

Biohacking

Key Legal, Moral and Commercial considerations

Biohacking is a rapidly growing movement that combines technology, biology, and self-experimentation to optimize human performance and well-being. It encompasses a range of practices, from genetic modifications and wearable technology to cognitive enhancement and nutritional interventions. In the European Union (EU), where health, technology, and data privacy regulations are extensive, the rise of biohacking challenges traditional legal and ethical boundaries and raises complex regulatory questions. While biohacking offers individuals unprecedented control over their physical and mental capabilities, it often operates on the fringes of legality, exploiting regulatory gaps. This article explores biohacking's core practices and examines the legal frameworks, including treaties like the Oviedo Convention, the General Data Protection Regulation (GDPR), and other relevant EU policies, along with the regulatory loopholes that biohackers navigate and the broader implications for regulators and society.

Defining the biohacking

In traditional dictionaries, biohacking is often portrayed as a narrow and sometimes controversial practice. The *Oxford English Dictionary*, for instance, defines it as "the activity of exploiting genetic material experimentally without regard to accepted ethical standards, or for criminal purposes" (*Oxford English Dictionary*). This definition emphasizes biohacking's potential for risk and unconventional methods of biological manipulation. Similarly, *Merriam-Webster* describes it as "biological experimentation (as by gene editing or the use of drugs or implants) done to improve the qualities or capabilities of living organisms, especially by individuals and groups operating outside traditional medical or scientific research environments" (*Merriam-Webster Dictionary*). These definitions highlight biohacking as a self-directed, experimental practice typically conducted outside conventional scientific settings.

For the purposes of this work, we will hereby operate with our own definition: **externally induced, concealed gene (information hoovering, sequestrating, doctoring, and/or) intervention for non-transparent ends.** (Bajrektarevic, 2010)

Biohacking has evolved into a form of "DIY¹ biology," where individuals — often outside institutional frameworks — apply biological science and technology to optimize their bodies and biological systems. According to Meyer (2020), biohacking thrives in peer production environments where knowledge and resources are openly shared, allowing individuals to take control of their biology through accessible tools, including wearable devices, supplements, and even genetic modification. This approach reflects a democratization of science that disrupts traditional boundaries

¹ "Do It Yourself"

between professional and amateur scientists, raising ethical concerns around safety, privacy, and regulation (Meyer 2020).

As a grassroots movement, biohacking blends biology with principles of open science and DIY experimentation. Delfanti (2013) suggests that biohacking challenges conventional scientific hierarchies by emphasizing collaboration and open access to biological knowledge and tools. Biohackers frequently conduct experiments on themselves or their environments to push the limits of human biology, promoting a democratized science culture. This movement advocates for peer production and low-cost technologies as a form of resistance against proprietary, closed scientific systems (Delfanti 2013). Coenen et al. (2017) report that biohacking integrates diverse life sciences techniques beyond the confines of traditional academic and corporate research, further blurring the lines between professional and amateur scientists.

While many biohacking techniques are health-focused, others pursue aesthetic, psychological, or even transhumanist objectives, exploring the extension of human capabilities through technology.

Constituting elements

- **Lifestyle optimization**

Lifestyle optimization in biohacking focuses on improving well-being through practical and measurable changes in daily routines. It targets areas such as diet, sleep, physical performance, and mental capacity, often using tools like wearable devices to track health metrics and guide adjustments. Popular methods include intermittent fasting, cold exposure, and the use of natural supplements.

Diet is a fundamental aspect of biohacking. Approaches like intermittent fasting and ketogenic diets aim to enhance metabolism, reduce inflammation, and promote fat loss. Nutrigenomics, which examines the relationship between nutrients and gene expression, supports personalized dietary strategies that align with genetic predispositions, balancing hormones and improving overall health.

Sleep quality is another priority. Biohackers use devices to monitor sleep patterns and test different techniques, such as adjusting room temperature, changing meal timings, or taking supplements like melatonin. Biohackers usually share their findings online, creating a collaborative community that exchanges ideas and refines methods for better rest.

Physical enhancement often centers on strategies like High-Intensity Interval Training (HIIT), which delivers significant physiological benefits through brief yet intense exercise sessions.

