commercially implemented in the circumstances of a deep regulatory gap. The consequence is not only legal uncertainty for the participants of transactions, but – at a deeper level – an erosion of the ability of law to perform its fundamental functions: the protection of individual rights, attributing liability for damage done, and setting limits on permissible interference with legally protected interests.

Biocomputing – broadly understood as computing involving information processing using

biological systems including DNA, RNA and genetically modified living cells – is a particularly representative example of the phenomenon being described. This is not because it is one of the most widely deployed technologies – in this respect, it is clearly second to artificial intelligence. Its properties, however, raise questions before the law that are not answered by the existing regulatory regimes in a complete and coherent manner: the questions about the legal status of a being that is both a living organism and a computational device; about the liability for damage generated by a biological system capable of autonomous evolution; about the protection of personal data when the information is carried by human genetic material. In this sense, biocomputing is not so much a new legal problem as an instrument that reveals a fundamental and previous problem – the structural inability of the law to regulate phenomena whose properties go beyond the limits of existing disciplinary divisions.

The aim of this study is to provide a multi-faceted analysis of this problem: (1) a theoretical legal analysis of legislative inertia as an inherent feature of the normative system; (2) a legal-dogmatic analysis of the state of biocomputing regulation at the level of EU law and Polish law, aimed at identifying specific normative gaps; (3) the formulation of postulates to manage the inevitable lag of the law, and not – which should be emphasised – to eliminate it, as this objective is considered structurally unachievable.

The analysis is guided by three research hypotheses, corresponding to the three aims set out above: first, that legislative inertia constitutes a structural and inevitable feature of the normative system rather than a remediable defect of the legislative process; second, that biocomputing, owing to its ontological, liability-related and intellectual-property-related hybridity, generates normative gaps that cannot be closed through incremental amendment of the existing regulatory categories of EU and Polish law; and third, that the appropriate response to this phenomenon consists in managing, rather than eliminating, the regulatory lag, through a combination of framework legislation, ratification of the Oviedo Con-

vention¹, institutional reform and reform of legal education. As regards the state of research, the theoretical problem of the gap between law and technology has already been extensively addressed in the anticipatory-governance and pacing-problem literature associated with G. Marchant and R. Brownsword, discussed in detail in Parts 1 and 2 below; by contrast, the sector-specific regulatory analysis of biocomputing developed in Parts 3–6 of this study concerns an area in which the specialised literature remains markedly less developed.

The study is located at the intersection of legal theory, environmental law, intellectual property law, and personal data protection law – such interdisciplinary nature is not a methodological choice, but a necessity resulting from the nature of the issue under analysis. Given the doctrinal and theoretical character of the analysis undertaken, the study does not follow the IMRAD scheme (Introduction, Materials & Methods, Results and Discussion), which was developed for the reporting of empirical research based on the collection of primary data. Instead, the article adopts an argumentative-thematic structure customary in legal-dogmatic and legal-theoretical scholarship, proceeding from a general theoretical account of legislative inertia, through a doctrinal analysis of the state of biocomputing regulation, to the identification of normative gaps and the formulation of *de lege ferenda* proposals. This structure corresponds to the conceptual and normative nature of the research problem, which is not amenable to an empirical reporting format.

I. Legislative inertia as an inherent feature of the legal system: Legal-theoretical approach

Law, as a product of human activity, is inextricably rooted in the era during which it was shaped. It regulates existing conditions, describes phenomena that have already occurred, and organises reality that has taken on sufficiently perma-

¹ Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Oviedo Convention), Oviedo, 4 April 1997, CETS no. 164.

nent forms for the legislator to be able to see it, name it, and subject it to regulation. This characteristic is not a flaw in the normative system; it is a consequence of its nature: for law to be binding, it must be understandable, and the condition for understandability is a reference to phenomena that already exist and can be described in legal language². The lag of law behind reality – described in the literature as legislative inertia – is therefore not a pathological effect requiring correction, but a structural feature of the normative system, similar to the inertia of any complex institutional organism.

In a legal-theoretical sense, legislative inertia (Latin: *inertia legislatio*) refers to a state of structural and functional lag in the lawmaking process relative to rapidly changing social, technological, and economic realities. It is a situation in which the legal system – due to its procedural, formal, and systemic nature – is unable to respond adequately and in a timely manner to new phenomena in social reality. The consequence is the emergence of legal grey areas, the growing importance of soft forms of regulation, and the erosion of the effectiveness and legitimacy of positive law³. Legislative inertia reflects a fundamental tension between normative stability and the dynamics of social reality – a tension that has long been noticed by legal philosophy, which the contemporary technological revolution has made particularly pronounced.

The ontological basis of this phenomenon is in the essence of law as a normative system, which is supposed to ensure stability, predictability, and social order. Every normative act is the result of a process that is inherently longer than the very phenomenon being regulated. Inertia is thus embedded in the architecture of the normative system so deeply that its elimination would entail the annihilation of those properties of law

that constitute its value⁴. In the epistemological dimension, legislative inertia reflects the cognitive limitations of the legislator, who is unable to fully anticipate the effects of technological innovations. R. Dworkin, when analysing law as an interpretative practice, has pointed out that law always “catches up” with social notions of justice, never anticipating them⁵. This statement, formulated in the context of the relationship between law and morality, applies with at least equal accuracy to the relationship between law and technology.

Legal scholars identify several mechanisms that generate legislative inertia. The first is proceduralism: law-making is subject to multi-stage procedures – from the legislative initiative, through public consultations and inter-ministerial arrangements, to parliamentary debates and the *vacatio legis* – an inherent feature of which is the prolongation of the normative system’s response time⁶. The second is the necessity of axiological deliberation: the law must be rooted in the value system of society, which requires a time-consuming debate on the moral consequences of new solutions. The third is fragmentation of competence – responsibility for law-making is dispersed amongst parliaments, governments, specialised administrative bodies and – in the pan-European context – EU institutions. The fourth is institutional conservatism (*status quo bias*): law-making bodies naturally tend to preserve the existing order, considering any change as a risk to the coherence of the system and legal certainty⁷.

As regards new technologies, all these mechanisms work with increased intensity and are mutually reinforcing. The pace of technological

² H.L.A. Hart, *The Concept of Law*, Oxford 1961, pp. 121–132; Polish translation: idem, *Pojęcie prawa*, Warszawa 1998.

³ Cf. P. Nonet, P. Selznick, *Law and Society in Transition: Toward Responsive Law*, New York 1978, pp. 73–113.

⁴ A. Kaufmann, *Über die Stabilität des Rechts*, “Archiv für Rechts- und Sozialphilosophie” 1979, vol. 65, pp. 161–174.

⁵ R. Dworkin, *Law’s Empire*, Cambridge 1986, pp. 225–258; Polish translation: idem, *Imperium prawa*, Warszawa 2022, pp. 81–91.

⁶ M. Korycka-Zirk, *Reguły prawne jako istota pojęcia prawa w ujęciu H.L.A. Harta*, “Studia Iuridica Toruniensia” 2010, vol. 6, pp. 81–100.

⁷ K. Izdebski, G. Kopińska, M. Berek, P. Frączak, P. Wolejko, *Polski Bezład Legislacyjny. Raport Obywatelskiego Forum Legislacji z prac IX kadencji Sejmu*, Warszawa 2023, pp. 9–10.

progress is of an episodic nature, while the law is changing evolutionarily – and no known legal system has broken this asymmetry in a lasting way. It is not about the flaw of a particular lawmaking entity or the inefficiency of a particular legal system. It is a structural property of law as such, observable in all legal orders. The legal regulation of railways emerged only after the commencement of railway traffic; the regulation of the automotive sector followed the widespread adoption of motor vehicles; and the regulation of the Internet developed only once computer networks had transformed established forms of communication and commerce. This is not a matter of neglect, but a structural feature of the legal system.

There are also dissenting voices in academia. The most widely discussed attempt to challenge the inevitability of legislative inertia is the concept of anticipatory governance developed by G. Marchant of Arizona State University⁸. In Marchant's view, the reactive model (react-and-regulate) should be replaced by a proactive approach, based on technological foresight and early involvement of experts and decision-makers⁹. In 1980, D. Collingridge described the structural dilemma of regulation of new technologies, which now bears his name¹⁰: at an early stage, technology is too poorly understood to be regulated; when its effects become known, it is already so entrenched, both socially and economically, that it is difficult and costly to control. This is an information dilemma and a dilemma of authority at the same time – and none of the known regulatory strategies fully resolve it.

These concepts have significant theoretical value. However, their common weakness is that, at the level of statutory law, they essentially operate only as a proposal. Regulation (EU) 2024/1689

(the AI Act)¹¹ – referred to as a model example of anticipatory regulation – was drafted before artificial intelligence had reached its current scale of impact, and yet required significant amendments during the legislative process; some of its provisions became obsolete before its entry into force¹². This situation illustrates the essence of the Collingridge dilemma: even a deliberate attempt to prepare the law for future realities ends with the need of catching up – although with a smaller gap. Most anticipatory instruments operate as soft law, which in itself confirms that statutory law – due to its structural nature – is incapable of staying ahead of technological reality.

Instead of asking a question about eliminating legislative inertia, one should ask a pragmatic question: How can we manage the inevitable law lagging behind technology while minimising its negative consequences? The answer to this question requires understanding that the growing gap between the emergence of a new technological phenomenon and legislative response is neither fixed nor naturally limited. The law has always responded with a delay, but in the past, this delay was shorter – not because the law was more efficient, but because technologies developed more slowly. Today, that asymmetry has reached a level that generates real legal, ethical, and social problems. It is this dimension of the phenomenon, rather than inertia itself, that is the proper subject of concern and analysis – and this is what this study focuses on, using biocomputing as a case study that particularly vividly illustrates the tension in question¹³.