Cognitive improvement is also a major focus, with methods that include mindfulness, neurostimulation, and the use of nootropics. Substances like caffeine and L-theanine enhance focus and reduce fatigue, while others, such as modafinil, improve memory, attention, and executive function, enabling sharper mental performance.

- **DIY biology**

DIY biology represents a more experimental branch of biohacking, often involving community labs where enthusiasts use biological tools and techniques typically reserved for professional researchers. Examples include genetic manipulation, open-source insulin production (such as in the Open Insulin Project), or developing personalized medical treatments. One of the primary uses of DIY bio is genetic engineering, where individuals experiment with organisms like bacteria or yeast to modify genetic material. This can include projects like creating fluorescent bacteria or altering plants to produce new compounds. Meyer notes that technologies such as CRISPR² have made gene editing more accessible to non-professional scientists, allowing for experimentation with genetic material at a relatively low cost (Meyer 2020).

- **Grinders and transhumanism**

At the extreme end of the biohacking spectrum are individuals known as "grinders" or DIY transhumanists. These biohackers embrace invasive procedures, including the implantation of electronic devices (such as microchips) to enhance sensory capabilities or monitor health data. Their goal is often to transcend biological limits, entering the realm of cyborgism. Ethical and regulatory concerns are prevalent in this area due to the experimental and sometimes dangerous nature of these modifications (Coenen 2017; The Medical Futurist 2024). Grinders push the boundaries of self-experimentation, frequently employing devices such as RFID chips for unlocking doors, magnets implanted in fingertips for sensing electromagnetic fields, or even more advanced biotechnologies aimed at enhancing sensory perception or communication capabilities. Fuisz emphasizes the lack of legal frameworks to address the potential risks or unintended consequences of these experiments. This lack of regulation presents both an opportunity for innovation and a potential hazard, as these practices exist outside the traditional boundaries of medical and scientific research (Fuisz 2017).

Moral considerations and legal limitations

The rapid rise of biohacking has sparked debates about its safety and the ethical implications of self-experimentation. While many biohackers claim that their efforts help to advance health technologies, others criticize the movement for lacking adequate regulatory oversight. For example, invasive body modifications raise concerns about safety, legality, and potential misuse. On the other hand, biohacking movements like DIY biology advocate for open access to scientific tools, which may contribute to more affordable healthcare solutions, such as producing cheaper medications like insulin (University of Southern California 2024).

Currently, the tension between innovation and regulation in biohacking is widely discussed. Excessive regulation might stifle creativity and personal freedom, but too little might lead to widespread harm. The challenge is to strike a balance that allows biohackers to innovate while protecting public safety and ethical standards. This raises the question of whether new laws and regulations should be created specifically for

² Clustered Regularly Interspaced Short Palindromic Repeats

biohacking, or whether existing medical and scientific frameworks are sufficient to address these concerns (Fuisz 2017).

EU Regulatory framework

The rapid growth of biohacking, particularly in DIY biology and personal health modification, has raised complex legal and ethical challenges within the EU. While biohacking itself is not explicitly addressed by a singular legal framework, its various practices intersect with numerous existing EU regulations. These frameworks—governing data protection, medical devices, genetic modification, and ethical biomedical research—indirectly regulate biohacking activities. As the line between personal experimentation and formal biomedical innovation blurs, it becomes essential to understand how EU regulations address the safety, privacy, and ethical considerations surrounding this emerging field. This chapter will explore the key EU treaties and directives that apply to biohacking, highlighting the specific legal provisions that biohackers must navigate to ensure compliance with EU standards.

- **General Data Protection Regulation (GDPR) (EU) 2016/679**

The General Data Protection Regulation is a cornerstone of EU law concerning the protection of personal data and privacy. Article 9 of the GDPR specifically addresses the "Processing of special categories of personal data," which includes biometric data used for uniquely identifying a person, as well as genetic data. Since many biohacking practices involve the collection and processing of such data—either for self-monitoring, health tracking, or experimentation—biohackers must comply with this provision. Article 9(1) generally prohibits the processing of these special categories of data unless the data subject has given explicit consent (Article 9(2)(a)) or the processing is necessary for medical diagnosis or scientific research (Article 9(2)(i)).

- **Clinical Trials Regulation (EU) No 536/2014**

The Clinical Trials Regulation sets out specific requirements for conducting clinical trials involving human subjects. Article 28 of this regulation focuses on informed consent, mandating that participants must be fully informed of the objectives, risks, and benefits of the trial before they can participate. For biohackers engaging in any form of human experimentation, particularly in the realm of medical devices or novel health interventions, compliance with this article is essential to ensure that ethical standards are met. Furthermore, Article 35 establishes provisions for vulnerable populations, such as individuals with reduced autonomy, who may be more susceptible to harm from risky biohacking experiments.

- **Medical Device Regulation (MDR) (EU) 2017/745**

The Medical Device Regulation applies to all medical devices placed on the market within the EU, including those used in biohacking activities. Article 2(1) of the MDR defines a medical device as "any instrument, apparatus, appliance, software, implant, reagent, material, or other article" intended for medical purposes, such as diagnosis, prevention, or treatment of diseases. This

regulation is relevant to biohackers who develop or modify devices for health enhancement or biomedical experimentation. Additionally, Article 5(1) of the MDR mandates that any device used in a medical context must comply with EU conformity assessment procedures, ensuring that the device is safe, effective, and bears a CE marking.

- **Biotechnology Directive (Directive 98/44/EC)**

Biotechnology Directive governs the legal protection of biotechnological inventions in the EU. Articles 5 and 6 of the directive directly address the patentability of biotechnological inventions, particularly concerning genetic engineering. Article 5(1) states that "The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions." However, Article 5(2) allows for the patenting of isolated elements of the human body, such as gene sequences, under specific conditions. This is highly relevant for biohackers involved in genetic editing or modification, as they must ensure compliance with the directive's provisions regarding patent protection and the ethical use of genetic materials.

- **The Oviedo Convention on Human Rights and Biomedicine**

The Oviedo Convention, also known as the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, is a crucial legal instrument in regulating bioethical issues. While not binding across all EU member states, it establishes ethical principles for biomedical research and medical practices. Article 5 of the Convention outlines the necessity of informed consent in medical interventions, stating that any procedure related to health may only be carried out after the person has been informed and has provided free and informed consent. Article 13 of the Convention prohibits genetic modifications aimed at altering the genome of descendants, thereby setting ethical boundaries on genetic biohacking practices that could affect future generations.

- **Genetically Modified Organism (GMO) Regulation (EC) No 1829/2003**

For biohackers involved in genetic modification, the Genetically Modified Organism (GMO) Regulation is essential. Article 4 of this regulation sets out requirements for the authorization of GMOs intended for human consumption, while Article 16 requires rigorous risk assessments before any GMOs can be released into the environment. These provisions ensure that biohacking activities involving genetic engineering must meet strict safety standards to protect both public health and the environment. Additionally, Directive 2001/18/EC on the deliberate release of GMOs into the environment mandates a notification and approval process for biohackers intending to experiment with genetically modified organisms outside controlled laboratory environments.

- **EU Charter of Fundamental Rights**

The EU Charter of Fundamental Rights provides a broader ethical and human rights context that applies to biohacking. Article 1 guarantees human dignity, while Article 3 protects the right to physical and mental integrity, particularly in the context of medical or scientific experimentation. Biohackers must ensure that their practices respect these fundamental rights, especially in cases where human subjects are involved. Article 3 also explicitly prohibits the use of the human body and its parts as a source of financial gain, a provision that could be relevant to biohackers engaging in the commercialization of biotechnological innovations involving the human body.

EU Regulatory gaps and legal loopholes

While the European Union has implemented a range of regulations that indirectly govern aspects of biohacking—such as the GDPR for data privacy, the MDR for devices, and the Biotechnology Directive for genetic modification—these frameworks were not specifically designed with biohacking in mind. As a result, gaps exist in their coverage, particularly around practices like DIY biology, self-experimentation, and citizen-led research. Furthermore, the rapid pace of technological advancement in biohacking often outstrips the adaptability of existing laws, leading to ambiguity in critical areas such as liability, safety standards, and ethical boundaries. This chapter will examine these legal loopholes, the gaps in EU regulations that biohackers may exploit, and explore the challenges policymakers face in closing these regulatory voids.