⁸ G.E. Marchant, *The Growing Gap Between Emerging Technologies and the Law*, [in:] *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight: The Pacing Problem*, G. Marchant, B. Allenby, J. Herkert (eds.), Dordrecht 2011, pp. 19–39.

⁹ Idem, *Governance of Emerging Technologies as a Wicked Problem*, "Vanderbilt Law Review" 2020, vol. 73(6), pp. 1861–1905.

¹⁰ D. Collingridge, *The Social Control of Technology*, London 1980, pp. 11–20.

¹¹ Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No. 300/2008, (EU) No. 167/2013, (EU) No. 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.07.2024).

¹² 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, Brussels, 21.04.2021, COM(2021) 206 final.

¹³ Cf. N. Luhmann, *Das Recht der Gesellschaft*, Frankfurt am Main 1993, pp. 38–65; M. Gładzowski, *Teoria syste-*

2. Artificial intelligence as a particular but not exceptional phenomenon: The spectrum of regulatory problems brought by new technologies

The public and academic debate that has taken place in recent years is dominated by the legal and ethical issues of artificial intelligence. The AI Act is the most widely discussed piece of legislation on new technologies in the history of European law. The literature on the regulation of algorithms, liability for decisions of autonomous systems, and the protection of data processed by language models amounts to tens of thousands of items. This situation would not deserve criticism, were it not for the fact that the concentration of scholarly attention on artificial intelligence is at the expense of other technologies that give rise to at least equally serious legal concerns, while operating in conditions of a vastly deeper regulatory vacuum. From a legal perspective, artificial intelligence is indeed a significant phenomenon, yet not exceptional or unique¹⁴.

R. Brownsword, one of the most prominent researchers of law-and-technology theory in the Anglophone world, points out that law today faces the challenge of not one innovation but of a wave of breakthrough innovations, each of which in its own way crosses the boundaries of existing conceptual categories, each of which raises questions about liability, ownership, agency and human rights, and each of which appears before lawmakers have managed to deal with the previous one¹⁵. Taken together, they create a regulatory environment of complexity that legal systems have never known before.

Apart from artificial intelligence, at least four technological areas deserve separate, serious legal consideration. The first is genetic engineering,

especially genome editing using the CRISPR-Cas9 system. The possibility of precise modification of the DNA sequence of living organisms, including humans, raises questions before the law that traditional legal categories cannot accommodate: about the legal subjectivity of genetically modified beings, about the limits of interference in genetic material in the context of the principle of human dignity, about responsibility for the effects of modifications emerging in subsequent generations, about the intellectual property of genetic sequences as a product of research¹⁶. F. Baylis points out that the decision to allow hereditary editing of the human genome cannot be made by the scientific community in isolation from society – yet technology is ahead of both the public debate and any regulatory consensus¹⁷. The case of Chinese researcher H. Jiankui, which in 2018 resulted in the birth of genetically modified children, shows that the lack of binding regulations of international law is not a purely academic issue, but has direct consequences for the biological integrity of specific people.

The second area is neurotechnologies, technologies that read, interpret and modify human brain activity, including non-invasive brain-computer interfaces, deep brain stimulation implants and devices to decode neuronal signals. M. Ienca and R. Andorno point out that the system of human rights in its current form is not sufficient to protect an individual from the dangers of neurotechnology, and call for four new categories of neurocognitive rights to be distinguished: cognitive freedom, mental privacy, mental integrity, and psychological continuity¹⁸. None of these rights have so far been codified in a binding act of international law, while national legal systems – including Polish law – do not even contain terminology to describe the factual situations generated by neurotechnologies.

mów autopojetycznych Niklasa Luhmanna – między metafizyką a metabiologią, "Przegląd Pedagogiczny" 2009, no. 1, pp. 39–55.

¹⁴ Cf. R. Brownsword, *Law, Technology and Society: Re-Imagining the Regulatory Environment*, London–New York 2019, pp. 1–24.

¹⁵ *Ibidem*, pp. 3–8.

¹⁶ See M.A. Heller, R.S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, "Science" 1998, vol. 280(5364), pp. 698–701.

¹⁷ F. Baylis, *Altered Inheritance: CRISPR and the Ethics of Human Genome Editing*, Cambridge 2019, pp. 1–19.

¹⁸ M. Ienca, R. Andorno, *Towards New Human Rights in the Age of Neuroscience and Neurotechnology*, "Life Sciences, Society and Policy" 2017, vol. 13(1).

The third area is nanotechnology, understood as the design and application of materials in the form of objects with the size of one to a hundred nanometres. Manipulation of matter at the atomic level generates the risk of biological and environmental interactions that cannot be predicted based on the macroscopic properties of these substances. J. Kuzma and A. Kokotovich point out that the regulatory framework for nanotechnology remains fragmented at both national and international levels, with regulators operating under deep uncertainty about the risk profile of nanoparticles used in medicine, cosmetics, and the food industry¹⁹.

The fourth area – and one that is the subject of detailed analysis herein – is biocomputing, i.e. biocomputation in a broad sense: the use of biological systems for information processing. Biocomputing has a distinctive feature among these technologies: it is a technology that is located at the junction of several regulatory orders at the same time – it touches on biotechnology law, personal data protection law, intellectual property law, environmental law and biosafety law, and potentially also medical law and criminal law. None of the existing branches of law have the instruments to cover the problem comprehensively, which creates not one but many overlapping regulatory gaps²⁰. This multidimensional incompatibility makes biocomputing a case study of particular importance for the purposes of legal analysis.

3. Biocomputing as a challenge for conceptual categories of the law: Characteristics of technology from the legal perspective

Any analysis of the regulatory implications of biocomputing requires that the nature of this technology be first outlined – not for fondness of natural sciences, but because its technical characteristics

determine which categories of law prove incompatible with the reality in question, and for what reason. A lawyer who does not know the difference between a biocomputer and a traditional electronic computer or a living organism is unable to identify where existing regulations prove insufficient.

Biocomputing – understood as a broad family of technologies utilising biological systems for information processing – is not a consistent phenomenon. Scientific literature distinguishes at least three main categories of biocomputing, differing in computational substrate, mechanism of operation and – crucially from the legal perspective – the risk profile and potential social consequences²¹. The first category comprises molecular computers, in which nucleic acid molecules – DNA or RNA – or proteins serve as the information carrier and computing substrate. The second category consists of cellular computers, in which genetically modified living cells function as a computational unit. The third category comprises hybrid systems, integrating biological components with electronic circuits, such as bio-FET devices, in which biomolecules act as sensors and the signal is processed by conventional semiconductor circuits²².

The moment considered as the birth of biocomputing in a scientific sense is 1994, when L. Adleman published in “Science” a paper documenting the solution to a mathematical Hamiltonian path problem using DNA molecules and standard enzymatic reactions²³. He demonstrated that computation is not exclusively the domain of electronic systems and that biological material can serve as a computing substrate. In the subsequent decades, research developed in several parallel directions, including DNA computers, biomolecular automata, and synthetic biology systems designed to perform complex regulatory functions in living cells.

¹⁹ J. Kuzma, A. Kokotovich, *Nanotechnology, Society, and Policy Issues*, “Nanotechnology Law & Business” 2011, vol. 8(4), pp. 361–372.

²⁰ Cf. G.E. Marchant, K.W. Abbott, B. Allenby (eds.), *Innovative Governance Models for Emerging Technologies*, Cheltenham 2013, pp. 1–15.

²¹ Y. Benenson, *Biomolecular Computing Systems: Principles, Progress and Potential*, “Nature Reviews Genetics” 2012, vol. 13(7), pp. 455–468.

²² *Ibidem*, pp. 456–458.

²³ L.M. Adleman, *Molecular Computation of Solutions to Combinatorial Problems*, “Science” 1994, vol. 266(5187), pp. 1021–1024.

From the legal perspective, the key factor is not the technical mechanisms of biocomputation, but its systemic properties – the traits that distinguish a biocomputer from all categories of objects and subjects recognised by current law. These properties can be grouped into three problem areas.

First, an ontological problem emerges there. The legal systems currently in force distinguish two basic categories of objects and subjects of legal relations: things and legal entities. Naturally, the biocomputer does not fit into either of them. In its basic form, namely a genetically modified cell performing computational functions, the biocomputer is a living being capable of metabolism, replication and evolution, and at the same time a man-made information processing device. It is not a thing (tangible object), because it has the characteristics of an organism; it is not an organism within the meaning of environmental law, because its properties have been engineered; it is not an electronic device, because it functions according to biochemical principles. This ontological inadequacy is not a definitional defect that can be removed by an amendment – it is a consequence of the nature of technology, which cannot be captured in a conceptual scheme determined for separate fields: biology and computer science.

Second, there is the problem of liability. The traditional liability regimes – tort liability, contractual liability, and liability for a dangerous product – are based on the assumption of traceability of the causative agent and predictability of the effects of the system. A biocomputer as a living organism capable of replication and adaptation can behave in an unpredictable way, and its computational decisions may be the result of biological processes that were not intended by its designer. Y. Benenson points out that biomolecular computational systems have the capacity to autonomously process information in ways that cannot be fully predicted at the design stage²⁴. The question therefore arises without a definitive answer: Who is to be held liable for damage caused by the biocomputer system – the designer of the genetic sequence, the manufacturer of the hybrid device, or the user?

²⁴ Y. Benenson, *op. cit.*, pp. 460–463.

Third, the problem of intellectual property is also still to be solved. A DNA sequence designed to perform the computational function is at the same time an invention within the meaning of patent law, biological information potentially protected as a trade secret, and, if the computer is based on sequences taken from humans, personal data within the meaning of the General Data Protection Regulation (GDPR)²⁵. M. Heller and R.S. Eisenberg pointed out that the proliferation of exclusive rights in biomedical research could paradoxically lead to the phenomenon of anticommons, a state in which the excessive fragmentation of intellectual property rights hinders innovation instead of supporting it²⁶. This problem is particularly severe with regard to biocomputation: when a DNA sequence is both the source code of a computational programme and the genetic material of a living organism, the existing tools for protecting intellectual property become mutually contradictory or inadequate.