- **Biohacking outside of institutional oversight**

One of the primary challenges in regulating biohacking is the distinction between institutional and non-institutional research. EU regulations, such as the Clinical Trials Regulation (EU) No 536/2014, are designed to oversee formal clinical trials conducted by medical institutions or companies. However, biohacking often occurs in informal or private settings, such as personal labs or at home, outside the purview of these established oversight mechanisms. This means individuals engaging in self-experimentation or DIY biology may bypass the stringent safety and ethical guidelines required for institutional research, such as informed consent, independent ethics committee approval, and public safety measures.

Moreover, many biohackers operate outside traditional research funding structures, meaning their activities do not fall under the purview of Horizon Europe³ or other EU funding programs, which impose strict ethical and regulatory compliance on grant recipients. As a result, a substantial amount of biohacking activity exists in an unregulated space, where enforcement is minimal.

- **Self-experimentation and personal autonomy**

One of the most complex areas of biohacking regulation involves self-experimentation, where individuals modify or enhance their own biological

³ https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe_en (accessed 24 November 2024)

systems. While EU laws, such as the MDR, establish clear standards for the safety and effectiveness of medical devices, they are primarily intended for commercial products rather than personal use. Biohackers who implant devices into their own bodies or modify their own biological systems may argue that these interventions fall under personal autonomy and bodily integrity, concepts protected by Article 3 of the EU Charter of Fundamental Rights, which guarantees the right to physical and mental integrity.

The loophole here is that self-experimentation may evade scrutiny because biohackers are often both the researchers and the subjects of their own experiments. As long as the devices or modifications are not sold commercially or performed by third parties, these activities may not be subject to strict medical regulation. This creates ambiguity in terms of accountability and risk management, particularly when biohacking results in harm to the individual or unintended consequences for others, such as environmental risks from genetically modified organisms.

- **Ambiguities in genetic modification and biotechnology**

Biohacking frequently involves genetic modification, whether through gene-editing technologies like CRISPR or synthetic biology. The Biotechnology Directive governs the legal protection of biotechnological inventions but is focused primarily on patent law and intellectual property rather than regulating amateur genetic experimentation. While this directive addresses the patentability of biotechnological inventions, it offers limited guidance on the regulation of private or hobbyist genetic modification projects, especially those not intended for commercial use.

Furthermore, EU GMO regulations, such as Regulation (EC) No 1829/2003 and Directive 2001/18/EC, require authorization and risk assessment for the release of genetically modified organisms into the environment. However, biohackers working in private settings may develop GMOs without the intent of formal release or commercialization, creating a regulatory loophole where small-scale genetic modification experiments are conducted with minimal oversight.

The issue is further complicated by the fact that biohackers may claim their activities are forms of scientific exploration or artistic expression, allowing them to circumvent regulations that typically apply to commercial or institutional activities.

- **Data privacy and ethical challenges**

Biohacking often involves the collection of personal health data, whether through implanted sensors, biometric monitoring, or genetic testing. The GDPR governs the collection and processing of personal data, including biometric and genetic information. However, biohackers may exploit certain ambiguities in the GDPR, particularly regarding consent and the use of personal data for self-experimentation or non-commercial purposes.

For instance, Article 9 of the GDPR prohibits the processing of special categories of personal data unless the individual has given explicit consent. In biohacking, where the data subject and the experimenter are often the same person, consent is not as rigorously monitored or enforced as it would be in institutional research. This creates potential risks in terms of data security,

ethical use of personal data, and the potential for misuse of sensitive genetic information.

Moreover, biohackers who share data within communities or on open-source platforms may inadvertently expose personal health information without adhering to GDPR compliance, particularly when cross-border data transfers are involved.

- **Legal and ethical responsibility for community-based biohacking**

Biohacking communities often work collaboratively, sharing knowledge, techniques, and even experimental results. These activities, while fostering innovation, also raise questions about responsibility and accountability. If an individual biohacker suffers harm or if a genetically modified organism inadvertently affects the environment, it remains unclear who would bear legal liability. The EU's existing legal frameworks primarily address institutional responsibility (e.g., corporations or research institutions) rather than distributed, decentralized communities of individuals.