A comparison of the problem nodes presented above demonstrates that the regulatory gap in the area of biocomputing is not the lack of a single norm that needs to be completed. It lies in the fundamental inadequacy of the conceptual categories of the entire legal system – civil law, administrative law, criminal law, intellectual property and data protection law – with a being that does not fit into any of the existing paradigms. It is this multidimensional inadequacy that makes biocomputing a particularly striking example of legislative inertia at its most profound.

4. The state of legal regulations concerning biocomputing: A critical analysis of the regulatory gap

The analysis of the current law from the perspective of its regulatory capacity regarding

²⁵ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (OJ L 119/1, 4.05.2016).

²⁶ M.A. Heller, R.S. Eisenberg, *op. cit.*, pp. 698–701.

biocomputing leads to a clear conclusion: none of the current legal regimes – neither at the EU level nor at the Polish law level – covers biocomputing in a complete, coherent, and functionally adequate manner. This is not about minor technical loopholes that could be fixed with an amendment to a single normative act, but about a structural mismatch of conceptual categories and regulatory tools that were designed for different factual situations.

4.1. EU law level: The current regulations and their inadequacy

EU law does not contain any biocomputing-specific legal act. Directive 98/44/EC on the legal protection of biotechnological inventions²⁷ regulates the protection of products of genetic engineering. Article 3(2) thereof provides that inventions relating to biological material isolated from its natural environment or produced by means of a technical process are patentable. This provision could cover designed DNA sequences performing computational functions, and formally probably does. However, the fundamental weakness of the Directive lies elsewhere: it uses the concept of “biological function” of a sequence as the basis for protection, whereas in biocomputing a DNA sequence performs a computational function. Neither the Directive nor the case law of the Court of Justice of the European Union based on it provide for a situation in which a DNA sequence is at the same time the source code of a computer programme. The question arises, without a normative answer: Does protection under Directive 98/44/EC cover a DNA sequence as a computational instrument, since its industrial application is not intended for biological but IT purposes?

Regulation No. 1829/2003 on genetically modified food and feed²⁸ and Directive 2001/18/EC on the deliberate release into the environment

of genetically modified organisms²⁹ establish a risk assessment and authorisation system for GMOs intended for food, feed and agricultural uses. Biocomputers do not fall into any of these categories. The risk assessment procedures provided for in those acts are structurally inadequate for assessing the biological risks generated by organisms designed to process information – the risk of replication, evolution and uncontrolled spread of biocomputers has a completely different profile than the risk associated with GMO cultivation.

General Data Protection Regulation protects genetic data, defining it in Article 4(13) as personal data concerning inherited or acquired genetic characteristics of a natural person. Article 9(1) thereof classifies them as a special category of data, prohibited from processing without an explicit legal basis. The question that the GDPR leaves unanswered in the context of biocomputation is fundamental: Does the DNA sequence of a natural person, used as a carrier of computational information – not for diagnostic or therapeutic purposes, but as a medium for recording data – constitute personal data within the meaning of Article 4(1) GDPR? If so, do the data processing rules, including the right of erasure, apply to the DNA sequence functioning as a biological hard disk? These questions are not speculative in nature; they are a direct consequence of the existing applications of biocomputation in biological cryptography and biological data storage.

The AI Act does not cover biocomputing, even indirectly. Biocomputer systems are not AI systems within the meaning of Article 3(1) thereof, which defines an AI system as a machine system based on software. A biocomputer is not software-based – it is based on biological matter. The AI Act can only serve as a comparative point of reference here, since even the most advanced existing system for regulating new technologies

on genetically modified food and feed (OJ L 268/1, 18.10.2003).

²⁷ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ L 213/13, 30.07.1998).

²⁸ Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003

²⁹ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106/1, 17.04.2001).

is unable to cover biocomputation without violating the basic principles of legal interpretation.

The only international legal instrument comprehensively addressing the limits of interference with human biological material is the Oviedo Convention. Poland signed the document in 1999, but has not ratified it so far³⁰, which means that the provisions setting a minimum standard for the protection of human biological integrity do not bind Polish authorities and courts of law. This is a loophole of a decisional nature, not a technological one, and as such deserves special critical attention.

4.2. Polish law level: No dedicated regulation and inadequacy of general provisions

Under Polish law, biocomputing is not subject to any specific regulation. There is no law on biocomputing, no specific provisions concerning bio-computational organisms, and not even a legal definition that would allow a biocomputer to be classified under any of the existing regulatory categories.

The Act of 22 June 2001 on microorganisms and genetically modified organisms³¹ implements Directive 2001/18/EC. A biocomputer based on a genetically modified bacterial cell formally meets the definition of a GMO within the meaning of this Act and, in principle, is subject to its provisions. However, the procedures provided for therein – the risk assessment, consent for contained use, authorisation for release into the environment – were designed with agricultural and industrial GMOs in mind. None of these procedures provides for a risk assessment specific to computational organisms, such as the risk arising from the uncontrolled replication of a biocomputer that duplicates not only its own genetic material but also the data it processes. The Act also does not regulate the issue of ownership of the results

of calculations performed by GMOs, nor liability for computational errors resulting in damage.

The Civil Code is the foundation of the private-law understanding of the subjects and objects of legal relations. Article 45 thereof defines things as tangible objects. A biocomputer could be qualified as a thing – but such a qualification would be deeply dysfunctional. A thing, in the meaning of civil law, is a passive being, devoid of attributes of life and the ability to act autonomously. A biocomputer is a living organism capable of metabolism, replication and evolutionary adaptation – and it is these characteristics that determine its computational value. Qualifying a biocomputer as a thing leads to a paradox: the owner of a thing can freely dispose of it, including destroying it. Meanwhile, destroying a biocomputer may mean destroying a living organism, which – especially when the biocomputer is based on human cells – raises serious ethical and legal objections for which the Civil Code does not provide any solution. Recognising a biocomputer as a legal subject is, in turn, completely excluded under current law: legal personality is only granted to natural and juridical persons, and Polish law does not provide for any intermediate category.

Pharmaceutical Law³² may potentially come into play for therapeutic applications of biocomputing – biological drug delivery systems based on DNA or modified cells. This issue deserves to be highlighted, even if its full analysis goes beyond the scope of this paper: biocomputing systems used for diagnostic or therapeutic purposes do not obviously fall into the category of either a medicinal product or a medical device. Their qualification – and thus their path to market authorisation – remains an open regulatory question.

4.3. Identification of normative gaps

Against the background of the analysis carried out, it is possible to identify four fundamental regulatory gaps, the existence of which

³⁰ Poland signed the Convention on 7 May 1999; the instrument of ratification has not yet been deposited. Cf. data of the Council of Europe available at <https://www.coe.int> (access: May 2026).

³¹ Consolidated text, Journal of Laws 2022, item 546, as amended.

³² Act of 6 September 2001 – Pharmaceutical Law (consolidated text, Journal of Laws 2022, item 2301, as amended).

is not a coincidental omission on the part of the legislature, but a structural consequence of the described legislative inertia.

First, there is no legal category for the biocomputer. Existing civil law does not have a conceptual category that would allow the biocomputer to be classified without internal contradiction. It is not a thing within the meaning of Article 45 of the Civil Code, because it is a living being; it is not a legal entity, because it is not a person; it is not a product within the meaning of the Directive on liability for defective products, because its “defects” may be the result of biological processes independent of the manufacturer. This three-dimensional inadequacy means that the biocomputer operates in legal transactions as a being without status, which has direct consequences for the possibility of seeking damages, concluding an insurance contract, or determining jurisdiction in cross-border disputes.

Second, environmental law and biosafety regimes prove to be inadequate. In formal terms, the Act on microorganisms and GMOs covers bio-computers, but its risk assessment procedures are tailored to the biological risks of agricultural and industrial organisms, not computational ones. A self-replicating and evolving bio-computer generates risks that have a very different profile: the risks of uncontrolled data replication, interference with the natural biological processes of the organism, and, in the long term, evolution of computational functions towards directions unforeseen by the designer. The GMO regime provides no tools for assessing such risks.

Third, there is a conflict between intellectual property regimes. A DNA sequence designed to perform computational functions can potentially fall under three different protection regimes with mutually inconsistent scopes: patent law as a biotechnological invention, copyright law as a work similar to computer source code, and trade secret protection as know-how. Each of these regimes grants different rights, imposes different obligations, and provides different durations of protection. The absence of a clear conflict-of-law rule that determines priority in the case of a hybrid subject of protection creates a state of legal uncer-

tainty for biocomputer developers and entities intending to use their results.

Fourth, the issue of personal data also remains open. While the GDPR protects genetic data as a special category of personal data, it does not provide for situations in which a DNA sequence serves as a carrier of information unrelated to the health or physiology of the person from whom the biological material originates. The question whether a natural person’s DNA sequence, encoded as a biological hard drive, constitutes their personal data remains without a normative answer. Furthermore, the data minimisation principle set out in Article 5(1)(c) GDPR is difficult to operationalise in the context of biological data storage, for how can one minimise the amount of genetic data used as a computational medium, given that the volume of the code is determined by computational requirements, not by the needs of the data controller?

Taking these four gaps together allows us to formulate an assessment which also serves as a starting point for considering possible regulatory responses: the existing legal framework is more than incomplete in relation to biocomputing. It is structurally inadequate in relation to it, and no partial amendment will remedy this inadequacy without first resolving the conceptual questions that current law leaves open.

5. Why is the gap widening? An analysis of the causes of the growing disproportion between innovation pace and legislative response

Legislative inertia is an inherent feature of law as a normative system – not an anomaly that needs correction. However, if the inertia remains constant, but its negative effects keep growing, it shows that it is not the nature of law that has changed, but the nature of technology – and that change is exactly what should be analysed.