As a result, EU regulations struggle to define clear accountability in cases where harm is caused by biohacking activities. This loophole means that biohacking communities can operate with a degree of legal anonymity, potentially exposing both individuals and society to unregulated risks.

Regulatory mechanisms extension ?

While the EU has established a robust legal framework to regulate biotechnology, medical devices, and personal data, these regulations were largely designed with formal institutions and commercial enterprises in mind. Biohacking, as a decentralized and often informal practice, exploits several legal loopholes, particularly concerning self-experimentation, private genetic modification, and community-based research. These gaps allow biohackers to operate with minimal oversight, raising concerns about safety, ethical responsibility, and the environmental impact of biohacking activities.

Moving forward, policymakers will need to address these regulatory gaps by creating adaptable legal frameworks that account for the unique nature of biohacking. This may involve introducing new rules specific to DIY biology, tightening enforcement mechanisms, and clarifying liability in cases of harm or environmental damage. Furthermore, fostering collaboration between biohackers and regulators could help create a balanced approach that encourages innovation while ensuring public safety and ethical standards are upheld.

- **Clarifying the legal status of self-experimentation and personal biohacking**

The legal status of self-experimentation and personal biohacking remains ambiguous under EU regulations, as existing frameworks primarily address institutional or commercial medical research. This gap leaves biohackers who experiment on

themselves unregulated, particularly in areas involving medical devices and genetic modification.

To address this, EU policymakers should establish clear guidelines that uphold individual autonomy while ensuring public safety. These should include minimum safety standards for medical devices, implanted technologies, and genetic editing tools used in personal biohacking. Amending the Medical Device Regulation (MDR) to encompass DIY tools and creating a registration process for self-experimenters could further clarify legal responsibilities.

However, balancing personal autonomy with regulatory oversight poses challenges, as biohackers often view their activities as expressions of personal freedom. Additionally, enforcing regulations on private, non-commercial activities remains a significant hurdle, complicating compliance and oversight efforts.

- **Regulating DIY biology and non-institutional research**

Biohacking often occurs outside traditional research institutions, with individuals or small groups conducting genetic modification and synthetic biology experiments in private or community spaces. These decentralized activities pose risks to individuals and the environment, yet current regulations are inadequate for effective oversight.

To address this, a licensing framework for DIY biology labs should be developed, requiring biohackers working with sensitive technologies, such as genetic engineering tools, to register with national regulatory bodies. This framework should mandate safety protocols, risk assessments, and periodic inspections to ensure adherence to health and environmental standards. Additionally, the GMO Directive should be expanded to include small-scale, non-commercial genetic modification projects, subjecting biohackers to the same rigorous risk assessments as institutional researchers.

- **Enhancing data protection and ethical standards in biohacking**

The rise of biohacking poses challenges to data privacy and ethics under the General Data Protection Regulation (GDPR). Biohackers often collect and share personal health data for self-experiments, operating outside traditional medical oversight. This raises concerns about data security and ethical handling of biometric and genetic information.

To address these issues, GDPR enforcement should include specific guidelines for biohackers, requiring them to meet the same consent and data protection standards as institutional researchers. National ethics committees could review and approve high-risk biohacking projects involving genetic or biometric data, ensuring compliance with ethical standards.

Resistance from biohacking communities, which value openness and decentralized practices, and the complexity of enforcing GDPR in global, cross-border networks remain significant obstacles.

- **Fostering collaboration between policymakers and the biohacking community**

Regulating biohacking effectively requires bridging the gap between policymakers and the biohacking community. Heavy-handed regulation risks stifling innovation, as biohackers often operate at the forefront of biotechnology. Constructive dialogue is essential to close regulatory gaps while encouraging innovation.

Policymakers should engage biohackers through workshops, conferences, and advisory committees to better understand their needs and concerns. A regulatory sandbox could allow biohackers to test new technologies in a monitored environment, fostering innovation while ensuring public safety.

Challenges include mistrust from biohackers, who may view regulation as a threat to their freedom, and the rapid evolution of biohacking technologies, which makes it difficult for policies to keep pace. Building trust and creating adaptable regulations will be key to addressing these issues.