The first and fundamental cause of the widening gap is the dynamic acceleration of the pace of technological innovation against the linear pace of legislation. In just three decades, from Adle-

man's 1994 experiment to advanced computing systems based on human cells, biocomputing has undergone a process, the equivalent of which used to take centuries in the history of industrial technology. Innovation cycles have been shortened to the point where the regulation of one generation of technology is enacted as the next generation is being implemented in laboratory environments. This is not a matter of lawmakers' will or public administration efficiency; it is a matter of mathematical incompatibility: the episodic pace and the linear pace cannot converge at any point.

The second reason is the emergent nature of the effects of computational biotechnology. As a living organism capable of evolution, the biocomputer can generate factual states that cannot be predicted at the design stage of technology, let alone at the lawmaking stage. The legal system is based on the predictability of effects; a legal rule must be able to be applied to a specific fact, and the fact must be describable in legal categories. A law that cannot describe future facts cannot regulate them in advance. This is a cognitive limitation that cannot be removed within the current legislative paradigm.

The third reason is the multidisciplinary nature of biocomputing and the resulting fragmentation of competency. Biocomputing touches upon civil law, criminal law and administrative law, as well as intellectual property law, data protection, environmental law and pharmaceutical law. Each of these branches is governed by separate authorities, separate procedures and separate interpretative traditions. The lack of a horizontal coordination mechanism between these regulatory regimes means that every individual piece of legislation, even if it were perfect in its own right, generates new inconsistencies at the interface with neighbouring regulations. This dysfunction is particularly acute in the field of EU law, where competences relating to biotechnology, data protection and intellectual property are divided amongst the various Directorates-General of the European Commission, which operate without sufficient horizontal coordination.

The fourth cause is the information asymmetry between the scientific and legislative commu-

nities. A lawmaker makes regulatory decisions in a state of deep uncertainty about the current state of technology. Expert consultation mechanisms do exist, but they are initiated too late – usually only after the technology has already generated specific legal problems that require an immediate response. In the case of biocomputing, an additional dimension of this asymmetry is the interdisciplinary nature: a legal expert does not have knowledge of computational biology, a biological expert does not have legal knowledge; the synthesis of both perspectives, which is necessary for a reliable assessment of regulatory risk, remains an extremely rare competence.

The fifth cause, which deserves to be noted separately, is the insufficient preparation of legal professionals to work in conditions of technological complexity. A lawyer who does not know the basics of molecular biology is not able to formulate adequate questions about the legal status of the biocomputer; a legislator lacking technical competence is condemned to inadequate or excessively restrictive regulation, inhibiting innovation without a proportionate effect of safeguarding legally protected values. The education gap is thus not a cause comparable to those mentioned above but rather a catalyst – it exacerbates the negative effects of each of them.

6. Managing the inevitable delay: Proposals *de lege ferenda* and proposed systemic action

Assuming that legislative inertia is a structural and inevitable phenomenon, it is reasonable to ask a pragmatic question: not how to eliminate the lag in the law concerning biocomputing, but how to manage it by minimising the negative effects on the legal order, protection of individual rights and public security. The proposals set out below are varied in nature – some concern the substance of the law (*de lege ferenda*), some relate to the processes of law-making, and others pertain to the institutions supporting the legal system. The response to the challenge posed by biocomputing and, more broadly, by new bio-

logical technologies, cannot be solely legislative in nature.

The most urgent is to adopt, at the EU level or, failing that, at the national level, a framework law on biocomputing technologies, the key feature of which should be deliberate normative openness: regulating not so much specific factual situations as the principles and mechanisms applicable to an entire class of phenomena, regardless of their technical form. The model legislation should be a principles-based regulation similar to the GDPR – delegating details to implementing acts that can be easily updated in line with technological developments, and containing mandatory review mechanisms on a two-year or three-year cycle. The framework act should address – at least at the level of principles – three issues identified as regulatory gaps: the legal status of the biocomputer as a subject of legal relations; the rules governing liability for damage caused by bio-computational systems; and the basic rules for the protection of biological data processed computationally.

Poland remains one of the few Council of Europe member states that have signed but not ratified the Oviedo Convention. The ratification alone will not solve the problem of regulating biocomputing (the Convention had been agreed before this technology was devised), but it sets a minimum standard for protecting human biological integrity and is fundamental to any regulation of human genetic material. The lack of ratification means that Polish courts and administrative bodies cannot directly rely on these standards as binding norms of international law – this is a gap that does not require legislative innovation, but only an appropriate political decision.

It seems appropriate to set up a permanent expert council on new biological technologies, modelled on the European Group on Ethics in Science and New Technologies (EGE) attached to the European Commission, to monitor technological developments, identify emerging regulatory gaps and prepare legislative recommendations before specific legal problems reach a scale requiring immediate response. The council should include lawyers, molecular biologists, computer scientists, ethicists and representatives of civil

society, without prioritising any of those groups. The interdisciplinary nature of the council is not an aesthetic postulate, but a prerequisite for its functional effectiveness.

No regulatory system may exceed the level of competence of the lawyers who create and apply it. The reform of the curricula of legal studies is not about replacing legal dogma with bioinformatics courses. It consists in introducing – as a mandatory element of education – the subjects developing the ability to understand and critically assess new technologies in the legal context: the law of new technologies as a separate discipline, as well as interdisciplinary subjects that teach the identification of legal questions where technology creates unprecedented factual states. In order to achieve this goal, Polish academia needs to overcome institutional divisions between the faculties of law and the faculties of exact and natural sciences.

Existing artificial intelligence, machine learning, and big data analysis tools can be – and are already being – used in some jurisdictions to identify areas in which technological developments indicate that a regulatory gap is likely to emerge. Such systems do not make law; they are merely tools to support people's choices; their value lies in reducing the time between the technological phenomenon and its identification by the regulatory apparatus. This proposal is not intended to regulate the future through algorithms, but is a project to give the lawmakers an early warning tool. Legislative inertia is inevitable, but its scale may vary.

Conclusions

The analysis carried out above allows for the formulation of several conclusions of varying generality, which together provide an answer to the research question asked in the title hereof.

The first conclusion is both theoretical and practical: legislative inertia is a structural and inevitable phenomenon, not a pathology that can be rectified through reforming the legislative process. Law governs the reality it knows and cannot effectively regulate the reality unknown at the time of adopting the specific norm. Attempts at

anticipatory regulation (Marchant's concept of anticipatory governance or the risk-based model adopted in the AI Act) are intellectually valuable, but in practice confirm the very thesis they aim to refute: even deliberate attempts to get ahead of reality with the law end up just catching up, only with a smaller gap. Accepting this conclusion is a prerequisite for a reliable reflection on the relationship between law and technology.

The second conclusion concerns the specificity of biocomputing as a regulatory challenge. Of the new biological technologies, biocomputing is a particularly difficult case, not because of the scale of its social impact – which is yet to be revealed – but because of its ontological hybridity. A being that is both a living organism and a computing device does not fit into any conceptual category of the current law. This multidimensional inadequacy generates the four overlapping normative gaps identified above. None of them are accidents in the legislator's work, as all are a direct consequence of an inherent feature of law.

The third proposal concerns the urgency of action despite the impossibility of full regulation. Assuming the inevitability of inertia and the structural inevitability of normative gaps, the basic task of the legal system becomes the management of delay, not its elimination. This means: creating a legal framework that is open and principle-based, capable of covering facts that are unpredictable at the time of its adoption; institutionalising expert knowledge at the interface between law and natural sciences; the reform

of legal education. These proposals have different temporal horizons: the ratification of the Oviedo Convention is a political decision that can be taken immediately; the adoption of a framework law requires multi-year work; reforming law school curricula is a project with a generational horizon.

The fourth conclusion is of a methodological nature. A legal analysis of technological phenomena requires an interdisciplinary approach that goes beyond the traditional model of a lawyer relying on an *ad hoc* expert opinion. The complexity of legal questions raised by biocomputing points to the need to develop a new model of legal expertise: not a biotechnology specialist, but a lawyer capable of engaging in a substantive dialogue with an expert and identifying legal questions where the technical expert might not notice them.

The fifth conclusion focuses on changing the perspective from which law and the legal community should look at the problem of legislative inertia. The prevailing approach treats the delay of law as a deficit that needs to be corrected. The approach proposed in this study is different: legislative inertia is a trait of law, not its flaw; it is a symptom of the fact that law is a human artefact and, as such, cannot go before human cognition. The task of legal research is not to design regulatory systems devoid of delay; it is to develop rules for managing delays with the right balance and moderation. Biocomputing is, and will remain for many years, an area where this ability will be put to the test most.

Abstrakt

Inercja legislacyjna w dobie nowych technologii. Biocomputing jako symptom systemowej dysfunkcji prawa

Słowa kluczowe: inercja legislacyjna; biocomputing; luka regulacyjna; nowe technologie; regulacja bezpieczeństwa biologicznego

W artykule podjęto problematykę inercji legislacyjnej jako immanentnej cechy systemu normatywnego w kontekście przełomowych innowacji technologicznych. Biocomputing, czyli przetwarzanie informacji przy użyciu systemów biologicznych, służy jako studium przypadku ukazujące nieprzystawalność istniejących kategorii prawnych do zjawisk wymagających regulacji. Analizą objęto pra-

wo unijne i prawo polskie. Zidentyfikowano cztery zasadnicze luki normatywne: brak właściwej kategorii prawnej dla biokomputera, nieadekwatność reżimu bezpieczeństwa biologicznego, kolizję reżimów własności intelektualnej oraz nierozstrzygniętą kwestię danych genetycznych jako nośnika informacji obliczeniowej. Sformułowano postulaty de lege ferenda dotyczące zarządzania nieuchronnym opóźnieniem prawa, w tym postulat ustawy ramowej, ratyfikacji konwencji z Oviedo, powołania interdyscyplinarnej rady eksperckiej oraz reformy kształcenia prawniczego.

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