- **Addressing liability and accountability in biohacking**

Liability and accountability in biohacking remain significant legal gaps, especially in decentralized communities where responsibility for harm—whether to individuals, the public, or the environment—is unclear. This issue is critical in cases such as failed self-experimentation or accidental release of GMOs.

A clear liability framework is needed to assign accountability for damages, potentially by extending product liability laws to cover DIY medical devices and implementing environmental rules for GMO-related risks. Biohackers engaging in high-risk experiments should also be required to obtain liability insurance to ensure responsibility and mitigate harm.

Challenges include difficulties in identifying responsible parties in anonymous or collaborative biohacking networks and the lack of a developed insurance market to cover biohacking risks, which may make coverage costly or inaccessible.

- **Tackling biopiracy in biohacking**

Biohacking's focus on democratizing biotechnology risks perpetuating biopiracy—the unauthorized use of genetic resources and traditional knowledge without equitable benefit-sharing. Frameworks like the Convention on Biological Diversity (CBD) and Nagoya Protocol address biopiracy, but their adaptation to biohacking requires further attention (Bajrektarevic & Sari).

Biohackers should adopt Access and Benefit Sharing (ABS) practices, ensuring prior consent and equitable agreements with indigenous communities to protect resource providers' rights. Governments must strengthen ABS legislation and require biohackers to follow simplified protocols when accessing genetic resources, addressing gaps in enforcement and accountability.

Challenges include weak enforcement of ABS mechanisms in countries with limited oversight and inconsistent national laws, which create compliance difficulties for biohackers working on cross-border projects. Harmonized legal frameworks are essential for effective regulation and equitable practices.

- **Preventing environmental crime in biohacking**

Biohacking poses risks to the environment through activities such as genetic modification and the disposal of biological materials, which may inadvertently contribute to environmental crime. Offenses like illegal waste disposal and unauthorized resource use are aggravated by weak regulations and the decentralized nature of biohacking, which often lacks institutional oversight (Bajrektarevic 2021).

To address these issues, governments must align national and international laws on hazardous waste, biodiversity, and genetic resources to ensure ecological safety. Partnerships between regulators, biohackers, and environmental organizations can improve compliance and reduce harm through clearer accountability and monitoring.

Challenges include the informal structure of biohacking, which makes enforcement difficult, and resource limitations faced by authorities, leaving environmentally harmful practices unchecked. Clear regulations and collaborative efforts are essential to prevent ecological damage.

Conclusion

While it is essential to address the regulatory gaps in EU biohacking laws, overly restrictive measures risk pushing biohackers further into the gray area of unregulated activities. To foster a productive balance between innovation and safety, policymakers should focus on creating flexible, supportive frameworks that encourage responsible biohacking without stifling creativity or experimentation.

Rather than imposing overly strict regulations, the EU can adopt a more collaborative approach, working with the biohacking community to co-create guidelines that prioritize safety while respecting the autonomy of biohackers. This can be achieved by establishing a regulatory sandbox, where biohackers are given the freedom to innovate in a controlled and monitored environment. Such a framework would allow biohackers to experiment with cutting-edge technologies while receiving guidance on regulatory compliance and safety standards, ensuring that their work aligns with public health and ethical norms.

Providing funding and grants for biohacking projects through programs like Horizon Europe would also create an incentive for biohackers to operate within legal frameworks. By offering financial support and structured resources, the EU can encourage biohackers to collaborate with formal institutions and conduct their work transparently, with access to safety protocols and ethical oversight. This will help integrate biohackers into the broader scientific community, fostering innovation in a safe and ethical space without limiting their freedom.

At the same time, ensuring clearer liability guidelines for biohacking projects is important to protect both individuals and the public. Rather than imposing rigid

enforcement, the focus should be on developing systems that provide clarity around accountability while offering biohackers the flexibility to experiment safely.

In summary, closing the regulatory gaps in biohacking requires a balanced approach that promotes freedom and innovation while ensuring safety and ethical responsibility. By fostering collaboration, providing support, and creating adaptive regulations, the EU can cultivate an environment where biohackers can continue to push boundaries without being forced into legal gray areas, contributing positively to the future of biotechnology.

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